Project Report

Medical Device Supply Chains

An Overview and Description of Challenges During the COVID-19 Pandemic

Peggy G. Chen, Edward W. Chan, Nabeel Qureshi, Shoshana Shelton, and Andrew W. Mulcahy

RAND Health Care

PR-A328-2-v2
September 2021
Prepared for the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation

About This Project Report

The Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2) can result in coronavirus disease 2019 (COVID-19) which caused a pandemic resulting in multiple and prolonged disruptions to the supply chain for multiple goods and services worldwide. Hospitals found that inventory management approaches that had been adopted to optimize efficiency were not able to address rapidly surging demand, particularly for COVID-19 relevant medical devices such as personal protective equipment (PPE), ventilators, and testing supplies and equipment. The supply chain for these devices is complex, and it involves a variety of raw materials and multiple organizations. A greater understanding of the supply chain for these COVID-19 relevant medical devices could provide nuance and context for ongoing supply challenges while supporting system resilience in the long term.

The purpose of this report is to provide an introduction to the supply chain for COVID-19 relevant medical devices and related challenges faced in ramping up production of these devices during the COVID-19 pandemic.

This research was funded by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation under Contract Number HHSP233201500038I and carried out within the Payment, Cost, and Coverage Program in RAND Health Care.

RAND Health Care, a division of the RAND Corporation, promotes healthier societies by improving health care systems in the United States and other countries. We do this by providing health care decisionmakers, practitioners, and consumers with actionable, rigorous, objective evidence to support their most complex decisions. For more information, see www.rand.org/health-care, or contact

RAND Health Care Communications
1776 Main Street
P.O. Box 2138
Santa Monica, CA 90407-2138
(310) 393-0411, ext. 7775
RAND_Health-Care@rand.org

Contents

Figures and Table

Figures

Table

Abbreviations

CDC	Centers for Disease Control and Prevention
CGMP	current good manufacturing practices
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
COVID-19	coronavirus disease 2019
EO	ethylene oxide
EUA	emergency use authorization
FDA	Food and Drug Administration
GMP	good manufacturing practices
GPO	group purchasing organization
HHS	U.S. Department of Health and Human Services
NIOSH	National Institute for Occupational Safety and Health
PCR	polymerase chain reaction
PPE	personal protective equipment
RNA	ribonucleic acid
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2

1. Introduction

The coronavirus disease 2019 (COVID-19) pandemic "caused an unprecedented surge in the demand for medical products" (AdvaMed, 2020a). The U.S. supply chain for COVID-19 relevant medical devices, such as personal protective equipment (PPE), ventilators, and testing supplies and equipment, was unprepared to satisfy this higher demand, and this led to shortages (Ranney, Griffeth, and Jha, 2020). Many of these devices continue to be listed on the Food and Drug Administration (FDA) medical device shortage list (U.S. FDA, 2021d).

During the COVID-19 pandemic, hospitals nationwide, many of which had implemented a just-in-time approach (Waters-Fuller, 1995) for purchasing and inventory management to increase cost efficiency, had limited inventory of supplies like PPE and found themselves having to reuse PPE in order to avoid depleting their supply. Ventilator and other equipment shortages reported elsewhere in the world prompted U.S. health care leaders to begin considering protocols for rationing ventilators, along with testing, treatments, and other care. The inability to field sufficient numbers of diagnostic tests quickly hampered efforts to track the speed and extent of COVID-19's spread. Existing national stockpiles of PPE and other COVID-19 relevant supplies, intended to bridge the gap between surges in demand and the supply chain catching up, were depleted as increased manufacturer production proved too slow to meet increased demand in light of COVID-19-related personnel and safety requirements.

The purpose of this report is to provide an introduction to the supply chain for COVID-19 relevant medical devices and related challenges faced in ramping up their production during the COVID-19 pandemic. The report first presents an overview of medical device supply chains in general and then describes how supply chains for specific COVID-19 relevant devices (we define these as ventilators, PPE, and COVID-19 diagnostic testing equipment and supplies) differ from the general approach. This nuance is important because COVID-19 relevant devices are heterogeneous, with similarities but also important differences in their respective supply chains. Furthermore, for each type of device, manufacturers differ in how they source components and produce finished items. Consequently, this report is not intended to be, and does not serve as, a comprehensive description of manufacturing processes or supply chains for any one of these devices. Rather, it uses these devices and the experiences of some device makers to conceptualize larger lessons and identify areas of potential future research related to the supply chain.

We also note that our focus in this report is specifically on the supply chain for medical *devices*, rather than the supply chain for delivering health care *services* more generally. For example, we address the PPE supply chain but not the myriad health care services relying on PPE. Likewise, we focus on supply chains for COVID-19 testing equipment and supplies but not on the personnel required to conduct and analyze tests, as required by the Clinical Laboratory

Improvement Amendments (CLIA) (U.S. FDA, 2020d). Health care services often require a range of inputs in addition to medical devices, such as clinical labor, physical space, information technology, and administrative staff, all of which were affected by the COVID-19 pandemic.

Approach

We started by developing a basic understanding of manufacturing operations and supply chains, as described in the business literature. For instance, Hugos, 2011, lays out the basic structure of supply chains, while Goldratt, 2012, talks about how to identify constraints that limit manufacturing output. We then reviewed the peer-reviewed and gray literature to identify papers and other resources that describe supply chains for the identified COVID-19 relevant devices. We conducted searches in both the PubMed and EBSCO databases using such terms as "supply chain," "supply," "ventilator*,"[1] "ventilator tubing," "personal protective equipment," "N95 mask," "N95 respirator," "surgical mask," protective clothing (MeSH), "surgical gown," "gloves," "surgical gloves," "nitrile gloves," "latex gloves," "diagnostic test," "reagent*," "vial," "swab*," "collection tube*," blood preservation (MeSH),[2] "capillary blood testing," "lancet," "pipette," "low gas permeable bags," "dessicant," and "dessicant pouch." Searches also used various terms for COVID-19 (e.g., coronavirus, novel coronavirus, COVID-19, SARS-CoV-2) in order to identify publications discussing supply chain shortages that occurred during the COVID-19 pandemic. We also identified appropriate trade publications (e.g., *Medical Device and Diagnostic Industry*, *Medical Product Outsourcing Magazine*, *Supply Chain Dive*, *Medical Device News Magazine*) and searched their archives for relevant articles. Additionally, we searched the websites of relevant government agencies (e.g., FDA; Centers for Disease Control and Prevention [CDC]; National Academies of Sciences, Engineering, and Medicine; and Office of the Assistant Secretary for Preparedness and Response). Finally, given the prominence of supply chain issues with COVID-19 relevant devices in the press, we identified news stories of interest using targeted internet searches. We limited our search to documents published between January 1995 and May 2020.

We identified major stakeholder groups through an initial scan of resources identified through this search (relevant manufacturers, distributors, and trade organizations). We then searched for national groups representing these stakeholder groups and identified relevant white papers and reports posted on the websites of these organizations.

---

[1] The * indicates the use of "stemming", a search technique used for reducing words to their stem or root form, allowing searches to include all derivative forms of the word.

[2] Medical Subject Headings (MeSH) are a controlled vocabulary thesaurus of terms created by the National Library of Medicine. They provide uniformity and consistency to the indexing and cataloguing of biomedical literature and allows searches to quickly identify articles of interest.

In order to confirm and expand our understanding of COVID-19 relevant device supply chains as ascertained from the literature review, we invited several individuals to discuss the supply chain for specific devices or groups of devices, both in general and related to changes in the supply chain during the COVID-19 pandemic. We held a total of nine discussions between May 2020 and February 2021 (with individuals from two associations representing medical device makers, one PPE maker, two ventilator makers, one maker of test devices, one chemical company, one distributor, and one organization representing hospitals). A notetaker recorded key points from each phone conversation.

Organization of This Document

In Chapter 2, we provide an overview of the processes in medical device supply chains generally. In Chapter 3, we provide specifics, where available, in the supply chains for three types of COVID-19 relevant devices: ventilators, PPE, and tests. In Chapter 4, we discuss the challenges in the supply chain for COVID-19 relevant devices during the COVID-19 pandemic. While many challenges were common across devices, each type of device also had its own unique challenges. In Chapter 5, we discuss potential strategies that may be implemented to address future surges that may occur in the supply chain. In Chapter 6, we conclude with a discussion of topics for further research that ASPE may wish to consider.

Finally, because all COVID-19 relevant medical devices are regulated by FDA, we provide a high-level overview of those regulatory processes in the appendix.

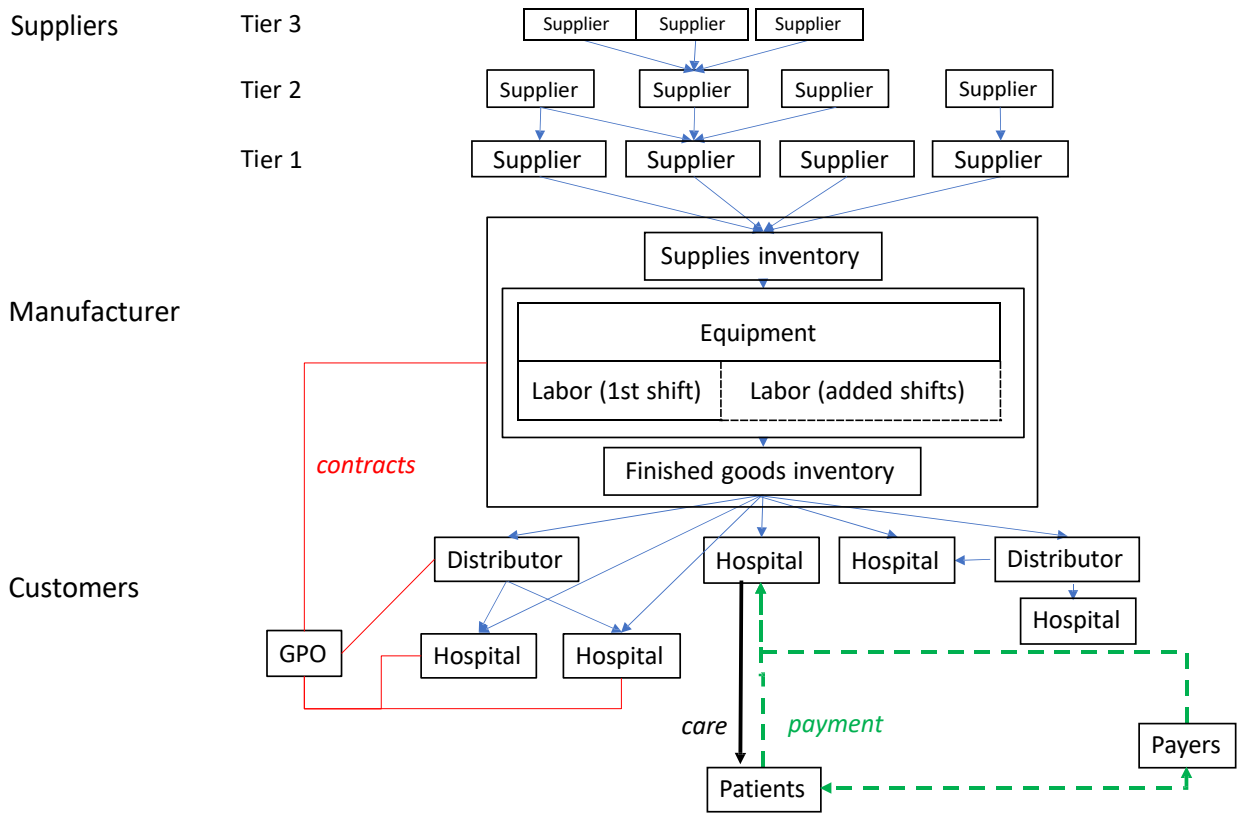
2. The Supply Chain

In this chapter, we describe a generalized supply chain for devices that will ultimately be used in a hospital setting. This is a generalization, and the next chapter will provide specifics on this process for various COVID-19 relevant devices.

The process begins with manufacturing, which can be thought of as the use of equipment and labor to turn supplies, such as raw materials and components, into finished products that will be sold to customers. In this report, we use the term **manufacturer** to mean the organization that produces an end product of interest. However, getting end products into the hands of customers does not involve the manufacturer alone.

In Figure 2.1, we show a simplified and generalized supply chain. The physical movement (transportation) of goods from suppliers to manufacturers and manufacturers to customers is depicted by the blue arrows. The dotted red lines illustrate *contracts*; these represent the financial and contractual agreements that connect the various components in the supply chain. The green dashed lines indicate payment for patient care.

Figure 2.1. Supply Chain



NOTES: Blue arrows indicate transportation of materials and goods. Red dotted lines indicate contractual relationships. Green dashed lines indicate payment for patient care. GPO = group purchasing organization.

At the heart of the supply chain is the **manufacturer**. Manufacturers purchase components (defined as "any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device" [U.S. FDA, 2020a]) from **suppliers**, which in turn have their own suppliers. Depending on where in the supply chain suppliers fall, their customers may be other suppliers or the manufacturer of the actual end product.

After manufacturers assemble the finished product, it often must be sterilized (often by a contract sterilizer, another type of supplier). Once the finished product has been sterilized, it can be sold to **customers**. For this report, we have designated two major categories of customers—*distributors* and *hospitals*.

Distributors represent an intermediate point for some goods in the journey from the manufacturer to hospitals. They are organizations that obtain goods directly from manufacturers (typically from multiple manufacturers), store these goods, and ship them, often bundled with other goods, to hospitals. In most cases, distributors purchase goods outright from manufacturers, taking title and ownership. However, particularly for high-value goods, a consignment model may be used in which manufacturers retain ownership and title of goods that are shipped to and stored locally by distributors or, more commonly, by hospitals and paid for only upon use (CardinalHealth, undated; McKesson, 2012).

Hospitals are the other main customer category considered for the supply chain described in Figure 2.1, but we also acknowledge this term is an oversimplification. In practice, customers for medical devices are a diverse group and might include any end user from a small, privately owned physician practice to large, multistate integrated health care delivery systems. However, given the central role of hospitals in the COVID-19 pandemic, we focus on them in this report.

Additionally, ensuring the supply of devices reaches health care workers in hospitals is just one component enabling the provision of health care services. A range of other inputs beyond medical devices is needed to provide health care services to patients, including health care workers, clinical laboratory staff, housekeeping services and other hospital staff, physical space, prescription drugs, and information technology, to name a few. This report focuses on the supply chain for medical devices only and does not discuss the other vital inputs required for health care delivery.

There is another entity that often plays a role in the movement of goods from manufacturer to hospitals. *GPOs*) are membership organizations that combine the purchasing power of their members (e.g., hospitals, physician practices) to negotiate more favorable contract terms. They are not customers directly, but they are involved in the purchasing process and, hence, appear in Figure 2.1in a dashed-line box.

Finally, *patients* and *payers* are important stakeholders who may influence the supply chain in tangible ways. The entire supply chain as depicted in Figure 2.1 is designed to ensure that health care can be provided to patients in an appropriate manner. Further, although customers may have contracts with manufacturers or distributors to provide certain medical devices, some patients may require specialized devices (e.g., latex-free options for patients with allergies). Although this is typically done through existing supply chains, it does add complexity to the process because it is an additional device that needs to be produced, distributed, shipped, and managed. Payers, both public and private, may also influence supply chains through their policies that determine whether certain devices are reimbursable. This may be done through a number of avenues, including formularies, prior authorization, and utilization review.

One additional entity, which is not shown explicitly in the figure but which undergirds the entire supply chain, is the regulatory environment in which provision of health care and the production of devices exist, specifically the FDA's Center for Devices and Radiological Health. This includes product-specific regulations regarding the marketing and distribution of devices in the United States, as well as device safety and effectiveness. Because these regulations create the context in which the supply chain operates, we provide a high-level overview of FDA regulatory processes and requirements in the appendix.

In what follows, we provide a detailed overview of the processes involved in each element of the supply chain, starting from the top:

- suppliers
- manufacturers
- customers (hospitals, though distributors and GPOs play roles)
- patients and payers.

General Supply Chain Processes

Suppliers

Manufacturers of medical devices do not make every item that goes into their products by starting from raw materials. Indeed, manufacturers we spoke with typically did not buy raw materials at all. Rather, they bought machined parts, electronic components, chemicals, and materials from suppliers around the world. Those suppliers, in turn, buy supplies from other suppliers, and so on. Suppliers are referred to in tiers, based on their relationship to the manufacturer being discussed: Tier 1 suppliers sell goods to the manufacturer, Tier 2 suppliers sell to Tier 1 suppliers and are thus one step further removed from the manufacturers, Tier 3 suppliers sell to Tier 2 suppliers, and so on (Luo, 2018). The number of suppliers involved can be vast. One major manufacturer of medical devices said that across all lines of business, it had 100,000 Tier 1 suppliers alone. If Tier 2 and 3 suppliers were counted, there would likely be a million suppliers involved.

Because purchasing supplies involves a commitment of capital as well as storage costs, manufacturers typically keep their inventory of supplies as minimal as practical, in keeping with just-in-time practices (Waters-Fuller, 1995). Consequently, there may not be much inventory to absorb a disruption to the supply line or a dramatic increase in demand volume. Before COVID-19, it was not always a single item that was difficult to keep in supply. On any given day, any item could become a limiting factor: One device maker said that production was once held up for a couple of days because of a shortage of the ink used to label a product.

According to AdvaMed, a trade association for medical device manufacturers (AdvaMed, 2020b), medical device manufacturing often makes up only a small piece of the global market for any component. Many items used in the manufacture of medical devices are commonly used across different types of equipment. As one medical device manufacturer told us in an interview, "We are buying a lot of the same components that the electronic world buys." Diversification ensures that surges in demand from any single sector, such as medical devices, are not likely to overwhelm the suppliers. It also allows suppliers to recognize the importance of their product in a demand surge and, in cases such as a public health emergency, shift production from other sectors to their medical devices market, to accommodate the priority.

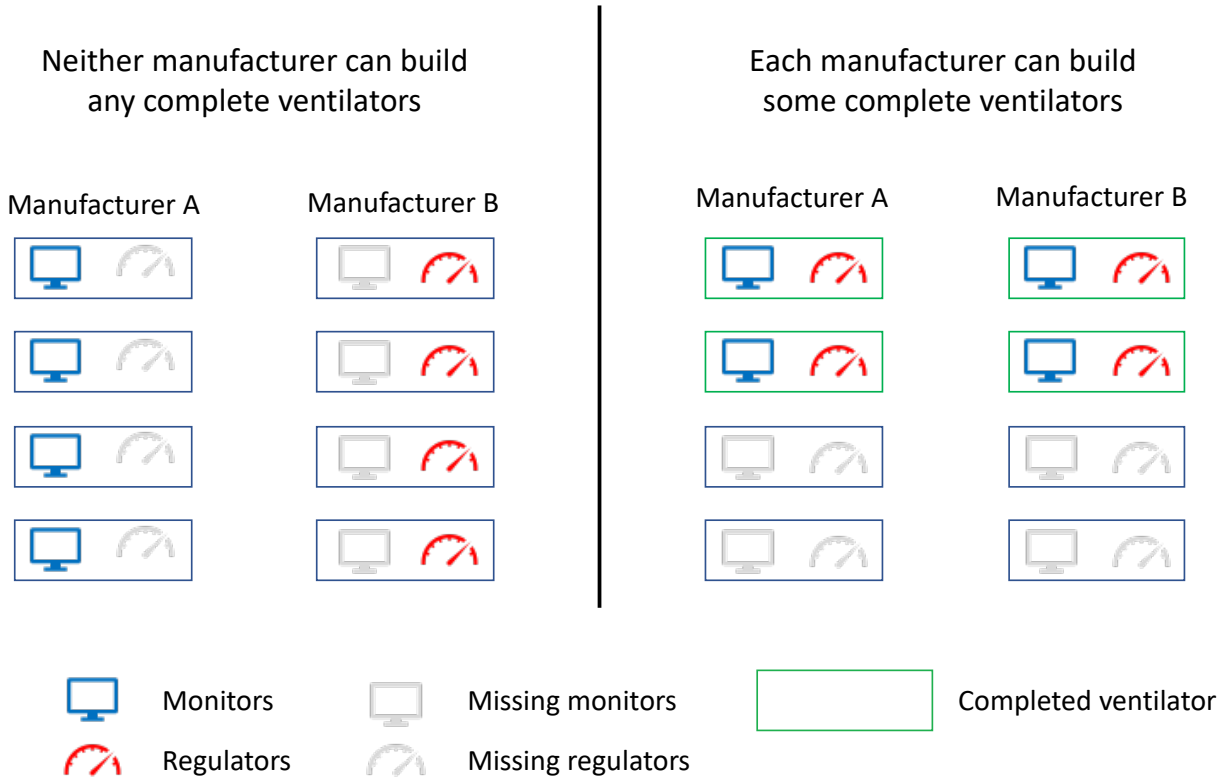
However, there are instances in which components are specific to a particular medical device. This is more common when the component is highly technical (e.g., a pressure regulator) and cannot be used on any device except that for which it was designed (e.g., a ventilator). Such components may have exacting specifications because of their potential function in highly regulated end products, and thus the barrier to entry is high. As a result, there are not many different sources for the item. Moreover, competing manufacturers may seek to purchase the same items from the same sources. If two manufacturers need the same item from the same supplier, the combined output of finished product from the two manufacturers will be limited by the supply of the item they are competing for.

The situation can be more challenging because products require multiple components, all of which could be in short supply. As a hypothetical example, consider a ventilator that requires both a regulator and a monitor. If one manufacturer were to buy up the entire supply of regulators in the market, while a different manufacturer bought up the entire supply of monitors, neither manufacturer would be able to produce any ventilators, because both would be lacking components that their competitor possessed. An example of this hypothetical situation is shown in Figure 2.2. In such situations, having a third party conduct coordination can be helpful.

As difficult as it is for a manufacturer of end products to cope with a substantial increase in demand, the difficulty is felt as much, if not more so, by suppliers, particularly smaller ones. Expanding the suppliers' manufacturing capacity carries with it the same challenges as those of the manufacturers, but potentially with greater financial risk. Suppliers have to expand their labor force and increase equipment capacity in short order. This is especially difficult for small suppliers and brings with it solvency risk if demand from manufacturers were to stop.

Manufacturers we spoke with reported providing technical assistance as well as financial assistance in bearing the solvency risk to their suppliers.

Figure 2.2. Example of Poor Allocation of Parts Among Competing Manufacturers



Finally, we note that many medical devices are required to be sterile (free of bacteria or other microorganisms) to prevent potential transmission of disease upon use (CDC, 2016b). This is often done by a contract sterilizer, which can be considered yet another type of "supplier." Although sterilization of heat-stable items such as scalpels and retractors used for surgery can be done using high heat (often steam), medical devices made of materials such as plastic or resin, those with hard-to-reach crevices (such as catheters), or items that cannot withstand moisture from steam sterilization (such as wound dressings) require low-temperature sterilization using methods such as ethylene oxide (EO) or ozone (CDC, 2016a).

Transportation

Industry associations report that, measured by dollar value, two-thirds of all finished medical technology used in the United States is made domestically. Of the imports from other countries, most (again by dollar value) are from the European Union (12.5 percent), followed by Mexico

(5.3 percent), and then China (3.3 percent) (AdvaMed, 2020b). However, focusing on such statistics, which consider only finished goods, risks minimizing how dependent even domestic manufacturing of medical devices is on imported supplies, including raw materials and medical device components. In some cases, overseas suppliers are used because of their expertise, though production cost may come into play. For instance, producing supplies or even end products close to where raw materials are located is more cost-effective than shipping raw materials. Regardless of the reason, the use of overseas suppliers means that raw materials and/or medical devices components must be transported between suppliers and manufacturers.

Normally materials are transported by sea, for cost reasons. While slow, the lead time can be factored into production planning, and, as mentioned earlier, the pipeline can serve as a buffer to short-term supply disruptions. However, in an emergency, waiting for supplies to move by sea is not viable. In such situations, transportation of essential supplies may be shifted to air.

Manufacturers

Production Equipment

Devices are typically manufactured on assembly lines, where, conceptually, discrete items enter at one end, are processed and assembled with other items along the way, and exit as finished products. Assembly lines are often optimized for mass production of one product: They are set up to make one product very efficiently, but this degree of specialization means that the system cannot be adapted to produce a different product without a potentially large degree of effort, downtime, and expense. This is particularly likely to be the case for items that are produced in relatively high volume.

In contrast, lower-volume items might be produced in a flexible manufacturing system, where a batch of one item is produced over some period of time, then the equipment is reconfigured to produce a different product. The benefit of flexible manufacturing systems is that the equipment can produce more than one type of item. A price is typically paid in terms of the equipment being more complicated and expensive, and less efficient at producing at high volumes than dedicated equipment would be. Manufacturing in a system that cycles between different products usually results in an inventory of more finished goods at any given time, since any batch that is produced must cover not only baseline demand but also demand when the production line is devoted to producing other items.

Manufacturers typically size their capacity to anticipated demand. They can usually keep up with small surges in demand but do not have much excess capacity sitting idle, because building significant excess capacity requires capital investment in equipment and therefore money and space (Trivedi, 2020).

Labor

Labor is a vital component in manufacturing. For some manufacturing, production may essentially be automated, with workers simply troubleshooting and conducting quality control activities. However, for many medical devices, specialized labor may be required to operate the manufacturing lines.

Maintenance and Repair

Maintenance and repair does not apply to consumable goods, which are disposable and often single use. However, some medical devices, particularly complex machines such as ventilators or laboratory equipment, need regular maintenance and service. Hospitals needing to service such devices often face restrictive warranties and agreements and other obstacles that can prevent them from obtaining service outside the manufacturer.

Hospital clinical staff (including therapists, nurses, and physicians) have several support options when they need to troubleshoot medical devices. Hospitals maintain in-house technicians, typically health care technology management professionals or biomedical repair technicians (Advancing Safety in Health Technology, 2020). If hospitals lease equipment from a medical equipment supply company, repairs and maintenance are typically included in the contract costs (Baird and Custer, 2020). Those services are often provided via one of the options described below.

If hospitals do not have in-house technicians who can maintain and service their complex machinery, they may turn to third-party biomedical equipment **maintenance and repair companies**. The alternative to in-house or third-party service technicians is to enter into a **repair service contract** with the manufacturer. Very often, hospitals use varying combinations of these options depending on the type of machinery owned or leased and under what terms.

There are important differences between these options. According to one health care executive, manufacturer repair service contracts are often priced "between ten and twenty percent of the cost of the device" (Lauterbach, 2020). Although in-house and third-party technicians can likely handle minor issues like tubing disconnections or providing support for device settings, if the issue requires servicing or repair of the device, options may be limited. Some in-house technicians may have the ability, under a hospital's contract with the manufacturer, to contact the manufacturer's technical support team, or in-house technicians may have knowledge of servicing and repair approaches from attending the costly training classes offered by manufacturers. However, hospitals often maintain a wide variety of medical devices (including ventilators) from several manufacturers, which can quickly compound the costs to support in-house technicians, given that training and certification programs offered by manufacturers can cost up to $7,000 per technician trained (Scher, 2020).

Larger third-party service providers may have partnerships with many manufacturers and be able to provide service on a wider range of medical devices from a range of manufacturers

(Agiliti, 2020). Technicians have reported needing to "wade through a labyrinthine system of fees, requests, certifications, and training programs before servicing the devices" (Scher, 2020).

Aside from being able to access service manuals, parts, and training necessary to perform service and repair, some manufacturers use software locks (requiring passcodes or other proprietary unlocking technology) to make modifications or even to obtain the diagnostic readout (Koebler, 2020; Linder, 2020; Scher, 2020). Even obtaining service manuals can be challenging.

Medical device manufacturing trade groups have argued that patient safety issues may arise if repairs are done by outside technicians (Gibson, 2020; Koebler, 2020). However, a 2018 FDA study reported that "many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices" and that "the continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system" (U.S. FDA, 2018a).

Customers

Below, we describe the broad category of customers and how they function in the supply chain, particularly in setting the level of demand for goods. Then we describe the two major types of customers: *hospitals* and *distributors*.

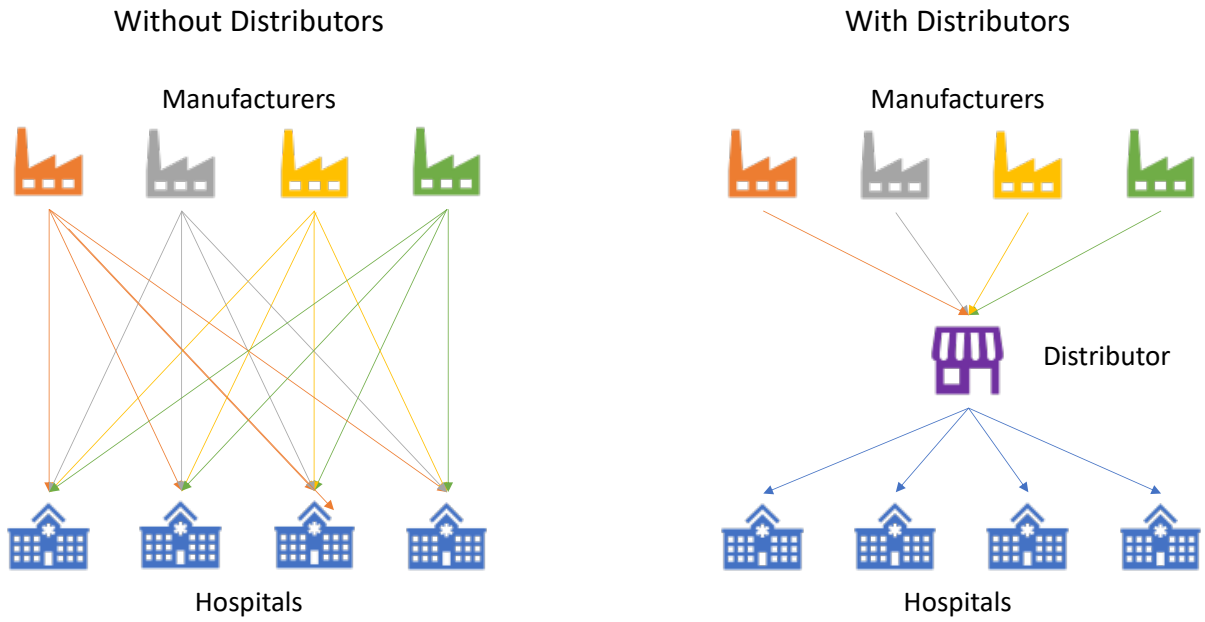
Customers play an important role in the ability of a supply chain to cope with surges by providing the demand signal that drives decisionmaking up the chain. Customers may drive demand directly, based on their tastes or preferences (which in turn may be influenced by factors including media, advertisements, or politicians). Customer demand may also be affected indirectly such as through changes in the overall population (an aging population might drive greater demand for technologies to support independent living) (Euromonitor International, 2020) or changes in disease prevalence (higher rates of obesity drive increased demand for diabetes-related products such as insulin) (Basu et al., 2019). Predictable demand means that production can occur at a stable rate, with items built to stock, where they wait in inventory until being sold (Patel et al., 2017). One company estimated it does four inventory turns per year; in other words, items stay in inventory on average for about a quarter of a year. By comparison, drug manufacturers we spoke to reported producing in large batches, making enough in each production run to cover several months. This suggests around two inventory turns per year, which would be consistent with estimates reported in some online sources (Ready Ratios, 2020). At the other extreme, a high-volume retailer might have as many as nine turns a year (Franco, undated).

Distributors

Distributors are one category of customer. Some examples of larger distributors are McKesson, Cardinal Health, and AmeriSource Bergen. Distributors negotiate with a number of different manufacturers to purchase a wide variety of products. These products are then stored in central warehouses and sold, usually along with other products from other manufacturers, to the

ultimate end users. Often, hospitals use distributors to purchase high-volume consumable goods such as PPE. Distributors buy goods from manufacturers, store them, and resell them to hospitals and other health care providers. Distributors earn a fee by providing a service that consolidates and simplifies the process for both hospitals and manufacturers. Figure 2.3 illustrates how a distributor can help simplify procurement.

Figure 2.3. Flow of Deliveries Without and With Distributors



The advantage to hospitals is that rather than negotiating contracts and managing purchase orders and deliveries from one manufacturer to procure gloves, another for pipettes, and a third manufacturer for ventilator tubing, hospitals need only deal with one organization. Another advantage is that distributors typically work with multiple manufacturers. Thus, a shortage from one manufacturer might be addressed with products from another. Finally, because distributors maintain stocks of products and deliver them to hospitals when needed, the distributors relieve hospitals of having to carry larger amounts of inventory themselves.

There are also advantages for manufacturers to working with distributors. By effectively consolidating purchases from multiple hospitals, the distributor simplifies the outbound logistics for the manufacturer. And because the distributor typically takes ownership of items purchased from the manufacturer, the distributor incurs the credit risk and billing burden of selling items to hospitals. In addition, for items lacking brand recognition by hospitals, such as with PPE, distributors provide value by sourcing, vetting, and establishing contracts with manufacturers.

However, some have raised concerns that established contracts between manufacturers and distributors can limit choices for hospitals if a distributor's contracted suppliers run out of an

item and the distributor is unwilling to source, or ineffective at sourcing, on the open market (Mehrotra, Malani, and Yadav, 2020).

Hospitals

For the sake of simplicity, we refer to the second category of customers for COVID-19 relevant medical devices as "hospitals." In practice, customers for these devices are a diverse group and may include any end user from a small, privately owned physician practice to large, multistate integrated health care delivery systems. For devices sold through retail channels, patients themselves may be the end-user. However, given the central role of hospitals in the COVID-19 pandemic, we focus on them in this report.

Hospitals typically purchase some goods directly from manufacturers, especially large, high-cost equipment, while working through distributors or other entities for other items. In general, hospitals function as independent entities, though hospitals within the same health system often, but not always, function together. Indeed, hospitals in the same market often compete with one another for patients, workforce, and payer contracts. An additional method through which hospitals work together, albeit through an intermediary, is GPOs, indicated within the dashed-line box in Figure 2.1.

Group Purchasing Organizations

GPOs are organizations that combine the purchasing power of their members, which are hospitals, in order to gain leverage to negotiate more favorable contract terms. GPOs negotiate contracts with manufacturers and distributors on behalf of their members. Hospitals do not buy products from the GPO. Rather, when hospitals in the GPO purchase devices from a distributor or manufacturer, they purchase according to the price negotiated by the GPO. In some circumstances, the GPO-negotiated price paid by the hospital to the distributor may be lower than what the distributor paid to purchase the device from the manufacturer. In such cases, the distributor will get money back from the manufacturer in the form of a "chargeback."

Nearly all hospitals are members of GPOs, and in 2014, it was reported that approximately 72 percent of hospital purchases were made through GPOs (Becker's Hospital Review Staff, 2014a; Fulton, 2019). Some hospitals are members of more than one GPO and may make purchases through a GPO as well as on their own. However, interviewees told us many GPO contracts include a commitment level, requiring members to order a certain amount of their supplies through the GPO or face financial penalties (e.g., hospitals would forgo end-of-year rebates for hitting their ordering targets), which limits purchasing outside the GPO.

GPOs make money in two ways. The first is through administrative fees paid by manufacturers to be included in GPO catalogs and on their contracts. These fees are disclosed to member hospitals (HSCA, undated). Most GPOs do not charge hospitals for GPO membership, though this varies. Many GPOs also make money by providing services that are outside the

traditional scope of work, such as supply chain consulting and even manufacturing (Kacik, 2018).

GPOs affect the structure of the medical device supply chain in numerous ways. Critics of GPOs, including individuals we interviewed, contend that the large purchasing power of GPOs pushes manufacturers to focus on prices instead of supply chain resilience, while forcing small manufacturers out of the market in favor of a few larger ones (Bruhn, Fracica, and Makary, 2018). This may be particularly true for already low-margin products such as medical gloves. Some have expressed concerns that GPOs introduce particular challenges during surges in demand: Larger hospitals making more significant purchases may have their orders preferentially filled, which can lead to disparities in access to supplies. In addition, given the absence of "failure to supply" arrangements in most GPO contracts, hospitals have little recourse if manufacturers are unable to fill contracts negotiated through GPOs (Devaiah et al., 2020).

GPOs contend that they help lower prices and bring efficiency to the market through negotiations, and that they find the newer, smaller innovative manufacturers that hospitals would not be able to find on their own.

Some industry researchers have noted that the GPO approach "breaks down in two cases: when the price of a specific drug, typically one with a single supplier, gets 'too high,' and when a drug or set of drugs is in short supply" (Conti and Krongold, 2018). Although the article cited was specific to drugs, the same would presumably apply to medical devices. In recent years, alternative approaches have begun to emerge. For instance, in the wake of hospital consolidations and mergers, some larger hospital systems brought at least some of their purchasing functions in-house by creating or acquiring their own GPOs or similar entities (Bruhn, Fracica, and Makary, 2018). Others have created regional GPOs that combine the purchasing power of hospitals in a particular geographic region (Burns, 2014).

Consolidated Service Center Model

Another approach, often used by larger hospital-based health care delivery systems, is the consolidated service center. In this model, hospitals serve as their own primary distributor, obtaining goods from various manufacturers and even other distributors. These goods are stored centrally and distributed among the hospital system's various settings—typically, both acute and nonacute settings and across multiple hospital sites.

Procurement in Practice

As shown in Figure 2.1, hospitals typically do not purchase all the goods they need using a single method. Overall, hospitals determine the most advantageous approach for purchasing a variety of goods, balancing their existing relationships with GPOs, distributors, or available consolidated service centers with their own staff availability to negotiate and manage purchases directly from manufacturers. Generally, lower-cost, larger-volume goods such as PPE are purchased through GPOs (via distributors) or directly from distributors, while more expensive,

lower-volume goods are purchased directly from manufacturers. However, these are not hard-and-fast rules. Individuals from an organization representing hospitals told us that some manufacturers do not work directly with hospitals and that their goods can be obtained only through distributors. This allows manufacturers to contract with a few distributors rather than with hundreds of hospitals. Other manufacturers work only with hospitals, cutting out distributors completely. And still other manufacturers may do both.

Patients and Payers

Hospitals provide health care services to patients using the medical devices flowing through the supply chains we detail in this report. Most patients receiving these services are covered by health insurance; a small proportion are not. Health insurance is offered in the United States primarily via commercial insurers, either through a current or former employer or purchased on the individual market. Other large government programs like Medicare and Medicaid cover significant shares of the U.S. population. Patients with health insurance pay for coverage through premiums and, if applicable, contributions from their employers. Patients with health insurance often must pay a share of the cost of care out-of-pocket. Patients without coverage may be billed directly for the entire cost of care. We refer to the source of coverage that ultimately pays for services as the "payer," although in some cases the insurer offering a health plan may be a different entity than the payer (for example, in cases where an employer is a payer and an insurer operates the health plan on behalf of the employer).

Medicare, Medicaid, and commercial payers usually pay for services holistically, using approaches such as the diagnosis-related group approach, rather than paying for specific services, devices, or other inputs individually. For example, payers typically pay for an inpatient stay of a certain type regardless of whether a ventilator was used, PPE was used, or specific tests were performed during the stay. However, the rates for these services typically reflect a mix of historical and/or assumed costs involved in providing the service, so hospital and other providers' costs associated with devices are indirectly reflected in payments.

Medicare uses two prospective payment systems, the Inpatient Prospective Payment System (IPPS) and the Outpatient Prospective Payment System (OPPS), to pay for most inpatient and outpatient facility services. Medicare uses a separate Physician Fee Schedule (PFS) to pay for professional services like office visits. Depending on context, services listed on the IPPS, OPPS, and PFS can be more or less directly related to the use of a device. For example, there are separate professional services for performing and interpreting diagnostic advanced imaging (like magnetic resonance imaging), a service closely aligned with the use of a specific medical device. Under all three systems, payment rates are prospective in that they are set ahead of time. Many other payers use similar approaches to pay for health care services.

These systems incentivize providers to use an efficient mix of inputs when furnishing health care services because the provider retains the margin between the prospective rate and the actual cost of providing care. Providers choose which device vendors to use, both for consumables and

for capital medical devices like ventilators and imaging machines. Payment is typically not linked to using a specific type of device, and it is even less common that payers will insist on using a device from a particular manufacturer. Payers will in some cases limit coverage for specific uses of some types of devices—for example, limiting coverage of separately paid advanced imaging services to patients meeting certain clinical criteria.

Medicare and other payers have some exceptions for certain expensive or new implantable devices where there are separate or "pass through" payments (Centers for Medicare & Medicaid Services [CMS], 2020b). Separate payment for new devices is necessary because Medicare's and other prospective payment systems are based on historical (i.e., lagged) cost and other data. Providers face weaker incentives to control utilization of devices in cases where separate payments are made.

3. Supply Chains for COVID-19 Relevant Devices

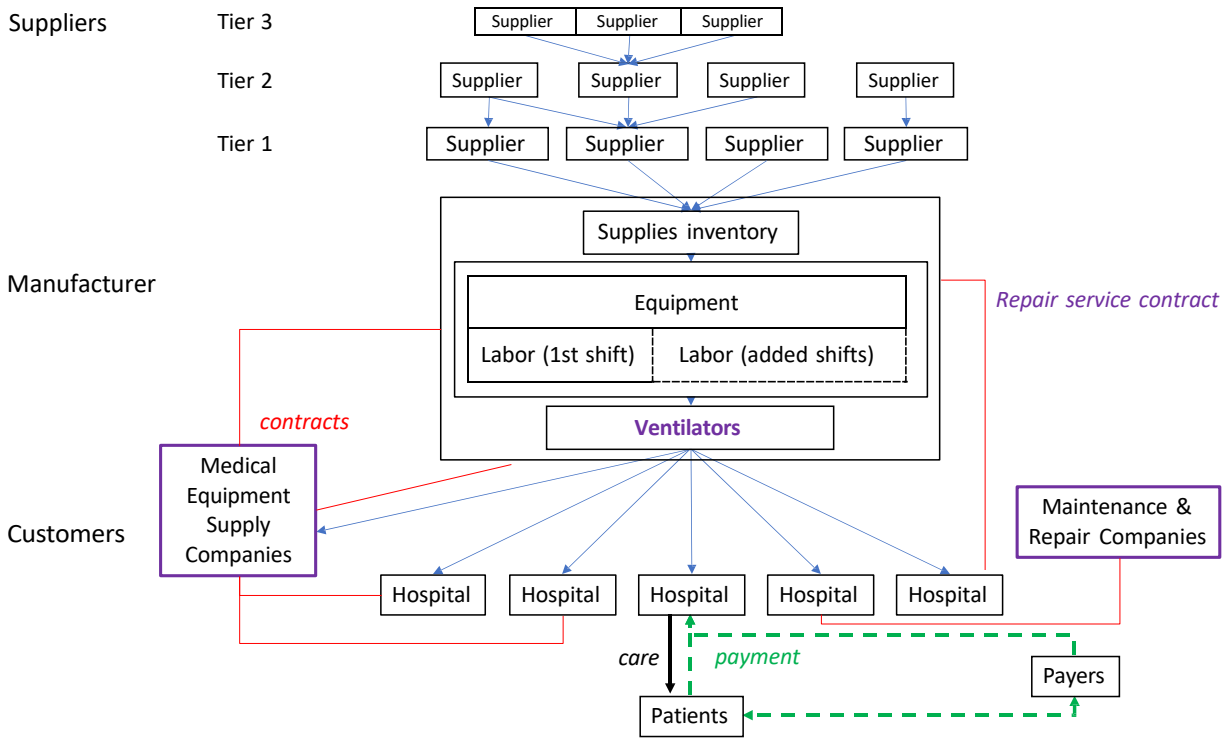
In the preceding chapter, we laid out the general processes for the supply chain for medical devices. Below, we provide additional details for specific COVID-19 relevant devices where information and detailed descriptions were available. Where data on supply and demand are available, we have cited it. However, comprehensive centralized data about COVID-19 relevant medical devices were not publicly available early in the COVID-19 pandemic, even for big-ticket devices such as ventilators that, theoretically, might be easier to track than a disposable item such as a surgical gown. This is a substantial limitation to existing data systems, and we discuss this systemic weakness in Chapter 5, "Strategies for Future Surges."

Ventilators

Ventilators are durable equipment, though their use involves disposable items. The durable components consist of machinery to pressurize air, valves that regulate the pressure at which the air is delivered, and electronics to monitor and control the delivery. The disposable components are the patient-contacting circuits—essentially plastic tubes that connect the ventilator to the patient. Ventilators and their components are used when a patient's own lungs are unable to appropriately exchange gases (expel carbon dioxide and take in oxygen) on their own. This happens in SARS-CoV-2 infection because the inflammation caused by the virus and the patient's own immune response fills the lungs with fluid. A ventilator is able to produce pressures greater than a patient can generate on his or her own, in essence forcing gas exchange.

The supply chain for ventilator components mirrors the general supply chain described in Figure 2.1. However, there are a few important differences to note in the supply chain for ventilators themselves, which we depict in Figure 3.1. The differences are highlighted by the purple outlined boxes, titled **Medical Equipment Supply Companies** and **Maintenance and Repair Companies**, and the text, **Repair service contract**. These components of the ventilator supply chain are described below.

Figure 3.1. Ventilator Supply Chain



NOTE: Blue arrows indicate transportation of materials and goods. Red dotted lines indicate contractual relationships. Green dashed lines indicate payment for patient care.

Suppliers

The overall supply chain for ventilators and ventilator components follows the same general model, though with different degrees of complexity. While the supply chain for disposable ventilator components is relatively simple, a ventilator can have upward of 1,500 parts. One ventilator manufacturer we spoke with reported having 200 suppliers to provide the necessary components for its ventilators. In some instances, these individual components may be used by other manufacturers across various other types of devices, both medical and nonmedical (e.g., for automotive or other equipment manufacturing). However, there are instances in which components are very specific to a particular medical use. This can lead to situations where different manufacturers are essentially competing for the same items.

Transportation

We did not identify any deviance from the general model in regard to the transportation of ventilators or ventilator components.

Manufacturers

We did not identify major deviations from the generally described process for manufacturing of ventilators and ventilator components.

Production Equipment

We did not identify major deviations from the generally described use of production equipment in the production of ventilators for manufacturers already producing ventilators.

Labor

We did not identify major deviations from the generally described processes for labor in the production of ventilators for manufacturers already producing ventilators.

Maintenance and Repair

Maintenance and repair does not apply to consumable goods such as disposable ventilator components. However, ventilators are complex machines that need regular maintenance and service. We did not identify major deviations from the generally described processes for maintenance and repair for ventilators.

Customers

Consumable items, including disposable ventilator circuits, are typically sold through distributors (Mehrotra, Malani, and Yadav, 2020), as depicted in the general supply chain in Figure 2.1.

However, durable equipment such as ventilators are sold directly to hospitals or health care organizations. As shown in Figure 3.1, another route for hospitals to acquire ventilators is to lease them from **Medical Equipment Supply Companies** (Henry, 2020). There are various types of medical equipment supply companies. Some cater to patients themselves, offering rentals or purchases of durable medical equipment such as wheelchairs, hospital beds, and continuous positive airway pressure (C-PAP) machines. Another category of medical equipment supply companies specializes in providing durable medical equipment such as ventilators, infusion pumps, and EKG (electrocardiogram) machines to hospitals (Baird and Custer, 2020).

Ventilators are expensive and infrequently purchased (relative to high-volume items such as PPE), with purchases driven by equipment replacement cycles and hospital budget cycles via capital equipment. With vendor-customer relationship management, this results in stable forecasts of demand that enable production planning.

Regulations

Ventilators and ventilator accessory components are regulated by FDA as Class II devices, and all are subject to Premarket Notification and current good manufacturing practice (CGMP)

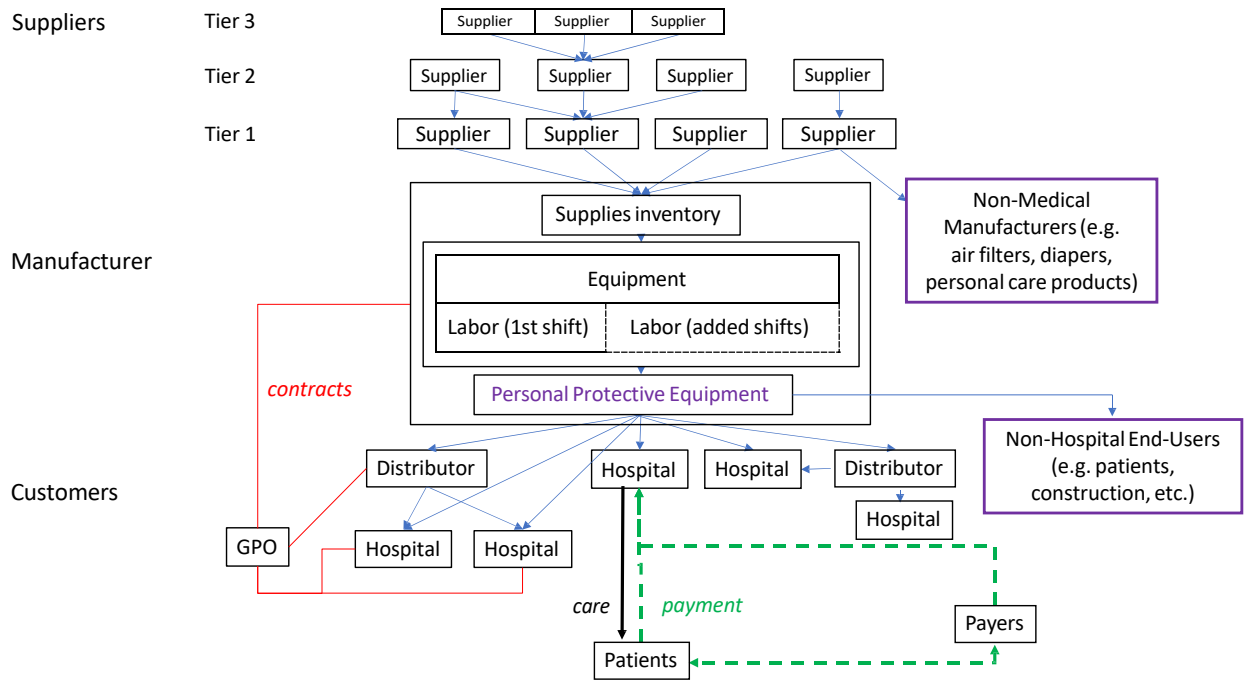
requirements (U.S. FDA, 2020r; U.S. FDA, 2020u). See the appendix for a description of these requirements.

Personal Protective Equipment

A variety of PPE is used in the provision of medical care to patients with COVID-19. Because PPE items are intended to be disposable, it is a low-margin, high-volume business. Three common examples of PPE are masks, gowns, and gloves. Masks primarily consist of a nonwoven fabric made of synthetic fibers, such as polypropylene, that are melted together in a tight, random pattern that serves to filter air particles. Gowns are also made of nonwoven fabric; here the fabric's purpose is not filtration but, rather, water resistance. Gloves may be made of synthetic rubber (e.g., nitrile) or natural rubber and are also meant to protect the wearer from contact with potentially infected surfaces.

Although the supply chain for PPE generally mirrors the generic supply chain described in Figure 2.1, there are a few important distinctions particularly at the customer level, which we depict in Figure 3.2. The main difference is highlighted by the purple outlined boxes titled **Nonmedical Manufacturers** and **Nonhospital End Users**.

Figure 3.2. PPE Supply Chain



NOTE: Blue arrows indicate transportation of materials and goods. Red dotted lines indicate contractual relationships. Green dashed lines indicate payment for patient care.

Suppliers

The main input needed to produce masks and gowns is nonwoven fabric, which is also used by **Nonmedical Manufacturers** in a number of areas, including in the agricultural industry (e.g., as crop cover, landscape fabric, and weed control), production of personal care items (e.g., baby wipes and diapers), lining for high-performance clothing, and air conditioning filters (Association of the Nonwoven Fabrics Industry, 2020). Natural rubber is an important supply for other types of PPE, such as gloves, and is also used in many other applications, such as wiper blades and tires. Nitrile rubber is a synthetic polymer that is also used to manufacture gloves; it also has industrial applications because of its general resistance to heat, oil, and other chemicals (J-Flex, 2020).

Transportation

The Congressional Research Services (CRS) estimates that imports from other countries to the United States typically account for anywhere from roughly 35 to 90 percent of total PPE supply, depending on the category of PPE. However, CRS notes that the data underlying these estimates is complicated, particularly since there are no agreed-upon guidelines, standards, or definitions of what specific products make up the various categories of PPE, or even what constitutes PPE (Congressional Research Services, 2020a). Some types of PPE, such as N95s, have an even higher rate of production overseas—nearly 90 percent of N95s are imported to the United States, mostly from China (Dai, Bai, and Anderson, 2020). Natural rubber, used in the production of some types of PPE such as gloves, is largely grown in Asia, with Thailand, Indonesia, and Malaysia collectively accounting for 70 percent of global production (GEP Worldwide, 2019). Rather than shipping raw material across the ocean, it is more cost-effective to process and manufacture it near the source, before shipping. Not surprisingly, Malaysia is the world's largest producer (by country) of medical gloves, providing approximately 60 percent of global exports (Moel and Reeves, 2020).

Having manufacturers produce PPE outside the United States necessitates the transportation of these products to the United States. Beyond the challenges of slow cargo ship transportation that have been previously discussed and the capacity limitations of air transport, border restrictions also caused problems.

Manufacturers

Production Equipment

Both nonwoven fabric suppliers and PPE manufacturers have described investing in additional equipment to expand their production in response to the H1N1 influenza pandemic in 2009. However, they also noted that after that pandemic, demand was drastically reduced, resulting in significant financial hardship because there were no long-term purchase guarantees (Mendoza et al., 2020).

Labor

Most PPE manufacturers are located outside the United States and faced the labor shortages that resulted from border closures and restrictions on movement already described in Chapter 2.

Stateside, manufacturers have reassigned existing labor supply to manufacture PPE rather than their usual products (e.g., cars, clothing) (Korosec, 2020; Mazzoni, 2020; Noble and Grzelewski, 2020) .

Maintenance and Repair

PPE is typically meant to be single use. Therefore, there are no contracts for maintenance and repair.

Customers

As shown in Figure 3.2, there is an additional category of customer for PPE that is not present for other COVID-19 relevant devices discussed in this report. Many types of PPE, including goggles, gloves, and masks, are frequently purchased by **Nonhospital End Users** such as patients who buy these items in pharmacy and other medical supply stores and consumers in other industries such as construction and mining.

Consumable items, such as PPE, are typically sold through distributors (Mehrotra, Malani, and Yadav, 2020) before being purchased by hospitals. PPE is a low-margin, high-volume business to which few people have paid attention outside of occasional demand surges (Patel et al., 2017).

Regulations

Among COVID-19 relevant PPE, medical gloves (U.S. FDA, 2020y; U.S. FDA, 2020ab), face shields (Hinton, 2020a), and some types of isolation gowns (U.S. FDA, 2020t; U.S. FDA, 2020x) are Class I devices (Hinton, 2020a). Gloves and gowns are required to undergo Premarket Notification and are also subject to good manufacturing practice (GMP) requirements. Face shields were authorized for use under an emergency use authorization (EUA) and, therefore, received waivers for CGMP and some labeling requirements (Hinton, 2020a). N95 masks are officially known as N95 filtering facepiece respirators and are regulated as Class II devices by FDA (U.S. FDA, 2020w). They must undergo Premarket Notification and are subject to CGMP requirements (U.S. FDA, 2020e). See the appendix for a description of these requirements.

Among PPE, N95 masks pose a special case for regulation. The National Institute for Occupational Safety and Health (NIOSH) is the federal agency that provides testing and approval for certain types of medical equipment that affect workplace safety, including N95 masks. Thus, some products are tested and approved by NIOSH as N95 respirators (meaning they are certified to filter out at least 95 percent of very small particles from the air that pass through them) (CDC, 2020a) *and* those items are also regulated by FDA (NIOSH, 2020).

NIOSH's sole interface with manufacturers is in regard to testing the effectiveness of N95 masks.

Testing Supplies and Equipment

Testing supplies and equipment refers to the components needed to conduct clinical laboratory testing, each of which is manufactured by a different process. Because there are a myriad of clinical laboratory tests that *can* be conducted, we focus here on those that are required to test for SARS-CoV-2 infection. Nearly all of the components needed for these tests can be used for other tests as well. These supplies and equipment include (Global Reporting Centre, 2020a)

- nasopharyngeal swabs for collecting the sample
- blood collection kits for serology tests
- universal transport medium for transporting the sample to a lab
- chemical reagents to process the sample
- controls to verify the test instrument and reagents are functioning properly
- platforms and instruments such as micropipettes, pipette tips, micro-centrifuge tubes, and a vortex mixer for precisely moving and mixing liquid during the testing process
- testing machinery such as ribonucleic acid (RNA) extraction machines, thermocyclers, and polymerase chain reaction (PCR) machine.

There are two broad categories of COVID-19 tests: *diagnostic tests* detect the presence of various components of the SARS-CoV-2 virus and indicate active infection; *antibody tests* detect the presence of antibodies to the SARS-CoV-2 virus and indicate past infection. Table 3.1 provides further details on the different types of tests.

Table 3.1. Types of COVID-19 Tests

	Diagnostic Test		Antibody Test[a]
	Molecular Test	**Antigen Test**	**Antibody Test**
Identifies	Current infection	Current infection	Past infection
Detects	RNA from the SARS-CoV-2 virus	Nucleocapsid protein (N protein) from the surface of the SARS-CoV-2 virus	Antibodies (IgM or IgG) to components of the SARS-CoV-2 virus (N protein or Spike protein)
May also be referred to as	PCR test Nucleic acid amplification test Loop-mediated isothermal amplification	Rapid antigen test	Serology test[b]
Sample needed	Nasal swab, throat swab, or saliva sample	Nasal swab	Blood

[a] See U.S. FDA, 2020o.

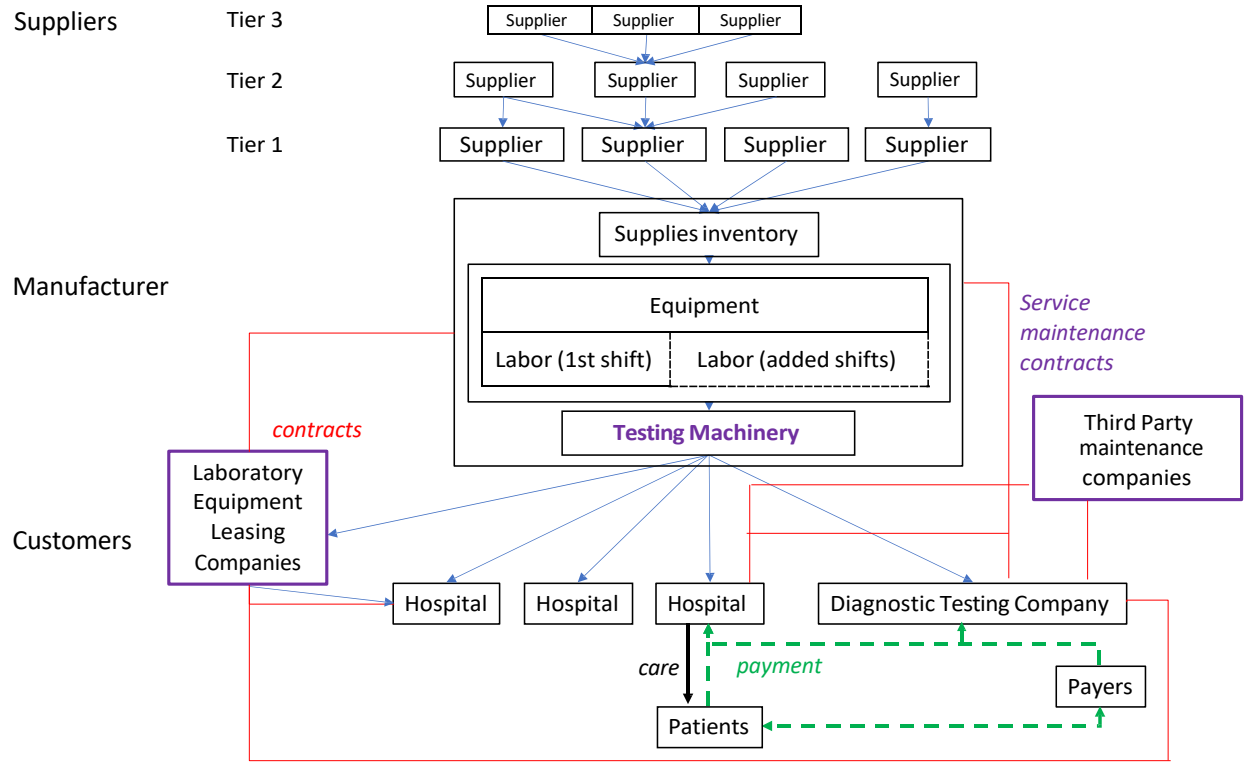
[b] There are also serology tests that detect components of the body's adaptive immune response (e.g., T cells) to the SARS-CoV-2 virus. They are designed to complement antibody testing and are generally not used alone. Therefore, they are not included here. See U.S. FDA, 2020o.

Additionally, while FDA has reviewed, and continues to review, COVID-19 diagnostic tests, it regulates the diagnostic molecular test by requiring verification and validation for all steps of testing. This includes but is not limited to (1) the components of a test kit (e.g., primers and probes, buffers, enzyme mix, control components) and (2) materials required for testing but not included in a test kit (e.g., analyzers [thermocyclers and PCR machines], centrifuges, reagents, other components). Because of the sensitive nature and complexity of the relationship between test kit components and equipment, on the one hand, and other supplies needed for analysis, on the other, FDA authorizes molecular diagnostic tests for specific test-analyzer combinations supported with the numerous recommended validation tests (U.S. FDA, 2018d; U.S. FDA, 2020b; U.S. FDA, 2020ab).

The supply chain for consumable testing components (e.g., pipettes, swabs, chemical reagents) mirrors the general supply chain described in Figure 2.1, with one key difference. With the advent of home testing kits (Abbott, undated), patients are able to collect their own samples and perform analysis at home in some instances, making the patients themselves the customer.

However, there are several important differences to note for the supply chain for the complex testing machinery, such as PCR machines and thermocyclers, which we depict in Figure 3.3. The differences are highlighted by the purple outlined boxes, titled **Laboratory Equipment Leasing Companies, Third Party Maintenance Companies,** and the text, **service maintenance contracts**. These components of the testing machinery supply chain are described below.

Figure 3.3. Testing Machinery Supply Chain



NOTE: Blue arrows indicate transportation of materials and goods. Red dotted lines indicate contractual relationships. Green dashed lines indicate payment for patient care.

Suppliers

We did not identify major deviations from the generally described processes for suppliers in the production of testing equipment or testing machinery.

Transportation

We did not identify any deviance from the general model in regard to the transportation of testing equipment or supplies. However, there is an additional component of transportation in regard to testing, which we discuss in the customers section, below.

Manufacturers

We did not identify major deviations from the generally described process for manufacturing of testing machinery and testing components.

Production Equipment

We did not identify major deviations from the generally described process for the use of production equipment in the manufacturing of testing machinery and testing components.

Labor

We did not identify major deviations from the generally described process for the use of labor in the manufacturing of testing machinery and testing components.

Maintenance and Repair

Some COVID-19-related equipment, such as test tubes, pipettes, and swabs, require no maintenance as they are meant to be single-use disposable items. For more complex equipment, such as PCR machines and thermocyclers, laboratories may maintain a wide variety of approaches for maintenance and repair, as described in Chapter 2. Larger hospital systems, particularly those within an academic medical center, may have technicians on staff who are able to perform simple repairs. As is the case with ventilators, many of the complex machines required to perform COVID-19-related testing may have similarly restrictive warranties requiring authorized service repairs only (Bio-Rad Laboratories, 2011). When hospitals or laboratories lease their testing machinery from laboratory equipment leasing companies, these contracts typically include service and repair. Many laboratories choose to enter into **service maintenance contracts** with manufacturers or **third-party providers** for maintenance and/or repair of their complex and expensive equipment. These contracts may range from basic packages providing limited on-site repair services and/or preventive maintenance to more advanced packages that include multiple visits for preventive maintenance and multiple and potentially expedited on-site repair services. Some contracts cover both parts and labor, while others cover only parts or only labor (Palashis, 2019; Spectrofuge, undated). Additionally, some COVID-19-related testing machinery needs to be recalibrated periodically in order to ensure accurate functioning, and this may also be included in service maintenance contracts.

Customers

One unique facet of diagnostic testing is that the act of testing is commonly split into two parts: the sample collection, for which swabs, transport medium, and collection tubes are needed, and sample analysis, which uses reagents, pipettes, buffering solutions, and testing machinery. These two steps may or may not occur in the same facility. Hospitals may collect the patient sample and perform the analysis in their own laboratory, or they may send the sample to a diagnostic testing company. Patients may visit the hospital to obtain a diagnostic test, or they may go directly to **diagnostic testing companies** that specialize in clinical laboratory services. Finally, with the advent of at-home testing and analysis kits, in some instances, patients themselves may be the customer (Abbott, undated).

Many, but not all, hospitals perform diagnostic testing in their own clinical laboratories. Some hospitals outsource some or all laboratory tests to diagnostic testing companies such as Quest Diagnostics and LabCorp. These companies may operate clinical labs that are physically located inside the hospital's facilities, or their labs may be located off-site, making them an additional customer for diagnostic testing components and equipment.

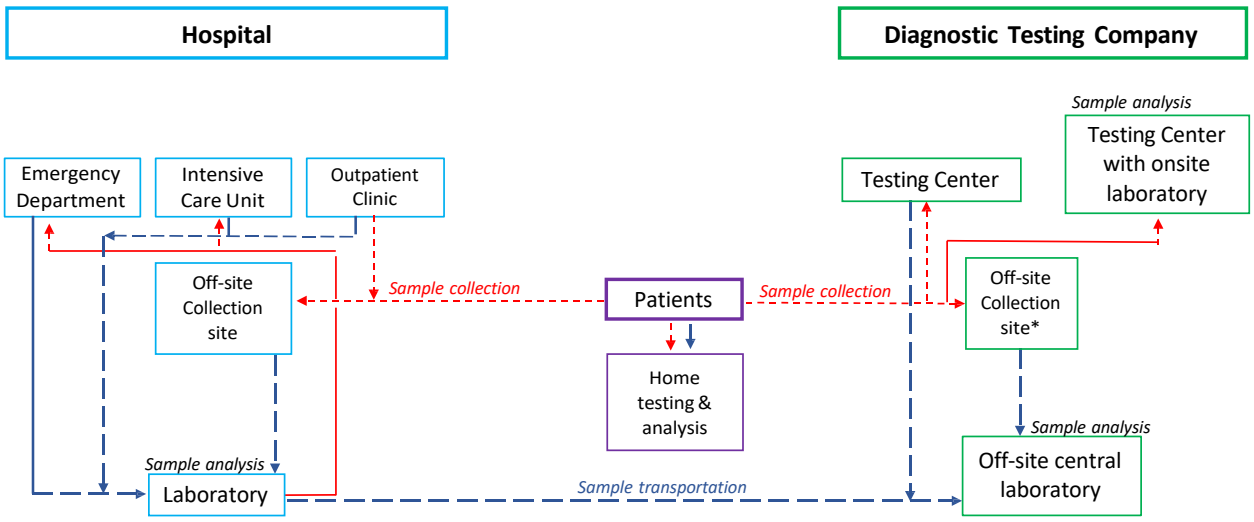
Thus, in terms of identifying customers for diagnostic testing supplies and equipment, some devices (e.g., swabs, transport tubes) need to be acquired by the collection site, and others (e.g., pipettes, reagents, testing machinery) need to be acquired by the analysis site. In some cases, collection and analysis sites are the same facility.

In general, consumable items, such as swabs, pipettes, and transport tubes for diagnostic testing, are typically sold through distributors (Mehrotra, Malani, and Yadav, 2020). Before the COVID-19 pandemic, the supply of such items was rarely noticed, and their demand was relatively predictable. However, with COVID-19, demand for things like swabs, particularly the specialized swabs needed for optimal sampling for the PCR diagnostic test, skyrocketed (Weber and Jewett, 2020). The more expensive testing machinery required to conduct many types of COVID-19 tests, such as PCR machines and thermocyclers, may be purchased directly by hospitals or diagnostic testing companies, or they may be leased from **Laboratory Equipment Leasing Companies**.

Transportation

For most COVID-19 relevant medical devices, transportation is largely an issue of suppliers getting components to manufacturers, or manufacturers getting their goods to customers. However, for testing equipment and supplies, because of the unique division of sample collection and sample analysis, there is often also the need to transport collected samples to the analysis site. Figure 3.4 illustrates the complexities of sample collection and sample analysis. The arrows show the flow of the sample, with the red dotted arrows indicating sample collection, from patient to sample swab, and the blue dashed arrows indicating sample transportation, from collection site to laboratory for analysis.

Figure 3.4. Sample Collection and Analysis Workflows



NOTE: Red dotted arrows indicate sample collection. Blue dashed arrows indicate sample transportation. * = might include the patient's home.

When hospitals conduct their own analyses of samples they have collected, those samples must still be internally transported since patient samples may be obtained in the hospital's own laboratory but are also likely to be obtained in other locations, including the emergency department, intensive care unit, or an outpatient clinic. Hospitals maintain pneumatic tube systems as well as internal staff to transport samples internally between departments.

In another permutation, the hospital collects the patient sample on-site and then contracts with a diagnostic testing company to perform the analysis, requiring those samples to be transported from the hospital to the analysis site. Even when samples are collected at a diagnostic testing company (e.g., a Quest Laboratory site), individual testing centers may not have the capability to perform the analysis on-site and may send samples to a centralized off-site laboratory that processes samples for a number of testing sites that are part of the diagnostic testing company.

Diagnostic testing companies maintain a vast network of couriers and logistics support to ensure collected samples are transported efficiently and appropriately between collection and analysis sites (Quest Diagnostics, 2020).

Regulations

Swabs (U.S. FDA, 2020s) and pipettes are regulated by FDA as Class I devices (U.S. FDA, 2020v). Swabs and the types of pipettes used in most testing equipment are exempt from both Premarket Notification and CGMP requirements (U.S. FDA, 2020s; U.S. FDA, 2020i). The machinery on which COVID-19 diagnostic tests are run (e.g., nucleic acid amplification systems, multiplex test systems) (U.S. FDA, 2020p; U.S. FDA, 2020z) are Class II devices and are exempt from Premarket Notification (U.S. FDA, 2020r) but subject to CGMP requirements (U.S. FDA, 2020z; U.S. FDA, 2020o; U.S. FDA, 2020q). In addition to the machinery and various materials (e.g., swabs, pipettes) required for COVID-19 diagnostic testing, there are a wide variety of chemical reagents that serve as assays, buffers, and test controls as well as primers/probes for conducting tests, which are generally classified as Class I or Class II by FDA. See the appendix for a description of these requirements.

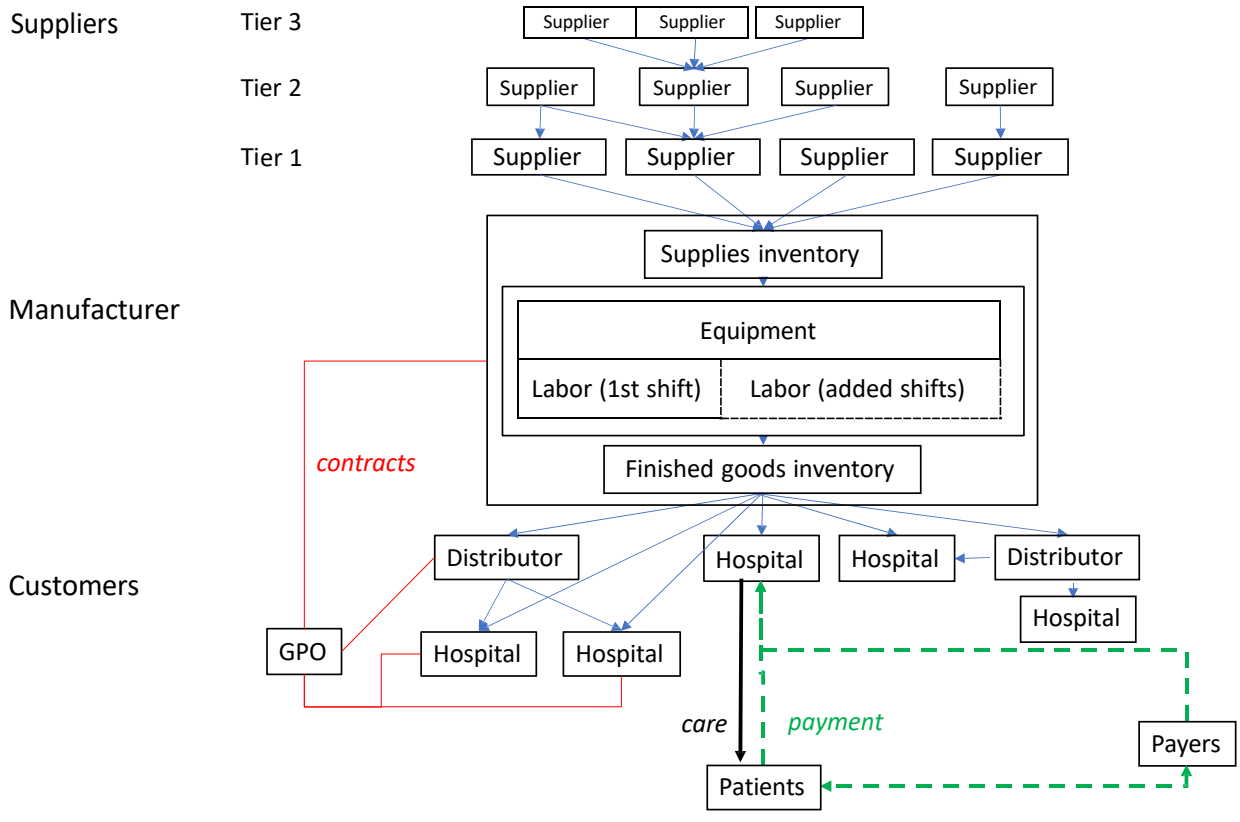
Typically, manually performed tests are authorized for use by laboratories certified to perform high-complexity tests, while automated tests are authorized for use by laboratories certified to perform moderate complexity tests and/or at the point-of-care by facilities operating under a CLIA Certificate of Waiver (U.S. FDA, 2020d). Thus, even with a diagnostic test authorized under an FDA emergency use authorization (EUA), the laboratories performing the tests must still operate in accordance with standing CMS CLIA regulations CMS, 2021a; U.S. FDA, 2020d).

4. Challenges to the Supply Chain During the COVID-19 Pandemic

In the preceding chapters, we described the general supply chain for medical devices and then focused specifically on three types of COVID-19 relevant medical devices: ventilators, PPE, and testing equipment and supplies. In this chapter, we describe the challenges that the COVID-19 pandemic imposed on each component of the device supply chains previously described.

We focus on general challenges to the device supply chains during the COVID-19 pandemic at each step from suppliers through customers. Subsections delve into the specific challenges faced in producing specific COVID-19 relevant devices. For reader convenience, Figure 4.1 is a repeat of Figure 2.1, depicting the overall simplified and generalized supply chain.

Figure 4.1. Supply Chain



Suppliers

During the COVID-19 pandemic, the substantial and rapid increase in demand made it challenging for manufacturers to cope. Because increased manufacturer demand also creates increased supplier demand, suppliers (particularly smaller ones) felt these extreme demand pressures as much as, if not more than, manufacturers (Ranney, Griffeth, and Jha, 2020).

Several interviewees told us that one strategy for managing the increased demand was that manufacturers communicated with their Tier 1 suppliers and worked with them to communicate the urgency to Tier 2 suppliers, and so on, to ensure that common supplies were prioritized for the production of medical devices.

In addition, as mentioned previously, another important type of supplier is the contract sterilizer. Devices that are required to be sterile are not considered ready for distribution or sale until they are sterilized. Half of sterile medical devices in the United States are sterilized using EO (U.S. FDA, 2020j). Although not all gloves or gowns used as PPE are required to be sterile (U.S. FDA, 2021a), those that have this requirement are sterilized using EO given their sensitivity to high heat and moisture. However, EO is considered an air pollutant and EO emissions are regulated and monitored by the Environmental Protection Agency "(EPA) and other entities (Environmental Protection Agency, 2021; Occupational Safety and Health Administration, undated; Environmental Protection Agency, 2021). During the COVID-19 pandemic, there were substantial concerns with potential shortages of sterilized medical devices owing to the closure of contract sterilizer facilities in order to undergo construction and retrofitting to reduce EO emissions (U.S. FDA, 2021h). Many of these closures preceded the COVID-19 pandemic, but the ongoing closure of these facilities posed a challenge to the supply chain for many medical devices. We note that none of the COVID-19 relevant medical devices discussed in this report appear to have been affected by these facility closures, although the shortages included many vital medical devices for providing health care, including surgical kits, feeding tubes, and various types of catheters (U.S. FDA, 2021h; U.S. FDA, 2021j).

Ventilators

When complex devices with many components are needed quickly and in large quantities, problems can arise. Imperfect information on the part of suppliers and manufacturers and the resulting lack of coordination can result in deadlock situations. For instance, since ventilators are composed of multiple components, a manufacturer must have every component in order to manufacture a ventilator. Even if a ventilator manufacturer has a surplus of one component, a shortage of another component results in not being able to manufacture a ventilator. To alleviate component shortages, AdvaMed created VentConnect (AdvaMed, 2020a), an online platform where ventilator manufacturers and potential suppliers can communicate and coordinate with one another for needed ventilator components and ensure optimal distribution of those components.

Personal Protective Equipment

The main supply challenge in manufacturing PPE during the COVID-19 pandemic has been a bottleneck in the supply of nonwoven fabric (also called melt-blown fabric) required to manufacture PPE such as gowns and N95 masks (Feng and Cheng, 2020). In 2019, U.S. manufacturers produced just 15 percent of the world's nonwoven fabric, a material used for many other products as well as PPE. In the COVID-19 pandemic, U.S.-based manufacturers have ramped up their production, but through the end of 2020, supply was not sufficient to meet demand (Mendoza et al., 2020). U.S. manufacturers have reported being offered markups and other incentives to fulfill orders for nonwoven fabric (Hufford and Evans, 2020). Industry watchers also signaled another potential supply issue—polypropylene or polyethylene resin, which is melted and used to manufacture nonwoven fabrics. Shortages of this raw material also hampered PPE production during the 2009 H1N1 influenza pandemic (Morrison, 2020).

Nonwoven fabric and polypropylene are used to manufacture products for other industries, including the agricultural industry (e.g., as crop cover, landscape fabric, and weed control), production of personal care items (e.g., baby wipes and diapers), lining for high-performance clothing, and air conditioning filters (Association of the Nonwoven Fabrics Industry, 2020). Thus, during a significant surge in demand, such as during the COVID-19 pandemic, supplies that might have been sent to nonmedical manufacturers could be diverted to manufacturers producing PPE for the health care industry. Textile industry publications have reported on such shifts in capacity, reducing or pausing production in "automotive and construction" and increasing production for medical uses (McIntyre, 2020).

Testing Supplies and Equipment

During the pandemic there have been shortages of critical supplies needed for COVID-19 testing kits. Surveys of clinical labs noted severe shortages of swabs and transport media (Association for Molecular Pathology, 2020), news reports have indicated that swabs and pipettes have been in short supply (Pfeiffer, Anderson, and Woerkom, 2020), and other reports cite a shortage of reagents needed to conduct COVID-19 testing (Herper and Branswell, 2020). Although comprehensive data describing shortages nationwide are not available, Premier, a major distributor to hospitals, reported that internal data show that demand for pipettes and micro-pipette tips among its hospitals has increased 50 percent since May 2020 and that hospitals are typically ordering nearly triple the volume they were previously ordering (Premier, 2021).

Transportation

One manufacturer explained that in early 2020, when COVID-19 was being reported only in China, a major concern was how the disease and subsequent shutdown would affect the supply of parts coming from China. The fact that items were shipped by sea meant that two months of supplies were already on ships in transit, thus providing a two-month buffer. When suppliers in

China were able to reopen, subsequent shipments to the manufacturer had to be sent by air to ensure that the manufacturer's production was not disrupted.

However, the decline in passenger air travel globally brought on by the COVID-19 pandemic caused disruptions to the transportation of supplies. Travel restrictions imposed by countries, combined with a general decrease in the number of travelers willing to fly, resulted in passenger airlines parking much of their fleet. Because passenger airplanes normally carry around half of all air cargo, this resulted in a loss of air cargo capacity, even though airlines turned some passenger flights into all-cargo runs. Meanwhile, the pandemic created an acute need for supplies, resulting in increased demand for air cargo capacity. This mismatch in the supply of and demand for air cargo capacity caused air transportation delays and increased costs (Freed and Baertlein, 2020). Decreased air cargo capacity also caused an increase in demand for cargo shipment by sea, resulting in bidding wars and higher prices due to limited capacity there (Qiu, Singh, and Khasawneh, 2020).

Interviewees reported that the U.S. government effort, Project Airbridge, which ended in late June 2020 (Federal Emergency Management Agency, 2020), provided help in moving essential supplies. Under Project Airbridge, the federal government paid to ship medical supplies by air, bypassing transportation delays. However, that relief was temporary, and one manufacturer noted that it would have been useful to have regulations in place to help control freight costs during pandemic situations. Interviewees argued that in emergency situations, manufacturers of essential products should not have to compete on the open market for freight capacity.

In addition to air transportation challenges, border restrictions caused problems. Countries closed their borders in an effort to keep the virus out (Salcedo, Yar, and Cherelus, 2020), and nearly 70 nations placed restrictions on the export of medical supplies (Congressional Research Service, 2020). Setting up necessary exemptions for medical supplies to cross the border took one company two weeks. Even when the flow of people and goods was allowed, interviewees reported border crossings could take two days as trucks were stuck waiting in line.

Finally, interviewees described confusing, sometimes contradictory, and constantly changing import/export regulations by many countries. At times, they were able to secure U.S. government support in order to navigate these regulations, but absent that, there were significant delays in moving products across borders. One interviewee noted that HealthcareReady (Healthcare Ready, 2019), an organization established after Hurricane Katrina to foster collaboration between industry and government entities to strengthen the medical supply chain, had been useful during COVID-19 as a resource providing clarity and up-to-date information about rapidly changing regulations and policies, particularly regarding movement of PPE between countries.

Personal Protective Equipment

As described in Chapter 3, most PPE manufacturers are located outside the United States. Having manufacturers produce PPE outside the United States necessitates the transportation of

these products to the United States. Beyond the challenges of slow cargo ship transportation that have been previously discussed and the capacity limitations of air transport, border restrictions also caused problems. Many countries shut down borders in an effort to keep the virus out (Salcedo, Yar, and Cherelus, 2020), meaning not only people but also goods could not cross borders. In addition, many countries introduced restrictions and even bans on exporting various COVID-19 relevant equipment, including PPE (International Trade Centre and Trade and Market Intelligence, 2020). Such restrictions could even affect other types of devices. For instance, in our interviews, we learned that one manufacturer of test kits ran afoul of the restriction on the export of PPE, as the test kits included a set of PPE to be used by the person collecting samples. The PPE had to be removed before the test kit could be exported.

Testing Supplies and Equipment

COVID-19 relevant testing components and testing machines are manufactured both in the United States and abroad, particularly in Europe and Asia. Further, suppliers may be located globally. Therefore, the restrictions placed on transportation of goods owing to the COVID-19 pandemic were another contributing factor to shortages of testing supplies and equipment (Behnam et al., 2020).

Manufacturers

Building additional manufacturing capacity during a surge in demand takes time. Some of the necessary components of manufacturing equipment, like tooling and molds, are generally not built in-house and could take months to produce. In the subsections below, we describe how things such as production equipment and labor affected manufacturers' ability to increase production.

One strategy to rapidly increase production in response to a demand surge is to use a contract manufacturer (Haigney, 2020). A manufacturer may set up additional production lines for needed products with the contract manufacturer. Alternatively, a manufacturer might use the contract manufacturer to produce other devices, in order to make room in its own facility to make the device in question. However, one manufacturer noted that there are few contract manufacturers that can take on the electronic work necessary for its devices, severely limiting alternative options, particularly for specialized and complex products.

Manufacturers and contract manufacturers are regulated by FDA (described further in the appendix). However, we note that changes in manufacturing potentially require additional regulatory review and oversight. The process of obtaining regulatory approvals for moving technology from one factory to another could take up to 18 months, depending on the device's

classification.[3] As a result of both the time and financial investment involved, companies may not be willing to build more production capacity without some assurance that demand will not dry up, leaving them with unused manufacturing lines and mountains of unsold inventory.

Ventilators

At the beginning of the COVID-19 pandemic, there were fears that there would not be enough ventilators to address estimated patient care needs. According to interviews, demand for ventilators increased by a factor of 20, as customers (in this case, hospitals) placed large orders in hopes of securing enough ventilators to handle anticipated patient needs. In 2019, U.S. manufacturers were estimated to have produced 700 ventilators a week. This increased to 2,000 a week by the end of March 2020 and jumped tenfold to 7,000 a week by the end of April 2020 (Mikulic, 2020).

In early March 2020, GM and Ford, among other car manufacturers, shut down their manufacturing plants owing to the pandemic (Beresford, 2020). By late March 2020, they had begun partnerships to develop ventilators (Albergotti and Siddiqui, 2020); and in early April 2020, President Trump invoked the Defense Production Act (Trump, 2020) to facilitate the production of ventilators by a number of organizations, including those that already produced ventilators (e.g., Phillips) as well as organizations that normally produce other things (e.g., Ford, GM). For organizations such as Phillips, which was already producing ventilators, the major manufacturing challenge was similar to the challenges of other COVID-19 relevant devices: obtaining sufficient supplies to ensure availability of all the components needed to assemble a complete ventilator. For car companies such as Ford and GM, an additional manufacturing challenge was to adapt assembly lines intended for one purpose to a very different purpose with different regulations.

Although Ford and GM do not typically produce medical equipment, one important advantage to note is that "these companies already work with components that are similar to the ones found in ventilators . . . cars are highly complex products that require a unique amount of knowledge, planning, coordination, and logistics to build" (O'Kane, 2020). Further, an engineering director at Ford noted, "There's thousands and thousands of parts that we assemble, and each of those parts is made up of a number of subassemblies that are sourced [from] around the world at multiple tiers deep" (O'Kane, 2020). Of note, both GM and Ford partnered with existing ventilator manufacturers (GM with Ventec Life Systems and Ford with GE's Healthcare division) because even if equipment, labor, and expertise are transferrable, there are important aspects of licensing and regulation that are not easily transferrable across manufacturers.

[3] When a device is cleared or approved to be marketed by FDA, certain changes in manufacturing process or systems need to be approved by FDA. For more detail, see U.S. FDA, 2020l.

Nontraditional ventilator manufacturers such as Ford and GM ultimately delivered 50,000 and 30,000 ventilators, respectively, by the end of their contracts (Associated Press, 2020b).

Personal Protective Equipment

In contrast to other types of COVID-19 relevant devices discussed in this report, PPE represents a special situation for manufacturers. While ventilators and testing swabs have little use outside medical settings, various types of PPE, including goggles, gloves, and masks, are frequently used in industries outside of health care and often manufactured by the same companies that manufacture these items for medical use (3M Personal Safety Division, 2020). In a pandemic situation requiring a surge in supply, nonmedical products may be diverted into the medical product supply chain. For instance, N95 masks have long been used by construction workers, those in the mining industry, and even by homeowners tackling weekend projects. Many of those masks were diverted to health care workers early in the pandemic (Bond, 2020).

We also note that in addition to existing manufacturers of PPE, several other industries, including the automotive industry (Korosec, 2020; Noble and Grzelewski, 2020) and the fashion industry, retooled operations to produce various types of PPE (Mazzoni, 2020; National Council of Textile Organizations, 2020). There have also been new entrants to the N95 mask market, with NIOSH certifying nearly 94 new brands, including 19 U.S. manufacturers (Dearen, Linderman, and Mendoza, 2021).

Testing Supplies and Equipment

Despite new entrants to the U.S. market for COVID-19 relevant testing supplies, one major U.S. hospital distributor, Premier, reported in January 2021 that the average time between hospitals placing an order for COVID-19 relevant testing and treatment supplies and receiving those supplies has increased from just a few days in the fall of 2020 to over 25 days in January 2021, indicating manufacturers had not yet been able to meet demand given recent surges (Premier, 2021).

In addition, during the COVID-19 pandemic, manufacturers that previously manufactured other things, such as dental products, began making testing swabs (Hauer, 2020). Some companies even began using new methods, such as 3-D printing, to manufacture swabs (Repko, 2020). Finally, we note that, because no COVID-19 diagnostic test existed previously, a large number of manufacturers, both domestic and international, are now producing COVID-19 diagnostic tests for use in the United States (Thomas, 2020). Most of these manufacturers also make other diagnostic tests, but others normally are not large producers of in-vitro diagnostic tests (e.g., the CDC).

Production Equipment

The challenges of expanding production capacity through acquiring additional equipment are generally related to the capital costs of acquiring equipment.

Ventilators

For nontraditional ventilator manufacturers such as GM and Ford, there were costs associated with retrofitting existing factories to assemble ventilators rather than cars (Korosec, 2020; Noble and Grzelewski, 2020), and these costs were built into the contracts to supply ventilators.

Personal Protective Equipment

Because of unstable demand following the H1N1 influenza pandemic in 2009, manufacturers described hesitancy to invest in the equipment needed to substantially ramp up production during COVID-19 (Mendoza et al., 2020).

Testing Supplies and Equipment

Industry experts have reported that most large in-vitro diagnostic companies producing COVID-19 testing kits do not typically have sufficient excess capacity to address a surge in demand such as presented by the COVID-19 pandemic. Many have had to expand existing capacity or build new capacity, which cannot be done immediately (Bonislawski, 2020).

Labor

In situations where a rapid increase in production is needed, assuming sufficient supplies, the first course of action is to increase the number of worker shifts, going from one shift a day to two. This allows the company to maximize the use of existing production lines. This was the approach taken by manufacturers during COVID-19: moving to multiple shifts as quickly as they could find labor to staff them.

Interviewees reported that they did not have difficulties in filling their labor requirements. In some cases, companies shifted workers from other manufacturing lines to work on COVID-19-related devices. When this was an option, companies considered it fortunate that COVID-19-related devices represented a small portion of existing business, and so there was surge capacity available. Companies also hired additional workers, including through temporary employment agencies (Mannino, 2020). Workers did require training, but this was not reported as being a difficult hurdle to overcome.

As manufacturers producing COVID-19 relevant devices ramped up production for those devices, workers on those production lines likely saw stable, if not increased, work. However, demand for other medical devices fell as regular medical visits and elective surgeries were delayed. Given the specialization required for some COVID-19 relevant device production lines, companies may not have been able to shift workers from other manufacturing lines, and there have been reports of furloughs for workers in a wide variety of medical device manufacturing (Condon, 2020; Moore, 2020).

Manufacturers, however, did report labor challenges related to COVID-19 restrictions. As countries went into lockdown, manufacturers had to ensure that their workforces, as well as those of their suppliers, would be recognized as essential workers. COVID-19 restrictions were even

more challenging when borders were involved. Particularly in the case of suppliers of components as well as makers of PPE and testing components that are located overseas, the employees of a factory may live in a neighboring country and thus cross the border to get to work. Manufacturers also rely, often heavily, on migrant labor from neighboring countries (Tho, 2020). COVID-19-related border closures prevented companies from being able to get their labor pools to their worksites; therefore, exemptions for workers in essential industries had to be sought (Shepard, 2020).

Finally, we note that the labor discussed in this report refers to the labor required to manufacture the relevant device. There are many other types of labor that are important to the delivery of health care, including health care workers such as physicians, nurses, laboratory staff, and respiratory therapists. The COVID-19 pandemic not only exacerbated existing workforce shortages but also caused additional workforce shortages (Goldhill, 2020; Jacobs, 2020). A discussion of the workforce requirements for health care delivery during COVID-19 is beyond the scope of this report. These issues have been extensively discussed elsewhere (CDC, 2021; Los Angeles Times Staff, 2021a).

Ventilators

For car manufacturers that began assembling ventilators during the COVID-19 pandemic, a substantial degree of additional training was needed to ensure their existing workforces would be able to assemble a ventilator instead of a car (Stoll, 2020).

Personal Protective Equipment

Because many types of PPE are largely manufactured outside the United States, those companies faced the labor shortages that resulted from border closures and restrictions on movement already described in Chapter 2.

Testing Supplies and Equipment

Similar to the situation for PPE, because many testing components and testing machines are manufactured outside the United States, those companies faced the labor shortages that resulted from border closures and restrictions on movement already described in Chapter 2.

Maintenance and Repair

Ventilators

During the COVID-19 pandemic, one study reported that nearly half of biomedical technicians surveyed had faced challenges obtaining information or parts necessary to the function of critical hospital equipment, including ventilators (Proctor and O'Reilly, 2020). A CBS news report said, "Manufacturers often won't supply parts to those who haven't completed costly training by the companies themselves" (Gibson, 2020). Moreover, manufacturer-

authorized repair technicians were in short supply, and travel restrictions and other COVID-19-related limitations have made them even more scarce (Gibson, 2020; Wyden and Kullolli, 2020).

Manufacturer actions during the COVID-19 pandemic were varied. One website began posting ventilator repair manuals and received a cease-and-desist order from a ventilator manufacturer (Linder, 2020; Scher, 2020), while other manufacturers, including GE (GE Healthcare, 2020) and Medtronic (Medtronic, 2020), posted information online to ensure rapid access in the maintenance and servicing of their ventilators. Senator Ron Wyden (D-Oreg.) has proposed legislation that would "allow trained repair technicians to more easily access information and tools required to complete maintenance and repair of critical medical infrastructure in preparation for and as part of a response to the current COVID-19 crisis" (Ron Wyden, 2020).

Personal Protective Equipment

Although PPE is designed to be single use and disposable, it is notable that during COVID-19, CDC issued guidance on reusing PPE, particularly N95 respirators, in shortage situations (CDC, 2020b).

Additionally, at the height of the pandemic, with substantial N95 respirator shortages, FDA coordinated with CDC, NIOSH, and other subject matter experts on EUAs for decontamination and bioburden reduction systems, which are meant to decontaminate devices such as N95 respirators "so that they can be reused by healthcare personnel" (U.S. FDA, 2021f). Recently, with the increased domestic supply of new respirators approved by CDC and NIOSH, FDA made the recommendation to transition away from these systems (U.S. FDA, 2021g; U.S. FDA, 2021i).

Testing Supplies and Equipment

During the COVID-19 pandemic, the challenges around maintenance and repair for testing supplies and equipment mirror those described above for ventilators. One study reported that nearly half of biomedical technicians surveyed had faced challenges obtaining information or parts necessary to the function of critical hospital equipment, including ventilators and some laboratory equipment (Proctor and O'Reilly, 2020). A CBS news report said, "Manufacturers often won't supply parts to those who haven't completed costly training by the companies themselves" (Gibson, 2020). Moreover, manufacturer-authorized repair technicians were in short supply, and travel restrictions and other COVID-19-related limitations have made them even more scarce (Gibson, 2020; Wyden and Kullolli, 2020).

Customers

As described in Chapter 2, customers are a vital component of the supply chain because they provide the demand signal for manufacturers to understand how much product to produce. Before COVID-19, demand for devices discussed in this report was stable (Mehrotra, Malani,

and Yadav, 2020). During COVID-19, demand for all types of medical devices has ceased being predictable (Ranney, Griffeth, and Jha, 2020). To complicate matters further, throughout the COVID-19 pandemic, geographic and temporal variations in disease burden have continually shifted, making demand even more unpredictable and unstable.

According to interviews with manufacturers, demand for some items increased by up to 20-fold, driven by hospitals and distributors that wanted to ensure they would have sufficient supply. Even products not thought of as being related to COVID-19, such as diabetes products, experienced huge swings in demand (Phillips, 2020). Manufacturers whose volume might be measured in the low hundreds per week were able to quadruple production over the span of a few weeks. But no manufacturer of COVID-19-related devices could keep up with the scale of COVID-19 demand increases over the long term.

Allocating limited production across competing customers became a concern for manufacturers. Different states and countries engaged in bidding wars (Associated Press, 2020a). A purely market-driven approach would sell the product to the highest bidder. There was also the complication that, during the COVID-19 pandemic, nearly 70 nations placed restrictions of some type on the export of medical supplies (Congressional Research Service, 2020), making even market-based approaches untenable. Further, more than one manufacturer expressed the viewpoint that allocation of limited stocks should not be based on price but rather on need. For instance, 3M, a manufacturer of N95 masks, announced in April 2020 that it would not increase prices on N95 masks during the pandemic (3M, 2020). That, however, left the matter of how to prioritize competing orders. Aside from factors such as export restrictions, governments in some countries took on the role of coordinating supply and demand for relevant products. For instance, in South Korea, in response to high prices for face masks and subsequent shortages, the government took over control of production, pricing, and distribution of face masks in order to ensure an adequate and fairly distributed supply (Chung, 2020; Kim, 2020). In Taiwan, the government required existing mask manufacturers to increase their production, fixed prices for masks, and oversaw the distribution of masks in order to ensure sufficient supply, adequate health care worker access to N95 masks, and equitable distribution (Chiang, Chiang, and Chiang, 2020; Lane, 2020). Absent such centralized coordination in the United States, manufacturers had to make their own assessments of where they thought the greatest need was, tracking case counts and building their own models and algorithms as cases spiked first in China, then Europe, and then other hotspots around the world.

As noted above, for the sake of simplicity, we refer to customers for COVID-19 relevant medical devices as "hospitals." In practice, customers for COVID-19 relevant medical devices are a diverse group and might include any end user from a small, privately owned physician practice to large, multistate integrated health care delivery systems. However, given the central role of hospitals in the COVID-19 pandemic, we focus on them in this report. In addition, for some types of COVID-19 relevant devices, such as PPE and testing supplies, there are also

additional categories of customers (broadly, nonmedical customers and sometimes patients themselves).

Ventilators

At the beginning of the COVID-19 pandemic, the United States did not maintain statistics on the number of ventilators nationally. Available data at that time suggested the nation had just shy of 63,000 ventilators, but this was an estimate based on data from a survey conducted in 2009 (Rubinson et al., 2010). The Society for Critical Care Medicine noted in a blog posting that "adding together full-featured and basic hospital ventilators, SNS [Strategic National Stockpile] ventilators, and hospital-based anesthesia machines increases the estimated number of ventilators to over 200,000 devices nationally" (Halpern and Tan, 2020). Although some outlets have quoted a need for up to one million ventilators (Global Reporting Centre, 2020b), this is a misreading of the data. The Society for Critical Care Medicine reported on research findings indicating that nearly one million patients might *need mechanical ventilation* (Halpern and Tan, 2020). Such a large number of ventilators would likely not be needed, however, since all one million patients would not be admitted to the intensive care unit (ICU) simultaneously, and a single ventilator can be used to treat many patients, though not simultaneously.

We do note that "ventilator splitting," in which several ventilator circuits are joined to a single ventilator to allow multiple patients to use a single ventilator simultaneously, was done on a limited scale early in the pandemic. FDA did provide guidance for ventilator splitting, while cautioning that this practice should be limited to "situations where there are no other alternatives for invasive ventilation" (U.S. Food and Drug Administration, 2021b). Since then, ventilator splitting has been largely dismissed as a large-scale approach to addressing ventilator shortages (American Society of Anesthesiologists, 2020; Petersen, Friend, and Merritt, 2020). Nonetheless, the overall takeaway is that at the beginning of the COVID-19 pandemic, there were fears that there would not be enough ventilators to address estimated patient care needs. According to interviews, demand for ventilators increased by a factor of 20, as customers, unsure of what their needs would be, placed giant orders. In 2019, U.S. manufacturers were estimated to have produced 700 ventilators a week. This increased to 2,000 a week by the end of March 2020 and jumped tenfold to 7,000 a week by the end of April 2020 (Mikulic, 2020). The U.S. government boosted additional production by contracting with a variety of manufacturers. Some contracts were canceled in September 2020 as the Strategic National Stockpile reached maximum capacity (with 120,000 ventilators ready for deployment) (Associated Press, 2020c), and medical professionals' understanding of how best to treat patients affected by SARS-CoV-2 progressed. Over time, ventilators were used less frequently to treat of COVID-19 patients, particularly in earlier stages of disease (National Institutes of Health, 2020). Instead, increased emphasis was placed on less invasive modes of maintaining oxygenation and ventilation both because patients did not appear to derive additional benefit from mechanical ventilation and because of concerns

about increased spread of SARS-CoV-2 through droplets dispersed during mechanical ventilation (National Institutes of Health, 2020; Siddiqui, 2020).

Personal Protective Equipment

During the COVID-19 pandemic, demand for all types of PPE (e.g., masks, gloves, gowns) grew by triple digits compared with a 2019 baseline (Schmidt, 2020), and some industry analysts predict continued growth in demand beyond 2020 (Bhaskar, 2020). Premier, a major distributor of medical supplies, has reported that demand for N95 masks has grown 500 percent since July 2020 (Premier, 2021). Others have reported that demand has grown up to 1,000 percent over baseline demand (Iati, 2021). All types of PPE continue to appear on the FDA shortage list (U.S. FDA, 2021d).

PPE supply has increased from both domestic and foreign manufacturers; however, the overall picture of whether supply has met demand is not entirely clear (Dearen, Linderman, and Mendoza, 2021). While some report that demand largely continues to outpace supply and hospitals largely continue to ration and reuse PPE, particularly N95 masks, some news outlets have reported a surplus of N95 masks (Dearen, Linderman and Mendoza, 2021; Iati, 2021; Noguchi, 2021; Tin, 2021). There are a number of potential reasons for this seeming paradox. First, hospital fears over future surges and inadequate PPE supply have caused many to stockpile PPE. Hospitals that previously kept a 2–3 day supply of PPE on hand now report keeping a 2–12 month supply (Dearen, Linderman, and Mendoza, 2021). Although some hospitals have resumed pre-COVID single-use practices, many continue rationing and reuse, with some noting it will take a long time for staff to return to pre-COVID single-use practices (Grimm, 2020; Noguchi, 2021). At the same time, U.S. manufacturers have reported a surplus of N95 masks they are unable to sell, with some even receiving recent federal permission to export N95 masks (Jacobs, 2021; Lieber, 2021; Tin, 2021). Here, the challenges include entrenched contracting practices in which the lowest bid always wins (generally favoring foreign manufacturers), hospital wariness about purchasing brands they are unfamiliar with due to concerns about counterfeits and low quality, and the difficulty of breaking into the hospital market without a prior relationship with hospital procurement officers or a distributor (Dearen, Linderman, and Mendoza, 2021; Jacobs, 2021; Lieber, 2021; Tin, 2021).

During a surge in demand, such as in the COVID-19 pandemic, appropriate PPE that might be sold through nonhospital supply chains such as hardware stores can be redirected for medical use. This was done at the organizational level, such as when Home Depot redirected N95 shipments to hospitals, as well as on a smaller scale nationwide as individuals donated N95s and other PPE to local hospitals (Ma, 2020; Vigdor, 2020). There have even been technology solutions to match those with PPE to health care workers in need of PPE (Get Us PPE, 2021).

Testing Supplies and Equipment

During the COVID-19 pandemic, there was a need to massively increase testing capacity throughout the nation. In response, hospitals and diagnostic testing companies made alternatives for COVID-19 testing available, such as setting up drive-through testing sites (Amir-Behghadami and Janati, 2020; Wan, 2020) or even going to patients' own homes (Quest Diagnostics, undated). Testing may take place on-site (e.g., in a hospital or diagnostic testing center parking lot) or off-site (e.g., in a local sports stadium parking lot). Thus, in some cases, the customer for testing supplies may be not only the hospital or health care delivery organization but also the patients themselves, such as in the case of home-testing kits.

Still, the demand for COVID-19 testing exceeded the supply of tests and equipment (Mervosh and Fernandez, 2020), and the United States faced shortages in testing supplies, such as swabs (Behnam et al., 2020). As of the end of 2020, demand for testing supplies and equipment continued to be high. Premier, a major distributor to hospitals, reported that internal data show that demand for pipettes and micro-pipette tips among its hospitals has increased 50 percent since May 2020 and that hospitals are typically ordering nearly triple the volume they were previously ordering (Premier, 2021).

Hospitals

As described in Chapter 2, hospitals typically function independently and often in competition with one another. However, during COVID-19, hospitals have worked together, particularly in coordinating bed availability and moving patients where there was space (Kemp, 2020).

Group Purchasing Organizations

The benefits and drawbacks of GPOs were discussed in Chapter 2. In the wake of COVID-19 pressures on the supply chain, GPO leaders argued that because they have visibility on larger patterns of demand nationwide, they can help their members remain flexible and proactive, without overreacting, during demand surges (Barlow, 2020).

Patients and Payers

During the COVID-19 pandemic, CMS introduced new billing codes and guidance for hospitals' provision of testing, inpatient acute care, inpatient quarantine, prior authorizations, and telehealth related to COVID-19 (CMS, 2020a). A full discussion of the payment changes implemented during the COVID-19 pandemic is beyond the scope of this report but has been extensively discussed elsewhere (America's Health Insurance Plan, 2021; CMS, 2021b).

Regulations

A number of federal agencies have responsibility for monitoring the use of COVID-19 relevant medical devices. FDA regulates medical devices sold in the United States to ensure their safety and effectiveness. More specifically, the FDA's Center for Devices and Radiological Health regulates firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States (U.S. FDA, 2020i; U.S. FDA, 2020m). Further details on FDA requirements can be found in the appendix.

In addition to FDA, NIOSH, operated by CDC, is responsible for conducting research and making recommendations for preventing work-related injuries and illness (NIOSH, 2018). Although NIOSH is typically classified as a nonregulatory agency, in regard to COVID-19 relevant medical devices, it is responsible for rules regarding approval of respiratory protective equipment such as N-95 respirators (CDC, 2018).

Ventilators

To help increase the availability of ventilators and ventilator-like devices, FDA issued an "umbrella" EUA in March 2020 authorizing "the emergency use of certain ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as 'ventilators'), ventilator tubing connectors, and ventilator accessories" (U.S. FDA, 2021c; U.S. FDA, 2021e). This EUA and the associated relaxation of some of the usual regulatory requirements are one reason nontraditional ventilator manufacturers were able to begin ventilator production so quickly (Teschler, 2020; U.S. FDA, 2018e). Absent these regulatory flexibilities, such changes can take months.

Personal Protective Equipment

FDA worked with NIOSH to recognize NIOSH-approved N95s as FDA authorized when designated for use in health care settings during the response to the COVID-19 public health emergency, without the same manufacturers having to obtain both NIOSH approval and FDA authorization separately (Hinton, 2021).

FDA has also issued an umbrella EUA for KN95 masks that allow them to be used when N95 masks are not available (U.S. FDA, 2021i). KN95 masks are filtering facepiece respirators that serve a similar function to N95 masks, but their effectiveness has been certified by Chinese government agencies instead of by NIOSH (Oklahoma State Department of Health, undated). KN95 masks under the EUA are FDA registered but not NIOSH approved as N95 masks (U.S. FDA, 2020n). We also note that as they are authorized for distribution under an EUA, the CGMP requirement was waived (Hinton, 2020b; U.S. FDA, 2018i). This umbrella EUA was closed as of October 15, 2020. FDA created a separate umbrella EUA for non-Chinese foreign filtering facepiece respirators not approved by NIOSH, which was closed as of March 24, 2021 (U.S. FDA, 2021i).

Testing Supplies and Equipment

On February 4, 2020, FDA issued an EUA to CDC for its COVID-19 test; laboratories were only allowed to run the CDC test for COVID-19. However, reliability issues with the initial CDC test owing to a faulty reagent and the shortage of FDA-authorized testing supplies and equipment caused problems for the COVID-19 response. In late February 2020, FDA changed its policy to allow some laboratories to develop and run their own tests—laboratory developed tests. Because of ongoing research and patient care efforts, many academic medical centers already had the reagents and machinery required to conduct COVID-19 testing, and several developed their own tests (Boston University Back2BU, undated; Danesh, 2020).

Since then, FDA has issued a number of EUAs for COVID-19 diagnostic test kits (generally consisting of the reagents required to conduct a particular type of test) (U.S. FDA, 2021l; U.S. FDA, 2020o).

Additionally, early in the COVID-19 pandemic, pooled testing (CDC, 2020c) was thought to be an effective approach for conserving limited testing supplies and equipment. Pooled testing is done by combining samples from several people and conducting a single test to detect COVID-19. If the pooled sample is negative, all individual samples that contributed to the pool can be presumed negative. If the pooled sample is positive, all individual samples contributing to the pool must then be tested separately. FDA did issue EUAs for pooled testing (U.S. FDA, 2020g), including guidance on the maximum number of tests that should be pooled together, since a greater number of samples pooled together compounds the number of individual tests that must then be run if the pooled sample is positive. However, pooled testing is only effective for conserving resources when overall COVID-19 positivity rates are low. By the late spring/early summer of 2020, COVID-19 positivity rates in the United States rose beyond the threshold (often set at 10 percent) at which pooled testing would be useful (Wu, 2020).

5. Strategies for Future Surges

In the course of our literature review and interviews, we identified challenges to increasing production across devices and manufacturers, which we describe below.

Better Information About Demand

As the COVID-19 pandemic began, demand for some items increased while demand for other items fell and did so in ways that companies did not expect. This made it difficult for companies to appropriately shift production to meet demand. Companies hoped that governments or the World Health Organization (WHO) would provide insight on the demand for items across the market. However, it is not clear that the United States government is in a position to actually know with any certainty what hospitals or health care agencies would be purchasing, particularly with enough lead time for the manufacturers to have been able to prepare. Available models, at best, provided only aggregate information about total country caseloads. Few offered the detailed, granular information needed to provide insight on cases in various regions,[4] let alone translate those case numbers into estimates of demand for specific medical devices. Nonetheless, the epidemiological forecasts made by public health agencies, as well as by academic researchers, could be adapted to improve information about demand in order to signal to manufacturers which areas of the country or world are likely to soon experience surges of cases and hospitalizations, and which medical devices they may need as a result.

An accurate depiction of demand also relies, however, on customers placing accurate orders only for what they need, rather than placing orders for 50 ventilators across multiple manufacturers in hopes of receiving the 10 ventilators that they need. Improved information about demand may also require better information from hospitals and end users themselves regarding their true needs, in terms of the number of any specific devices they actually need.

Finally, during COVID-19, some states began collecting data about hospital bed and equipment availability alongside infection and death rates (Drees, 2020). Although these data have been used to understand capacity (e.g., ICU bed availability) (Los Angeles Times Staff, 2021b), they might also be used to understand potential demand and allocate supply accordingly for any future surges. This would require ongoing, higher-quality, standardized data collection at a national level to allow for monitoring of medical equipment and supplies held by hospitals, manufacturers, and distributors across the nation, in preparation for future pandemics (Davenport, Godfrey, and Redman, 2020; Devaiah et al., 2020).

[4] See, for instance, the model from the Institute for Healthcare Metrics and Evaluation, undated.

Improved Coordination Among Companies

A commonly cited challenge in increasing capacity was the difficulty in getting the necessary supplies, particularly when suppliers are small and have competing demands. Representatives of one chemical company noted they had spent weeks calling various suppliers and manufacturers because they were interested in understanding whether a raw material or chemical their company manufactured was the bottleneck in any production processes for COVID-19-related products, in hopes of redirecting production to meet those demands and alleviate the bottleneck. This was a frustrating and time-consuming endeavor because of the sheer number of suppliers and manufacturers. That company expressed a desire for a coordination mechanism to match up organizations that need items with organizations that can supply them, including those that do not ordinarily do so but whose production could be changed to meet urgent needs. Companies also expressed a desire for a similar mechanism for matching available labor to companies or matching idle manufacturing capacity to need. The efforts undertaken through VentConnect (AdvaMed, 2020a), a platform connecting component suppliers with ventilator manufacturers, and later through MedDeviceNetwork, an expansion of the VentConnect platform to include medical devices and diagnostics for fighting the COVID-19 pandemic, might be one model for such coordination (AdvaMed, 2020c).

We asked one of the device maker associations whether this would be an appropriate role for them. While the interviewee noted that this was a role one of the other associations was playing with certain types of items, the interviewee thought that, more generally, government needed to be the facilitating entity. The reason was that in the absence of government playing a role, the bigger companies would likely crowd out the others in the discussions.

Regulatory Relief

Relief from government restrictions was another topic that emerged in our literature review and interviews. Interviews conducted early in the pandemic indicated that because of regulations, securing approval for setting up a new production line in a new facility could take months. While such regulations make sense in normal situations, the expedited approvals and waivers that were issued by federal agencies (e.g., FDA EUAs) during the COVID-19 pandemic have been vital for lowering many barriers to rapid response (U.S. FDA, 2020h).

Beyond regulations related to manufacturing and production, border shutdowns brought about by the pandemic also threatened to hamper production. Manufacturers and their suppliers had to be declared essential so that they could stay open and their employees could go to work. This was especially challenging when workers lived across a national border from their workplace. Obtaining the necessary exemptions took time, which slowed production through the supply chain.

Finally, manufacturers and associations expressed concern about the rise of protectionism and nationalism, and more specifically prohibitions of exports, increases in tariffs, and other

policies to secure supply of inputs or final products for domestic rather than foreign markets. While they understood the desire for each country to increase production within its own borders and keep those products for itself, they argued that no country can fully make all the products itself and that the reality is that supply chains are global. Therefore, in their view, tariffs that increase costs and restrictions that prevent the flow of supplies and products across borders only harm the ability to respond to emergencies. Further, constantly shifting regulations from different countries add yet another layer and another delay in getting products from manufacturers to hospitals. Organizations such as HealthcareReady were cited by interviewees as being a vital resource for navigating rapidly changing regulations and requirements (Healthcare Ready, 2019).

Greater Price Transparency

Interviewees expressed concerns about potentially anticompetitive practices of GPOs such as utilizing sole source contracts (giving one manufacturer among many that produce a product the exclusive right to sell products through the GPO), levying financial penalties to hospitals for buying off-contract, and following a "pay to play" model in which manufacturers pay GPOs to be listed in their catalogs and offered as an option to member hospitals (Bruhn, Fracica, and Makary, 2018). There are concerns that such practices have led to a narrow supply chain in which a few manufacturers may be responsible for "an entire regional or national supply chain" (Bruhn, Fracica, and Makary, 2018).

GPOs are not subject to antikickback statutes (HSCA, undated), and despite federal requirements for GPOs to report those fees to member hospitals, it is difficult for hospitals to compare prices because competitor data are not publicly reported (Becker's Hospital Review Staff, 2014b). There have been calls to reevaluate GPOs' exemption from antikickback statutes in order to promote price transparency and competition, which could help build greater supply chain resilience (Bruhn, Fracica, and Makary, 2018).

6. Future Research Directions

As the U.S. Department of Health and Human Services (HHS) looks at strengthening the nation's medical and public health preparenedness to handle future public health emergencies, there are important considerations for policymaking and future research.

Improved Data Systems

As described briefly in the prior chapter, improved data systems are needed throughout the supply chain to understand existing supply of medical devices in order to accurately determine ongoing needs. Ongoing, higher quality, standardized data collection at a national level would allow real-time monitoring of supplies held throughout the supply chain (by hospitals, manufacturers, and distributors) in preparation for future pandemics (Davenport, Godfrey and Redman, 2020; Devaiah et al., 2020). There are numerous flaws in existing data, including the inability in some cases accurately determine what portion of existing PPE are produced domestically (Congressional Research Services, 2020a). Future research could seek to: identify effective data systems at a local or regional level to understand what components may be scalable to a national level; integrate data across the supply chain to improve overall visibility on supply and demand; and develop standardized definitions and data collection methods across the supply chain to ensure accurate accounting.

Analyzing Workforce Capacity and Surge Capacity

Our analysis was limited to the production of COVID-19 relevant medical devices only, and did not encompass the workforce needed to actually utilize those devices to deliver healthcare. Workforce shortages among physicians, nurses, respiratory therapists, laboratory staff and others have been well-documented during the COVID-19 pandemic (Centers for Disease Control and Prevention, 2021; Los Angeles Times Staff, 2021a). Some components of the healthcare workforce, already understaffed even prior to the COVID-19 pandemic, were further stressed. (Goldhill, 2020; Jacobs, 2020). Future work could explore effective strategies for alleviating these workforce shortages and expanding the workforce during pandemic or other emergency situations.

Incentives for Maintaining Surge Capacity

In a public health emergency, the demand for medical devices increases far beyond normal levels. While stockpiles are kept to meet immediate needs, the expectation is that manufacturers will increase production. But manufacturers we interviewed noted that supply chains have been

asked to respond in a way that they are not designed to. Companies will size their production according to the market signal. As a result, companies cannot rapidly scale up production on short notice, because it does not make economic sense for companies to keep more capacity than they need. Even in the midst of skyrocketing demand, companies may be loath to increase capacity for fear that demand will dry up and they will be left with more equipment, employees, supplies, and products than they need.

Incentives are needed to encourage companies to invest in, and maintain, surge capacity. One of the device manufacturers interviewed pointed out that it held a contingency contract with the Department of Defense that committed the company to delivering a certain number of units within a certain period of time if the contract were to be activated. Because of this contract, the company maintained extra production capacity as well as the supplies necessary to produce to that level. The contingency contract was indeed activated, and while the contracted amount was insufficient to meet COVID-19 requirements, it put the company in a better position to surge. Thus, contingency contracts are a way to encourage companies to maintain extra capacity in reserve. A similar approach was taken in South Korea to incentivize manufacturers to develop diagnostic tests, guaranteeing a minimum quantity that would be purchased (U.S. Food and Drug Administration, 2021k).

Contingency contracts are not the only way to incentivize capacity. Moreover, they may not be able to provide sufficient incentive on their own if the contingency is rarely activated. There may be a need to ensure a certain level of business to companies that are willing to maintain extra capacity. Alternatively, the government may need to directly provide assistance in the form of grants or loans to encourage manufacturers to purchase equipment or supplies to maintain excess capacity. The government could purchase such equipment and supplies on behalf of the manufacturer, thus holding the risk itself. The government might also enact policies akin to those enacted after the 2008 financial crisis for financial institutions, requiring hospitals and/or local public health systems to maintain a certain level of supplies in preparation for future pandemics (Devaiah et al., 2020). Such an approach could be hampered by the fact that many COVID-19 relevant medical devices have a limited shelf life and would need to be replenished periodically. Designing a viable incentive system to encourage health systems and manufacturers to make such a substantial investment could be another area of further research for HHS.

Ensuring the Health of the Industrial Base

As noted above, economic pressures will cause companies to not want to invest too heavily in capacity. The economic challenge is compounded when considering domestic production capacity. During a crisis, supplies are scarce, so customers may be willing to pay several times the normal price for an N95 mask, making domestic production viable. However, manufacturers fear that once the crisis subsides, customers will not be willing to pay the higher manufacturing costs associated with domestic production and will purchase from lower-priced offshore

competitors instead. Domestic manufacturers of N95 masks that had ramped up production during the 2009 H1N1 outbreak found themselves without customers once the emergency ended.

The COVID-19 pandemic showed the danger of relying on offshore production. In the early days of the pandemic, borders closed, preventing labor and goods from traveling. Moreover, some countries specifically stopped the export of vital supplies in an effort to ensure their own needs could be met. Another danger revealed by the COVID-19 pandemic is that of relying on a few suppliers for specific and vital components. For instance, although some components used to build highly technical devices such as ventilators are used in many types of electronics, other components such as pressure regulators have limited applications beyond their intended use and cannot be easily substituted. Shortages of such components can create bottlenecks in the supply chain, making it additionally vital to identify and bolster supply chain resilience. Thus, there are compelling reasons to foster a healthy domestic industrial base for medical devices.

Only a sustained market signal would lead domestic manufacturers to stay in the market. One potential solution suggested by one of the associations would be for the federal government to provide guarantees, such as a guaranteed level of demand, so that companies would feel confident in increasing capacity. Another could be some form of subsidy so that domestic producers are not at a price disadvantage against foreign competitors, thus encouraging private sector customers to buy from domestic manufacturers. Such subsidies may well run afoul of free-trade agreements, however. Developing an incentive structure to support domestic manufacturing of vital supplies would be another area of research for HHS.

Further, we have described the challenges that domestic PPE manufacturers faced in getting their products to market on a large scale. These challenges include long-standing contracting practices that generally favor the lowest bid, hospitals' discomfort with purchasing unfamiliar brands (often because of concerns about quality or counterfeits), and the difficulty of breaking into the hospital market without a prior relationship with hospital procurement officers or a distributor (Dearen, Linderman, and Mendoza, 2021; Jacobs, 2021; Lieber, 2021; Tin, 2021). In light of these challenges, it may be beneficial to examine the role of GPOs and distributors, along with hospital purchasing habits as a barrier to entry for domestic production of medical devices. Bolstering systematic approaches to ensuring quality and clear processes to access hospital markets, along with addressing issues related to price transparency as discussed in Chapter 4, are important additional steps to help ensure the health of domestic manufacturers.

Developing Methods for Allocation

With demand (including stockpiling or hoarding) for critical medical devices outstripping supply, bidding wars ensued. Interviewees described the desire to not simply sell devices to the highest bidder but rather to allocate the limited supply according to need. Companies wanted to be able to make decisions in the most appropriate way that would do the most good for the most people. But how might that be done? Academic supply chain research provides some insights.

Conceptually, even small increases in demand can result in outsized disruption to supply chains. Consider a case with just four entities: There is one hospital, which buys from a single distributor, which in turn buys from a single manufacturer, which buys from a single supplier.[5] Each week the hospital places its orders, leading the distributor to place its orders, and so on. Everything is fine until one day the use of masks goes up. Fearing an impending shortage, the hospital places a larger-than-usual order with its distributor, enough to cover its increased usage and then some. Seeing an increase in demand from its customer, the distributor places an even larger-than-usual order from the manufacturer. And so on. By the time one reaches the top of the supply chain, a 10-percent increase in end-user demand could perhaps be amplified into a tenfold increase in demand. And that is for a simple supply chain with only four entities.

The medical devices supply chain is more complicated in reality since there are multiple hospitals, multiple distributors, multiple manufacturers, and so on. Hospitals that fear that their usual distributor might not be able to fulfill their orders may place orders with other distributors. Other hospitals may do likewise, leading the distributor to place additional orders, perhaps with multiple manufacturers. Thus, not only is the demand signal distorted and amplified, but there is now the added complication of having to allocate product among competing customers. The market solution to allocating limited product would rely on pricing. This, however, results in bidding wars among customers, as was seen during COVID with states bidding against each other for ventilators and N95 masks. Allocation based on customers' ability to pay may not lead to supplies getting to those who need them the most.

Allocating scarce inventory fairly in the face of competing demand requires central coordination. But the ability of the coordinating body to determine where devices are needed the most requires visibility into not only what the true demand is at each location but what the current supplies are at each location. Using mathematical models to predict runout time, the coordinator would then be able to allocate inventory to the locations most in danger of running out. Accomplishing this would require hospitals to share the consumption rate of items as well as their inventory levels with the coordinating body, which requires a degree of trust. To earn that trust, the coordinating body would need to be transparent about the rules by which supplies are allocated, while at the same time protecting each hospital's proprietary information from competitors. Designing the mathematics as well as the organizational arrangements of such a system could be an area of research for HHS.

One approach for supply allocation that has been suggested is for the government to step in as a coordinating body to guarantee availability of supplies and discourage hoarding in future pandemics. Such an approach assumes that different regions are likely to experience high caseloads at different times. Thus, regions with low caseloads could either delay acquisition of

[5] This conceptual framework is similar to the "The MIT Beer Game" (Dizikes, 2013), a game in which players attempt to manage a supply chain.

supplies or even share existing supplies with regions with high caseloads in exchange for priority access to future supplies and/or a government "backstop" to replenish their supplies when needed (Hastings Roer and Globus-Harris, 2020).

Conclusion

In this report we have examined the supply chain for certain medical devices that are in high demand during the COVID-19 pandemic and the challenges involved in increasing their production. One thing is certain: It is not easy for a supply chain to cope with a multifold increase in demand. There are economic disincentives for hospitals or health care organizations to keep large amounts of inventory sitting unused "just in case." Similarly, manufacturers will not want to keep large amounts of finished goods inventory, nor will they keep large amounts of supplies, production equipment, and labor sitting idle. Improving supply chain response to public health emergencies will require a combination of policies and incentives to change the decision calculus for the entities involved so that they are willing to keep more inventory on hand and more capacity in reserve, as well as to develop processes and procedures to more flexibly move resources as needed. This may also require government to play a role in coordinating across companies and adjudicating across competing customers. These are areas that HHS may want to consider in future policymaking and future research.

Appendix. Medical Device Regulations

Overview

In this section, we provide a general overview of FDA regulatory requirements, since all COVID-19 relevant medical devices are regulated by FDA.

Device Regulations

The specific requirements that apply to any particular device are determined by the device's classification level (see next section). Below, we briefly describe each requirement in order to provide a complete overview of the process; in Chapter 3, we provide specifics about applicable regulatory requirements for the COVID-19 relevant devices discussed in this report:

- Establishment registration. Organizations that produce or distribute devices in the United States must register annually with FDA, which includes paying an annual fee (U.S. FDA, 2020c). In general, this requirement applies to manufacturers of end products (as opposed to manufacturers of components or parts for an end product), whether they are domestic or foreign. It also applies to categories of manufacturers such as contract manufacturers, which produce an end product on behalf of another company (U.S. FDA, 2020i).

  When products are manufactured outside the United States, both the *foreign manufacturer and* the *initial importer* must register with FDA. The *foreign manufacturer* is a manufacturer located outside the United States. The *initial importer* is defined as "any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes final delivery or sale of the device to the ultimate consumer or user" (U.S. FDA, 2020i). The initial importer must be physically located in the United States and is also responsible for medical device reporting, described below (U.S. FDA, 2019c), reporting any recalls or corrections (U.S. FDA, 2020f; U.S. FDA, 2020k), and, for some types of devices, tracking them even after they are commercially distributed. (This requirement does not apply to any of the devices discussed in this report and is meant to allow identification of devices whose failure would have serious adverse health consequences) (U.S. FDA, 2018c). Thus, for any device, more than one entity can be registered with FDA.
- Medical device listing. Firms must list the devices they produce/distribute and the activities that are performed on/with those devices (U.S. FDA, 2020c).
- Premarket Notification 510(k) or Premarket Approval. This is typically the most time-consuming step in the FDA regulatory process (U.S. FDA, 2018c). *Premarket Notification 510(k)* requires a submission to FDA demonstrating that a sponsor's device is "'substantially equivalent' to a predicate device (an already cleared device currently

legally marketed in the U.S.) in terms of intended use, technological characteristics, and performance testing" (U.S. FDA, 2020e). Some products are exempt from this step via the 510(k) exemption process (U.S. FDA, 2020q). *Premarket Approval* (PMA) is "the most stringent type of premarket submission. Before the FDA approves a PMA, the sponsor must provide valid scientific evidence demonstrating reasonable assurances of safety and effectiveness for the device's intended use" (U.S. FDA, 2020e).

- Investigational device exemption (IDE) for clinical studies. An IDE allows organizations to use a device that has not previously been authorized to be marketed or distributed to undergo a clinical study to collect safety and effectiveness data required for a PMA submission or a select few device types for a Premarket Notification 510(k) to FDA (U.S. FDA, 2019c). Alternatively, IDEs allow organizations to conduct clinical studies for investigative purposes, not to support a new or expanded indication for use or labeling claim.
- Quality system regulation. This step addresses the requirements for manufacturers to ensure the quality of their products. These quality systems are called CGMPs. "Because the regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device. . . . Operating within this flexibility, it is the responsibility of each manufacturer to establish requirements for each type or family of devices that will result in devices that are safe and effective, and to establish methods and procedures to design, produce, distribute, etc. devices that meet the quality system requirements. The responsibility for meeting these requirements and for having objective evidence of meeting these requirements may not be delegated even though the actual work may be delegated" (U.S. FDA, 2018b). This regulation applies to any device "that is suitable for use or capable of functioning" (U.S. FDA, 2018b).

  Of note, the CGMP requirements do not apply directly to component manufacturers (e.g., suppliers) but rather to the manufacturer of the end product (even if that product is meant to be used with another product; for instance, a swab for a testing kit). Although there were discussions about requiring component manufacturers/suppliers to adhere to CGMP requirements in the late 1990s, in the public comment and testimony period it was determined that such an approach would likely increase component costs and, moreover, that "many component suppliers would refuse to supply components or services to the medical device industry. This would be especially likely to occur, it was suggested, where medical device manufacturers account for a small fraction of the supplier's sales" (U.S. FDA, 1996). When considering COVID-19 relevant products, it is clear that applying CGMPs to suppliers would be particularly burdensome for

manufacturers of very complex devices, such as ventilators or machinery used for testing. In the final rule, which applies currently, FDA decided to "continue to focus its inspections on finished device manufacturers and expects that such manufacturers will properly ensure that the components they purchase are safe and effective" (U.S. FDA, 1996). Thus, it is incumbent upon manufacturers to ensure the quality, safety, and effectiveness of the supplies that compose their end products. However, FDA also notes that suppliers are a key part of the manufacturing team and that it may be necessary to engage some key suppliers in quality system discussions (U.S. Food and Drug Administration Center for Devices and Radiological Health, 1997).

In addition, there is the issue of how FDA regulations apply to the repair and service of medical devices. FDA defines servicing as an activity that "returns or maintains a finished device's safety and performance specifications" (U.S. FDA, 2018a). The FDA's quality system requirements designate that "each manufacturer who receives a service report that represents an event which must be reported to FDA . . . shall automatically consider the report a complaint and shall process it in accordance with the [FDA] requirements" (U.S. FDA, 2019a). This means that data on device performance that come from manufacturers' servicing of those devices should be included in the manufacturer's quality system reporting processes. Although FDA initially considered including service data from other entities (e.g., hospital staff or third-party servicers) in the quality system requirement, it ultimately determined that these entities are "outside the control of the original equipment manufacturer" (U.S. FDA, 2018a). Thus, nonmanufacturer servicers are not currently required to submit device performance data to FDA reporting systems. Here, we note that FDA itself has stated that "comments, complaints, and adverse event reports alleging inadequate servicing pertain to activities more accurately described as remanufacturing," in which the device's performance, safety specifications, or intended use is significantly changed (U.S. FDA, 2018a). FDA *does* require remanufacturing firms to abide by the same existing FDA requirements that apply to original manufacturers.

- Labeling requirements. FDA requires devices to be labeled with information including the name and place of business of the manufacturer or distributor and other relevant information (U.S. FDA, 2019a).
- Medical device reporting. This component of regulation is meant to "detect and correct problems in a timely manner" (U.S. FDA, 2020i). It requires manufacturers, distributors, and end users to "report certain device-related adverse events and product problems to the FDA" (U.S. FDA, 2020f). Such adverse event reports are currently made through an online portal (U.S. FDA, undated).

Regulatory Classification

Medical devices fall into three FDA regulatory categories based on the level of oversight needed to ensure safety and effectiveness (U.S. FDA, 2020a). Manufacturers of all devices, regardless of classification, must comply with some components of regulation such as registration, listing, and labeling. Depending on classification level, some devices may be exempt from Premarket Notification and/or quality system regulations (CGMPs). The three FDA regulatory categories are as follows:

- Class I devices present the lowest potential risk of user harm. FDA reports that "47% of medical devices fall under this category and 95% of these are exempt from the regulatory process." Certain Class I devices are exempt from Premarket Notification and CGMPs, although they must register and list their products (U.S. FDA, 2017; U.S. FDA, 2020a).
- Class II devices have slightly higher risk of user harm. FDA reports that "43% of medical devices fall under this category" (U.S. FDA, 2017) and require the manufacturer's declaration of device safety and effectiveness. Most are subject to Premarket Notification along with other regulatory requirements. Some Class II devices are exempt from GMP requirements and Premarket Notification.
- Class III devices present a greater potential risk of harm to the user and are subject to a greater level of in-depth scrutiny. FDA describes these as "devices [that] usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. 10% of medical devices fall under this category" (U.S. FDA, 2017). These devices are subject to the more stringent Premarket Authorization process along with the other regulatory requirements. Examples of Class III devices include implantable pacemakers and breast implants.

References

3M, "Fighting Fraud to Help the Front Line," webpage, April 22, 2020. As of January 5, 2021: https://news.3m.com/English/3m-stories/3m-details/2020/Fighting-fraud-to-help-the-front-line/default.aspx

3M Personal Safety Division, *Surgical N95 vs. Standard N95—Which to Consider?* Revision 3, June 2020. As of August 28, 2021: https://multimedia.3m.com/mws/media/1794572O/surgical-n95-vs-standard-n95-which-to-consider.pdf

Abbott, "Taking COVID-19 Testing to a New Level," webpage, undated. As of January 5, 2021: https://www.abbott.com/BinaxNOW-Test-NAVICA-App.html#/

AdvaMed, "AdvaMed Announces VentConnect Online Platform to Scale the Production and Distribution of Ventilators," news release, May 4, 2020a. As of September 15, 2020: https://www.advamed.org/industry-updates/news/advamed-announces-ventconnect-online-platform-to-scale-the-production-and-distribution-of-ventilators/

———, *Principles for Preparedness: The Medical Technology Industry's Plan to Respond to an Extraordinary Health Care Crisis*, June 4, 2020b. As of August 18, 2021: https://www.interamericancoalition-medtech.org/regulatory-convergence/wp-content/uploads/sites/4/2021/06/AdvaMed-COVID-BlueRibbon-OnePager_6-4-20.pdf

———, "AdvaMed Expands VentConnect Platform to Advance Production of COVID MedTech," news release, August 3, 2020c. As of August 28, 2021: https://www.advamed.org/industry-updates/news/advamed-expands-ventconnect-platform-to-advance-production-of-covid-medtech/

Advancing Safety in Health Technology, "Healthcare Technology Management," webpage, 2020. As of November 1, 2020: https://www.aami.org/HTM

Agiliti, "Manufacturer Services and Logistics Support," webpage, 2020. As of November 1, 2020: https://www.agilitihealth.com/manufacturer-services-logistics-support/

Albergotti, Reed, and Faiz Siddiqui, "Ford and GM Are Undertaking a Warlike Effort to Produce Ventilators. It May Fall Short and Come Too Late," *Washington Post*, April 4, 2020. As of November 1, 2020: https://www.washingtonpost.com/business/2020/04/04/ventilators-coronavirus-ford-gm/

American Society of Anesthesiologists, "Joint Statement on Multiple Patients per Ventilator," news release, March 26, 2020. As of November 1, 2020: https://www.asahq.org/about-asa/newsroom/news-releases/2020/03/joint-statement-on-multiple-patients-per-ventilator

America's Health Insurance Plan, "Health Insurance Providers Respond to Coronavirus (COVID-19)," webpage, April 8, 2021. As of July 13, 2021: https://www.ahip.org/health-insurance-providers-respond-to-coronavirus-covid-19/

Amir-Behghadami, Mehrdad, and Ali Janati, "The Importance of Designing and Implementing Participatory Surveillance System: An Approach as Early Detection and Prevention of Novel Coronavirus (2019-nCov)," *American Journal of Infection Control*, Vol. 48, No. 6, 2020, p. 731.

Associated Press, "Providers in Bidding War with States, Federal Agencies on Medical Supplies," March 29, 2020a. As of September 15, 2020: https://www.modernhealthcare.com/supply-chain/providers-bidding-war-states-federal-agencies-medical-supplies

———, "GM, Ford Complete US Contracts to Build Thousands of Ventilators," *Fox 2 Detroit*, September 1, 2020b. As of August 28, 2021: https://www.fox2detroit.com/news/gm-ford-complete-us-contracts-to-build-thousands-of-ventilators

———, "HHS Canceling Ventilator Contracts, Says Stockpile Is Full," *PBS News Hour*, September 2, 2020c. As of August 28, 2021: https://www.pbs.org/newshour/politics/hhs-canceling-ventilator-contracts-says-stockpile-is-full

Association for Molecular Pathology, "Assocation for Molecular Pathology SARS-CoV-2 Molecular Testing: Summary of Recent SARS CoV-2 Molecular Testing Survey," 2020. As of September 15, 2020: https://www.amp.org/AMP/assets/AMP_SARS-CoV-2_Survey_Report_FINAL.pdf?pass=98

Association of the Nonwoven Fabrics Industry, "About Nonwovens," webpage, 2020. As of November 1, 2020: https://www.inda.org/about-nonwovens/

Baird, Jeffrey S., and Kelly T. Custer, "Renting Equipment to Hospitals During the COVID-19 Crisis," *HomeCare*, March 30, 2020. As of August 28, 2021: https://www.homecaremag.com/renting-equipment-hospitals-during-covid-19-crisis

Barlow, Rick Dana, "GPOs Not Allowing Coronavirus Outbreak to Eclipse Supply Chain Operations," *Healthcare Purchasing News*, February 24, 2020. As of January 8, 2021:

https://www.hpnonline.com/sourcing-logistics/article/21126227/gpos-not-allowing-coronavirus-outbreak-to-eclipse-supply-chain-operations

Basu, Sanjay, John S. Yudkin, Sylvia Kehlenbrink, Justine I. Davies, Sarah H. Wild, Kasia J. Lipska, Jeremy B. Sussman, and David Beran, "Estimation of Global Insulin Use for Type 2 Diabetes, 2018–30: A Microsimulation Analysis," *The Lancet Diabetes & Endocrinology*, Vol. 7, No. 1, 2019, pp. 25–33.

Becker's Hospital Review Staff, "50 Things to Know About the Country's Largest GPOs," *Becker's Hospital Review*, July 30, 2014a. As of August 28, 2021: https://www.beckershospitalreview.com/hospital-management-administration/50-things-to-know-about-the-country-s-largest-gpos.html

———, "GPOs Save Money, but Is It Enough? The Case Against Group Purchasing," *Becker's Hospital Review*, September 17, 2014b. As of January 8, 2021: https://www.beckershospitalreview.com/hospital-management-administration/gpos-save-money-but-is-it-enough-the-case-against-group-purchasing.html

Behnam, Mohammad, Arnav Dey, Tony Gambell, and Vaibhav Talwar, "COVID-19: Overcoming Supply Shortages for Diagnostic Testing." *McKinsey & Company*, 2020. As of August 28, 2021: https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/covid-19-overcoming-supply-shortages-for-diagnostic-testing

Beresford, Colin, "Details of Increasing Plant Shutdowns amid COVID-19 Pandemic," *Car and Driver*, March 25, 2020. As of November 1, 2020: https://www.caranddriver.com/news/a31753194/ford-gm-honda-shutdown-us-plants/

Bhaskar, Sanjiv, "Impact of COVID-19 on Demand for PPE in the Healthcare Industry," Frost & Sullivan, 2020. As of November 1, 2020: https://ww2.frost.com/wp-content/uploads/2020/04/PPE-healthcare-infographic.pdf

Bio-Rad Laboratories, *C1000 Touch™ Thermal Cycler*, 2011. As of August 28, 2021: https://www.bio-rad.com/webroot/web/pdf/lsr/literature/10021377.pdf

Bond, Michaelle, "As Construction Resumes, Some Workers Are Finding a Shortage of Recommended N95 Masks," *Philadelphia Inquirer*, May 17, 2020. As of August 28, 2021: https://www.inquirer.com/real-estate/coronavirus-construction-n95-masks-pennsylvania-20200517.html

Bonislawski, Adam, "Huge Demand for COVID-19 Rapid Antigen Testing May Face Manufacturing Constraints," *Modern Healthcare*, October 8, 2020. As of August 28, 2021: https://www.modernhealthcare.com/supply-chain/huge-demand-covid-19-rapid-antigen-testing-may-face-manufacturing-constraints

Boston University Back2BU, "Inside BU's Clinical Testing Lab," webpage, undated. As of January 5, 2021: https://www.bu.edu/back2bu/boston-university-clinical-testing-lab/

Bruhn, William E., Elizabeth A. Fracica, and Martin A. Makary, "Group Purchasing Organizations, Health Care Costs, and Drug Shortages," *JAMA*, Vol. 320, No. 18, 2018, pp. 1859–1860.

Burns, Lawton Robert, *The Performance of Group Purchasing Organizations (GPOs) in the Health Care Value Chain: A Literature Review*, Philadelphia: The Wharton School at the University of Pennsylvania, 2014. As of August 28, 2021: https://www.supplychainassociation.org/wp-content/uploads/2018/05/AHA_AHRMM_Wharton_2014_LitRe.pdf

CardinalHealth, "Medical Device Manufacturer Solutions," webpage, undated. As of January 5, 2021: https://www.cardinalhealth.com/en/services/manufacturer/medical-manufacturer/medical-device-manufacturer-solutions.html

CDC—*See* Centers for Disease Control and Prevention.

Centers for Disease Control and Prevention, "Low-Temperature Sterilization Technologies: Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)," webpage, September 18, 2016a. As of July 13, 2021: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/low-temp.html

———, "Sterilization: Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)," webpage, September 18, 2016b. As of July 13, 2021: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.html

———, "NIOSH Regulations," webpage, March 28, 2018. As of June 29, 2021: https://www.cdc.gov/niosh/regulations.html

———, "Personal Protective Equipment: Questions and Answers," webpage, August 8, 2020a. As of November 2, 2020: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

———, "Implementing Filtering Facepiece Respirator (FFR) Reuse, Including Reuse After Decontamination, When There Are Known Shortages of N95 Respirators," webpage, October 19, 2020b. As of February 18, 2021: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html

———, "Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing," webpage, October 23, 2020c. As of January 5, 2021: https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html

———, "Strategies to Mitigate Healthcare Personnel Staffing Shortages," webpage, March 10, 2021. As of July 13, 2021: https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html

Centers for Medicare and Medicaid Services, "Coverage and Payment Related to COVID-19 Medicare," May 23, 2020a. As of January 5, 2021: https://www.cms.gov/files/document/03052020-medicare-covid-19-fact-sheet.pdf

———, "List of Device Category Codes for Present or Previous Pass-Through Payment and Related Definitions," July 1, 2020b. As of December 16, 2020: https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/complet-list-devicecats-opps.pdf

———, "Clinical Laboratory Improvement Amendments (CLIA)," webpage, March 9, 2021a. As of July 13, 2021: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA

———, "Coronavirus Waivers & Flexibilities," webpage, June 3, 2021b. As of July 13, 2021: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers

Chiang, Cho-Hung, Cho-Hsien Chiang, and Cho-Han Chiang, "Maintaining Mask Stockpiles in the COVID-19 Pandemic: Taiwan as a Learning Model," *Infection Control and Hospital Epidemiology*, 2020, pp. 1–2.

Chung, Doug J., "What South Korea Teaches the World About Fighting COVID," *Harvard Business School*, May 27, 2020. As of August 28, 2021: https://hbswk.hbs.edu/item/what-south-korea-teaches-the-world-about-fighting-covid

CMS—*See* Centers for Medicare & Medicaid Services.

Condon, Alan, "Stryker, Zimmer Biomet & More: How 12 Device Companies Are Controlling Costs During COVID-19," *Becker's Spine Review*, April 24, 2020. As of January 5, 2021: https://www.beckersspine.com/orthopedic-a-spine-device-a-implant-news/item/48787-stryker-zimmer-biomet-more-how-8-device-companies-are-controlling-costs-during-covid-19.html

Congressional Research Service, *COVID-19 and Domestic PPE Production and Distribution: Issues and Policy Options,* 2020a. As of <Please provide access date here>: https://fas.org/sgp/crs/misc/R46628.pdf

———, *Export Restrictions in Response to the COVID-19 Pandemic*, 2020b. As of August 28, 2021:
https://crsreports.congress.gov/product/pdf/IF/IF11551

Conti, Rena M., and Joseph Krongold, "Getting by on Their Own Supply: The Economics of Hospitals as Generic Prescription Drug Manufacturers," *Health Affairs Blog*, March 15, 2018. As of August 28, 2021:
https://www.healthaffairs.org/do/10.1377/hblog20180313.717895/full/

Dai, Tinglong, Ge Bai, and Gerard F. Anderson, "PPE Supply Chain Needs Data Transparency and Stress Testing," *Journal of General Internal Medicine*, Vol. 35, No. 9, 2020, pp. 2748–2749.

Danesh, Noah, "UCLA Researchers' More Efficient, Less Expensive COVID-19 Test Authorized by FDA," *Daily Bruin*, October 15, 2020. As of January 5, 2021:
https://dailybruin.com/2020/10/15/ucla-researchers-more-efficient-less-expensive-covid-19-test-authorized-by-fda

Davenport, Thomas H., A. Blanton Godfrey, and Thomas C. Redman, "To Fight Pandemics, We Need Better Data," *MIT Sloan Management Review*, August 25, 2020. As of January 8, 2021:
https://sloanreview.mit.edu/article/to-fight-pandemics-we-need-better-data/

Dearen, Jason, Juliet Linderman, and Martha Mendoza, "Hospitals Still Ration Medical N95 Masks as Stockpiles Swell," *AP News*, February 16, 2021. As of February 18, 2021:
https://apnews.com/article/hospitals-ration-n95-masks-coronavirus-b40b902991b75d8ae4000a20bccd6af4

Devaiah, Anand, Michael Wijaranakula, Chinmay Kommuru, and Rena M. Conti, "Medical Product Procurement in a Time of Federalism: The COVID-19 Challenge," *Health Affairs Blog*, 2020. As of August 28, 2021:
https://www.healthaffairs.org/do/10.1377/hblog20200515.360276/full/

Dizikes, Peter, "The Beer Game," *MIT Technology Review*, October 22, 2013. As of September 22, 2020:
https://www.technologyreview.com/2013/10/22/175775/the-beer-game/

Drees, Jackie, "How States Are Collecting Data to Track COVID-19 Equipment Shortages, Hospital Beds," *Becker's Health IT*, April 7, 2020. As of January 5, 2021:
https://www.beckershospitalreview.com/data-analytics/how-states-are-collecting-data-to-track-covid-19-equipment-shortages-hospital-beds.html

Environmental Protection Agency, "Agency Actions on Ethylene Oxide," webpage, May 26, 2021. As of July 13, 2021:
https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/agency-actions-ethylene-oxide#regulations

Euromonitor International, *How Ageing Populations and Rising Longevity Drive Megatrends*, January 2020. As of August 28, 2021: http://www.hbsab.org/s/1738/images/gid8/editor_documents/2019-2020/pdflib_ttg/20200310_how_ageing_population_and_rising_longevity_drive_megatrends.pdf?gid=8&pgid=61&sessionid=9d65c0a5-7edd-4467-b99d-94f48d121082&cc=1

Federal Emergency Management Agency, "FEMA Phasing Out Project Airbridge," news release, June 18, 2020. As of August 28, 2021: https://www.fema.gov/news-release/20200726/fema-phasing-out-project-airbridge

Feng, Emily, and Amy Cheng, "COVID-19 Has Caused a Shortage of Face Masks. But They're Surprisingly Hard to Make," *National Public Radio*, March 16, 2020. As of September 15, 2020: https://www.npr.org/sections/goatsandsoda/2020/03/16/814929294/covid-19-has-caused-a-shortage-of-face-masks-but-theyre-surprisingly-hard-to-mak

Franco, Jeff, "Examples of Inventory Turnover Ratios," undated. As of July 13, 2021: https://smallbusiness.chron.com/examples-inventory-turnover-ratios-12489.html

Freed, Jamie, and Lisa Baertlein, "Air Freight Rates Head Back to Earth as Virus-Driven Boom Cools," *Reuters*, June 18, 2020. As of September 15, 2020: https://www.reuters.com/article/us-health-coronavirus-airlines-freight/air-freight-rates-head-back-to-earth-as-virus-driven-boom-cools-idUSKBN23Q0ID

Fulton, Deirdre, "Group Purchasing Organizations Reduce Supply Costs by 13.1 Percent," *Healthcare Finance*, May 20, 2019. As of January 5, 2021: https://www.healthcarefinancenews.com/news/group-purchasing-organizations-reduce-supply-costs-131-percent

GE Healthcare, "ICU Ventilator User Resources," 2020. As of August 28, 2021: https://www.gehealthcare.com/products/ICU-Ventilation-User-Resources

GEP Worldwide, "Global Natural Rubber Production All Set to Increase in 2019," March 18, 2019. As of January 5, 2021: https://www.gep.com/blog/mind/global-natural-rubber-production-all-set-to-increase-in-2019

Get Us PPE, "Get Us PPE," webpage, 2021. As of February 18, 2021: https://getusppe.org/give/

Gibson, Kate, "Manufacturers Hinder Repairs of Crucial COVID Hospital Equipment, Critics Warn," *CBS News*, July 8, 2020. As of November 1, 2020: https://www.cbsnews.com/news/medical-equipment-makers-hinder-repairs-of-ventilators-says-consumer-group/

Global Reporting Centre, "Testing," webpage, October 6, 2020a. As of November 1, 2020: https://globalreportingcentre.org/medical-supply-crisis/testing/

———, "Ventilators," webpage, October 6, 2020b. As of November 1, 2020: https://globalreportingcentre.org/medical-supply-crisis/ventilators/

Goldhill, Olivia, "'People Are Going to Die': Hospitals in Half the States Are Facing a Massive Staffing Shortage as Covid-19 Surges," *Stat News*, November 19, 2020. As of February 18, 2021: https://www.statnews.com/2020/11/19/covid19-hospitals-in-half-the-states-facing-massive-staffing-shortage/

Goldratt, Eliyahu M., *The Goal: A Process of Ongoing Improvement*, 3rd ed., Great Barrington, Mass.: North River Press, 2012.

Grimm, Christi A., *Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020*, Office of the Inspector General, 2020. As of February 18, 2021: https://oig.hhs.gov/oei/reports/oei-06-20-00300.pdf

Haigney, Susan, "Contractors Balance Increased Demand During COVID-19," *PharmTech.com*, July 2, 2020. As of September 15, 2020: https://www.pharmtech.com/view/contractors-balance-increased-demand-during-covid-19-0

Halpern, Neil A., and Kay S. Tan, "United States Resource Availability for COVID-19," *Society of Critical Care Medicine*, May 12, 2020. As of November 1, 2020: https://sccm.org/Blog/March-2020/United-States-Resource-Availability-for-COVID-19

Hastings Roer, Elizabeth, and Isla Globus-Harris, *A Mechanism to Reduce Medical Supply Shortfalls During Pandemics*, Santa Monica, Calif.: RAND Corporation, PE-A187-1, 2020. As of July 27, 2021: https://www.rand.org/pubs/perspectives/PEA187-1.html

Hauer, Sarah, "A Grafton Company Switched from Making Dental Supplies to Producing Millions of COVID-19 Testing Swabs," *Milwaukee Journal Sentinel*, October 1, 2020. As of July 13, 2021: https://www.jsonline.com/story/money/business/2020/10/01/grafton-firm-switched-dental-supplies-covid-19-testing-swabs/5864668002/

Healthcare Ready, "About Healthcare Ready," webpage, 2019. As of January 5, 2021: https://healthcareready.org/about/

Henry, Diana, "Demand for Ventilators Soar During COVID-19," *LTi Technology Solutions*, April 2, 2020. As of November 1, 2020: https://www.ltisolutions.com/demand-for-ventilators-soar-during-covid-19/

Herper, Matt, and Helen Branswell, "Shortage of Crucial Chemicals Creates New Obstacle to U.S. Coronavirus Testing," *Stat News*, March 10, 2020. As of September 15, 2020: https://www.statnews.com/2020/03/10/shortage-crucial-chemicals-us-coronavirus-testing/

HHS Press Office, "HHS Announces New Ventilator Contracts, Orders Now Totaling over 130,000 Ventilators," news release, April 13, 2020. As of August 28, 2021: https://www.hhs.gov/about/news/2020/04/13/hhs-announces-new-ventilator-contracts-orders-now-totaling-over-130000-ventilators.html

Hinton, Denise M., Chief Scientist, Food and Drug Administration, letter to Manufacturers of Face Shields; Health Care Personnel; Hospital Purchasing Departments and Distributors; and Any Other Stakeholders, April 13, 2020b. As of November 1, 2020: https://www.fda.gov/media/136842/download

———, letter to Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators manufactured in China; Health Care Personnel; Hospital Purchasing Departments and Distributors; Importers and Commercial Wholesalers; and Any Other Applicable Stakeholders, October 15, 2020c. As of November 2, 2020: https://www.fda.gov/media/136664/download

———, letter to Rochelle P. Walensky, July 12, 2021. As of August 28, 2021: https://www.fda.gov/media/135763/download

HSCA, "FAQ," webpage, undated. As of January 8, 2021: https://www.supplychainassociation.org/about-us/faq/

Hufford, Austen, and Melanie Evans, "Critical Component of Protective Masks in Short Supply," *Wall Street Journal*, March 7, 2020. As of February 18, 2021: https://www.wsj.com/articles/coronavirus-pressures-supply-chain-for-protective-masks-11583552527

Hugos, Michael H., *Essentials of Supply Chain Management*, 3rd ed., Hoboken, NJ: John Wiley & Sons, 2011.

Iati, Marisa, "More Experts Now Recommend Medical Masks. Good Ones Are Hard to Find," *Washington Post*, February 2, 2021. As of February 18, 2021: https://www.washingtonpost.com/health/2021/02/02/medical-mask-shortage/

Institute for Healthcare Metrics and Evaluation, "Hospital Resource Use," undated. As of August 5, 2021: https://covid19.healthdata.org/global?view=resource-use&tab=trend&resource=all_resources

International Trade Centre and Trade and Market Intelligence, "COVID-19 Temporary Trade Measures," 2020. As of November 1, 2020: https://www.macmap.org/covid19

Jacobs, Andrew, "Now the U.S. Has Lots of Ventilators, but Too Few Specialists to Operate Them," *New York Times*, November 22, 2020. As of February 18, 2021: https://www.nytimes.com/2020/11/22/health/Covid-ventilators-stockpile.html

———, "Can't Find an N95 Mask? This Company Has 30 Million That It Can't Sell," *New York Times*, February 10, 2021. As of February 18, 2021: https://www.nytimes.com/2021/02/10/health/covid-masks-china-united-states.html

J-Flex, "What Is Nitrile/NBR Rubber?" webpage, 2020. As of July 13, 2021: https://www.j-flex.com/what-is-nitrile-nbr-rubber/

Kacik, Adam, "Cutting Links out of the Healthcare Supply Chain," *Modern Healthcare*, February 3, 2018. As of August 28, 2021: https://www.modernhealthcare.com/article/20180203/NEWS/180209982/cutting-links-out-of-the-healthcare-supply-chain

Kemp, Adam, "Local Hospitals Working Together to Prevent COVID Crush," *The Oklahoman*, November 7, 2020. As of August 28, 2021: https://oklahoman.com/article/5675666/local-hospitals-working-together-to-prevent-covid-crush

Kim, E. Tammy, "How South Korea Solved Its Face Mask Shortage," *New York Times*, April 1, 2020. As of August 28, 2021: https://www.nytimes.com/2020/04/01/opinion/covid-face-mask-shortage.html

Koebler, Jason, "Hospitals Need to Repair Ventilators. Manufacturers Are Making That Impossible," *Vice*, March 18, 2020. As of November 1, 2020: https://www.vice.com/en/article/wxekgx/hospitals-need-to-repair-ventilators-manufacturers-are-making-that-impossible

Korosec, Kirsten, "GM, Ford Wrap Up Ventilator Production and Shift back to Auto Business," *TechCrunch*, September 1, 2020. As of November 1, 2020: https://techcrunch.com/2020/09/01/gm-ford-wrap-up-ventilator-production-and-shift-back-to-auto-business/

Lane, Lisa, "Taiwan's Amazing Mask System: Apps, IDs and Convenience Stores," *World Crunch*, April 24, 2020. As of August 28, 2021: https://worldcrunch.com/coronavirus/taiwan39s-amazing-mask-system-apps-ids-and-convenience-stores

Lauterbach, Cole, "Amid COVID-19 Pandemic, Hospitals Usually Can't Fix Their Own Ventilators," *The Center Square*, July 27, 2020. As of November 1, 2020: https://www.thecentersquare.com/illinois/amid-covid-19-pandemic-hospitals-usually-can-t-fix-their-own-ventilators/article_a6fe026a-cf64-11ea-864a-6f3d5288048f.html

Lieber, Dave, "Two Guys Start a D-FW Mask Factory but Can't Catch a Break. Forget Made in Texas. China Always Wins," *Dallas Morning News*, January 22, 2021. As of February 18, 2021:
https://www.dallasnews.com/news/watchdog/2021/01/22/two-guys-start-a-dfw-mask-factory-but-cant-catch-a-break-forget-made-in-texas-china-always-wins/

Linder, Courtney, "Hospitals Need to Fix Ventilators. Why Won't Manufacturers Let Them?" *Popular Mechanic*, April 16, 2020. As of November 1, 2020:
https://www.popularmechanics.com/science/health/a32144222/hospitals-ventilators-right-repair-covid-19/

Los Angeles Times Staff, "Thousands of Health Care Workers Sickened by Coronavirus, Worsening Crisis in L.A. County Hospitals," *KTLA*, January 6, 2021a. As of August 28, 2021:
https://ktla.com/news/local-news/thousands-of-health-care-workers-sickened-by-coronavirus-worsening-crisis-in-l-a-county-hospitals/

———, "Tracking the Coronavirus in California Hospitals," *Los Angeles Times*, January 8, 2021b. As of January 8, 2021:
https://www.latimes.com/projects/california-coronavirus-cases-tracking-outbreak/hospitals/

Luo, Sophie, "What Is a Tier 1 Company or Supplier?" *Insight*, December 18, 2018. As of September 15, 2020:
https://insightsolutionsglobal.com/what-is-a-tier-1-company-or-supplier/

Ma, Michelle, "How You Can Donate Protective Equipment to Help Hospitals Fight Coronavirus," *Wall Street Journal*, April 3, 2020. As of February 18, 2021:
https://www.wsj.com/articles/how-you-can-donate-protective-equipment-to-help-hospitals-fight-coronavirus-11585323638

Mannino, Gabrielle, "New FDA-Approved COVID-19 Test Prompts Need for 1,200 Workers at Abbott Labs," *King 5*, August 27, 2020. As of September 15, 2020:
https://www.king5.com/article/money/business/new-fda-approved-covid-19-test-prompts-need-for-1200-workers-at-abbott-labs/97-62cccc5f-9068-4db5-bbb9-0e1fb7c1810c

Mazzoni, Mary, "15 Companies Retooling Their Operations to Fight COVID-19," *Triple Pundit*, May 1, 2020. As of November 1, 2020:
https://www.triplepundit.com/story/2020/companies-retooling-operations-covid-19/88921

McIntyre, Karen, "Nonwovens Supply Shifts," *Nonwovens Industry*, May 5, 2020. As of February 18, 2021:
https://www.nonwovens-industry.com/issues/2020-05/view_features/nonwovens-supply-shifts/

McKesson, "McKesson IntelliShelf Supply: Point of Use Hospital Supply Chain Solution Drives a Healthy Business," June 21, 2012. As of January 8, 2021: https://www.slideshare.net/supply22chain/mckesson-intellishelf-supply-point-of-use-hospital-supply-chain-solution-drives-a-healthy-business

Medtronic, "Permissive License—Open Ventilator Files," 2020. As of November 1, 2020: https://www.medtronic.com/content/dam/medtronic-com/global/Corporate/covid19/documents/permissive-license-open-ventilator.pdf

Mehrotra, Preeti, Preeti Malani, and Prashant Yadav, "Personal Protective Equipment Shortages During COVID-19—Supply Chain–Related Causes and Mitigation Strategies," *JAMA Health Forum*, Vol. 1, No. 5, 2020, p. e200553.

Mendoza, Martha, Juliet Linderman, Thomas Peipert, and Irena Hwang, "Shortages of Key Material Squeezes Medical Mask Manufacturing," *Frontline*, September 10, 2020. As of November 1, 2020: https://www.pbs.org/wgbh/frontline/article/covid-n95-medical-mask-shortage-manufacturing/

Mervosh, Sarah, and Manny Fernandez, "Months into Virus Crisis, U.S. Cities Still Lack Testing Capacity," *New York Times*, July 15, 2020. As of January 5, 2021: https://www.nytimes.com/2020/07/06/us/coronavirus-test-shortage.html

Mikulic, Matej, "Ventilator Production Change in the U.S. Before and During the COVID-19 Pandemic until April 2020," *Statista*, May 20, 2020. As of November 1, 2020: https://www.statista.com/statistics/1118835/ventilator-production-change-in-us-due-to-covid-19/

Moel, Marie-Morgane Le, and Samuel Reeves, "Surgical Glove Makers Struggle to Keep Pace with Booming Demand," *Medical XPress*, September 4, 2020. As of January 5, 2021: https://medicalxpress.com/news/2020-09-surgical-glove-makers-struggle-pace.html

Moore, Kathleen, "BD Furloughs 85 Employees as Demand Sinks for Medical Products," *Post Star*, May 12, 2020. As of January 5, 2021: https://poststar.com/news/local/bd-furloughs-85-employees-as-demand-sinks-for-medical-products/article_c25fa6b5-68ee-57e1-a6ba-2272dbe45a56.html

Morrison, Shannon, "Supply Chain Impacts—Where Are All the N95 Masks?" *NC State University*, April 1, 2020. As of November 1, 2020: https://poole.ncsu.edu/thought-leadership/need-to-know-supply-chain-impacts-where-are-all-the-n95-masks/

National Council of Textile Organizations, "Textile Industry Unites to Play Critical Role for the Nation's Production of PPE Products," April 9, 2020. As of February 18, 2021:

https://www.globenewswire.com/news-release/2020/04/09/2014590/0/en/Textile-Industry-Unites-to-Play-Critical-Role-for-the-Nation-s-Production-of-PPE-Products.html

National Institute for Occupational Safety and Health, "About NIOSH," webpage, March 28, 2018. As of November 1, 2020:
https://www.cdc.gov/niosh/about/default.html

———, "NIOSH-Approved N95 Particulate Filtering Facepiece Respirators," webpage, October 30, 2020. As of November 1, 2020:
https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/n95list1-a.html

National Institutes of Health, "Oxygenation and Ventilation," webpage, 2020. As of November 1, 2020:
https://www.covid19treatmentguidelines.nih.gov/critical-care/oxygenation-and-ventilation/

NIOSH—*See* National Institute for Occupational Safety and Health.

Noble, Breana, and Jordyn Grzelewski, "GM, Ford Produce 80,000 Ventilators, Conclude Historic 'Arsenal of Health' Effort," *Detroit News*, September 1, 2020. As of November 1, 2020:
https://www.detroitnews.com/story/business/autos/2020/09/01/general-motors-ford-conclude-arsenal-health-ventilator-production/5637770002/

Noguchi, Yuki, "Why N95 Masks Are Still in Short Supply in the U.S.," *NPR*, January 27, 2021. As of February 18, 2021:
https://www.npr.org/sections/health-shots/2021/01/27/960336778/why-n95-masks-are-still-in-short-supply-in-the-u-s

Occupational Safety and Health Administration, "Ethylene Oxide," undated. As of August 5, 2021:
https://www.osha.gov/ethylene-oxide

O'Kane, Sean, "How GM and Ford Switched out Pickup Trucks for Breathing Machines," *The Verge*, April 15, 2020. As of November 1, 2020:
https://www.theverge.com/2020/4/15/21222219/general-motors-ventec-ventilators-ford-tesla-coronavirus-covid-19

Oklahoma State Department of Health, "KN95s," webpage, undated. As of November 2, 2020:
https://coronavirus.health.ok.gov/kn95s

Palashis, Ted, "3 Reasons to Consider Contract Maintenance for Your Laboratory Equipment," *Overbrook*, July 24, 2019. As of December 16, 2020:
https://www.theoverbrookgroup.com/3-reasons-to-consider-contract-maintenance-for-your-laboratory-equipment

Patel, Anita, Maryann M. D'Alessandro, Karen J. Ireland, W. Greg Burel, Elaine B. Wencil, and Sonja A. Rasmussen, "Personal Protective Equipment Supply Chain: Lessons Learned from Recent Public Health Emergency Responses," *Health Security*, Vol. 15, No. 3, 2017, pp. 244–252.

Petersen, Lonnie G., James Friend, and Sidney Merritt, "Single Ventilator for Multiple Patients During COVID19 Surge: Matching and Balancing Patients," *Critical Care*, Vol. 24, No. 1, 2020, p. 357.

Pfeiffer, Sacha, Meg Anderson, and Barbara Van Woerkom, "Despite Early Warnings, U.S. Took Months to Expand Swab Production for COVID-19 Test," *National Public Radio*, May 12, 2020. As of September 15, 2020: https://www.npr.org/2020/05/12/853930147/despite-early-warnings-u-s-took-months-to-expand-swab-production-for-covid-19-te

Phillips, Quinn, "Insulin Makers: Supply Is Stable amid Coronavirus, but Demand Is High," *Diabetes Self-Management*, April 2, 2020. As of September 15, 2020: https://www.diabetesselfmanagement.com/news-research/2020/04/02/insulin-makers-supply-is-stable-amid-coronavirus-but-demand-is-high/

Premier, "Premier Data: Supplies for COVID-19 Testing, Diagnostics and Treatment at Risk of Shortage," January 19, 2021. As of February 18, 2021: https://www.premierinc.com/newsroom/blog/premier-data-supplies-for-covid-19-testing-diagnostics-and-treatment-at-risk-of-shortage

Proctor, Nathan, and Kevin O'Reilly, *Hospital Repair Restrictions*, US PIRG Education Fund, 2020. As of November 1, 2020: https://uspirgedfund.org/sites/pirg/files/reports/Hospital_Repair_Restrictions_USPEF_7.8.20b.pdf

Qiu, Stella, Shivani Singh, and Roslan Khasawneh, "Boxed Out: China's Exports Pinched by Global Run on Shipping Containers," *Reuters*, December 10, 2020. As of January 5, 2021: https://www.reuters.com/article/us-global-shipping-container/boxed-out-chinas-exports-pinched-by-global-run-on-shipping-containers-idUSKBN28K0UA

Quest Diagnostics, "COVID-19 Active Infection," webpage, undated. As of January 5, 2021: https://questdirect.questdiagnostics.com/products/covid-19-active-infection/2713afd8-3d0c-4819-b877-6880a776cc46?utm_source=google&utm_medium=cpc&utm_campaign=71700000072344458&utm_content=58700006333237999&utm_term=p57662739961&gclsrc=aw.ds&gclid=CjwKCAiAoOz-BRBdEiwAyuvA67b425udz4JyAQMGSQPVApMi1tHNE6LhADc9T9v6UCzJacTCO_keHBoCwtsQAvD_BwE

———, "Courier Services," webpage, 2020. As of December 16, 2020: https://www.questdiagnostics.com/home/physicians/testing-services/specialists/hospitals-lab-staff/lab-info/courier-service/

Ranney, Megan L., Valerie Griffeth, and Ashish K. Jha, "Critical Supply Shortages—the Need for Ventilators and Personal Protective Equipment During the Covid-19 Pandemic," *New England Journal of Medicine*, Vol. 382, No. 18, 2020, p. e41.

Ready Ratios, "Inventory Turnover (Days) - Breakdown by Industry," 2020. As of July 1, 2021: https://www.readyratios.com/sec/ratio/inventory-turnover/

Repko, Melissa, "As Pressure Grows to Reopen Economy, a Scramble to Make Nasal Swabs for Coronavirus Testing Leads to 3D Printers," *CNBC*, April 22, 2020. As of August 28, 2021: https://www.cnbc.com/2020/04/22/coronavirus-3d-printing-companies-answer-the-call-for-swabs-for-covid-19-tests.html

Rubinson, L., F. Vaughn, S. Nelson, S. Giordano, T. Kallstrom, T. Buckley, T. Burney, N. Hupert, R. Mutter, M. Handrigan, K. Yeskey, N. Lurie, and R. Branson, "Mechanical Ventilators in US Acute Care Hospitals," *Disaster Medicine and Public Health Preparedness*, Vol. 4, No. 3, October 2010, pp. 199–206.

Salcedo, Andrea, Sanam Yar, and Gina Cherelus, "Coronavirus Travel Restrictions, Across the Globe," *New York Times*, as of September 15, 2020.

Scher, Isaac, "Hospitals Need Ventilators to Keep Severe COVID-19 Patients Alive. They Might Not Be Able to Fix Them Without Paying the Manufacturer $7,000 per Technician," *Business Insider*, June 3, 2020. As of November 1, 2020: https://www.businessinsider.com/ventilator-manufacturers-dont-let-hospitals-fix-coronavirus-right-to-repair-2020-5

Schmidt, Sarah, "The Soaring Demand for Personal Protective Equipment (PPE) During COVID-19," June 15, 2020. As of November 1, 2020: https://blog.marketresearch.com/the-soaring-demand-for-personal-protective-equipment-ppe-during-covid-19

Shepard, Liz, "Need to Cross the Border? Find out If You Are Exempt from the Coronavirus Closure," *Port Huron Times Herald*, March 20, 2020. As of March 21, 2020: https://www.thetimesherald.com/story/news/2020/03/20/coronavirus-border-crossing-personal-closure-exemptions/2888885001/

Siddiqui, Faiz, "The U.S. Forced Major Manufacturers to Build Ventilators. Now They're Piling up Unused in a Strategic Reserve," *Washington Post*, August 18, 2020. As of November 1, 2020: https://www.washingtonpost.com/business/2020/08/18/ventilators-coronavirus-stockpile/

Spectrofuge, "Should My Lab Purchase a Service Contract for Our Lab Equipment?" webpage, undated. As of December 16, 2020: https://spectrofuge.com/lab-purchase-service-contract-lab-equipment/

Stoll, John D., "Before Coronavirus, She Made Parts for Ford for 26 Years—Now She Makes Ventilators," *Wall Street Journal*, April 28, 2020. As of November 1, 2020: https://www.wsj.com/articles/before-coronavirus-she-made-parts-for-ford-for-26-yearsnow-she-makes-ventilators-11588066202

Teschler, Lee, "FDA Begins Approving Modified Bag Resuscitators for Use as Ventilators," *Medical Design & Outsourcing*, April 17, 2020. As of August 28, 2021: https://www.medicaldesignandoutsourcing.com/hack-the-crisis-that-was-fast-fda-begins-approving-modified-bag-resuscitators-for-use-as-ventilators/?utm_source=TrendMD&utm_medium=cpc&utm_campaign=Med_Design_and_Outsourcing_TrendMD_0&utm_content=Google%20Feedfetcher

Tho, Alexis See, "How World's Largest Glove Maker Meets Coronavirus Demand," *Financial Management*, March 17, 2020. As of January 5, 2021: https://www.fm-magazine.com/news/2020/mar/top-glove-malaysia-coronavirus-demand-23152.html

Thomas, "Top Suppliers of Medical Testing Kits," webpage, 2020. As of December 16, 2020: https://www.thomasnet.com/articles/top-suppliers/medical-testing-kits-suppliers/#_Updated_List_of

Tin, Alexander, "CDC Director Defends N95 Mask Restrictions Despite Greater Supply," *CBS News*, February 17, 2021. As of February 18, 2021: https://www.cbsnews.com/news/n95-mask-restrictions-cdc/

Trivedi, Anjani, "The World Needs Ventilators. Here's the Snag," Bloomberg, April 8, 2020. As of September 15, 2020: https://www.bloombergquint.com/global-economics/carmaker-ventilator-plans-are-virus-test-for-global-trade

Trump, Donald J., "Memorandum on Order Under the Defense Production Act Regarding the Purchase of Ventilators," April 2, 2020. As of August 4, 2020: https://trumpwhitehouse.archives.gov/presidential-actions/memorandum-order-defense-production-act-regarding-purchase-ventilators/

U.S. FDA—*See* U.S. Food and Drug Administration.

U.S. Food and Drug Administration, "MedWatch Online Voluntary Reporting Form," webpage, undated. As of November 1, 2020: https://www.accessdata.fda.gov/scripts/medwatch/

———, Code of Federal Regulations Title 21 Parts 808, 812, and 820, 1996. As of August 28, 2021: https://www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices/medical-devices-current-good-manufacturing-practice-cgmp-final-rule-quality-system-regulation

———, "Learn If a Medical Device Has Been Cleared by FDA for Marketing," webpage, December 29, 2017. As of November 1, 2020: https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing

———, *FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices*, May 2018a. As of November 1, 2020: https://www.fda.gov/media/113431/download

———, "Medical Device Tracking," webpage, September 27, 2018b. As of January 5, 2021: https://www.fda.gov/medical-devices/postmarket-requirements-devices/medical-device-tracking

———, "Quality System (QS) Regulation/Medical Device Good Manufacturing Practices," September 27, 2018c. As of November 1, 2020: https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices

———, "Emergency Use Authorization of Medical Products and Related Authorities," October 17, 2018d. As of August 28, 2021: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities

———, Code of Federal Regulations Title 21, 2019a. As of August 28, 2021: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=801

———, "Importing Medical Devices and Radiation-Emitting Electronic Products into the U.S.," webpage, August 8, 2019b. As of January 5, 2021: https://www.fda.gov/medical-devices/importing-and-exporting-medical-devices/importing-medical-devices-and-radiation-emitting-electronic-products-us

———, "Investigational Device Exemption (IDE)," webpage, December 13, 2019c. As of November 1, 2020: https://www.fda.gov/medical-devices/how-study-and-market-your-device/investigational-device-exemption-ide

———, 21CFR820.300, 2020a. As of August 28, 2021: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=820.3

———, *Molecular Diagnostic Template for Commercial Manufacturers*, 2020b. As of August 28, 2021:
https://www.fda.gov/media/135900/download

———, "Classify Your Medical Device," webpage, February 7, 2020c. As of November 1, 2020:
https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

———, "Clinical Laboratory Improvement Amendments (CLIA)," webpage, February 25, 2020d. As of June 29, 2021:
https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia

———, "Premarket Notification 510(k)," webpage, March 13, 2020e. As of November 1, 2020:
https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k

———, "Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities," webpage, May 22, 2020f. As of November 1, 2020:
https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities

———, "Coronavirus (COVID-19) Update: FDA Issues First Emergency Authorization for Sample Pooling in Diagnostic Testing," news release, July 18, 2020g. As of January 5, 2021:
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-first-emergency-authorization-sample-pooling-diagnostic

———, "FDA Combating COVID-19 with Medical Devices," August 25, 2020h. As of November 2, 2020:
https://www.fda.gov/media/136702/download

———, "Overview of Device Regulation," webpage, September 4, 2020i. As of November 1, 2020:
https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation

———, "Ethylene Oxide Sterilization for Medical Devices," September 24, 2020j. As of July 13, 2021:
https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices#ft1

———, "Corrections and Removals—21 CFR 806," webpage, September 29, 2020k. As of January 5, 2020:
https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices#5

———, “Device Registration and Listing,” webpage, October 1, 2020l. As of November 1, 2020: https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing

———, “How to Study and Market Your Device,” webpage, October 14, 2020m. As of November 1, 2020: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device#step2

———, “FDA Reissues Emergency Use Authorization for Certain Non-NIOSH.-Approved Filtering Face-Piece Respirators Manufactured in China,” news release, October 15, 2020n. As of November 2, 2020: https://www.fda.gov/news-events/press-announcements/fda-reissues-emergency-use-authorization-certain-non-niosh-approved-filtering-face-piece-respirators

———, “In Vitro Diagnostics EUAs,” webpage, October 30, 2020o. As of November 1, 2020: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

———, “Establishment Registration & Device Listing: cobas 6800 instrument; cobas 8800 instrument; KIT COBAS 6800/8800 BUFF NEG RMC IVD; KIT COBAS 6800/8800 UTIL CHAN 96T IVD,” November 2, 2020p.

———, “Medical Device Exemptions 510(k) and GMP Requirements,” November 2, 2020q. As of November 2, 2020: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

———, “Product Classification: Accessory to Continuous Ventilator (Respirator),” November 2, 2020r. As of November 2, 2020: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=149

———, “Product Classification: Applicator, Absorbent Tipped, Non-Sterile,” November 2, 2020s. As of August 28, 2021: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=2715

———, “Product Classification: Gown, Surgical,” November 2, 2020t.

———, “Product Classification: Mechanical Ventilator,” November 2, 2020u. As of November 2, 2020: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=193

———, “Product Classification: Micro Pipette,” November 2, 2020v.

———, “Product Classification: N95 Respirator with Antimicrobial/Antiviral Agent,” November 2, 2020w.

———, “Product Classification: Non-Surgical Isolation Gown,” November 2, 2020x.

———, “Product Classification: Powder-Free Non-Natural Rubber Latex Surgeon’s Gloves,” November 2, 2020y.

———, “Product Classification: Real Time Nucleic Acid Amplification System,” November 2, 2020z.

———, “Product Classification: Surgeon’s Gloves,” November 2, 2020ab.

———, “Medical Gowns,” webpage, January 13, 2021a. As of July 13, 2021: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns

———, “Using Ventilator Splitters During the COVID-19 Pandemic - Letter to Health Care Providers,” webpage, February 9, 2021b. As of June 29, 2021: https://www.fda.gov/medical-devices/letters-health-care-providers/using-ventilator-splitters-during-covid-19-pandemic-letter-health-care-providers

———, “Ventilators and Ventilator Accessories for COVID-19,” webpage, February 9, 2021c. As of June 29, 2021: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/ventilators-and-ventilator-accessories-covid-19#eua

———, “Medical Device Shortages During the COVID-19 Public Health Emergency,” February 18, 2021d. As of February 18, 2021: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency#shortage

———, “Ventilators and Ventilator Accessories EUAs,” webpage, April 28, 2021e. As of June 29, 2021: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas

———, “Decontamination System EUAs for Personal Protective Equipment,” April 30, 2021f. As of August 28, 2021: https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#decontamination

———, “FDA Recommends Transition from Use of Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities,” webpage, May 27, 2021g. As of July 1, 2021: https://www.fda.gov/medical-devices/letters-health-care-providers/fda-recommends-transition-use-decontaminated-disposable-respirators-letter-health-care-personnel-and

———, “Ethylene Oxide Sterilization Facility Updates,” webpage, June 2, 2021h. As of July 13, 2021:

https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates

———, "Personal Protective Equipment EUAs," June 14, 2021i. As of June 29, 2021: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#respirators

———, "Establishment Registration & Device Listing," July 12, 2021j. As of July 13, 2021: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm?start_search=1&showList=1&establishmentName=c%2Er%2E%20bard&regNum=&StateName=GA&CountryName=&OwnerOperatorNumber=&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=EstablishmentName20%25ASC&RegistrationNumber=1018233

U.S. Food and Drug Administration Center for Devices and Radiological Health, *Design Control Guidance for Medical Device Manufacturers*, March 11, 1997. As of August 28, 2021: https://www.fda.gov/media/116573/download

Vigdor, Neil, "Home Depot Halts Sales of N95 Masks amid Shortage, Company Says," *New York Times*, April 1, 2020. As of February 18, 2021: https://www.nytimes.com/2020/04/01/business/n95-face-masks-home-depot-virus.html

Wan, William, "Long Lines and Delayed Results Again Plague Coronavirus Tests as Thanksgiving Approaches," *Washington Post*, November 18, 2020. As of August 28, 2021: https://www.washingtonpost.com/health/2020/11/18/coronavirus-thanksgiving-test/

Waters-Fuller, Niall, "Just-in-Time Purchasing and Supply: A Review of the Literature," *International Journal of Operations & Production Management*, Vol. 15, No. 9, 1995, pp. 220–236.

Weber, Lauren, and Christina Jewett, "As Coronavirus Testing Gears Up, Specialized Swabs Running Out," *Kaiser Health News*, March 17, 2020. As of August 28, 2021: https://khn.org/news/as-coronavirus-testing-gears-up-specialized-swabs-running-out/

Wu, Katherine J., "Why Pooled Testing for the Coronavirus Isn't Working in America," *New York Times*, August 18, 2020. As of August 28, 2021: https://www.nytimes.com/2020/08/18/health/coronavirus-pool-testing.html

Wyden, Ron, "Wyden and Clarke Introduce Bill to Eliminate Barriers to Fixing Critical Medical Equipment During the Pandemic," news release, August 6, 2020. As of November 1, 2020: https://www.wyden.senate.gov/news/press-releases/wyden-and-clarke-introduce-bill-to-eliminate-barriers-to-fixing-critical-medical-equipment-during-the-pandemic-

Wyden, Ron, and Ilir Kullolli, "Hospitals Need to Be Able to Repair Their Own Medical Equipment," *Slate*, October 12, 2020. As of November 1, 2020:

https://slate.com/technology/2020/10/critical-medical-infrastructure-right-to-repair-act-ventilators.html