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International Trade Commission

# COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges

December 2020

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# United States International Trade Commission

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# **COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges**

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# Abbreviations and Acronyms

<b>Terms</b>	<b>Definitions</b>
AAMI	Association for the Advancement of Medical Instrumentation
ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
ANSI	American National Standards Institute
APIs	active pharmaceutical ingredients
ASTM	American Society for Testing and Materials
BARDA	Biomedical Advanced Research and Development Authority
BiPAP	bilevel positive airway pressure
CBP	U.S. Customs and Border Protection
CCP	COVID-19 convalescent plasma
CDC	Centers for Disease Control and Prevention
CDMO	contract development and manufacturing organization
COVID-19	coronavirus disease 2019, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
CPAP	continuous positive airway pressure
CROSS	Customs Rulings Online Search System
DNA	deoxyribonucleic acid
DHS	U.S. Department of Homeland Security
DOD	U.S. Department of Defense
DPA	Defense Production Act
EDIS	Electronic Document Information System (USITC)
EMT	emergency medical technician
EUA	Emergency Use Authorization (FDA)
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency
GPO	group purchasing organization
HFNO	high-flow nasal oxygen
HHS	U.S. Department of Health and Human Services
HIDA	Healthcare Industries Distributors Association
HS	International Harmonized Commodity Description and Coding System
HTS	Harmonized Tariff Schedule of the United States
ICU	intensive care unit
INDA	Association of the Nonwoven Fabrics Industry
IP	intellectual property
IRB	institutional review board
ITA	Information Technology Agreement (WTO)
kg	kilograms
N95 respirators	filtering facepiece respirators that filter at least 95 percent of airborne particles (not resistant to oil)
NAICS	North American Industry Classification System
NAPCS	North American Product Classification System
NBR	nitrile butadiene rubber
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NTR	normal trade relations
OWS	Operation Warp Speed
PAPR	Powered air purifying respirators
PhRMA	Pharmaceutical Research and Manufacturers of America
PPE	personal protective equipment

## COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges

<b>Terms</b>	<b>Definitions</b>
PCR	polymerase chain reaction
RADx	Rapid Acceleration of Diagnostics
R&D	research and development
RFP	request for proposal
RNA	ribonucleic acid
SMEs	small and medium-sized enterprises
SMS	spunbond-meltblown-spunbond (fabric)
SNS	Strategic National Stockpile
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO)
UCG	Unified Coordination Group (FEMA)
USDOC	U.S. Department of Commerce
USITC	U.S. International Trade Commission
WHO	World Health Organization
WTO	World Trade Organization



# Executive Summary

Beginning in early 2020, the country faced a daunting challenge as a highly contagious virus, known as SARS-CoV-2 (COVID-19), spread quickly around the world. By November 2020, nearly 13 million Americans had been infected by the virus and over 250,000 Americans had died due to COVID-19. The outbreak at the beginning of 2020 triggered an exponential increase in demand for goods used in response to the pandemic, which resulted in severe supply chain challenges and constraints for certain vital COVID-19 related products. Although there was a rapid response to these shortfalls across many key industries during the first half of 2020, it was not enough to meet the needs at the start of the pandemic. As of the writing of this report, some of the initial supply chain challenges have eased but a number remain. The improvement is attributable in part to U.S. manufacturers' launching or boosting production, increased imports of critical COVID-19 related goods, and a better understanding of the virus. However, as the pandemic continues, difficulties remain, and for certain COVID-19 related goods, supply constraints are not expected to wane until 2022.

The pharmaceutical industry is also ramping up to manufacture and distribute one or more vaccines as they are authorized by the U.S. Food and Drug Administration. The production and distribution of vaccines to inoculate against a novel virus presents specific challenges, such as storage conditions and the large number of doses and related medical consumables (e.g., syringes) needed in a short timeframe for a mass vaccination program.

This report, prepared by the U.S. International Trade Commission (Commission or USITC) at the request of the U.S. House Committee on Ways and Means and the Senate Committee on Finance, gives context on U.S. industries producing COVID-19 related goods and on the supply chain challenges and constraints that impacted the availability of such goods through September 2020.<sup>1</sup> The report includes a brief overview of broad U.S. industry sectors producing COVID-19 related goods and case studies on discrete products within each relevant industry sector. Each case study includes a product overview, information on the U.S. market, and a description of the U.S. industry and imports (including of key inputs). The case studies also include information on supply chain challenges and constraints, including a discussion of factors affecting domestic production and factors affecting imports of finished goods and key inputs.

The report focuses mostly on short-term barriers, including those that have prevented firms in the United States from ramping up production this year from a low or nonexistent level (e.g., difficulties with market entry or market acceptance). Understanding the short-term barriers is necessary—indeed, it is critical—but not sufficient: ramping up domestic production in the short term may be of little consequence in the long term if there exists no economic rationale for that production to continue. Although the report does discuss “crosscutting” structural factors affecting domestic production like relative labor costs, with more time and resources one could more thoroughly identify and analyze the most important long-term competitive factors affecting domestic production of COVID-19 related goods. Fully understanding how and why supply chains struggled—and continue to struggle—to provide us with

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<sup>1</sup> In certain instances, the Commission has been able to provide data and information beyond September 2020.

the critical products needed to fight COVID-19 can help us prepare for a future crisis of this kind and uncover broader insights about how our economy functions today.<sup>2</sup>

## Major Findings: U.S. Industry Sectors Producing COVID-19 Related Goods

*This report provides an overview of four key industry sectors producing COVID-19 related goods listed in the Commission's June 2020 report on Investigation 332-576, COVID-19 Related Goods: U.S. Imports and Tariffs. These sectors are medical devices, personal protective equipment (PPE), pharmaceuticals, and soaps and cleaning compounds.*

### U.S. Production and Employment

Entering the pandemic, the United States was a large global producer in certain sectors producing COVID-19 related goods, but a smaller producer in other categories of COVID-19 related goods. The United States is the largest global producer of both pharmaceuticals and medical devices by value, with pharmaceutical shipments of \$268.7 billion in 2019 and medical device shipments of \$123.9 billion in 2018 (table ES.1). The United States also has a large soap and cleaning compound manufacturing industry that generally supplies most of the domestic market. U.S. production of personal protective equipment (PPE), a subset of medical device manufacturing, totaled \$3.5 billion in 2017. U.S. production for the healthcare PPE market accounted for a relatively small share of global production. Among the three key industries producing COVID-19 related goods, the medical device industry is the largest employer (with 323,000 employees in 2019), followed by pharmaceuticals (306,000) and soap and cleaning compound manufacturing (55,000). Within medical devices, there are upwards of 15,000 workers engaged in PPE production in 2020.

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<sup>2</sup> Vice Chair Stayin and Commissioner Johanson do not join this paragraph as it raises issues that are outside the scope of the request letter from the House Ways and Means Committee and the Senate Finance Committee.

**Table ES.1** U.S. shipments and employment by industry sector, latest full year available and change from 2015

	U.S. shipments		U.S. employment	
	U.S. shipments, billion \$ (year)	U.S. shipments, change from 2015, in %	U.S. employment, in thousands (year)	U.S. employment, change from 2015 to 2019, in %
Medical devices	123.9 (in 2018)	10	323 (in 2019)	11
PPE (a subset of medical devices)	3.5 (in 2017)	NA	>15 (in 2020)	NA
Pharmaceuticals	268.7 (in 2019)	25	306 (in 2019)	9
Soaps and cleaning compounds	38.5 (in 2018)	-1	55 (in 2019)	4

Source: Census Bureau, Annual Survey of Manufactures and Economic Census data (accessed August–December 2020); Census Bureau, Manufacturers Shipments, Inventories, and Orders (accessed September 2020); Bureau of Labor Statistics, Quarterly Census of Employment and Wages (accessed October 2020); Manufacturers News Inc., IndustrySelect database, <https://www.industryselect.com> (accessed September 4, 2020); Nexis Dossier database (accessed various dates); Orbis database (accessed various dates); D&B Duns Market Identifiers Plus database; Lexis Advance (accessed various dates); data compiled from company Websites and media reports. Medical devices: NAICS 334510, 334517, 339112, 339113; PPE: NAPCS 2050375000; pharmaceuticals: NAICS 3254; soaps and cleaning compounds: NAICS 32561. Notes: NA=Not available. PPE is a subset of medical devices and is included in the broader medical device data. However, data are separately broken out where available. The PPE employment data are based on a list of manufacturing plants identified as producing goods for each of the products covered in the case studies, as well as a list of plants from Manufacturers News. The Manufacturers News data were filtered by industry code and the description of activities at the location. Therefore, although these data were retrieved in September 2020, they likely do not capture all of the firms that pivoted into PPE production in 2020 as their primary industry code would not have changed. For example, an automotive plant would remain classified as such, even after starting PPE production, and would not be captured in these data.

Following the onset of the pandemic in 2020, U.S. production in most of these four industry sectors grew as U.S. manufacturers attempted to satisfy burgeoning demand. Pharmaceutical shipments were 11 percent higher during July–September 2020 compared to the same period in 2019. Likewise, manufacturers of soaps and cleaning compounds increased production and employment during 2020. Both the PPE and medical device industries experienced a combination of demand trends that affected production. The manufacture of medical PPE rapidly increased over the course of the year, even as demand for PPE used for industrial applications reportedly declined. Similarly, despite significant demand from medical providers for many COVID-19 related medical devices, U.S. manufacturers faced lower demand for products used in elective medical procedures.

## U.S. Imports

Prior to the pandemic, U.S. imports in all sectors increased at a faster rate than domestic production, with growth in imports of medical devices and pharmaceuticals exceeding 30 percent from 2015 to 2019 (table ES.2). Patterns in 2020 mirror those noted for domestic production in the preceding section. In 2020, U.S. imports of pharmaceuticals rose at the same rate as the expanding domestic production, while medical device imports fell, reflecting the suspension of elective medical procedures and hesitancy among patients to enter re-enter the hospital settings once elective medical procedures resumed. U.S. imports of soaps and cleaning compounds increased at the fastest rate amid rapidly growing demand for disinfectants and hand sanitizer.

The source of U.S. imports of COVID-19 related goods varies by type of product. Europe is primarily a supplier of higher-value products, like novel pharmaceuticals and high-tech medical devices. Mexico and Asia supply a range of medical devices and parts, including lower-value-added products, as well as a large volume of pharmaceuticals, primarily generics and commodity chemicals used in a variety of

pharmaceutical (including generic) manufacturing. High-volume, low-margin imported PPE goods, supplying an estimated 80 to 90 percent of the U.S. PPE market directed toward healthcare applications, are largely sourced from Asia, including China, Malaysia, and Vietnam. Imports of soaps and cleaning compounds are largely sourced from Mexico and Canada, due to ease of transport for these bulky, heavy, and often caustic products.

**Table ES.2** U.S. imports by industry sector and supplier country

Industry sector	Value of imports, 2019, in billion \$	Change in value of imports, 2015 to 2019, in %	Leading suppliers in 2019 (as a share of U.S. imports, in %)	Import values, Jan–Sep 2020, in billion \$	Change in import values, Jan–Sep 2019 to Jan–Sep 2020, in %
Medical devices	53.3	33	By value: Mexico (17%), Ireland (15%), Germany (10%), China (10%), Switzerland (6%)	38.6	–3
Pharmaceuticals	150.9	37	By value: Ireland (25%), Germany (12%), Switzerland (11%), Italy (5%), India (5%) By volume: China (24%), India (15%), Mexico (12%), Canada (9%), Germany (6%)	125.5	11
Soaps and cleaning compounds	3.7	11	By value: Mexico (24%), Canada (22%), China (11%), Germany (9%), Japan (5%)	3.9	38

Source: USITC DataWeb/USDOC (accessed November 2020). Medical devices: NAICS 334510, 334517, 339112, 339113; pharmaceuticals: NAICS 3254; soaps and cleaning compounds: NAICS 32561.

Note: Data for PPE are not available. The volume of pharmaceutical imports totaled 680 million kg in 2019, up 27 percent from 2015. The volume of imports during January–September 2020 totaled 628 million kg, up 23 percent from the same time period in 2019. HTS subheadings for PPE are identified in the Commission’s June 2020 report. However, as noted in that report, many of the HTS 10-digit statistical reporting numbers encompass goods not related to the response to COVID-19. Therefore, PPE trade totals are not presented here. Chapter 4 of the report presents data for a subset of items that have been refined to better represent trade patterns in COVID-19 related PPE.

## Major Findings: Case Studies

*The report includes six case studies on COVID-19 related goods affected by supply chain constraints and bottlenecks due to the pandemic: mechanical invasive ventilators (“ventilators”),<sup>3</sup> N95 respirators, surgical and isolation gowns, medical and surgical gloves, COVID-19 test kits, and vaccines. Two additional products—surgical masks and hand sanitizer—are discussed in condensed case studies.*

## U.S. Market, Industry, and Imports

U.S. demand for all products covered in the case studies substantially increased in the first half of 2020, as compared to 2019.<sup>4</sup> The United States produced all the goods covered in the case studies before the

<sup>3</sup> Unless otherwise specified, the term “ventilator” in this report refers to mechanical invasive ventilators. For a discussion of the different types of ventilators, see the ventilator case study in chapter 4.

<sup>4</sup> In the case of vaccines, while the product is still in development, there is a substantial buildup in the production of the vaccine and medical consumables needed to inject the vaccine.

pandemic, as well as many of the inputs.<sup>5</sup> However, the extent of domestic production varied significantly. The U.S. industry supplied only a relatively small share of the domestic market for certain medical PPE, such as medical gloves and gowns, but supplied a large share of the domestic market for goods like ventilators, vaccines, N95 respirators, and hand sanitizer. U.S. production of all products increased in response to the pandemic, and for certain products, such as ventilators, supply rose quickly.

U.S. imports of most COVID-19 related goods covered in the case studies increased substantially beginning around April or May 2020, depending on the product. Imports of many products exceeded their normal levels by orders of magnitude. Medical and surgical gloves remain among the most hard-to-find items, with glove imports up only 17 percent during January–September 2020 and shortages expected to continue beyond 2021.

The main trends in U.S. demand, production and imports by industry were as follows:

## Ventilators

Data available to the Commission indicate that the total number of ventilators in the United States, as of March 2020, included 77,000 ventilators in U.S. hospitals, 12,000 to 13,000 ventilators stored in the Strategic National Stockpile (SNS),<sup>6</sup> and more than 8,000 ventilators in U.S. nursing homes.<sup>7</sup> U.S. hospital demand for ventilators grew rapidly in March 2020 as COVID-19 spread across the United States, outpacing supply. However, industry sources reported that by September 2020, U.S. ventilator supply and demand conditions had stabilized—reflecting increased production, improved hospital treatment regimens, and successful adaptation of other respiratory products and techniques. Further replenishment of the SNS’s stock of ventilators was also no longer needed.

The Commission identified six companies that produced a wide range of ventilators in the United States as of 2019, ranging from portable devices to critical care ventilators. When the pandemic struck, these firms increased production—including for government contracts—and, in some instances, did so in unique ways, such as partnering with automakers.

U.S. imports during 2018–19 averaged more than \$200 million annually. U.S. imports of finished ventilators appear to have started to increase from about April 2020.

## N95 Respirators

The U.S. market for N95 respirators<sup>8</sup> in 2019 was estimated at about 445 million units,<sup>9</sup> with the vast majority of the U.S. market concentrated in industrial end uses, such as mining, fire control, and construction. Estimates of the number of N95 respirators bought for the U.S. healthcare sector pre-

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<sup>5</sup> The United States did not produce COVID-19-specific test kits or vaccines before the disease was identified; however, it does have established testing and vaccine industries.

<sup>6</sup> The role of the Strategic National Stockpile is “to supplement state and local medical supplies and equipment during public health emergencies. HHS, ASPR, “Strategic National Stockpile,” updated October 9, 2020.

<sup>7</sup> Ventilators have a typical lifespan of up to 10 years. Data on the number of other ventilators in use in other applications in 2020, such as ventilators for home use or owned by emergency medical services, are not available.

<sup>8</sup> N95 respirators are designed to protect the wearer and filter at least 95 percent of airborne particles (not resistant to oil).

<sup>9</sup> AdvaMed, written submission to the USITC, September 30, 2020, 10.

pandemic range from about 22 million to 42 million units annually.<sup>10</sup> U.S. demand for N95 respirators increased substantially in response to COVID-19, with U.S. imports totaling 1.6 billion units during July–September 2020 alone.

Total U.S. N95 respirator production in 2019 was estimated at about 30 million respirators per month, accounting for roughly 80 percent of the U.S. market. Domestic production was primarily oriented toward industrial applications. In response to higher demand, U.S. firms significantly increased production capacity; by the end of 2020, domestic production is expected to reach 160 million to 180 million N95 respirators per month.

U.S. imports of N95 respirators substantially increased after the start of the pandemic. In July–September 2020, the only months for which data are available, 1.6 billion respirators were imported, or an average of over 500 million per month, with most respirators coming from China.

## Surgical Masks

The estimated size of the monthly market for surgical masks<sup>11</sup> increased from 108 million–140 million masks in 2019 to 375 million–425 million masks in the five months from March to July 2020 alone.<sup>12</sup>

In 2019, prior to the pandemic, domestic producers supplied 17 million surgical masks per month, representing about 15 percent of the U.S. market.<sup>13</sup> U.S. production by existing firms and new entrants has substantially increased during 2020.

Before the pandemic, imports were estimated to supply 85 percent of the market for surgical masks, with China accounting for most of the imports. Available data on U.S. imports show that imports of all disposable masks, including but not limited to surgical masks, totaled 10.8 billion units (\$1.5 billion) during July–September 2020.

## Surgical and Isolation Gowns

The U.S. market for surgical and isolation gowns, according to Commission estimates, was 800 million units (valued at roughly \$500–\$700 million) in 2019 and faced supply challenges because of a product recall even before the pandemic was declared. This market grew substantially in 2020 due to higher demand from hospitals, as well as from nontraditional customers such as doctors' offices, dental and ophthalmologist practices, police departments, and rescue workers.

There were very few producers of disposable and reusable surgical and isolation gowns in the United States in 2019; their output for that year is estimated at about \$70 million. Since March 2020, there

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<sup>10</sup> Premier, "Premier Inc. Survey Finds 86 Percent," March 2, 2020; industry representative, email message to USITC staff, October 8, 2020.

<sup>11</sup> A surgical mask differs from an N95 respirator, which fits closely on the face and is primarily intended to protect the wearer by filtering out airborne particles, including small particle aerosols and large droplets.

<sup>12</sup> Polowczyk, "White House COVID-19 Supply Chain Task Force Report," June 10, 2020; industry representatives, email messages to USITC staff, October 8 and 9, 2020.

<sup>13</sup> INDA, Meltblown Nonwoven Markets: COVID-19 Impact Analysis, 2020, 49; industry representative, email message to USITC staff, October 8, 2020.

have been a number of new entrants, and many U.S. apparel and textile firms have added domestic capacity by altering their product lines to include surgical gowns.

In 2019, U.S. imports of a broader grouping of U.S. HTS 10-digit statistical reporting numbers that include surgical and isolation gowns totaled \$1.7 billion. During January–September 2020, imports totaled 4.4 billion units, or \$5.0 billion (up by almost 300 percent from the same period in 2019). Imports supply the vast majority of the U.S. market, with China being the largest supplier of medical gowns to the United States.

## Medical and Surgical Gloves

Gloves continue to be one of the most highly constrained COVID-19 related products as of November 2020. The U.S. market for medical and surgical gloves was approximately 78 billion gloves in 2019. During January–September 2020, the U.S. market totaled approximately 67 billion gloves, up about 17 percent from the same period in 2019.

Before the pandemic, there were only two U.S. producers, neither of which accounted for a significant share of the medical and surgical gloves market. Both firms are currently in the process of expanding domestic production capacity. A third U.S. firm that traditionally produced a different type of glove announced that it was expanding its operations to include production of nitrile examination gloves.

U.S. imports of medical and surgical gloves totaled 78 billion gloves (\$2.1 billion) in 2019, which supplied the vast majority of the U.S. market. From January to September 2020, U.S. imports totaled almost 67 billion gloves (\$2.1 billion); as noted, this is up 17 percent from the same period in 2019. Malaysia is the leading supplier of gloves to the U.S. market.

## Test Kits for COVID-19

The demand for test kits increased rapidly over the course of the pandemic. Between February and November 2020, the number of tests performed per day rose from less than 10,000 to more than 1 million.<sup>14</sup>

Before the pandemic, U.S. firms produced supplies for various diagnostic tests (due to the variety of tests and supplies, comprehensive production totals for the types of goods used in COVID-19 testing are not available); these goods included test kits (including diagnostic reagents), products for collecting samples, and laboratory consumables. Once a diagnostic test was developed and authorized specifically for COVID-19, U.S. manufacturers ramped up production of many of these products.

The United States imports test kits and a range of related testing materials and components to supplement domestic production. The value of U.S. imports of diagnostic reagents used for certain COVID-19 molecular tests increased from 130 metric tons (\$34 million) in July 2020 to 234 million metric tons (\$41 million) in September 2020, the only time period for which data are available. They were primarily sourced, by volume, from Canada, China, and Europe, although China was the largest supplier by value. Imports of goods such as swabs and plastic consumables started to substantially increase

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<sup>14</sup> Since COVID-19 was not identified until 2020, there was no COVID-19 test market before January 2020. COVID Tracking Project, “National Data” (accessed November 9, 2020).

beginning in April or May 2020, depending on the product, and were mostly sourced from Canada, China, Europe, and South Korea.

## Vaccines

A vaccine for COVID-19, when available, will dramatically change the U.S. vaccines market. Industry sources note that 600–700 million units would be needed to inoculate the entire U.S. population for two-dose vaccines. Based on the current makeup of the front-runner vaccines, it is likely that two doses will be needed. Doses will be stored in vials (initially multidose vials), for which the U.S. market prior to COVID-19 was over 3 billion vials per year, according to industry representatives. The actual number of doses that will be needed depends on factors such as the dosage required to meet efficacy standards and the length of time achieved immunity persists (i.e., whether the vaccine will be an annual immunization). A factor in consumption is the number of people willing to get the vaccine. Finally, there will be a significant increase in demand for ancillary supplies, such as syringes.

Vaccine developers have taken a variety of approaches to manufacturing a COVID-19 vaccine in the United States, ranging from vertical integration to contracting with another firm to perform one or more steps in the production process. Collectively, the industry has the domestic capacity to produce hundreds of millions of doses annually, although some capacity is contracted to individual manufacturers and, therefore, production lines cannot be readily interchanged. U.S. manufacturers are also making significant investments in new production, accelerating existing expansion plans, and planning to hire hundreds of additional workers. The United States also produces a range of medical consumables needed for vaccine delivery, including glass vials, syringes, needles, and rubber stoppers.

U.S. imports of vaccines totaled 1.9 million kilograms (\$7.3 billion) in 2019. The largest import sources, by volume, were European suppliers (Belgium, Germany, and Ireland). For vaccine consumables, the United States primarily imports syringes and needles from Asia (China and South Korea), while vials are imported from a number of countries (primarily Mexico, France, China, Germany, and Italy).

## Hand Sanitizer

The United States was the largest global hand sanitizer market in 2019, with retail sales of almost \$200 million.<sup>15</sup> The pandemic boosted demand sharply in 2020, with monthly retail sales increasing from \$25 million in February 2020 to over \$150 million in June 2020.<sup>16</sup>

Before the pandemic, the United States had a substantial domestic hand sanitizer manufacturing industry, including producers of leading brands and private label (store) brands. In 2020, production rapidly increased as existing producers expanded their output and firms entered from other industries.

Comprehensive import data are not available, but ocean freight imports of hand sanitizer started to increase in April 2020 and peaked in July at more than 200 times higher than typical pre-pandemic levels. China was the largest source of these ocean freight imports, although Mexico also supplies the U.S. market.

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<sup>15</sup> Terlep, “One Company’s Hands-On Effort to Ramp Up Sanitizer Production,” March 16, 2020.

<sup>16</sup> Chaudhuri, “Unilever Capitalizes,” July 23, 2020.



Table ES.3 summarizes supply chain challenges and constraints for each of the COVID-19 related goods described above in 2020, and these constraints are detailed further in the following section.

**Table ES.3** Summary of supply chain challenges and constraints for COVID-19 related goods described in case studies

Case study	Factors affecting domestic production	Factors affecting imports
Ventilators	<ul style="list-style-type: none"> <li>• Shortage of parts and components due to shutdowns, export restrictions, and air freight capacity and costs</li> </ul>	<ul style="list-style-type: none"> <li>• Global supply/demand</li> <li>• Fraudulent broker transactions</li> <li>• Market entrance and acceptance: Not all products suitable for use in the U.S. market</li> <li>• Air freight capacity and costs</li> </ul>
N95 respirators	<ul style="list-style-type: none"> <li>• Lack of certainty on long-term demand</li> <li>• For new entrants, time and cost to bring to market</li> <li>• Time and cost to obtain machinery</li> <li>• Availability and cost of materials and components (meltblown nonwoven, elastic straps)</li> </ul>	<ul style="list-style-type: none"> <li>• Global supply/demand</li> <li>• Export restrictions</li> <li>• Market acceptance: Different designs and poor quality of foreign products, as well as issues with counterfeit and fraud</li> <li>• Higher prices</li> <li>• Air freight capacity and costs</li> </ul>
Surgical masks	<ul style="list-style-type: none"> <li>• Time and cost for regulatory approval</li> <li>• Startup costs with no guaranteed long-term market or Buy American provisions</li> <li>• Availability of materials (meltblown nonwoven)</li> </ul>	<ul style="list-style-type: none"> <li>• Global supply/demand</li> <li>• Air freight capacity and costs</li> <li>• Export restrictions</li> </ul>
Surgical and isolation gowns	<ul style="list-style-type: none"> <li>• Lack of certainty on long-term demand, including government contracts</li> <li>• Changes in government contracts</li> <li>• Understanding of FDA standards by new entrants</li> <li>• Labor costs</li> <li>• Availability of materials (SMS nonwoven)</li> </ul>	<ul style="list-style-type: none"> <li>• Global supply/demand</li> <li>• Export restrictions</li> </ul>
Medical and surgical gloves	<ul style="list-style-type: none"> <li>• Labor costs</li> <li>• Time and cost to expand production capacity</li> <li>• Availability of materials and machinery</li> </ul>	<ul style="list-style-type: none"> <li>• Factory closures due to lockdowns</li> <li>• Enforcement of forced labor violations</li> <li>• Scarcity of nitrile butadiene rubber (NBR)</li> <li>• Market acceptance: concern with using nonmedical gloves in medical settings</li> <li>• Higher prices and freight costs</li> </ul>
Test kits	<ul style="list-style-type: none"> <li>• Diagnostic tests: <ul style="list-style-type: none"> <li>○ Length of development period</li> <li>○ Contamination of initial test kits</li> <li>○ Shortage of supplies including specimen controls, reagents, plastic consumables</li> </ul> </li> <li>• Sample collection: <ul style="list-style-type: none"> <li>○ Market acceptance,</li> <li>○ Cost of new capacity, worker training</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Global supply/demand</li> <li>• Market acceptance/regulatory requirements/specialized equipment</li> <li>• Air freight capacity</li> </ul>

Case study	Factors affecting domestic production	Factors affecting imports
Vaccines	<ul style="list-style-type: none"> <li>• Length of development period</li> <li>• Time needed to expand production capacity, including fill and finish</li> <li>• Availability of inputs</li> <li>• Need for glass vials, syringes, needles</li> <li>• Cold chain storage and transport</li> <li>• Dosing intervals</li> </ul>	<ul style="list-style-type: none"> <li>• Factors affecting imports largely mirror the supply chain challenges and constraints that face the U.S. industry</li> <li>• Maintaining cold transport chain will also be a challenge for any imported vaccine</li> </ul>
Hand sanitizer	<ul style="list-style-type: none"> <li>• Shortage of alcohol initially and then other inputs</li> <li>• For new entrants, adapting to regulatory requirements</li> </ul>	<ul style="list-style-type: none"> <li>• Quality assurance</li> </ul>

Source: Compiled by USITC.

## Supply Chain Challenges and Constraints

The rapid increase in demand in the first half of 2020 led to significant shortages in a variety of COVID-19 related goods for the areas most affected by the pandemic. For domestic industries, many were able to continue current operations but faced challenges in increasing production (for certain products, from low levels) to meet growing demand. For importers of COVID-19 related goods, there were disruptions to normal levels of supply for some products, in addition to the challenges associated with a rapid increase in demand in the United States and around the world.

The ability of U.S. manufacturers to increase production, of new entrants to establish production, and of importers to acquire COVID-19 related goods was impacted by a broad range of factors in the first nine months of 2020. With the rapid onset of the pandemic, many of these factors converged within a period of weeks to constrain the ability of firms to deliver enough of the needed goods, such as PPE, to the U.S. market. To better understand these issues, the Commission developed a framework for categorizing and assessing the factors affecting domestic production and imports that contributed to the supply chain challenges and constraints experienced during the COVID-19 pandemic. This section organizes its discussion of the main supply chain challenges and constraints for products covered in the case studies in this report under each of the factors highlighted in the framework.

### Factors Affecting Domestic Production

#### Market size

**Typical annual demand:** U.S. demand for COVID-19 related goods rose sharply beginning in March 2020. However, U.S. producers faced, and continue to face, a conundrum when deciding whether to invest in domestic production, as there is little certainty about long-term demand and a concern that post-pandemic purchasers will revert to buying from the lowest-cost suppliers, which often manufacture overseas. While many producers invested in U.S. production regardless, given the urgent nature of the pandemic, many U.S. firms have expressed this concern. Further, some U.S. industry representatives have stated that nontransparent and changing government requests for proposals have made it difficult for them to secure government contracts that would offer some assurance of demand for their products. *(Products affected: N95 respirators, surgical masks, surgical and isolation gowns, test kits)*

## Product to market

**Product design:** Firms responding to the new virus by entering new industries or pivoting existing production to try to bring new and novel products to market require substantial time to develop these products. Even firms that are simply developing new versions of their products or replacing materials or inputs may encounter similar obstacles. *(Products affected: ventilators, N95 respirators, surgical masks, surgical and isolation gowns, test kits, vaccines)*

**Standards and Certifications:** Many products require regulatory approvals or must comply with relevant standards and certification requirements before they can be sold in the United States. For existing suppliers, these are not usually a barrier. However, for new firms entering the market during the pandemic, it may take longer to obtain the necessary certifications and approvals. *(Products affected: N95 respirators, surgical masks, surgical and isolation gowns, vaccines)*

**Market acceptance:** New entrants in the medical field often find it more challenging to sell their products, as purchasers tend to be cautious when buying from new suppliers. This was exacerbated during the pandemic by fraud and illicit products, making buyers even more wary. *(Products affected: N95 respirators, surgical masks, test kits, vaccines)*

## Production and delivery

**Materials, components, and other inputs:** As companies increased production, shortages developed for several key inputs of materials and parts as suppliers around the world struggled to meet demand and some plants supplying components were closed due to COVID-19 related shutdowns. Further, many of these inputs are typically shipped on passenger flights. The reduction in passenger travel caused by the pandemic limited air cargo volumes, and ocean cargo volumes simultaneously contracted as well, making the inputs more difficult to source. An additional problem was that higher demand linked to the pandemic pushed up prices for some inputs, increasing the costs for U.S. producers. Many U.S. firms were reluctant to raise prices, preferring to absorb these costs. *(Products affected: ventilators, N95 respirators, surgical masks, surgical and isolation gowns, medical and surgical gloves, test kits, hand sanitizer)*

**Production capabilities and costs:** Buying, installing, and getting new machinery up and running (or, for some firms, building new machinery in-house) is time consuming and costly. During the pandemic, this situation was compounded by increased competition for the same specialized equipment and difficulty in bringing overseas technicians and staff from equipment manufacturing firms to the site for service and support. In addition, certain products need to be sterilized before being shipped. U.S. sterilization capacity is reportedly strained. *(Products affected: N95 respirators, surgical masks, surgical and isolation gowns, medical and surgical gloves, test kits, vaccines)*

**Labor:** Many firms have had to hire more workers as part of ramping up production lines. In some instances, firms have reported difficulty in finding and training enough workers to quickly boost production. Further, some firms reported that the comparatively high cost of labor in the United States vis-à-vis foreign competitors makes it expensive to produce certain goods domestically and limits U.S. firms' ability to compete in the market. *(Products affected: surgical and isolation gowns, medical and surgical gloves, test kits)*

**Outbound logistics:** When a U.S. vaccination program launches, a potential supply chain challenge will be transporting vaccines to inoculation sites. Many vaccines must be kept cold during transport and at the delivery location before injection. Storage and transport of the vaccine necessitates low-temperature storage options such as freezers, the sourcing of which may prove to be difficult for some facilities. For mRNA-based platforms, storage requirements are typically well below freezing (e.g., -20 or -80 degrees Celsius). Many end-facilities that deliver vaccines are not typically outfitted in the United States to handle ultra-cold storage (-80 degrees Celsius). Broken cold-chain storage is a major concern as it is common to lose 5 to 20 percent or more of vaccines because of a break in the cold chain or other problems with distribution. Further complicating the supply chain is that the first vaccines available will likely require two doses, which is a significant logistical challenge. For the vaccines to be most effective, recipients need to comply with vaccine dosing intervals, and the available vaccines will not be interchangeable. *(Products affected: vaccines)*

## Factors Affecting Imports

### Product availability

**Available global supply:** As noted above, the spike in demand within the United States caused supply challenges. One factor limiting import responsiveness to this demand was that many other countries were seeking the same goods at the same time. Meanwhile, the closure of some foreign plants as part of COVID-19 related restrictions on economic activity, and reductions in the number of staff allowed to work in factories that were still open, lessened the global availability for some products. *(Products affected: ventilators, N95 respirators, surgical masks, surgical and isolation gowns, medical and surgical gloves, test kits)*

**Export restrictions:** Several countries imposed export controls that prohibited or limited exports of COVID-19 related goods. Further, procedures that did not explicitly limit exports, such as increased customs inspections in exporting countries, also impacted imports into the United States. *(Products affected: N95 respirators, surgical masks, surgical and isolation gowns)*

**Logistics disruptions:** The pandemic led to a reduction in both air- and ocean-going cargo space. The decrease in shipping options made it difficult for U.S. importers to access offshore supply networks. *(Products affected: ventilators, N95 respirators, surgical masks,)*

**Import restrictions:** U.S. limits on imports from particular companies due to labor violations have, in some instances, reduced the number of suppliers to the U.S. market. *(Products affected: medical and surgical gloves)*

### Market entry and acceptance

**Quality:** A significant increase in the number of counterfeit, illicit, and flawed products in the market made it harder to find legitimate products and made some firms more reluctant to import or purchase products from lesser known suppliers. In addition, some available foreign products allowed to enter during a national health emergency may not meet U.S. regulatory standards. Although such goods may be reported to meet certain performance requirements, there are instances where the quality was unacceptable and/or where the products were not accepted by the healthcare industry. *(Products affected: ventilators, N95 respirators, medical and surgical gloves, test kits, hand sanitizer)*

**Match between global production and U.S. demand:** Products used in other countries may differ from the products used and accepted in the U.S. market. *(Products affected: ventilators, N95 respirators, test kits)*

### **Prices and delivery costs**

**Logistics costs:** Freight costs, for both air- and ocean-going cargo, went up substantially as available capacity became more constrained. *(Products affected: ventilators, N95 respirators, surgical masks, medical and surgical gloves, test kits)*

**Product prices:** The price for some products rose to well above normal levels, making it difficult to purchase products at a reasonable cost. *(Products affected: N95 respirators, medical and surgical gloves)*



# Chapter 1

## Introduction

This report provides information on conditions in the U.S. industry, U.S. trade, and supply chains for selected goods used in the response to the COVID-19 pandemic. The report was prepared in response to a request letter received on August 13, 2020, from the U.S. House of Representatives Committee on Ways and Means and the U.S. Senate Committee on Finance (the Committees). The letter asked that the U.S. International Trade Commission (Commission or USITC) conduct a factfinding investigation to provide detailed information on COVID-19 related industry sectors and particular products identified in the Commission's prior report, *COVID-19 Related Goods: U.S. Imports and Tariffs* (Investigation No. 332-576). Information gathering and data collection for this report primarily took place during August–October 2020, and the report principally covers the period January through September 2020. This report was prepared as many of the events and developments discussed occurred and reflects the best available information at the time of writing.

## Background

The Committees' request letter directed the Commission to provide an overview of key U.S. industry sectors producing COVID-19 related goods, including, but not limited to, medical devices, personal protective equipment, and medicines (pharmaceuticals). The Committees requested that the overviews include, to the extent practicable, information on U.S. production, employment, and trade.

In addition, the Committees requested case studies on key products within these industry sectors. They asked that the Commission focus particularly on products for which shortages were reported in the first half of 2020, including products that were affected by supply chain fragility, blockages, or barriers. The Committees specifically mentioned N95 respirators, ventilators, vaccines, and COVID-19 test kits, and asked that the case studies include information on:

The U.S. industry, market, and trade, including, to the extent available:

- An overview of the product, including key components and the production process.
  - Information on the size and characteristics of the U.S. market.
  - An overview of the U.S. manufacturing industry, including key producers of finished goods and intermediate inputs, the extent of U.S. production, and employment.
  - Information on U.S. imports of finished goods and inputs, including leading source countries and supplying firms.
- Supply chain challenges and constraints, including, but not limited to:
  - Information on factors affecting domestic production, including, to the extent practicable, regulatory requirements that may impact entry into the market.
  - Information on foreign trade barriers and restrictions and other factors that may affect U.S. imports of finished goods or inputs needed for domestic production.

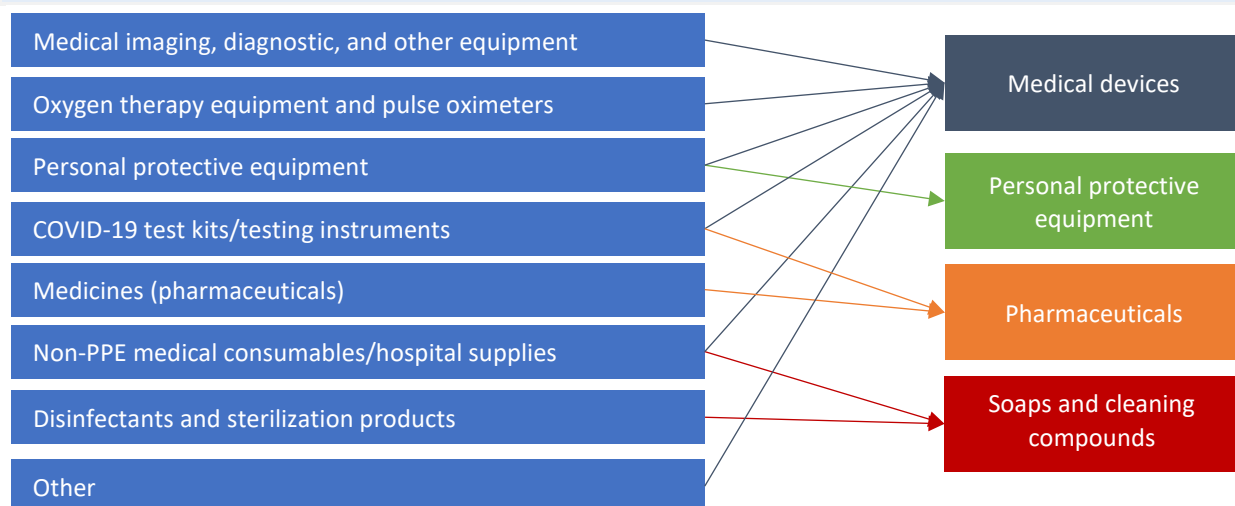
The Committees requested that the Commission submit its report no later than December 15, 2020, and, with the intent of providing the report to the public in its entirety, asked that the report not include any confidential business information.

## Analytical Approach and Scope

### Product Coverage

The Committees asked that the Commission build on its previous investigation and report in providing additional information on key U.S. industry sectors producing COVID-19 related goods. In that report, the Commission identified eight categories of COVID-19 related goods (figure 1.1). Owing to data availability considerations, these categories of goods were regrouped for the purposes of this report and are principally (although not entirely) contained in four key U.S. industry sectors—medical devices, personal protective equipment (PPE), pharmaceuticals, and soaps and cleaning compounds. There is some overlap in products between the sectors as we have defined them. In particular, most PPE is a subset of medical devices, but it is covered as a separate sector for purposes of this report.

**Figure 1.1** Correlation of categories of goods identified in the Commission’s June 2020 report (left) and industry sectors covered in this report (right)



Source: USITC, *COVID-19 Related Goods: U.S. Imports and Tariffs*, June 2020.

Note: The other category in the *COVID-19 Related Goods* report contains products such as wheelchairs, hospital beds, medical furniture, and oxygen cylinders. In this report, the medical device chapter contains one full case study (ventilators), the PPE chapter includes four full or condensed case studies (N95 respirators, surgical masks, surgical and isolation gowns, and medical and surgical gloves), the pharmaceuticals chapter contains two full case studies (test kits and vaccines), and the soaps and cleaning compounds chapter includes one condensed case study (hand sanitizer).

This report includes six case studies on COVID-19 related goods identified in *COVID-19 Related Goods: U.S. Imports and Tariffs* (Investigation 332-576). These case studies cover ventilators, N95 respirators, surgical and isolation gowns, medical and surgical gloves, test kits, and vaccines. In addition, the Commission added condensed case studies for two products (surgical masks and hand sanitizer) to



provide additional context on supply chain challenges and constraints.<sup>17</sup> As specified in the request letter, the case studies were selected based on products for which there were reported shortages in the first half of 2020, including those affected by supply chain fragility, blockages, or barriers. Shortages were identified based on a review of media reports, interviews with industry representatives, written submissions, and testimony at the Commission’s hearing. The Commission also used information gathered for the June report from a review of individual hospital and healthcare provider websites, which often identified healthcare providers’ most-needed items for the COVID-19 response. All of the goods selected for full case studies were entirely or in part included on the medical device shortage list released by the Food and Drug Administration (FDA) in August 2020 (except vaccines, which are not included in the scope of the FDA list). The vaccine case study differs from others in this report, as all supply chain challenges and constraints are not yet fully known given that, as of November 2020, a COVID-19 vaccine is not available.

## Time Period Covered in the Report

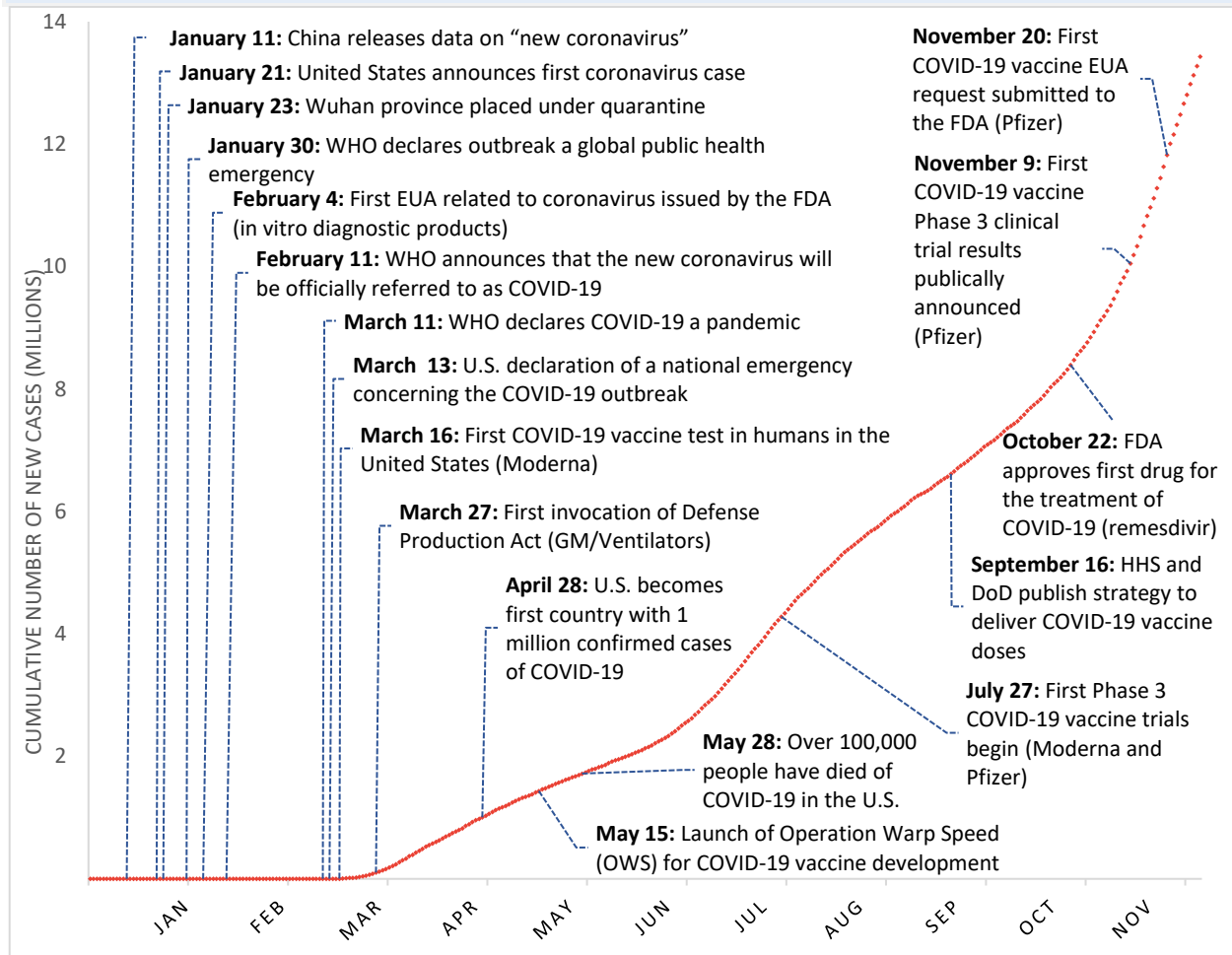
The request from the Committees did not specify a timeframe for information and data, other than to indicate that shortages in the first half of 2020 should guide the selection of case studies.<sup>18</sup> The overviews of U.S. industry sectors, except for PPE, provide data from 2015 to the most recent date for which data are available, which varies by data source. The case studies in the report—to the extent available, practicable, and applicable—include data and information through September 2020, primarily for 2019 and January–September 2020. This timeframe allows for a comparison of conditions before and after the start of the pandemic, a discussion of key events (figure 1.2), and inclusion of the most recent data available for imports of discrete COVID-19 related products. The data and analysis in this report, where possible, refer to specific time periods in 2020. However, in summary discussions and other instances, terms such as “the start of the pandemic” are often used. While the WHO declared COVID-19 a pandemic on March 11, 2020, these statements in this report are generalizations that typically refer to the February to March 2020 time period (i.e., after WHO declared a global public health emergency).

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<sup>17</sup> The condensed case studies on surgical masks and hand sanitizer do not cover every element included in the request letter; they focus on specific elements for which information and data were readily available.

<sup>18</sup> On December 11, 2020 FDA issued the first emergency use authorization for a vaccine for the prevention of COVID-19 in the United States. This authorization, and any subsequent or related events, occurred immediately prior to delivery of the report and are not discussed. FDA, “Pfizer-BioNTech COVID-19 Vaccine,” December 11, 2020.

**Figure 1.2** Timeline of selected global COVID-19 related events in relation to new U.S. confirmed cases (January 2020–November 2020)



Source: Compiled by USITC from CDC, “United States COVID-19 Cases,” (accessed December 1, 2020); FRASER, “Timeline of Events,” (accessed December 1, 2020); Grady, “Trial of Coronavirus Vaccine,” July 14, 2020; Johnson, “Two Coronavirus Vaccines,” July 27, 2020; FDA, “FDA’s approval of Veklury (remdesivir),” October 22, 2020; Pfizer, “Pfizer and Biontech Announce Vaccine Candidate,” November 9, 2020; Pfizer, “Pfizer and Biontech to submit Emergency Use Authorization,” November 20, 2020.

Note: EUA=Emergency Use Authorization; FDA=Food and Drug Administration; GM=General Motors; OWS=Operation Warp Speed; DOD=U.S. Department of Defense; WHO=World Health Organization; HHS=Human Health Services.

## Information Sources

The Commission obtained data and information in this report from both primary and secondary sources, including extensive interviews with government and industry representatives and sworn testimony presented at a public hearing held via live video conference on September 23 and 24, 2020. Participants at the hearing included company and industry representatives, academics, representatives of civil society, and foreign government officials. In addition, as described in the Commission’s notice of institution of investigation and public hearing published in the *Federal Register*, interested parties had

the opportunity to submit written submissions for the record.<sup>19</sup> The Commission used the information received in these submissions, as appropriate, throughout this report.

For the overview sections of the report, the Commission primarily used publicly available data from the U.S. Census Bureau (Census) and the U.S. Bureau of Labor Statistics (BLS).<sup>20</sup> In addition, the Commission incorporated data and information from other government sources, interviews, the Commission’s hearing, written submissions, media articles, firms’ financial reports and other company information, industry and market reports, and other sources.

To discuss the U.S. industry and supply chains for the case studies, the Commission took a multipronged approach. The Commission collected data on the U.S. market for, production of, and trade in COVID-19 related goods and inputs, drawing on official statistics, market reports, information provided by companies in written submissions, shipping manifest data, company databases, and other data sources. To the extent possible, the quantitative discussion includes the most recently available market, trade, and production data for 2020.<sup>21</sup> There was significant variability in the availability of quantitative information by case study. The Commission also relied heavily on qualitative information, such as company information and literature, testimony from the hearing, a review of published sources of information on industry developments and conditions, and interviews with industry representatives and U.S. government officials.

## U.S. Department of Health and Human Services

There are several U.S. government agencies involved in the research, development, and regulation of COVID-19 related products that are discussed across multiple chapters of the report. Many of the federal agencies and offices with COVID-19 related responsibilities are housed within the U.S. Department of Health and Human Services (HHS). HHS and the Federal Emergency Management Agency (FEMA) also lead the U.S. government’s coordinated response to COVID-19 through the Unified Coordination Group (UCG).<sup>22</sup> The COVID-19 related responsibilities of key HHS agencies and offices are listed in table 1.1.

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<sup>19</sup> The *Federal Register* notice is available in appendix B; the Calendar of Hearing is available in appendix C. A list of statements submitted to the Commission in response to the Federal Register notice about the investigation is available in appendix D.

<sup>20</sup> Trade data presented in this report are Census data from USITC’s DataWeb and are imports for consumption and domestic exports, unless otherwise noted.

<sup>21</sup> A number of statistical reporting numbers were added to the Harmonized Tariff Schedule of the United States (HTS) starting in July 2020 that are specific to COVID-19 related goods, and that provided more detail on U.S. imports of these goods in the third quarter of 2020.

<sup>22</sup> UCG efforts are focused on managing the medical supply chain; increasing testing capacity; developing, manufacturing, and distributing COVID-19 vaccines and therapeutics; and collecting data on racial and ethnic disparities related to COVID-19. UCG members also are working to replenish, rebuild, and modernize the Strategic National Stockpile (SNS). GAO, “Federal Efforts Could be Strengthened,” September 21, 2020, 10, 136–37.

**Table 1.1** Profiles of key HHS agencies’ COVID-19 related responsibilities

Agency, office, or program	Responsibilities
HHS/Office of the Assistant Secretary for Preparedness and Response (ASPR)	ASPR oversees advanced research, development, and procurement of qualified countermeasures (such as drugs, diagnostics, and vaccines), and manages the Strategic National Stockpile (SNS), among other duties.
HHS/ASPR/Biomedical Advanced Research and Development Authority (BARDA)	BARDA supports the transition of medical countermeasures from basic research to advanced development, clinical testing, FDA approval, and inclusion into the Strategic National Stockpile (SNS).
HHS/Centers for Disease Control and Prevention (CDC)	CDC supports public health and laboratory research related to new infectious diseases, including diagnostic test development, other research and development, and post-market surveillance.
HHS/CDC/National Institute for Occupational Safety and Health (NIOSH)	Within NIOSH, the National Personal Protective Technology Laboratory (NPPTL) conducts laboratory and field research, surveillance, standards development, interventions, and conformity assessment activities for personal protective technologies (such as respirators, clothing, gowns, and gloves).
HHS/Food and Drug Administration (FDA)	FDA oversees the safety, effectiveness, and quality of drugs, biologics, vaccines, and medical devices.
HHS/National Institutes of Health (NIH)	NIH supports medical and health foundational research and development of new medical products, including testing technologies, therapeutics, and vaccines.
HHS/NIH/National Institute of Allergy and Infectious Diseases (NIAID)	NIAID supports basic and applied research and the development of new medical products in response to infectious diseases.

Source: Compiled by USITC from: HHS, “ASPR Highlights,” August 5, 2020; HHS, “Biomedical Advanced Research and Development Authority,” July 22, 2020; CDC, “COVID-19 Response Highlights,” July 6, 2020; CDC, NIOSH, “NPPTL Fact Sheet,” 2018; FDA, “What We Do,” March 28, 2018; NIH, “NIH-Wide Strategic Plan for COVID-19 Research,” July 2020; NIAID, “Helping the NIAID Mission,” May 29, 2020.

The FDA oversees the safety and effectiveness of drugs and medical devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and biologics under the Public Health Service Act (PHSA).<sup>23</sup> FDA has several mechanisms in place to speed approval processes for drugs, biologics, and medical devices related to COVID-19 (see appendix F for a description of these processes). The FDA has particularly relied on another mechanism to facilitate the availability of COVID-19 related medical products: emergency use authorizations (EUAs). An EUA permits the FDA Commissioner to authorize the use of an unapproved medical product, or an unapproved use of an approved product, if the Secretary of HHS makes the requisite declaration of a public health emergency and other required criteria are met.<sup>24</sup>

## Organization of the Report

The report is organized as follows. Chapter 2 presents the framework used in this report to analyze supply chain challenges and constraints. Chapters 3 through 6 present information on key U.S. industry sectors producing COVID-19 related goods and provide case studies for goods within those industry sectors. These chapters are Medical Devices (chapter 3); Personal Protective Equipment (chapter 4); Pharmaceuticals (chapter 5); and Soaps and Cleaning Compounds (chapter 6). Appendix A contains the

<sup>23</sup> FFDC §§ 201(g) and 201(h), 21 U.S.C. §§ 321(g) and 321(h); PHSA § 351(i), 42 U.S.C. § 262(i).

<sup>24</sup> The statute provides that the Secretary of the U.S. Department of Health and Human Services (HHS) may during a declared public health emergency authorize the “introduction into interstate commerce” (e.g. the importation and sale) of a drug, device or biological product intended for use in an actual or potential emergency (referred to as an “emergency use”). FFDC §§ 564(a) and (b), 21 U.S.C. §§ 360bbb-3(a) and (b). See also FDA, “Emergency Use Authorization,” November 24, 2020.

request letter from the Committees. Appendix B reproduces the notice announcing this investigation that the Commission published in the *Federal Register*. Appendix C includes a list of the witnesses that appeared at the public hearing. Appendix D presents a list of statements submitted to the Commission in response to the *Federal Register* notice about the investigation. Appendix E provides tables of underlying data for information presented in this report as figures. Appendix F includes an overview of the FDA regulation of drugs, biologics, and medical devices. Appendix G includes a discussion of the issues of counterfeit and other illicit COVID-19 related goods, and the role of government agencies in responding to this issue.



# Chapter 2

## Analytical Framework

The ability of the U.S. healthcare industry to increase production and imports of COVID-19 related goods was impacted by a broad range of factors in the first nine months of 2020. With the rapid onset of the pandemic, many of these factors converged within a period of weeks to constrain the ability of firms to deliver enough of the needed goods, such as personal protective equipment (PPE), to the U.S. market. To provide context for the case studies in this report, the Commission developed an analytical framework to categorize and assess the factors that contributed to supply chain challenges and constraints experienced during the COVID-19 pandemic.

The framework was adapted from previous research by Commission staff developed for advanced technology products.<sup>25</sup> To adapt the framework to the wide-ranging products covered in this report, the Commission incorporated findings from other Commission reports, a review of the academic and business literature, and information gathered in this investigation. The framework is designed to support analysis at the domestic industry level (not at the firm level, which could entail a mix of domestic and foreign activities). Although the framework in this chapter discusses the factors affecting production and imports in general terms, the case studies focus on the factors that were challenges and constraints, as specified in the request letter.

The framework has two parts, with the first part covering the factors affecting U.S. production and the second part highlighting the factors affecting imports. The reason for separating these factors is that unlike a traditional competitiveness analysis, this report does not compare the competitiveness of the domestic industry against the competitiveness of the foreign industry. Rather, the domestic production framework focuses on the factors that impacted the ability of U.S. manufacturers to ramp up production of COVID-19 related goods, while the import framework focuses on factors shaping the ability of U.S. importers to acquire those goods abroad and to bring them into the United States.<sup>26</sup>

## Factors Affecting U.S. Production

### General Framework Overview

The domestic production framework identifies three key sets of factors affecting the ability of U.S. manufacturers to start or to increase production of COVID-19 related products domestically. They include market size, the ability of firms to develop and sell products, and capabilities and costs associated with production and delivery (figure 2.1), along with a number of subfactors. Many of these factors relate to the ability of U.S. firms to meet the rapid increase in demand for COVID-19 related goods soon after the onset of the pandemic in early 2020. The factors identified in the framework mainly cover production constraints and supply-chain bottlenecks (e.g., owing to shortage of production

<sup>25</sup> David, Semanik, and Torsekar, “Framework for Analyzing,” September 2018.

<sup>26</sup> Further, a factor that is a short-term barrier could be a long-term competitive advantage, and vice versa. For example, while the need to get a product certified could slow down a firm’s effort to ramp up production in the short term, in the long run the ability to meet these standards may give the firm a competitive advantage.

capacity, labor, raw materials, and transportation) that explain why U.S. firms were not able to meet this new demand in the short term.

This report focuses mostly on the short-term barriers to domestic production that prevented U.S. firms from ramping up production from a low or nonexistent level. However, there may be more structural economic factors requiring a more in-depth analysis that explain why domestic production of certain COVID-19 related goods was limited prior to the pandemic and may continue to be limited in the United States even in the long term.

**Figure 2.1** Factors affecting domestic production

#### Market Size

- Typical annual demand
- Types of products in demand

#### Product to Market

- Access to knowledge
- Intellectual property
- Market acceptance
- Product design

#### Production and Delivery

- Supply chain
- Production capabilities and costs
- Outbound logistics
- Services and support

#### Crosscutting Factors

- Innovation
- Labor
- Financing
- Standards, regulations, and certifications

Source: Compiled by USITC.

While many structural economic factors influence the competitiveness of the U.S. manufacturing sector, those most relevant for COVID-19 related goods are labor availability and cost, access to capital and financing, the ability of manufacturers to innovate, and differences in standards and regulations. Collectively these elements provide the United States with an advantage or a disadvantage vis-à-vis competitor countries, such as China. They speak to more long-term issues that will influence incentives for U.S. manufacturers to produce these products for the remainder of this pandemic and any possible new pandemics in the future.

## Market Size

The market is a significant consideration that affects the ability and willingness of manufacturers to start or expand domestic production. Three important market attributes that shape manufacturers' decisions are the size of the domestic market, whether the specific variation of the product in demand is the one



that a firm can produce, and the perceived longevity of the demand.<sup>27</sup> Manufacturers typically make decisions to invest in production capacity based on expected future demand, earnings, and return on investment.<sup>28</sup> Those that invest in production with no assurance of long-term demand are undertaking significant financial risk; there is no guarantee that they will get a favorable return on their investment, and they may, in fact, lose money.<sup>29</sup> These firms may face high future fixed costs with low capacity utilization rates.<sup>30</sup>

The consideration of long-term demand is particularly challenging for manufacturers investing in production during the COVID-19 pandemic. Manufacturers that make capital investments, such as in the production of disinfectants or materials for PPE, are doing so to serve an unprecedentedly high level of demand. Consequently, manufacturers that make such investments run the risk that they will incur significant financial losses either when demand returns to more normal levels or if they are unable to compete with imports. Some manufacturers have withheld investing in new production based on this concern (such as one producer of N95 respirators), while others (such as certain PPE producers) have invested regardless but are uneasy about the financial impacts of a future decline in demand.<sup>31</sup>

Shortages of toilet paper, although not discussed in this report, provide a useful illustration of this dynamic. The toilet paper market is split into two markets: consumer and commercial. When more people remained at home, there was a temporary increase in demand for consumer toilet paper—a demand that was reported to have increased even more due to hoarding. Toilet paper shortages occurred in the consumer market, in part, because manufacturers perceived the demand surge to be temporary and were reluctant to invest in the production changes needed to supply consumer toilet paper.<sup>32</sup>

## Product to Market

The ability of companies to develop products, including COVID-19 related goods, and sell them in the U.S. market is of particular importance for firms seeking to begin production. Once firms design a product, they need to ensure that the product complies with relevant standards, receives any necessary certifications, and obtains all required regulatory approvals. Obtaining the necessary approvals and

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<sup>27</sup> The demand that is more relevant may be domestic demand, foreign demand, or both.

<sup>28</sup> Demand is a major driver of investment, whether measured at the firm level or the national industry level. Research has also shown expected earnings to be a significant driver of corporate investment. OECD, “Lifting Investment,” 2015, 225–27; Ollivaud, Guillemette, and Turner, “Links between Weak,” 11–12; ECB, “What Is Behind,” 2015; Bachman and Zorn, “What Drives Aggregate Investment?” 2020, 1, 7; Klammer, Wilner, and Smolarski, “A Comparative Survey,” 110, 2002.

<sup>29</sup> This concern is most prominent for firms needing to make significant investments that will lead to higher fixed costs. For firms that can increase production primarily through raising their variable costs, this would be a less significant concern. Johansson, Pejryd, and Christiernin, “Consideration of Market Demand,” 2016, 311. The risk of a decline in demand is perennially a top concern for manufacturers. BDO, “2017 BDO Manufacturing,” July 2017. See also Vantrappen and Deneffe, “Joint Ventures Reduce,” April 6, 2016; Gennaioli, Ma, and Schleifer, “Expectations and Investment,” 2016, 379, 424; Vijlder, “What Is Driving Corporate Investment?” September–October 2016, 8–10.

<sup>30</sup> Manufacturers typically prefer not to maintain significant excess production capacity, which can impose a high cost. Shih, “Bringing Manufacturing,” April 15, 2020.

<sup>31</sup> See chapter 4 for a more complete discussion of the firms that invested in U.S. production.

<sup>32</sup> Moore, “How the Coronavirus,” May 19, 2020.

certifications is essential for COVID-19 related goods, which include highly regulated medical devices and pharmaceutical products where patient safety is paramount.

The final step in bringing a product to market is the ability to persuade potential customers to purchase the product on the market—for example, by convincing them that the new product is more advanced than competing products, more cost effective, easier to use, and so forth. Attributes can include product performance, quality, durability, ease of use, flexibility, energy efficiency, safety, connectivity, noise, size, weight, and environmental impact.<sup>33</sup> In the context of COVID-19, purchasers—particularly in the healthcare sector—place particular value on certain attributes, such as the quality of the product and whether it has been approved for medical use. Also, buyers must feel certain that they are not purchasing counterfeit products.

## Production and Delivery

This section will discuss each of the major factors impacting production and logistics. Although labor is an important factor impacting production, it will be discussed in the section on crosscutting factors, as it also impacts a firm’s ability to bring a product to market. For example, highly skilled workers are needed to develop products, improve these goods, and ensure they meet regulatory requirements.

### Materials, Components, and Other Inputs

A major factor that affects domestic production of COVID-19 related goods, as with other products, is the availability and cost of inputs and materials. Availability of raw material inputs and intermediate components are critical to producing the COVID-19 related goods discussed in this report. According to the most recently available data from the U.S. Bureau of the Census in its Annual Survey of Manufactures, material and supply costs account for 26 to 36 percent of U.S. product shipments’ value for the key industry sectors covered.<sup>34</sup> As the pandemic has unfolded, global demand has outstripped supply for many of these products, limiting U.S. producers’ ability to access inputs and driving up their costs.

U.S. producers have increasingly embraced global supply-chains to reduce supply costs.<sup>35</sup> The United States, for example, has the largest global medical device manufacturing industry, but the U.S. industry sources components for both low- and high-tech products from lower-cost countries, such as Mexico and China.<sup>36</sup> In addition to labor cost savings associated with producing abroad, producers have benefited from forming manufacturing clusters and establishing production in close proximity to other

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<sup>33</sup> David, Semanik, and Torsekar, “Framework for Analyzing,” September 2018, 20.

<sup>34</sup> In 2018, total cost of supplies and/or materials was 26.0 percent of the total value of pharmaceutical shipments (NAICS 3254) and 35.5 percent of the value of medical device shipments (NAICS 334510, 334517, 339112, 339113). Energy costs are usually a relatively small share of production costs for these industries, with the cost of purchased fuels and electricity representing 2 percent or less of the costs of supplies and materials in 2018 and less than 1 percent of the value of product shipments. USITC calculations using data from Census, “Annual Survey of Manufactures, 2018,” April 2020. For a discussion of U.S. energy cost changes over time and U.S. manufacturing, see Rose et al., “How Shifting Costs,” 2018, 3.

<sup>35</sup> Bamber and Gereffi, “Costa Rica in the Medical Devices Global Value Chain,” 2013.

<sup>36</sup> These include a broad range of products, from materials to electronic components such as printed circuit boards. Torsekar, “NAFTA and Medical Device,” November 2017; Torsekar, “China Climbs,” March 2018, 5–6.

steps of the supply chain.<sup>37</sup> For example, one industry representative stated that protective eyewear is primarily sourced from China, where the entire supply chain exists within the country, making eyewear production more affordable.<sup>38</sup> Other manufacturers have found it advantageous to locate production close to where raw material inputs are produced.<sup>39</sup> For example, latex gloves are primarily produced in Southeast Asia, primarily Malaysia, where rubber trees, a major raw material input, are grown.<sup>40</sup>

Fragmentation of production has increased the importance of supply chain resilience. Many firms have embraced more lean and efficient supply chains with low levels of inventory. While cost effective under stable business conditions, this approach leaves firms more vulnerable to production and shipping delays and supply shortages. Even when firms have adopted sophisticated strategies to ensure supply chain resilience, they find they have remained vulnerable to demand shocks and other disruptions to stages of the production process. One high-profile example of such shortages involves nonwoven fabric, a major input for N95 respirators.<sup>41</sup>

## Production Capabilities and Costs

Several factors contribute to the production capabilities of manufacturers seeking to produce high-quality products and to quickly ramp up production of those goods in response to the COVID-19 pandemic. Such factors include the quality of available labor and access to the technology needed to produce the product, including the necessary production machinery. Further, the lead time to bring production online is critical.<sup>42</sup> In addition to production capabilities, the cost of domestic production is a significant factor for firms considering expanding existing production or investing in a new plant.<sup>43</sup> Efficiency also plays into production cost and is typically associated with production capability.<sup>44</sup> Cost pressures are particularly relevant in the COVID-19 space for certain products such as PPE, as will be discussed later in the report.

## Outbound Logistics

Having sufficient, reasonably priced shipping capacity (shipping logistics) to deliver products to customers is an important consideration for domestic producers.<sup>45</sup> Customers in general expect on-time delivery and tight delivery time frames.<sup>46</sup> This expectation is especially true in the healthcare industry,

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<sup>37</sup> Antras and Gortari, “On the Geography of Global Value Chains,” 2020; Torsekar, “China Climbs,” March 2018, 8.

<sup>38</sup> USITC, hearing transcript, September 23, 2020, 36 (testimony of Joe Nadler, ArmouRx, Inc.).

<sup>39</sup> Bamber and Gereffi, “Costa Rica in the Medical Devices Global Value Chain,” 2013.

<sup>40</sup> USITC, hearing transcript, September 23, 2020, 104 (testimony of Wesley Cline, Zurn Industries).

<sup>41</sup> Tukamuhabwa et al., “Supply Chain Resilience: Definition, Review and Theoretical Foundations,” April 2015; Kamalahmadi and Parast, “Review of the Principles of Enterprise and Supply Chain Resilience,” November 2015; USITC, hearing transcript, September 23, 2020, 51 (testimony of Daniel Glucksman, International Safety Equipment Association).

<sup>42</sup> David, Semanik, and Torsekar, “Framework for Analyzing,” September 2018, 6–7.

<sup>43</sup> This includes labor and input costs, which are covered in separate sections of this chapter.

<sup>44</sup> David, Semanik, and Torsekar, “Framework for Analyzing,” September 2018, 10.

<sup>45</sup> David, Semanik, and Torsekar, “Framework for Analyzing,” September 2018, 8.

<sup>46</sup> David, Semanik, and Torsekar, “Framework for Analyzing,” September 2018, 6–9.

where providers routinely employ just-in-time supply chains to keep inventories and storage costs low.<sup>47</sup> Higher delivery costs and less frequent deliveries have become a particular concern during the pandemic. For example, domestic passenger flights in the past were an important way of moving lighter-weight, higher-value medical equipment. The sharp reduction in those flights has reduced the supply and frequency of air freight, as well as increased its cost.<sup>48</sup> These increases in costs and decreases in supply are occurring at the very time that the speed of delivery has become even more important as customers urgently need products to respond to the pandemic.

## Service and Support

Service and support have become increasingly critical in the context of the pandemic. Examples range from the ability to provide support and training for newly purchased dialysis machines to quickly responding to product quality or other issues.<sup>49</sup> The cost of providing after-sales service and support is also critical.

## Crosscutting Factors

There are several additional elements that may affect more than one of the factors discussed above and that also speak to structural economic factors impacting long-term competitiveness. For example, labor impacts a firm's production capabilities and costs, as well as its ability to innovate. These factors are discussed in more detail below.

### Labor

One determinant of the ability of U.S. manufacturers to produce in the long term is availability of labor. Firms need skilled workers for tasks such as developing and improving products, managing supply chains, and maintaining complex machinery. In the pharmaceutical industry, for example, only 30 percent of workers were involved in physical production as of May 2019.<sup>50</sup> In contrast, a much higher percentage of workers in the pharmaceutical industry than in other industries are in life, physical, and social science occupations (15 percent of pharmaceutical employment), management occupations (13 percent), business and financial operations occupations (8 percent), and sales and related occupations (6 percent).<sup>51</sup>

Labor costs are also a major determinant of U.S. manufacturing competitiveness. In the United States, manufacturing workers received an average wage of \$21.94 per hour as of December 2018.<sup>52</sup> Workers in

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<sup>47</sup> USITC, hearing transcript, September 24, 2020, 361–62, 394–95 (testimony of Michael Einhorn, Dealmed Medical Supplies); industry representative, telephone interview by USITC staff, September 2, 2020; industry representative, telephone interview by USITC staff, October 2, 2020; O'Leary, "The Modern Supply Chain Is Snapping," March 19, 2020.

<sup>48</sup> Lennane, "Air Freight Rates," April 17, 2020; David, Semanik, and Torsekar, "Framework for Analyzing," September 2018, 11.

<sup>49</sup> Moon, "California Recalls more than 10 Million N95 Masks," September 18, 2020.

<sup>50</sup> BLS, "Occupational Employment Statistics," May 2019.

<sup>51</sup> BLS, "Occupational Employment Statistics," May 2019.

<sup>52</sup> Trading Economics, "United States Average Hourly Wages" (accessed October 29, 2020). December 2018 was selected as a benchmark to facilitate comparison between earnings of manufacturing workers in the United States and other countries.

Germany and Italy earned wages that were significantly higher, while wages in the United Kingdom and South Korea were similar to U.S. wages. However, wages earned by workers in China, Malaysia, and Vietnam were much lower (table 2.1). The relatively high cost of U.S. labor compared to countries like China, Malaysia, and Vietnam is partially offset by the high productivity of American workers compared to most workers in those countries.<sup>53</sup> However, labor productivity in modern factories abroad may be higher than the economy-wide figures suggest,<sup>54</sup> and actual wages may vary over a wide range.<sup>55</sup>

The cost of labor impacts manufacturing decisions differently, depending on the labor intensities of products. Certain COVID-19 related goods, such as pharmaceuticals and soaps and cleaning compounds, have relatively low labor intensities.<sup>56</sup> Other products, however—such as certain PPE like gowns and gloves— have high labor intensities. As shown in the gloves case study in chapter 4 of this report, for example, glove production requires a significant number of workers even in automated plants. All else equal, since U.S. labor rates are relatively higher than in the major producing countries such as Malaysia, it is more difficult for U.S. producers to compete in these product areas in the long term.

**Table 2.1** Earnings and productivity of manufacturing workers in United States and selected major trading partners (in COVID-19 related industries)Country

Country	Earnings per hour, 2018 <sup>a</sup> (\$)	Value added per worker, 2017 <sup>b</sup> (1,000 \$)
United States	21.94	215
South Korea	21.98	169
Germany	33.72	92
Italy	23.07	84
China	5.20	44
Mexico	3.40	39
Malaysia	5.57	32
Vietnam	1.49	10
United Kingdom	19.21	n/a

Source: UNIDO, “INDSTAT 4 2020, ISIC Revision 4” (accessed November 30, 2020).

<sup>a</sup> Data on earnings per hour come from tables in Trading Economics, “China Average Yearly Wages in Manufacturing”; Trading Economics, “Malaysia Average Monthly Wages in Manufacturing”; Trading Economics, “Mexico Nominal Hourly Wages in Manufacturing”; Trading Economics, “South Korea Total Monthly Wages in Manufacturing”; Trading Economics, “United Kingdom Average Weekly Wages in Manufacturing”; Trading Economics, “United States Average Hourly Wages in Manufacturing”; Trading Economics, “Vietnam Wages in Industry and Construction” (all accessed October 29, 2020). Earnings reported on an annual or monthly basis and in national currencies were adjusted to earnings per hour assuming a 168-hour work month and using official exchange rates as of December 2018. Hourly earnings for Germany and Italy are from Statista, “Average Labor Costs.” Statista reports hourly cost of labor to employers, including value of benefits paid by employers, but not received as monetary compensation by workers. The cost is adjusted to represent only the wage part using data from the Conference Board’s ILC Program, “International Comparisons in of Hourly Compensation Costs,” Table 1 (accessed November 30, 2020).

<sup>b</sup> Value added per worker was calculated using UNIDO data on number of employees and total value added by labor in manufacturing.

Despite high productivity of the U.S. manufacturing workers, annual productivity growth of the U.S. manufacturing industry was under 1 percent in 2012–18, while wages grew by 2 percent per year.<sup>57</sup>

<sup>53</sup> Globally, Ireland ranked first in value added per worker (\$518,000 per worker), followed by the United States (\$215,000), Switzerland (\$169,000), Korea (\$169,000), and Singapore (\$150,000). UNIDO, “INDSTAT 4 2020, ISIC Revision 4” (accessed November 30, 2020).

<sup>54</sup> See, for example, the case of Mexico: Bolio et al., “A Tale of Two Mexicos,” March 1, 2014.

<sup>55</sup> Forced labor has been reported in the production of some COVID-19 related goods, such as in the production of gloves by certain companies in Malaysia, prompting U.S. enforcement action. This is discussed further in the PPE chapter.

<sup>56</sup> BLS, “Multifactor Productivity,” November 9, 2020.

<sup>57</sup> Rose et al., “How Shifting Costs,” December 11, 2018.

Over the last several decades, U.S. real wage growth has lagged behind productivity growth,<sup>58</sup> but in recent years, productivity-adjusted labor costs may have increased making it comparatively more expensive to produce in the United States.

## Financing

Access to capital and financing (whether from revenue, cash reserves, venture capital, equity investment, or low-interest bank loans) is important for manufacturers, including COVID-19 related goods producers.<sup>59</sup> Financing enables firms to invest in production capabilities and logistics, including research and development, new technologies, and marketing strategies.<sup>60</sup> The ability to attract initial funding from investors and other sources is especially important for new entrants, including those in advanced manufacturing or companies switching products, who often have to invest heavily when retooling their production lines, due in large measure to high fixed asset costs.<sup>61</sup> Additionally, access to capital can enable firms already in the market to respond to new entrants and competitors. Thus, investment in new firm entry and operational capabilities can have direct impacts on firm productivity and growth.<sup>62</sup>

A ranking of global manufacturing competitiveness conducted in 2016 notes that U.S. manufacturing firms have good access to private capital due to a variety of lending channels and the large pool of venture capital funds for high-technology products.<sup>63</sup> However, the pandemic and subsequent economic downturn have constrained capital access for many firms.<sup>64</sup> In the current economic climate manufacturers face several financial constraints, including reduced access to loans and fewer long-term purchase commitments to offset demand uncertainty.<sup>65</sup> Grants have been issued by individual states to increase production of certain products, and the federal government has awarded a number of contracts for production for short-term delivery. Nonetheless, these grants and contracts do not alleviate financial uncertainty related to anticipated longer-term demand reductions as the pandemic subsides, such as with the advent of a suitable vaccine or treatment.<sup>66</sup> Demand uncertainty can

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<sup>58</sup> Brill et al., “Understanding the Labor Productivity,” June 2017, 2–3; Bivens and Mishel, “Understanding the Historical Divergence,” September 2, 2015, 4–5.

<sup>59</sup> David, Semanik, and Torsekar, “Framework for Analyzing,” September 2018.

<sup>60</sup> Porter, “The Five Competitive Forces,” January 2008, 27; Torsekar, *Medical Devices and Equipment*, March 2007, 2–5; Deloitte Center for Industry Insights, *High-performing Manufacturers*, 2016, 6.

<sup>61</sup> Leonard, “Manufacturers Call on Government,” April 22, 2020; Graham, Suster, and Fried, “Should Your Startup Prioritize Profits or Growth?” July 8, 2017; McCue, “Advanced Manufacturing Expertise,” July 30, 2014; NIST, “Connecting Small Manufacturers,” November 2011, 20.

<sup>62</sup> Aghion et al., “Financial Constraints and Productivity Growth,” 2019. Here, the authors note that access to finance and productivity have a U-shaped relationship (where financial constraints can make it harder for firms to invest and innovate), which can impact long-term productivity; however, this restriction can push less efficient firms out of the market, increasing overall efficiency in the market. Krishnan, Nandy, and Puri, “Small Business Productivity” (accessed November 2, 2020); Samila, Sampsa, and Sorenson, “Venture Capital, Entrepreneurship, and Economic Growth,” 2011, 338–49.

<sup>63</sup> Deloitte, “Global Manufacturing Competitiveness Index,” 2016, 7.

<sup>64</sup> Federal Reserve of Dallas, “Small Business Hardships,” 2020.

<sup>65</sup> Andriotis and Rudegeair, “People Need Loans,” March 28, 2020; Federal Reserve of Dallas, “Small Business Hardships,” 2020; PWC, “Covid-19: What it Means,” April 20, 2020.

<sup>66</sup> Individual states, such as New York, have issued grants to help businesses investing in PPE production. *Rome Sentinel*, “Three Mohawk Valley Companies,” August 1, 2020.

significantly impact investment, particularly for firms with high upfront fixed costs.<sup>67</sup> As will be discussed in the subsequent chapters, several firms producing COVID-19 related goods have stated that long-term contracts, purchase orders, or other financial support is needed to induce firms to pivot to manufacturing COVID-19 related goods.

Several countries have instituted financing schemes, outside of any other financial support provided, specifically aimed at PPE producers to alleviate these concerns. For example, Chinese firms have benefited from large government subsidies to ease the burden of sunk fixed costs once demand subsides. Similarly, regional governments in China, such as Shanghai, have instructed banks to offer subsidized loans at low rates to ensure financial support for PPE firms, including multinationals.<sup>68</sup>

## Innovation

The ability of manufacturers to innovate—that is, to develop new or significantly improved products or processes—impacts their ability to bring products to market and to rapidly adapt production to meet escalating demand, among other factors.<sup>69</sup> The extent to which an industry in a country is able to innovate also depends, in part, on the ability of domestic firms to protect the intellectual property rights (IPRs) embodied in their products. Protecting IPRs helps firms to recoup the cost of innovating and marketing a new product, as well as retain the ability to fund further innovation efforts.<sup>70</sup> However, the need to maintain a balance between incentives for innovation and access to innovative products also is an important feature of a country’s innovation system, particularly when there is a public health emergency.

The existing industrial foundation is another element of the domestic environment needed to support rapid innovation during a pandemic. This is the “industrial commons,” which is a country’s “set of manufacturing and technical capabilities that support innovation across a broad range of industries.”<sup>71</sup> In the first nine months of 2020, firms needed to rapidly speed up their production processes or create entirely new production processes and supply chains for goods in high demand. The quick ramp-up in ventilator production for the strategic national stockpile, for example, was due to the combined capabilities of domestic ventilator manufacturers, auto producers, and others.<sup>72</sup> Ventilator

<sup>67</sup> Vijlder, “What Is Driving Corporate Investment?” September–October 2016, 8–10; Johansson, Pejryd, and Christiernin, “Consideration of Market Demand,” 2016, 311.

<sup>68</sup> Bradsher, “China Dominates Medical Supplies,” July 5, 2020; Reuters, “Unilever, 3M, on List of Firms Eligible,” February 19, 2020. Other countries (e.g., Italy and India) have also issued subsidized loans with generous repayment periods for PPE producers. Global Legal Monitor, “Italy: New Regulations Granting Government Funds,” April 6, 2020; *Economic Times*, “Sidbi to Provide Loans,” March 27, 2020.

<sup>69</sup> David, Semanik, and Torsekar, “Framework for Analyzing,” September 2018, 17; OECD/Eurostat, *Oslo Manual 2018*, 2018, 21.

<sup>70</sup> Governments grant patents and other IPR protections to incentivize innovation. These rights may enable the IPR owner to recoup up-front costs by charging higher prices and also may provide the foundation for the transfer of innovations through sales and licensing agreements. In return for exclusive rights, the patent applicant must disclose how to make or practice the invention, thus expanding the public stock of technical knowledge. Horan, Johnson, and Sykes, “Foreign Infringement,” October 2005, 13.

<sup>71</sup> Pisano and Shih, *Producing Prosperity*, 2012, 70–81.

<sup>72</sup> This is not to imply that all capabilities were available domestically; firms also relied on global sourcing of components, as discussed in the ventilators case study in chapter 3 of this report. It was critical for these domestic firms to be able to source from a global supply chain.

manufacturers provided access to proprietary designs and collaborated with firms in other industries and universities to connect with suppliers and boost output quickly.<sup>73</sup> In areas with almost no industrial commons, it is more difficult for manufacturers to ramp up production. For example, it took significantly longer for some countries with no experience in ventilator manufacturing to bring products to the market, even in small quantities.<sup>74</sup>

In response to the pandemic, firms were required to design entirely new products for the market, such as COVID-19 test kits and vaccines. Such innovation relies on the existing knowledge base, including experience developing products in response to past pandemics. Industry notes that continuing innovation and bringing innovative products to market is imperative in warding off future supply chain challenges and constraints for COVID-19 related goods.<sup>75</sup> U.S. businesses have been the leading investors in pharmaceuticals research and development (R&D), with U.S. expenditures more than four times the amount spent by China and Japan each, the next-largest sources of business R&D in pharmaceuticals in 2016.<sup>76</sup>

Ongoing efforts to develop and manufacture COVID-19 vaccines rely on past experience as well as current collaborations, open-source initiatives, and government funding. The efforts received an early boost from open-access projects led by the U.S. government, industry, and academia to make medical literature, patent documents, and datasets widely available.<sup>77</sup> Biopharmaceutical companies state that they are sharing clinical trial information with other companies and governments, as well as vaccine manufacturing capacity.<sup>78</sup> The public-private program Operation Warp Speed reportedly has awarded more than \$12 billion in vaccine-related contracts to assist biopharmaceutical companies in R&D and commercialization.<sup>79</sup>

### **Regulations, Standards, and Conformity Assessment**

The ability of firms to ensure their products meet standards, comply with regulations, and pass relevant conformity assessment procedures has a significant impact on the ability or willingness of manufacturers to invest and/or increase production. The industries producing COVID-19 related goods are, in many cases, subject to regulation because they produce goods such as medical devices and pharmaceuticals. These regulations extend from premarket approvals (for some products) to compliance with current good manufacturing practice to packaging and delivery. In this way, regulations impact multiple aspects of the framework.<sup>80</sup> In the first half of 2020, new market entrants needed to meet these requirements (although government agencies provided various accelerated routes to the market, such as Emergency

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<sup>73</sup> Chesbrough, "To Recover Faster," 2020, 411; Medtronic, "Medtronic Shares," March 30, 2020.

<sup>74</sup> Rueda, "Colombia Turns," August 25, 2020. See also Gerety, "Unmade in America," 68–75.

<sup>75</sup> Industry representatives, telephone interviews by USITC staff, November 16, 2020.

<sup>76</sup> NSF, "U.S. Business R&D," table 4-13, "Business Expenditures for R&D," January 15, 2020.

<sup>77</sup> The decision of Chinese researchers to share the genetic sequence of the virus also accelerated vaccine development. Chesbrough, "To Recover Faster," 2020, 411; WTO, "How WTO Members," September 18, 2020, 9.

<sup>78</sup> PhRMA and BIO, "Our Commitment to Beat Coronavirus," March 17, 2020.

<sup>79</sup> Operation Warp Speed reportedly has awarded more than \$12 billion in vaccine-related contracts to Moderna, Sanofi, GlaxoSmithKline, Pfizer, BioNTech, Novavax, Johnson & Johnson, and AstraZeneca. Bloomberg Businessweek, "Inside Operation Warp Speed's \$18 Billion," October 29, 2020.

<sup>80</sup> CRS, "Personal Protective Equipment," September 22, 2020, 1; FDA, "Step 3: Pathway," February 9, 2018.



Use Authorizations). At the same time, existing producers needed to remain in compliance while ramping up production or making modifications to current products.

Firms also must comply with a variety of regulations in other areas, and there may be significant differences in these regulations across countries and regions. India and China, for example, historically had less stringent environmental regulations than the United States for pharmaceutical production.<sup>81</sup> One problem area that PPE industry representatives noted in particular during this investigation was the use of forced labor.<sup>82</sup> U.S. Customs and Border Protection issued multiple Withhold Release Orders against Malaysian glove manufacturers for forced labor violations.<sup>83</sup> According to a recent report, firms in China allegedly are using Uighur forced labor in PPE production.<sup>84</sup>

## Factors Affecting Imports

The import framework describes the factors that impact the extent to which importers and buyers are able to purchase foreign-made products and import them into the United States.<sup>85</sup> The import framework includes three main factors: (1) product availability, (2) market acceptance, and (3) product and delivery prices/costs (figure 2.2).

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<sup>81</sup> Lupkin, “What Would It Take,” April 24, 2020.

<sup>82</sup> NCTO, written submission to USITC, September 23, 2020, 2; Vidalia Mills, written submission to USITC, September 23, 2020.

<sup>83</sup> CBP, “Withhold Release Orders,” July 15, 2020; Lee, “Amid Virus Crisis, U.S. Bars Imports,” July 16, 2020; CBP Office of Trade, “CBP Revokes Withhold Release Order,” March 24, 2020.

<sup>84</sup> Bengali, “The Gloves Help,” September 22, 2020; Xiao et al., “China Is Using Uighur,” July 19, 2020.

<sup>85</sup> This is similar to the approach used in earlier Commission research on agricultural competitiveness. The agriculture competitiveness framework includes three main criteria on which buyers make purchasing decisions: (1) delivered cost, (2) product differentiation, and (3) the reliability of supply. Given the unique circumstance of the pandemic, however, the framework used here is not a competitiveness framework. For example, the criterion importers and buyers are using here is less the reliability of supply than whether there is any available supply. Similarly, importers and buyers are not choosing among various differentiated products, but rather determining at a more basic level whether the products are eligible to be sold on the U.S. market and acceptable to end users. USITC, “China’s Agricultural Trade,” March 2011, E-6 to E-7.

**Figure 2.2** Factors affecting imports

Product availability

- Available global supply (including supply-demand balance)
- Contractual obligations of suppliers
- Knowledge of available suppliers
- Relationship between importers and suppliers
- Export restrictions
- Logistics (including shipping times)
- Import restrictions

Market entry and acceptance

- Intellectual property
- Supplier reputation
- Quality
- Match between global production and U.S. demand

Prices and delivery costs

- Product prices
- Logistics costs
- Import duties
- Export tariffs

Crosscutting factors (may apply to any factor above, and will be discussed under the relevant factor)

- Financing
- Regulations
- Standards and certifications

Source: Compiled by USITC.

## Product Availability

Once importers decide what products they want to import, they must first determine whether, and from where, the products are available for purchase. Some products may not be available on the open market or else have already been reserved by other customers. Shortages of some COVID-19 related products, such as N95 respirators, hand sanitizer, and ventilators, have led importers to search for new sources of supply, with many forced to pay significantly more than they previously needed to for such supplies.

Whether an importer has a preexisting relationship with a firm that can supply the product is also important. According to one report, 80 percent of U.S. imports are estimated to take place in pre-existing relationships.<sup>86</sup> When no relationship exists, imports can be impeded. For example, a supplier may offer more favorable credit terms to an importer if they have an established relationship.

Export restrictions are widespread for COVID-19 related goods and also affect product availability. The World Customs Organization identified almost 40 economies that implemented restrictions on the export of COVID-19 related medical supplies.<sup>87</sup> For example, China did not explicitly ban PPE exports, but

<sup>86</sup> Monarch and Schmidt-Eisenlohr, "Learning and the Value of Trade Relationships," November 2017, 1.

<sup>87</sup> WCO, "List of National Legislation" (accessed November 5, 2020).

implemented a number of policies that had the effect of limiting exports, as will be explained in the following chapters and in box 2.1.

**Box 2.1** Chinese export restrictions on COVID-19 related products

In March and April 2020, several Chinese government agencies issued notices or instituted rules to ensure the quality of COVID-19 related product exports; these notices and rules appear to have slowed or delayed exports of these products. First, on March 31, several Chinese government agencies jointly announced that exporters of medical supplies, effective April 1, would need to declare to Chinese customs that they had a certificate of registration for medical devices in China and that they had met the quality standards of the importing country.<sup>a</sup> This notice effectively banned exports of medical supplies by companies that were not licensed to sell those products in China.<sup>b</sup> Then, on April 10, Chinese customs announced that they would start inspecting exports of many COVID-19 related products.<sup>c</sup> These inspection requirements, which seemed to be in response to complaints from foreign governments and hospitals about receiving faulty equipment, may have slowed exports of such products.<sup>d</sup> Finally, on April 25, several Chinese government agencies jointly issued a notice rescinding, effective April 26, the restriction on exporting COVID-19 related products that were not licensed to sell in China, as long as they met the standards of the importing country.<sup>e</sup>

In addition to actions by the central Chinese government, local governments implemented policies that limited exports. For example, the city of Shanghai reportedly assumed responsibility for order handling and product delivery of 3M-produced respirators in Shanghai, impeding 3M China's ability to respond to orders.<sup>f</sup> Similarly, some mask and respirator exporters were reportedly ordered to sell all of their products to the local government. Key materials for production of these goods were also required to be sold domestically in some instances.<sup>g</sup>

<sup>a</sup> Government of China, "Notice Regarding Managing Exports of Medical Devices," March 31, 2020; Bradsher, "China Delays Mask and Ventilator Exports," April 11, 2020.

<sup>b</sup> International Trade Centre, "COVID-19 Temporary Trade Measures" (accessed October 29, 2020); Bradsher, "China Delays Mask and Ventilator Exports," April 11, 2020.

<sup>c</sup> Bradsher, "China Delays Mask and Ventilator Exports," April 11, 2020.

<sup>d</sup> Brunstrom, "U.S. Appeals to China to Revise Export Rules," April 16, 2020.

<sup>e</sup> Government of China, "Notice Regarding Further Strengthening the Export Quality," April 25, 2020; Liu and Lee, "China Eases Restrictions on Exports," April 26, 2020.

<sup>f</sup> Eilperin et al., "U.S. Sent Millions of Face Masks to China," April 18, 2020.

<sup>g</sup> Bai, "China's Face-Mask Makers," March 13, 2020; Hufford and Evans, "Critical Component," March 7, 2020; Hufford and Evans, "Coronavirus Outbreak Strains," February 6, 2020.

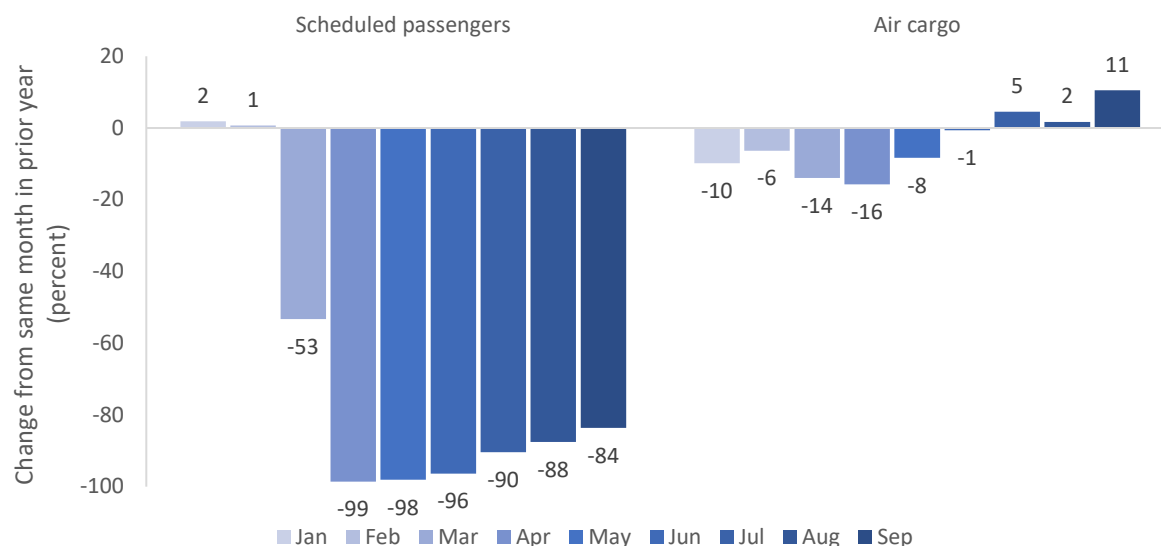
The logistics of transporting goods can also be a factor in product availability. The number of international passengers on U.S. airlines in April 2020 was 99 percent lower than in April 2019, and there was a 16 percent decline in international freight carried by U.S. airlines during those same two periods.<sup>88</sup> As significant air cargo is transported on passenger flights, the decline in the number of flights for much of 2020 meant less air cargo space was available. The reduction in international flights to the United States due to COVID-19 began on January 31, 2020, when the President issued a proclamation suspending entry, with certain exceptions, into the United States of immigrants and nonimmigrants from China.<sup>89</sup> Subsequent proclamations included limited entry into the United States from Brazil,

<sup>88</sup> USDOT, BTS, "U.S. Airlines Carried," November 10, 2020; USDOT, BTS, "U.S. Airlines September 2020 Passengers," November 12, 2020.

<sup>89</sup> Proclamation No. 9984, 85 Fed. Reg. 6709 (January 31, 2020).

European countries, and Iran.<sup>90</sup> China also limited entry into the country, and both China and the United States limited passenger flights between the two countries.<sup>91</sup>

**Figure 2.3** Change from the same month of the prior year, U.S. airlines scheduled transport of international passengers by number and international air cargo by weight, January–September 2020



Source: USDOT, BTS, “U.S. Airlines Carried,” November 10, 2020; USDOT, BTS, “U.S. Airlines September 2020 Passengers,” November 12, 2020. Note: September data are preliminary. Underlying data for this figure can be found in [appendix table E.1](#).

Beyond the decline in air transport, lockdowns and other restrictions on nonessential activities also reduced demand for non-COVID-19 products, leading carriers to reduce ocean freight capacity, which affected the availability of ocean freight for COVID-19 products.<sup>92</sup> Import restrictions can also be an issue for product availability. For some COVID-19 products, U.S. Food and Drug Administration (FDA) approvals may be a hurdle to importing and selling the product.

## Market Entry and Acceptance

Market entry and acceptance, or the extent to which a product can be sold in the U.S. market, can influence the supply of imports. The reputation of the supplier is an important factor when consumers are deciding whether to purchase the product. If the firm, or sometimes the source country, does not have a good reputation for producing the good, then consumers may be unwilling to purchase. Sales of counterfeit PPE reportedly have been rampant.<sup>93</sup> As of September 30, 2020, U.S. government officials

<sup>90</sup> CDC, “Travelers Prohibited,” September 14, 2020.

<sup>91</sup> This discussion focuses on China and the United States, but restrictions and limitations applied to other countries as well. DHS, “Notices of Arrival Restrictions,” March 20, 2020; DHS, “DHS Issues Supplemental,” February 2, 2020; USDOT, “U.S. Department of Transportation Modifies,” August 18, 2020; Zhang, “China’s Travel Restrictions,” September 23, 2020; Baker, “China, U.S. Open Door,” June 5, 2020; Baker, “China, U.S. Further,” August 19, 2020.

<sup>92</sup> Knowler, “Blanked April Sailings Soar as Carriers Prep,” April 1, 2020.

<sup>93</sup> USITC, hearing transcript, September 23, 2020, 148 (testimony of Abby Pratt, Advanced Medical Technology Association (AdvaMed)), 150 (testimony of Daniel Glucksman, International Safety Equipment Association (ISEA)); National Association of Manufacturers, “Countering Counterfeits,” July 2020, 4.

reported seizures of more than 177,000 imported COVID-19 test kits prohibited by the FDA, and 12.7 million imported counterfeit face masks, since the start of the pandemic.<sup>94</sup> Quality of product, which can be intertwined with supplier reputation, is also important for market acceptance, and in some cases poor quality can bar a product from entering the country.

Similarly, the products produced globally need to be a match for those in demand in the U.S. market. For example, while there is substantial availability of KN95 respirators, these products while authorized under an EUA have not been approved by National Institute for Occupational Safety and Health (NIOSH) as N95 respirators have and may not meet the same level of performance.<sup>95</sup> As a result, healthcare professionals are reluctant to use these respirators.<sup>96</sup>

## Prices and Delivery Costs

Price is a key factor affecting the demand for imported products. Usually, high factory gate prices abroad, and/or high markups from foreign suppliers, lead to decrease in demand. However, with heavy demand for many COVID-19 products during the pandemic, many consumers became less sensitive to price increases and continued purchasing products regardless of price. While the biggest determinant of the price of imported goods is usually the factory gate price charged by the foreign supplier, logistics costs, import duties, and sometimes export tariffs are also important components of the price a consumer encounters for imports in the domestic market.

Logistics costs vary significantly based on weight, quantity, and method of transit. As noted above, when lockdowns and other restrictions first occurred in March and April 2020, shippers reduced ocean freight capacity. Demand for freight has since rebounded and that capacity has been brought back online, but high demand has kept ocean freight prices well above levels from the previous year.<sup>97</sup> Prices are similarly high for air freight, with prices for air freight from Hong Kong to North America, for example, peaking at \$7.73/kg in May 2020, up from \$3.71/kg in May 2019 (figure 2.3). Prices remained high at \$5.66/kg in October 2020 (compared to \$3.49/kg in October 2019).<sup>98</sup>

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<sup>94</sup> Other seizures included 36,000 “antivirus” lanyards prohibited by the U.S. Environmental Protection Agency (EPA); 5,000 tablets of antibiotics, such as azithromycin; and 300,000 seizures of hand sanitizers. Roughly 51 percent of seized COVID-19-related goods originated in China and Hong Kong. Other top countries of origin included Canada, the United Kingdom, Vietnam, Japan, and Mexico. China was also a major source of respirators falsely labeled as “NIOSH-approved,” according to notices issued by NIOSH. U.S. government official, email message to USITC staff, October 22, 2020; CDC, NIOSH, NPPTL, “Counterfeit Respirators,” September 29, 2020.

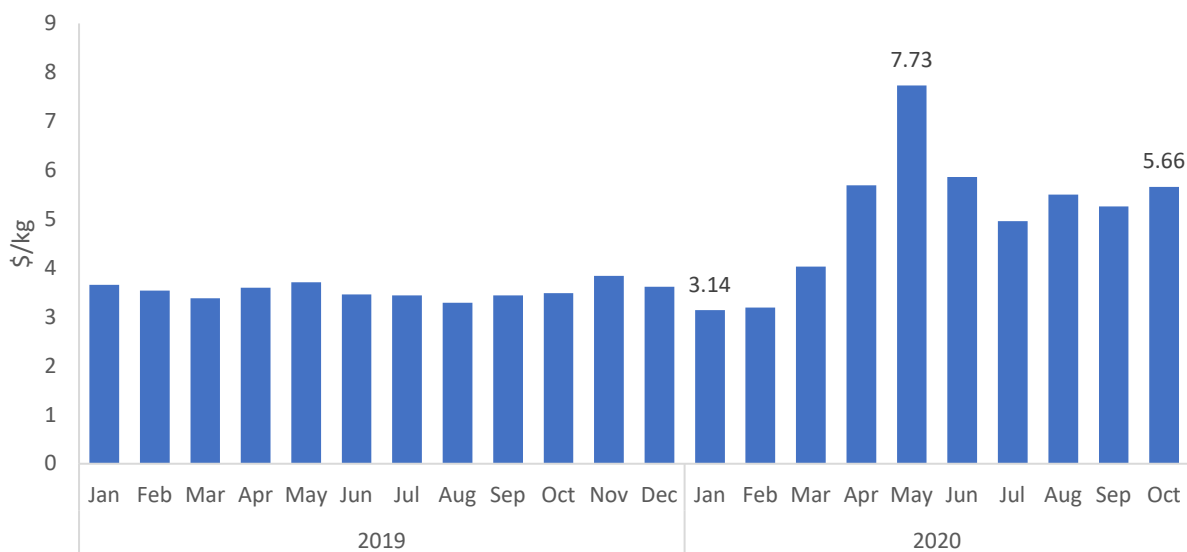
<sup>95</sup> Andrews et al., “PPE CASE: Filtration Efficiency,” 2020; Advisory Board, “Imported N95 Masks,” May 5, 2020.

<sup>96</sup> Industry representatives, telephone interviews by USITC staff, September 28 and 29, 2020

<sup>97</sup> Steer and Hale, “China-US Shipping Costs,” October 21, 2020.

<sup>98</sup> Air Cargo News, “TAC Index Monthly Airfreight Rates” (accessed October 29, 2020).

**Figure 2.4** Hong Kong to North America air freight rates, January 2019–October 2020



Source: Air Cargo News, “Airfreight Rates—TAC Index” (accessed November 15, 2020).

Note: Underlying data for this figure can be found in [appendix table E.2](#).

Import duties can also make up a significant share of costs.<sup>99</sup> The normal trade relations (NTR)<sup>100</sup> rates of duty for COVID-19 related goods identified in *COVID-19 Related Goods: U.S. Imports and Tariffs* ranged from free to 28.6 percent ad valorem,<sup>101</sup> with 57 percent of the identified HTS statistical reporting numbers not subject to duties. Certain COVID-19 related goods imports from China have been subject to temporary additional tariffs that can add as much as 25 percent to the price of U.S. imports.<sup>102</sup>

<sup>99</sup> For more on duties for specific COVID-19 related goods, see USITC, *COVID-19 Related Goods: U.S. Imports and Tariffs*, June 2020.

<sup>100</sup> Normal trade relations (NTR) tariffs are the tariff rates that World Trade Organization (WTO) member countries promise to impose on imports from other members of the WTO, in the absence of a free trade agreement, a trade preference program for developing countries, or other basis for imposing a different rate of duty. NTR tariffs are known as most-favored-nation, or MFN, tariffs outside the United States.

<sup>101</sup> A rate of duty expressed as a percentage of the appraised customs value of the imported good. A few items are also subject to specific tariffs, which are in dollars per unit (e.g., dollars per ton).

<sup>102</sup> The U.S. Trade Representative imposed the tariffs under section 301 of the Trade Act of 1974 after determining that certain acts, policies, and practices of China are unreasonable or discriminatory and burden or restrict U.S. commerce. 82 Fed. Reg. 40213.

# Chapter 3

## Medical Devices

The COVID-19 pandemic severely impacted the global medical device industry worldwide in 2020. The pandemic created an unprecedented global surge in demand for ventilators, dialysis machines, personal protective equipment (PPE), and other critical medical supplies, even as a cutback in elective procedures depressed demand for medical goods not used to treat coronavirus patients. For COVID-19 related goods, the demand surge overwhelmed the industry’s short-term capability to produce certain medical devices, such as ventilators. The U.S. industry responded by increasing and prioritizing production of these goods and forming new partnerships to manufacture them, although it faced challenges in areas such as sourcing medical-grade components and specialty parts. Imports of components and parts were partly constrained by a reduced international shipping capacity due to the pandemic.<sup>103</sup> But as the ramp-up of production brought quantity supplied closer to quantity demanded, and the need for certain devices waned, these challenges for certain products like ventilators were mostly resolved by September 2020.

The medical device industry produces a wide range of products used to diagnose and treat patients and to keep health care workers safe from infection. There is no single globally recognized definition for “medical devices,” although their scope ranges from relatively low-tech and low-cost goods that have long been in existence, such as syringes and other hospital supplies, to more costly high-tech products, such as medical imaging equipment made up of many components. The medical devices used in response to COVID-19 cover the range of these products, including syringes, dialysis machines, and ventilators. This chapter will start by discussing the U.S. medical device industry generally, including information on production, employment, and trade,<sup>104</sup> and then will include a case study on ventilators—one of the key products used in the response to COVID-19. Case studies for other products falling within the broad category of medical devices such as PPE are presented in chapter 4.

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<sup>103</sup> AdvaMed, written submission to USITC, August 28, 2020, 5, 11; USITC, hearing transcript, September 23, 2020, 20, 19, 75 (testimony of Abby Pratt, AdvaMed), 80 (testimony of Susan VanMeter, AdvaMed), 80 (testimony of Wesley Cline, Zurn Industries), 94 (testimony of Daniel Glucksman, ISEA), 137 (testimony of Scott Paul, Alliance for American Manufacturing), 159 (testimony of Lori Wallach, Public Citizen), 197 (testimony of Prashant Yadev, Center for Global Development), 257 (testimony of Ed Brzytwa, American Chemistry Council); Chadha et al., *Reimagining Medtech*, April 22, 2020.

<sup>104</sup> The NAICS codes for medical devices in this chapter include most PPE, as well as ventilators and a range of other products broadly falling in the category of medical devices. As a result, the trade and production data provided in this chapter’s “Overview of the U.S. Medical Device Industry and Market” cover this broader category of medical devices.

# Overview of the U.S. Medical Device Industry and Trade

## Introduction

The global medical device industry generated approximately \$456.9 billion in worldwide sales in 2019, the latest full year for which data were available.<sup>105</sup> The United States is a global leader in the industry in terms of the value of both annual production and exports.<sup>106</sup> The United States is also the leading spender among countries that are members of the Organisation for Economic Co-operation and Development (OECD) on medical device research and development (R&D).<sup>107</sup> U.S. production and value added increased from 2015 to 2018, as did employment, imports, and exports. In 2019, 16 of the world's top 30 medical device producers were headquartered in the United States.<sup>108</sup>

Medical device companies have global footprints and manufacture abroad to serve local markets. The U.S. medical device industry is structured around global supply chains and just-in-time delivery practices to keep manufacturing and inventory costs low.<sup>109</sup> There is significant global trade in medical device parts and components. The United States is a global leader in high-tech manufacturing, as well as in R&D and other innovative activities central to the medical device industry.<sup>110</sup>

The majority of medical devices discussed in this report are not typically purchased directly by consumers or patients themselves,<sup>111</sup> but rather by intermediaries such as group purchasing organizations (GPOs).<sup>112</sup> Medical devices are sold both directly by manufacturers and through distributors.

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<sup>105</sup> Business Research Company, "Medical Devices Global Market," July 2020.

<sup>106</sup> Auxergo, "The Current State of China's Medical Device Industry," April 10, 2019; OECD.Stat database (accessed October 14, 2020).

<sup>107</sup> OECD.Stat database (accessed October 14, 2020).

<sup>108</sup> Nine were headquartered in Europe and five headquartered in Japan. Many of these firms also manufacture other healthcare products, such as pharmaceuticals. The world's largest medical device firm by sales, Medtronic, is a U.S.-founded company with operational headquarters in the United States. However, since 2015, Medtronic has maintained its corporate headquarters in Ireland. MPO, "The 2020 Top Global Medical Device," July 21, 2020.

<sup>109</sup> AdvaMed, written submission to USITC, August 28, 2020, 7–9; USITC, hearing transcript, September 24, 2020, 349 (testimony of Linda Rouse O'Neill, HIDA), 358–59, 402–03 (testimony of Michael Einhorn, Dealmed Medical Supplies), 376 (testimony of Bryan Zumwalt, Critical Infrastructure Supply Chain Council).

<sup>110</sup> Curran, *Medical Device Manufacturing*, August 2020, 13, 24; OECD.Stat database (accessed October 14, 2020).

<sup>111</sup> MedPAC, "An Overview of the Medical Device Industry," June 2017, 209.

<sup>112</sup> GPOs aggregate purchases by healthcare facilities and use the leverage of high-volume purchases to negotiate discounts with manufacturers, distributors, and other vendors of a wide range of medical goods and services. American Association of Pediatrics, "Managing the Practice: Group Purchasing Organizations" 2020; Curran, *Medical Device Manufacturing*, August 2020, 12; USITC, hearing transcript, September 23, 2020, 203 (testimony of Scott Paul, Alliance for American Manufacturing); USITC, hearing transcript, September 24, 2020, 433 (testimony of Michael Einhorn, Dealmed Medical Supplies).



The medical devices described in this chapter include four U.S. industry groupings, as classified by the North American Industry Classification System (NAICS), shown in table 3.1.<sup>113</sup> The Food and Drug Administration (FDA) determines which products are considered medical devices in the U.S. market and therefore subject to its regulatory oversight (see appendix F).

**Table 3.1** Medical device industry coverage

NAICS	Description	Examples
334510	Electro-medical and electrotherapeutic apparatus manufacturing, or “electromedical equipment”	Pacemakers, magnetic resonance imaging equipment, medical ultrasound equipment, electrocardiographs, electromedical endoscopic equipment, dialysis machines, and ventilators.
334517	Irradiation apparatus manufacturing, or “irradiation equipment”	Irradiation and diagnostic imaging equipment such as X-ray machines, fluoroscopes, and computed tomography equipment products.
339112	Surgical and medical instrument manufacturing, or “instruments”	Medical, surgical, ophthalmic, and veterinary instruments and apparatus.
339113	Surgical appliances and supplies manufacturing, or “supplies”	Orthopedic devices, prosthetic appliances, surgical dressings, surgical sutures, personal safety equipment and clothing (except protective eyewear), hospital beds, and operating room tables.

Sources: NAICS Association, <https://www.naics.com>; SICCODE Business Data, <https://siccode.com>.

Note: Other categories typically included as medical devices include NAICS 339114 (dental equipment and supplies manufacturing), NAICS 339115 (ophthalmic goods manufacturing), and 339116 (dental laboratories). Most personal protective equipment (PPE) is a subset of NAICS 339113. NAICS Association, <https://www.naics.com>; SICCODE Business Data, <https://siccode.com>.

## U.S. Industry

### Overview of the U.S. Industry

More than 7,500 medical device establishments operate in the United States, including those owned by both U.S.-headquartered firms and subsidiaries of foreign-headquartered firms with U.S. operations.<sup>114</sup> Employing over 323,000 workers in 2019, these establishments are located throughout the country, but they are generally concentrated in states with large healthcare, high-tech, and research-based sectors.<sup>115</sup> The largest number of medical device establishments is in California (figure 3.1), which is also home to the largest cluster of medical device firms in the country by measures such as patent filings.<sup>116</sup>

<sup>113</sup> The NAICS selected for inclusion are the primary NAICS for medical devices identified by the Commission in its June 2020 report on COVID-19 related goods. USITC, *COVID-19 Related Goods: U.S. Imports and Tariffs (Updated)*, June 2020.

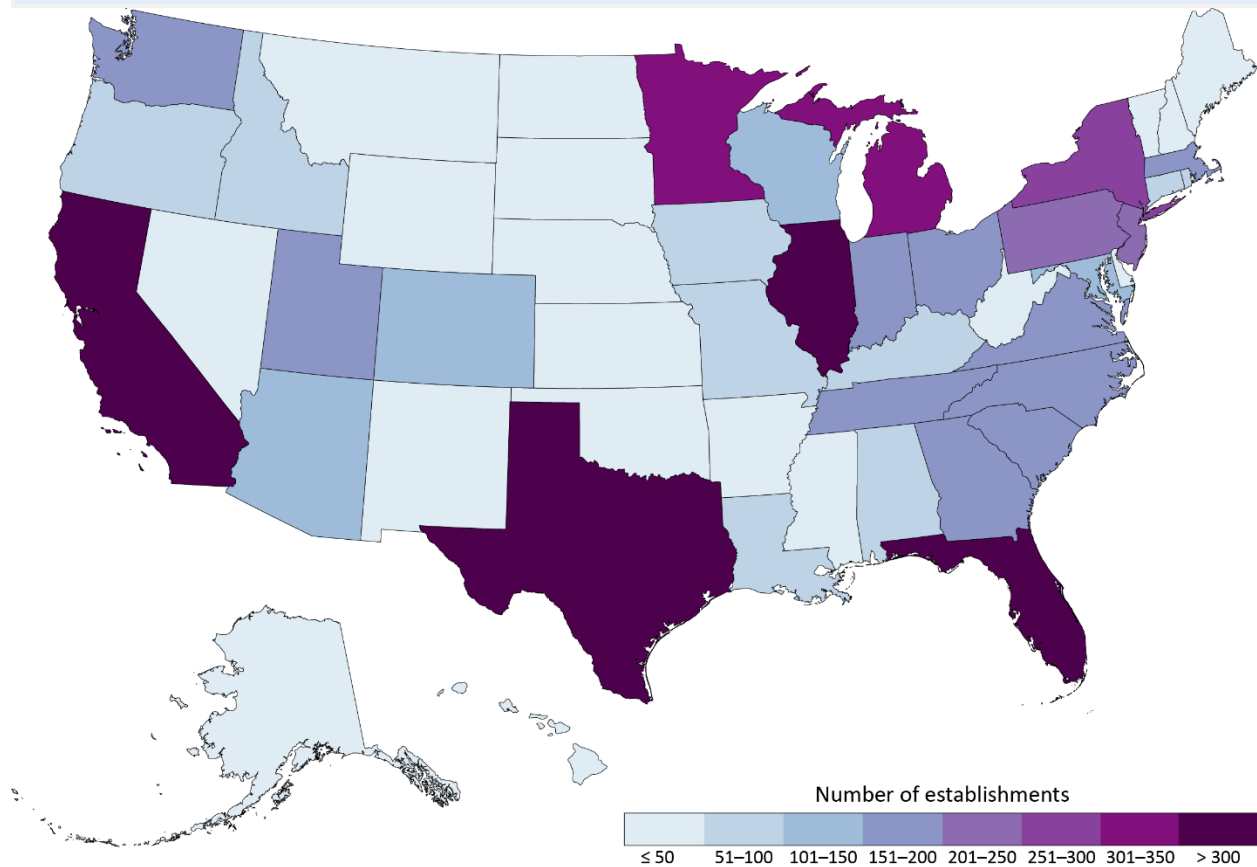
<sup>114</sup> Leading foreign-headquartered medical device firms with U.S. operations include Alcon (Switzerland), B. Braun Medical (Germany), Canon Medical Systems (Japan), EssilorLuxottica (France), Fresenius (Germany), Hitachi Healthcare (Japan), Hoya Vision (Japan), Olympus (Japan), Philips Healthcare (Netherlands), Siemens Healthineers (Germany), Smith & Nephew (United Kingdom), Smith & Nephew (United Kingdom), Sonova (Switzerland), and Terumo Medical (and Terumo Medical (Japan). MPO, “The 2020 Top Global Medical Device Companies,” July 21, 2020.

<sup>115</sup> BLS, Quarterly Census of Employment and Wages, 2019 average (accessed October 2020).

<sup>116</sup> Curran, *Medical Device Manufacturing*, August 2020, 26; MPO, “A Snapshot of the Hottest U.S. Medical Device Regions,” May 1, 2019.

The rest of the top 10 states with medical device establishments are Florida, Illinois, Massachusetts, Michigan, Minnesota, New Jersey, New York, Pennsylvania, and Texas.<sup>117</sup>

**Figure 3.1** Geographical distribution of establishments, medical device manufacturing, first quarter 2020



Source: Bureau of Labor Statistics (BLS), Quarterly Census of Employment and Wages, first quarter 2020, NAICS 334510, 334517, 339112, and 339113 (accessed October 2020).

Note: An establishment is “a single physical location at which business is conducted or services or industrial operations are performed.” Census Bureau, “Glossary” (accessed August 13, 2020). Underlying data for this figure can be found in [appendix table E.3](#).

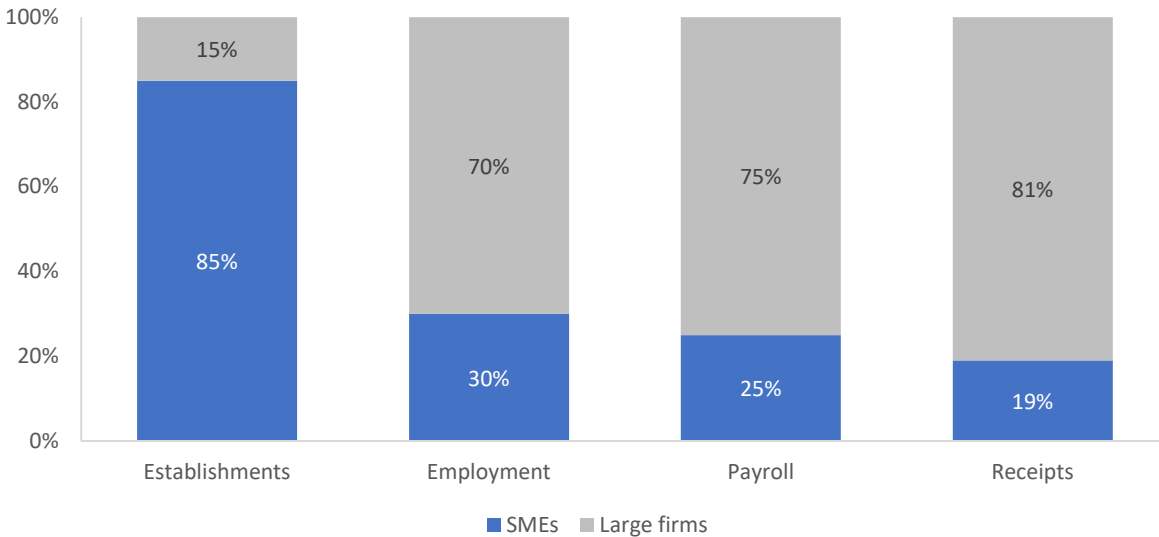
Most U.S. medical device manufacturers are small and medium-sized enterprises (SMEs) with fewer than 500 employees. Nevertheless, large firms account for more than 80 percent of receipts from sales and 70 percent of industry employment (figure 3.2). This reflects the significant role of large firms in the global industry. In 2019, the top 30 global medical device producers accounted for about two-thirds of the industry’s global sales.<sup>118</sup> Nonetheless, SMEs are an important source of intellectual property-based technological innovation in specific therapeutic areas. The medical device industry is characterized by frequent mergers and acquisitions: as new products are a key driver of industry sales, larger firms often acquire SMEs to acquire new intellectual property and expand their product lines. Larger firms are also better positioned to carry out the R&D necessary to bring new products to market, and they have long-

<sup>117</sup> BLS, Quarterly Census of Employment and Wages, 2019 average (accessed October 2019).

<sup>118</sup> MPO, “The 2020 Top Global Medical Device Companies,” July 21, 2020; Business Research Company, *Medical Devices Global Market Opportunities and Strategies*, July 2020.

established sales relationships with healthcare providers and GPOs. The United States is a slow-growth market for medical devices, with medical device prices held in check by long-term contracts and the pricing leverage held by GPOs.<sup>119</sup>

**Figure 3.2** Medical device establishments, employment, payroll, and receipts, by enterprise size, 2017 (in percent)



Source: Statistics of U.S. Businesses data from the Census Bureau, NAICS 334510, 334517, 339112, and 339113 (accessed October 2020).

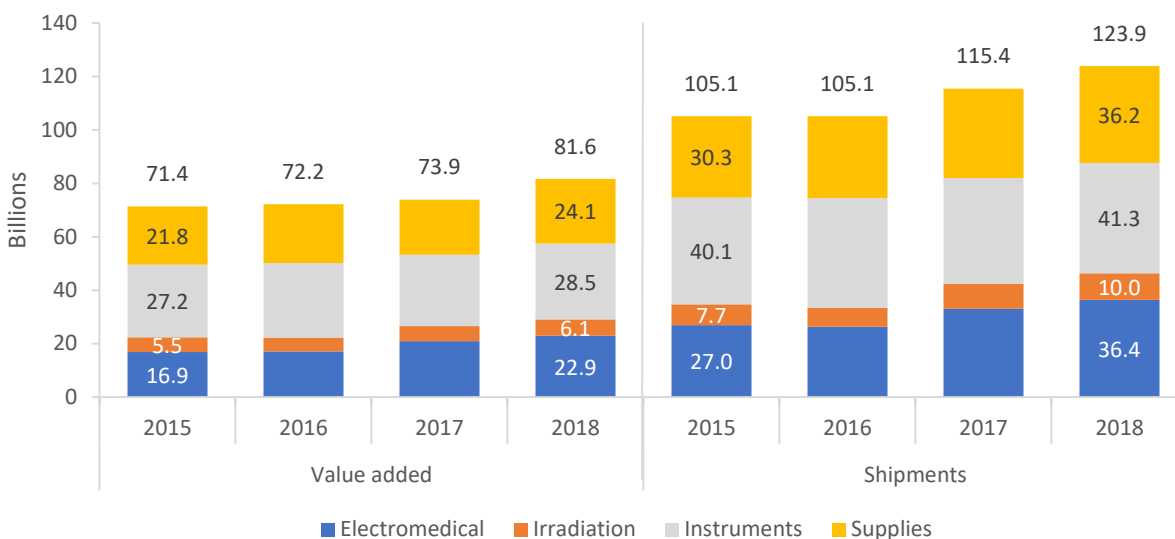
Note: Data for receipts are preliminary data. "Receipts (net of taxes collected from customers or clients) are defined as operating revenue for goods produced or distributed, or for services provided." Business size is based on the size of the enterprise. "An enterprise (or 'company') is a business organization consisting of one or more domestic establishments that were specified under common ownership or control." For more information, see Census, "Glossary" (accessed August 13, 2020). Underlying data for this figure can be found in [appendix table E.4](#).

## U.S. Production

Before the pandemic, U.S. manufacturing value added and shipments of medical devices moderately increased from 2015 to 2018. Manufacturing value added expanded by 14.4 percent during the period. Value added in the largest category, medical instruments, rose slightly from \$27.2 billion in 2015 to \$28.5 billion in 2018, and was outpaced by increases in value added for electromedical equipment and medical supplies. Medical device shipments grew by 17.9 percent during the period, led by shipments of electromedical equipment (e.g., dialysis machines and ventilators), which increased from \$27.0 billion in 2015 to \$36.4 billion in 2018, or by 35.1 percent (figure 3.3).

<sup>119</sup> Curran, *Medical Device Manufacturing*, August 2020, 12–13, 16, 22, 28, 32; MedPAC, "An Overview of the Medical Device Industry," June 2017, 209–11; Schnitzel, "Big Medical Device Companies," April 30, 2019.

**Figure 3.3** U.S. medical device shipments and value added, 2015–18 (in billion dollars)



Source: Annual Survey of Manufactures and Economic Census data from Census Bureau, NAICS 334510, 334517, 339112, and 339113 (accessed October 2020).  
 Note: Underlying data for this figure can be found in [appendix table E.5](#).

In line with broader U.S. industry production trends, capacity utilization and the number of plant hours per week for medical instruments and supplies firms fluctuated within a fairly consistent range from 2015 to 2019. However, capacity utilization fell substantially in the second quarter of 2020. The capacity utilization rate fell from 71.4 percent in the first quarter of 2020 to 64.1 percent in the second quarter, while average weekly plant hours fell from 59.8 to 50.7.<sup>120</sup> The 2020 second quarter decline reflected weak overall demand for medical device manufacturing. While demand for certain products used in the COVID-19 response substantially increased, this change was offset by weaker demand for other medical devices due to fewer elective procedures and reduced spending on non-COVID-19 related goods by hospitals and other purchasers.<sup>121</sup> Large global medical device companies such as Medtronic, Johnson & Johnson, and Abbott Laboratories reported large declines in medical device sales in the second quarter of 2020, including in the U.S. market.<sup>122</sup>

On March 14, 2020 the U.S. Surgeon General recommended that healthcare systems consider stopping elective procedures due to COVID-19. The Centers for Medicare and Medicaid Services (CMS) followed

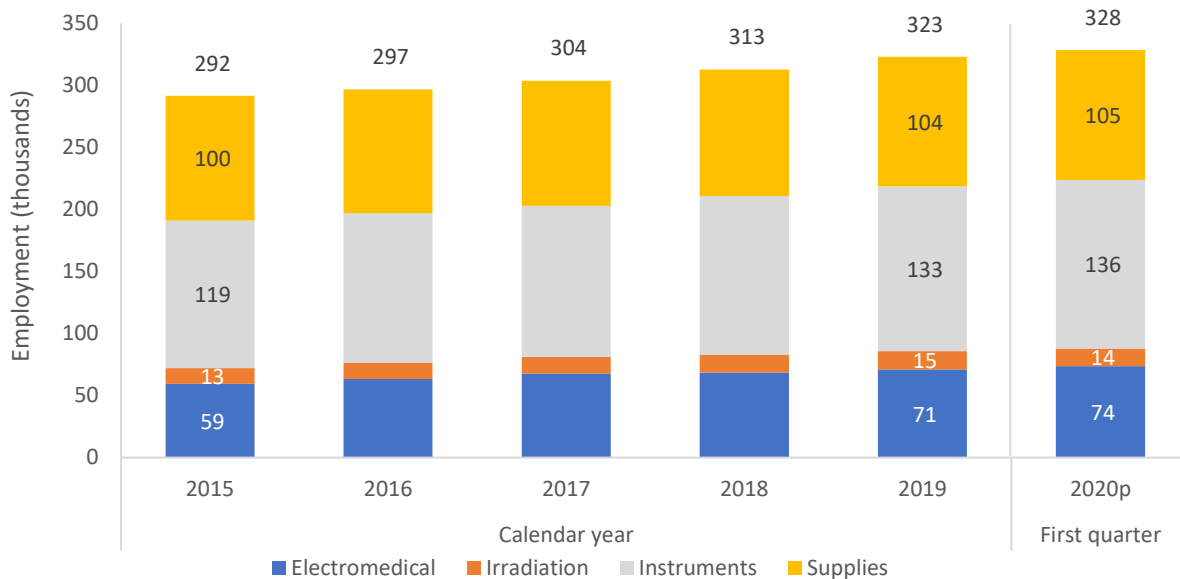
<sup>120</sup> Data are based on NAICS 3391, including dental and ophthalmic goods manufacturing that are not otherwise included in the data in this chapter; data do not include electromedical or irradiation apparatus manufacturing. Census, Quarterly Survey of Plant Capacity Utilization (accessed August–September 2020).  
<sup>121</sup> USITC hearing transcript, September 23, 2020, 35 (testimony of Nestor Jaramillo, CHF Solutions), 193 (testimony of Scott Paul, Alliance for American Manufacturing).  
<sup>122</sup> Abbott Laboratories, “Abbott Reports Second-Quarter 2020 Results,” July 16, 2020; Grant, “Medical Technology Stocks,” April 7, 2020; Johnson & Johnson, “2nd Quarter 2020 Results Presentation,” July 16, 2020; Johnson & Johnson, “Johnson & Johnson Reports 2020 Second-Quarter Results,” July 16, 2020; Medtronic, “Q1 FY21 Earnings Presentation,” August 25, 2020, 6; Medtronic, “Medtronic Reports Fourth Quarter and Fiscal Year 2020 Financial Results,” May 21, 2020; Medtronic, “Medtronic Reports First Quarter Financial Results,” August 25, 2020; “Siddhartha et al., “Reimagining Medtech,” April 22, 2020.

up with guidance to limit nonessential procedures to preserve resources, specifically noting issues with the availability of PPE, and to limit the exposure of patients and staff to COVID-19.<sup>123</sup> On the heels of these recommendations' states drafted and implemented their own directives on elective procedures.<sup>124</sup> The decline in elective procedures was also affected by hesitancy among patients to enter hospital settings. One survey conducted in June 2020 indicates that only 55 percent respondents would be willing to have surgery in a hospital if recommended by a physician.<sup>125</sup>

## U.S. Employment

U.S. employment in medical device manufacturing increased 11 percent from 2015 to 2019 (figure 3.4), reflecting the moderate increase in U.S. production. The largest percentage change in employment was in electromedical equipment manufacturing, the category that includes ventilators, which also accounted for the largest increase in production from 2015 to 2018.<sup>126</sup> Medical instrument manufacturing, the largest U.S. medical device industry in terms of shipments, accounted for the largest share of employment in 2019.

**Figure 3.4** U.S. employment, medical device manufacturing, 2015–19 and first quarter 2020 (in thousand employees)



Source: BLS, Quarterly Census of Employment and Wages, NAICS 334510, 334517, 339112, and 339113 (accessed August 2020).

Note: p=preliminary. These NAICS codes include most PPE; however, PPE is discussed separately in chapter 4. Underlying data for this figure can be found in [appendix table E.6](#).

<sup>123</sup> Nonessential or elective procedures included those performed in medical, surgical, and dental fields. CMS, “Non-emergent Elective,” April 7, 2020; Ambulatory Surgery Center Association, “State Guidance on Elective Surgeries,” updated April 20, 2020.

<sup>124</sup> Ambulatory Surgery Center Association, “State Guidance on Elective Surgeries,” updated April 20, 2020.

<sup>125</sup> Carmichael & Company, “Healthcare Consumers: A Changing Landscape,” June 2020.

<sup>126</sup> Census Bureau, Annual Survey of Manufactures and Economic Census data (accessed August 2020).

## U.S. Imports

In the years leading up to the pandemic, U.S. imports of medical devices rose 33 percent in 2015–19, from \$40.1 billion to \$53.3 billion, with the largest increase in imports of instruments (figure 3.5).<sup>127</sup> Imports of all categories of medical devices fell slightly in the first half of 2020 compared to 2019. Overall U.S. imports of medical devices fell 3 percent, from \$39.5 billion during January–September 2019 to \$38.6 billion during January–September 2020. Many factors contributed to this small decline in medical device imports in 2020. As discussed above, demand for non-COVID-19 related medical devices fell due to fewer elective procedures and lower spending on medical goods not specifically needed to treat COVID-19 patients.<sup>128</sup> Further, COVID-19 related population lockdowns abroad hindered manufacturing in some supplier countries.<sup>129</sup> Disruption of air- and ocean-going cargo shipments created transportation bottlenecks that slowed international freight deliveries. Some industry representatives stated that their dependence on China for medical goods and parts hindered their ability to source from abroad, but other industry representatives said China was not an important supplier for their operations.<sup>130</sup>

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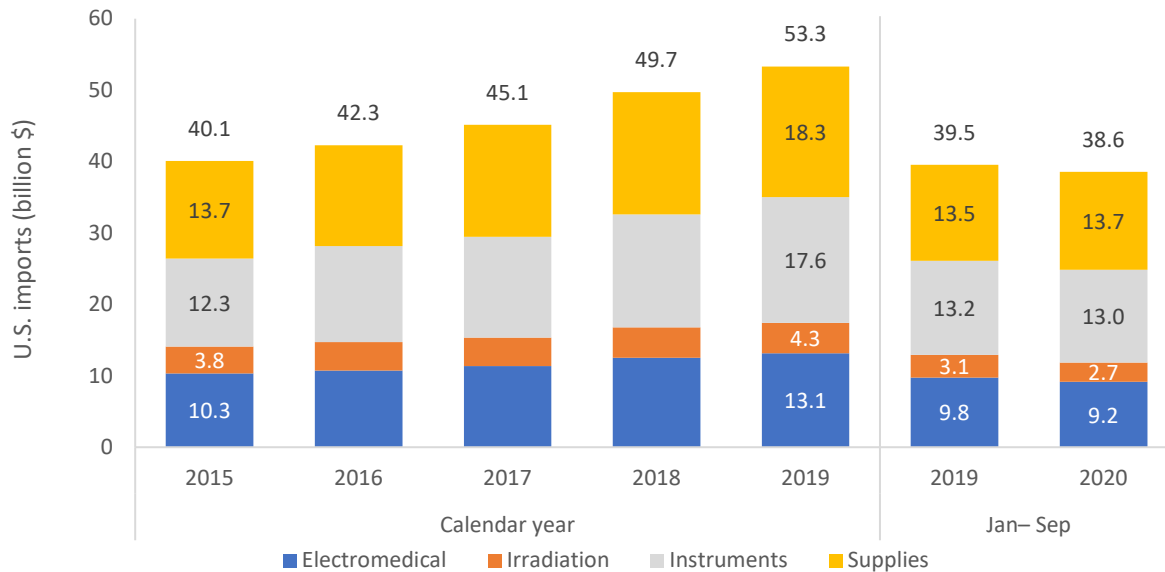
<sup>127</sup> Most medical devices enter the United States free of duty. Dutiable imports accounted for only 3.8 percent of the value of all U.S. medical device imports in 2019. Medical device industry representatives reported that certain medical goods and parts for medical devices imported from China needed to respond to COVID-19 were subject to section 301 duties. Many imports from other countries are eligible to enter duty free under the World Trade Organization’s (WTO) 1996 Information Technology Agreement (ITA) and the 2015 ITA expansion of duty-free treatment to certain high-tech goods, including some medical devices. WTO, “Trade in Medical Goods,” April 3, 2020, 8; WTO, “Information Technology Agreement,” accessed October 12, 2020; WTO, “20 Years of the Information Technology Agreement,” 2017, 61, 65; AdvaMed, “MedTech Industry Urges Additional Tariff Relief to Combat COVID-19,” April 29, 2020; Semiconductor Industry Association, submission to USTR, April 20, 2020.

<sup>128</sup> USITC hearing transcript, September 23, 2020, 35 (testimony of Nestor Jaramillo, CHF Solutions), 193 (testimony of Scott Paul, Alliance for American Manufacturing).

<sup>129</sup> AdvaMed, written submission to USITC, August 28, 2020, 11; USITC, hearing transcript, September 23, 2020, 20 (testimony of Abby Pratt, AdvaMed), 49, 78, 80 (testimony of Wesley Cline, Zurn Industries), 137 (testimony of Scott Paul, Alliance for American Manufacturing), 159 (testimony of Lori Wallach, Public Citizen); USITC, hearing transcript, September 24, 2020, 351 (testimony of Linda Rouse O’Neill, HIDA); industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>130</sup> AdvaMed, written submission to USITC, August 28, 2020, 7; USITC, hearing transcript, September 23, 2020, 19 (testimony of Abby Pratt, AdvaMed), 44, 97–98 (testimony of Daniel Glucksman, International Safety Equipment Association), 227 (testimony of Prashant Yadav, Center for Global Development); USITC, hearing transcript, September 24, 2020, 351 (testimony of Linda Rouse O’Neill, HIDA), 357, 427–28 (testimony of Michael Einhorn, Dealmed Medical Supplies), 368 (testimony of David Greer, Techman Sales), 380 (testimony of Robert M. Tobiassen, National Association of Beverage Importers).

**Figure 3.5** U.S. imports of medical devices, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)



Source: USITC DataWeb/USDOC, NAICS 334510, 334517, 339112, and 339113 (accessed November 2020).

Note: These NAICS codes include most PPE; however, PPE is discussed separately in chapter 4. Underlying data for this figure can be found in [appendix table E.7](#).

Mexico, Ireland, Germany, and China were the leading suppliers of medical devices to the U.S. market in 2019 (figure 3.6). Mexico, which accounted for the largest growth in the value of U.S. imports from 2015 to 2019, is an important and longstanding supplier of low-value finished goods, such as surgical equipment, and of parts such as certain electromechanical components for medical devices.<sup>131</sup> Ireland, another fast-growing import source, is an international low-tax jurisdiction that serves as global headquarters to many medical device firms. It is a hub for medical device-related R&D and high-tech manufacturing, typically focusing on the production of high-value intellectual property-based medical devices.<sup>132</sup> China remains a significant source of relatively low-value medical device equipment and parts.<sup>133</sup> However, China is also an increasing global source of medium- and high-tech devices.<sup>134</sup> Germany is Europe’s largest exporter of medical devices, and its R&D- and innovation-driven industry is

<sup>131</sup> USITC, hearing transcript, September 23, 2020, 198, 229 (testimony of Prashant Yadav, Center for Global Development); USITC, hearing transcript, September 24, 2020, 446–47 (testimony of Linda Rouse O’Neill, HIDA); Torsekar, “NAFTA and Medical Device Trade,” November 2017.

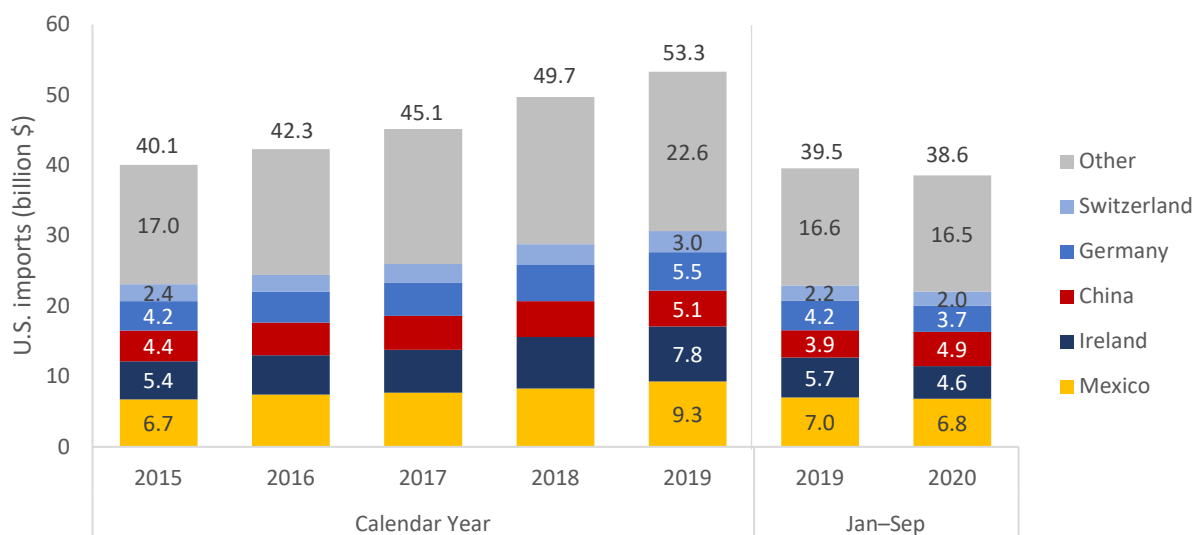
<sup>132</sup> In addition to Ireland-headquartered (but largely U.S.-based) Medtronic, many U.S.-headquartered firms and research institutions have R&D and production operations in Ireland. Hughes, “Made in Ireland: A Hub for Medtech,” November 15, 2019; Keena, “Ireland Second Only to Germany,” November 25, 2018.

<sup>133</sup> USITC, hearing transcript, September 23, 2020, 30, 98 (testimony of Joe Nadler, ArmouRx, Inc.), 53 (testimony of Daniel Glucksman, International Safety Equipment Association), 165 (testimony of Lori Wallach, Public Citizen); USITC, hearing transcript, September 24, 2020, 350 (testimony of Linda Rouse O’Neill, HIDA), 499 (testimony of Beth Hughes, American Apparel and Footwear Association).

<sup>134</sup> Curran, *Medical Device Manufacturing in the US*, August 2020, 13, 24; Torsekar, “China’s Changing Medical Device Exports,” January 2018.

a significant source of exports of machinery and components used to manufacture high-tech medical devices, such as machinery for making respirators and components for ultrafiltration equipment.<sup>135</sup>

**Figure 3.6** U.S. imports of medical devices, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)



Source: USITC DataWeb/USDOC, NAICS 334510, 334517, 339112, and 339113 (accessed November 2020).

Note: These NAICS codes include most PPE; however, PPE is discussed separately in chapter 4. Underlying data for this figure can be found in [appendix table E.8](#).

## U.S. Exports

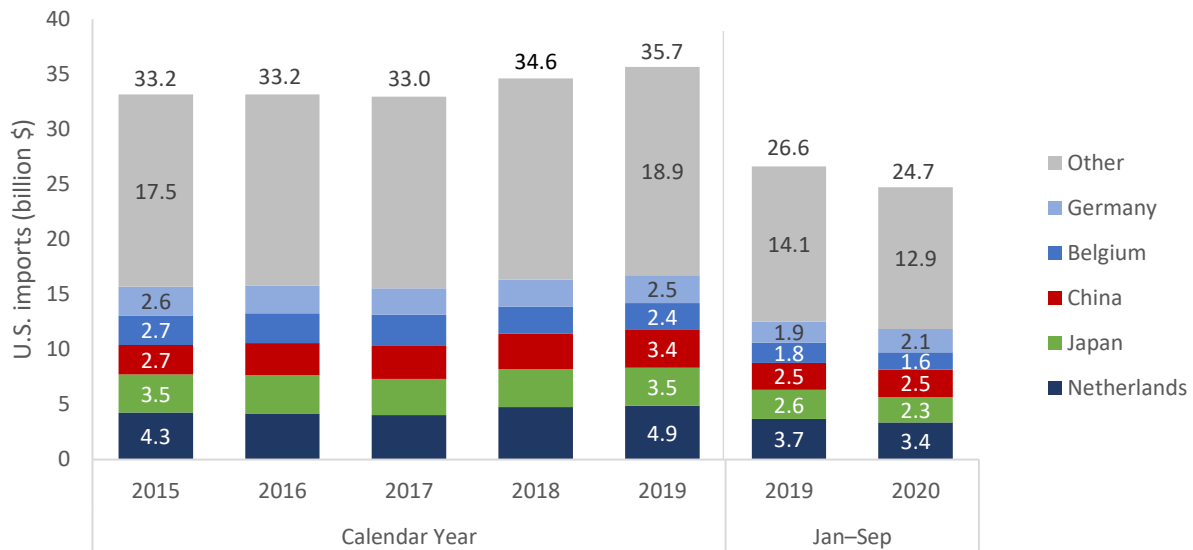
U.S. medical device exports increased from \$33.2 billion in 2015 to \$35.7 billion in 2019, then fell in the first three-quarters of 2020 compared to 2019 (figure 3.7). The main U.S. export markets for medical devices are Western Europe, Northeast Asia, and North America. China was the fastest-growing export market, with exports up \$716 million (27 percent) from 2015 to 2019.<sup>136</sup> Instruments ranked as the largest category of exports (accounting for 39.1 percent of exports in 2019), while irradiation apparatus ranked as the smallest (10 percent in 2019).

<sup>135</sup> USITC, hearing transcript, September 23, 2020, 43, 111 (testimony of Daniel Glucksman, International Safety Equipment Association), 127–28 (testimony of Nestor Jamarillo, CHF Solutions); USITC, hearing transcript, September 24, 2020, 574 (testimony of Dan Feibus, Vidalia Mills).

<sup>136</sup> USITC DataWeb/USDOC (accessed August 2020).



**Figure 3.7** U.S. exports of medical devices, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)



Source: USITC DataWeb/USDOC, NAICS 334510, 334517, 339112, and 339113 (accessed November 2020).

Note: These NAICS codes include most PPE; however, PPE is discussed separately in chapter 4. Underlying data for this figure can be found in [appendix table E.9](#).

## Ventilators

### Major Findings

- There was a sudden and dramatic increase in demand for ventilators during the early months of the COVID-19 pandemic, both in the United States and globally.
- The United States has a large domestic industry that assembles, tests, and oversees FDA certification for ventilators sold in the U.S. market.
- U.S. ventilator manufacturers were able to expand their internal production capacity but faced shortages of imported critical medical-grade components and inputs—some only available from sole-source suppliers. Further, transportation bottlenecks for inputs were significant impediments to domestic manufacturers.
- U.S. imports of finished ventilators were constrained by the fact that global demand significantly exceeded supply, that many foreign-made ventilators were not suitable for use in the U.S. market, and that severe reductions of air- and ocean-going transportation reduced the availability and increased the cost of international cargo transport to the United States.

### Introduction

By March 2020, U.S. health care professionals expressed significant concern over whether enough ventilators would be available to treat patients with COVID-19 related acute respiratory failure. With

widespread reports of surging demand, ventilator manufacturers worldwide swiftly worked to increase production.<sup>137</sup> Scaling up to meet this unprecedented increase in demand proved challenging, due to short-term constraints on sourcing certain imported inputs and transportation bottlenecks that resulted from disruption of air- and ocean-going cargo shipments.<sup>138</sup> However, industry sources reported that most of their parts-sourcing constraints were resolved by May 2020, and that by September 2020, U.S. ventilator supply and demand conditions had stabilized—reflecting increased production, improved hospital treatment regimens, and successful adaptation of other respiratory products and techniques.<sup>139</sup>

## Product Overview

Mechanical invasive ventilators (“ventilators”) are assisted-breathing devices used in hospitals, including in intensive care units (ICUs), and in other settings, such as nursing homes, emergency medical services, and individual homes. Ventilators can play an important role in treating patients with respiratory failure, a notable complication suffered by certain patients in severe cases of COVID-19.<sup>140</sup> Ventilators help patients breathe by generating pressure to blow air into the lungs; as needed, they can also help patients exhale and remove carbon dioxide from the lungs. Air flows through a flexible plastic tube inserted into an artificial airway created by inserting the tube through the mouth or nose and down the throat to the trachea (intubation), or incision in the neck directly into the trachea (tracheotomy/tracheostomy).<sup>141</sup> The ventilator assists with, or can take over, the breathing process while a patient’s lungs are unable to function. The ventilators generally described in this case study

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<sup>137</sup> AdvaMed, “Principles for Preparedness,” written submission to USITC, August 28, 2020, 5; Medtronic, “Correction: Medtronic Continuing,” March 18, 2020; FDA, “Medical Device Shortages,” September 24, 2020; HHS, “Optimizing Ventilator Use,” March 31, 2020; Ranney, Griffeth, and Jha, “Critical Supply Shortages,” April 30, 2020; Wells et al., “Projecting the Demand,” April 20, 2020.

<sup>138</sup> USITC, hearing transcript, September 23, 2020, 19 (testimony of Abby Pratt, AdvaMed), 227 (testimony of Prashant Yadev, Center for Global Development); industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>139</sup> Industry representatives, telephone interviews by USITC staff, September 14, 2020, and October 1, 2020; Kaiser Health News, “With Stockpile Full,” September 2, 2020; Medical Product Outsourcing, “HHS Terminates,” September 1, 2020; Stein, “HHS Terminating,” August 31, 2020.

<sup>140</sup> Unless otherwise specified, the term “ventilator” in this case study refers to mechanical invasive ventilators, which are often used in hospital ICUs. These ventilators provide the highest level of treatment for patients needing complex critical breathing care. This case study focuses on mechanical invasive ventilators since they were the primary device identified as in shortage by hospitals during the beginning of the pandemic. These ventilators were key to treatment protocols of patients with acute respiratory failure during the early days of the pandemic. Mechanical invasive ventilators also include portable units, such as those used by emergency medical services. Noninvasive ventilators are less complex mechanical ventilators that support a patient’s breathing by using a mask or mouthpiece, not intubation or a tracheotomy. Noninvasive ventilators include a variety of devices that can be used in hospital or home settings, particularly continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) devices used to treat breathing conditions such as sleep apnea. Some ventilators are both invasive and non-invasive devices and can be used in either mode. Non-mechanical ventilators, such as bag-valve-mouth resuscitators, are used as a stopgap measure to support breathing until patients can receive mechanical ventilation. Brochard, “Mechanical Ventilation,” 2003, 31–32; Edwards, “How Are Medical Ventilators Made?” (accessed October 20, 2020); Halpern and Tan, “United States Resource,” March 12, 2020; Rubinson et al., “Medical Ventilators,” 2010, 199–200; Siegel and Siemieniuk, “Acute Respiratory Distress,” June 17, 2020; industry representatives, telephone interview by USITC staff, September 14, 2020.

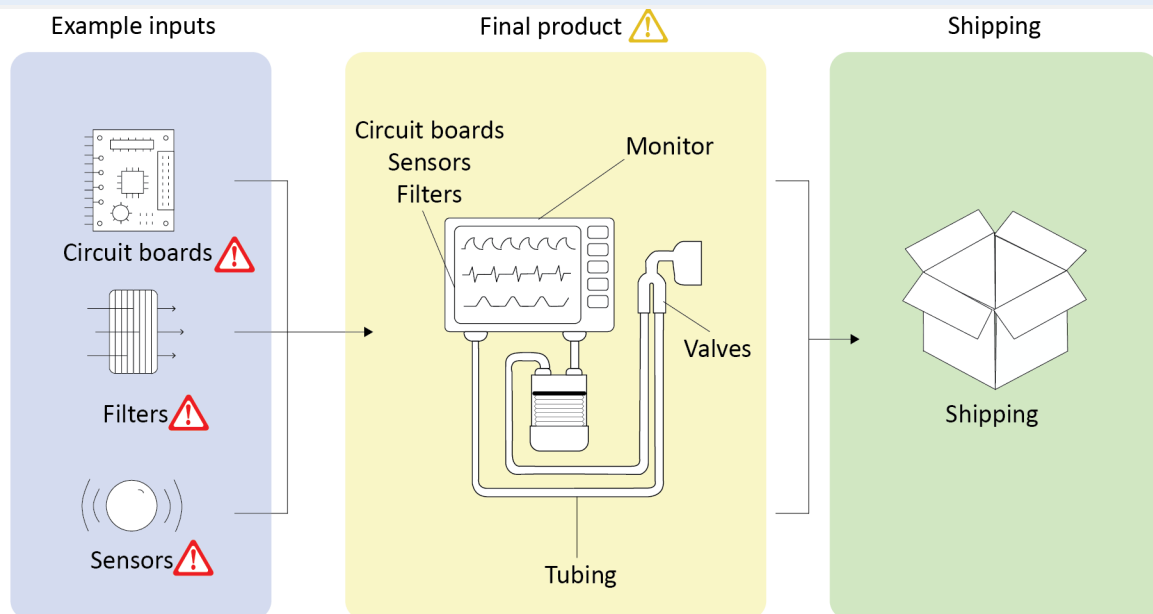
<sup>141</sup> IDSMed, “How Does a Ventilator Work?” January 23, 2019; Yale Medicine, “Tracheostomy,” 2020.

include highly configurable advanced instrumentation devices that allow medical staff to track dozens of breathing-related parameters based on patient needs.<sup>142</sup>

Ventilators are complex, software-controlled machines with some models containing over one thousand parts (figure 3.8). Ventilators are made up of discrete mechanical, electromechanical, electronic, and pneumatic components. These components manage functions such as control of inputs of electrical power and gas (air and oxygen), control of compressors that provide the pressurized gas flow, circuits that control and sequence delivery of gas to the patient, and patient monitoring systems. Select components include:

- The settings and monitoring components that regulate the volume, frequency, pressure, and oxygen levels delivered to the patient. They include circuit boards, semiconductors, alarms, sensors, and displays.
- The air-processing components that push air into the patient and capture exhaled air from the patient. They include humidifiers, valves for the air that flows to the patient, and filters to prevent contamination from entering the body.
- The air delivery components, such as tubes that connect the ventilator to the patient.<sup>143</sup>

**Figure 3.8** Ventilators: Identifying examples of key inputs and components that have caused supply chain challenges and constraints up through packaging



Source: Compiled by USITC staff.

Note: Red exclamation points indicate supply chain challenges and constraints, while yellow exclamation points represent less severe constraints.

<sup>142</sup> Noninvasive ventilators have fewer configuration and monitoring options but still treat patients' basic breathing needs. Rubinson et al., "Medical Ventilators in US Acute Care Hospitals," 2010, 199–200; Philips, "Philips Respironics V60 Ventilator" (accessed October 18, 2020).

<sup>143</sup> Edwards, "How Are Medical Ventilators Made?" (accessed October 20, 2020); Reuters, "Ventilators," April 22, 2020; WHO, "Ventilator, Intensive Care," 2011; Hess, Manaker, and Finlay, "The Ventilator Circuit," March 5, 2020; Medtronic, "Open Ventilator Self Service FAQ," 2020.

Ventilator manufacturers typically outsource the production of many device components and parts. Despite the complex and broad nature of ventilator supply chains, manufacturers reported they carefully control the sourcing of inputs, production, and distribution of their products.<sup>144</sup> Manufacturers must have their ventilators approved by FDA for use in the U.S. market. As discussed in more detail below, FDA responded to COVID-19 by issuing an umbrella emergency use authorization (EUA) in March 2020 that authorized the use of certain ventilators, ventilator tubing connectors, and ventilator accessories not approved in the United States.<sup>145</sup>

Ventilators have components and parts common to many modern industrial products, such as display monitors. For such components and parts, the ventilator industry makes up a small amount of total global demand. Industry sources reported that spikes in ventilator demand bring little risk of shortages or bottlenecks for these commonly used components and parts.<sup>146</sup>

Ventilators also have specialized parts, such as oxygenation membranes and certain medical-grade sensors and valves, and manufacturers reported they faced shortages of such parts immediately following the onset of the pandemic.<sup>147</sup> Many ventilator parts are specific to the manufacturer and are not standardized across the industry.<sup>148</sup> Even some common industrial components, like printed circuit boards, must be specially produced for ventilators, and only a fraction of circuit board manufacturers in the United States are capable of producing the medical-grade circuit boards ventilators use. Many of these specialized parts are produced by only a few firms, and some are even single-sourced due to proprietary technology, including components such as certain control sensors and valves that have been in short supply.<sup>149</sup>

These industry manufacturing patterns mean that ventilator production for the U.S. market involves complicated production processes and expansive global supply chains. Though there is significant domestic production of parts (as discussed below), ventilators often require parts from sources in

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<sup>144</sup> AdvaMed, written submission to USITC, August 28, 2020, 7; Benchhoff, “The Race to Build More Ventilators,” April 2, 2020; industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>145</sup> The FDA’s March 24, 2020, EUA authorized the use of certain devices and accessories that were not currently marketed in the United States or that had been modified in a way that normally would have triggered a new FDA approval process. These devices included certain ventilators, anesthesia gas machines modified for use as ventilators, positive pressure breathing devices modified for use as ventilators, ventilator tubing connectors, and certain ventilator accessories. FDA, “Coronavirus (COVID-19) Update: FDA Continues,” March 22, 2020; FDA, “Ventilators and Ventilator Accessories EUAs,” (November 13, 2020); FDA, “Ventilators and Ventilator Accessories,” March 2020; FDA, “Coronavirus (COVID-19) Update,” April 30, 2020. As noted in Chapter 1, EUAs are issued pursuant to FDCA § 564(b)(1), 21 U.S.C. § 360bbb-3(b)(1).

<sup>146</sup> AdvaMed, written submission to USITC, August 28, 2020, 7.

<sup>147</sup> USITC, hearing transcript, September 23, 2020, 19, 67 (testimony of Abby Pratt, AdvaMed); industry representative, telephone interview by USITC staff, September 14, 2020.

<sup>148</sup> Mirchandani, “Health Care Supply Chains,” August 18, 2020, 300–01.

<sup>149</sup> Among other things, ventilator circuit boards must meet the highest manufacturing standards for reliability and resistance to electronic interference from other electronic devices. Khan, “PCBs on the Medical Ventilator Frontlines,” April 27, 2020; Light, Mider, and Proper, “Ventilator Manufacturers Can Speed Up,” March 24, 2020; Royal Circuit Solutions, “Royal Circuits Producing Printed Circuit Boards,” May 4, 2020; Mirchandani, “Health Care Supply Chains,” August 18, 2020; industry representative, telephone interview by USITC staff, September 14, 2020; Yale School of Engineering and Applied Science, “Small but Critical Ventilator,” April 23, 2020.

multiple countries.<sup>150</sup> Production of ventilators in the United States consists largely of the final assembly and testing of the device’s functionality to ensure that the device meets FDA requirements.<sup>151</sup> Final assembly of ventilators may be further complicated by the need to use “clean rooms.”<sup>152</sup> In March 2020 FDA waived certain good manufacturing practice requirements with the aim of speeding the production of ventilators to respond to COVID-19.<sup>153</sup>

## U.S. Market

Ventilators provide respiratory support for patients in a variety of settings, including hospitals, nursing homes, long-term care facilities, and homes. Data available to the Commission indicate that the total number of ventilators in the United States, as of March 2020, included 77,000 ventilators in U.S. hospitals, 12,000 to 13,000 ventilators stored in the Strategic National Stockpile (SNS), and more than 8,000 ventilators in U.S. nursing homes.<sup>154</sup> Data on the number of ventilators in use in other applications in 2020, such as ventilators for home use or owned by emergency medical services, are not available. Ventilators have a typical lifespan of about 8 to 10 years.<sup>155</sup>

U.S. hospital demand for ventilators grew rapidly in March 2020 as COVID-19 began to spread more widely in the United States.<sup>156</sup> Hospitals, localities, and states all worked to significantly increase their ventilator procurement in anticipation of a surge in the number of patients thought to require this type of critical care. Some states ordered thousands of units, and some state governments reportedly competed among themselves for ventilator shipments.<sup>157</sup>

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<sup>150</sup> Medtronic, “COVID-19: It Takes A Village” (accessed November 13, 2020); industry representative, telephone interview by USITC staff, September 14, 2020.

<sup>151</sup> Industry representatives, telephone interviews by USITC staff, September 14 and October 1, 2020. For a general overview of the components of a ventilator, see Edwards, “How Are Medical Ventilators Made?” (accessed September 23, 2020).

<sup>152</sup> Used to produce certain medical goods, a clean room is a controlled environment that maintains high air quality, very clean surfaces and equipment, and strict standard sanitization practices for workers and, ultimately, patients. Philipp, “Why Cleanroom,” September 30, 2019; Price, “The Importance of Cleanrooms,” February 14, 2018.

<sup>153</sup> FDA, “Ventilators and Accessories for COVID-19,” April 27, 2020; FDA, “Enforcement Policy for Ventilators and Accessories,” March 2020.

<sup>154</sup> In March 2020, many states began self-reporting the number of ventilators within their state. USITC compiled these data from state websites and media reports. The data were available for 35 states and the District of Columbia, representing 88 percent of the U.S. population. For states where data were not available, USITC estimates are based on the number of ventilators per capita in all states for which data were available. A 2010 survey of U.S. hospitals yielded an estimate of 62,188 “full-feature mechanical ventilators” in U.S. hospitals. A report by the U.S. Center for Disease Control found there were 8,900 ventilators in the SNS in 2010. Rubinson et al., “Mechanical Ventilators,” 199–206; Faryon, “Nursing Homes,” April 7, 2020; Kobokovich, “Ventilator Stockpiling,” September 3, 2020, 1; Hsin-Chan Huang et al., “Stockpiling Ventilators,” June 2017.

<sup>155</sup> Grand View Research, “U.S. Mechanical Ventilators,” 2020,” 74.

<sup>156</sup> Ranney, Griffeth, and Jha, “Critical Supply Shortages,” April 30, 2020.

<sup>157</sup> National Governors Association, “Memorandum,” April 13, 2020; ABC News, “Competition Among State,” April 3, 2020; Cox, “Local Company Struggles,” August 3, 2020; Heim and Boulton, “Wisconsin Hospitals,” June 5, 2020; Kliff et al., “There Aren’t Enough,” March 18, 2020.

On April 1, 2020, the Federal Emergency Management Agency (FEMA) announced a process to distribute ventilators from the SNS to the states, given the perceived immediate need. By April 6, 2020, the U.S. Department of Health and Human Services (HHS) had distributed 4,400 ventilators to New York, 50 to Connecticut, 200 to Florida, 150 to Georgia, 30 to Guam, 450 to Illinois, 150 to Louisiana, 120 to Maryland, 400 to Michigan, 1,100 to New Jersey, 140 to Oregon, and 500 to Washington.<sup>158</sup>

The U.S. government ordered about 200,000 ventilators in the first half of 2020, many of them purchases by HHS for the SNS (table 3.2).<sup>159</sup> A large share of the HHS purchases were under the Defense Production Act (DPA) (box 3.1). In addition to HHS, agencies such as the Department of Defense and Department of Veterans Affairs made significant ventilator purchases in the first half of the year.<sup>160</sup> HHS ultimately terminated some of the initial ventilator contracts, however. In August 2020, Philips announced that HHS had terminated its DPA contract and that, as a result, Philips would only complete deliveries through August 2020. Philips supplied 12,300 ventilators of the initial 43,000 ventilator order.<sup>161</sup> On September 2, 2020, HHS announced the early termination of its contracts with Hamilton Medical and Vyair because the SNS had already reached its maximum capacity of nearly 120,000 ventilators.<sup>162</sup>

**Table 3.2** Selected HHS ventilator contracts, 2020

<b>Manufacturer(s)</b>	<b>Number of ventilators contracted and original delivery date(s)</b>
General Electric	2,410 by June 29, 2020
General Electric/Ford	50,000 by July 13, 2020
Hamilton Medical	25,574 by July 3, 2020
Medtronic	1,056 by June 22, 2020
Phillips Healthcare	2,500 by May 31, 2020
	40,800 by December 31, 2020
ResMed	2,550 by July 13, 2020
General Motors	30,000 by August 31, 2020
Vyair Medical/Spirit AeroSystems	22,000 by June 29, 2020
Zoll Medical	18,900 by July 3, 2020

Sources: HHS, “HHS Announces Ventilator Contract with GM,” April 8, 2020; HHS, “HHS Announces New Ventilator Contracts,” April 13, 2020; Moreno, “HHS: Ventilator Stockpile Is Full,” September 2, 2020; HHS, “HHS Announces Ventilator Contract with Philips,” April 8, 2020. Note: Table includes the following firms with foreign headquarters or parents: Hamilton Medical (Switzerland), Medtronic (Ireland), Philips Healthcare (Netherlands), Vyair (United Kingdom), and Zoll (Japan). Some firms may produce both invasive and non-invasive ventilators in the United States. Original delivery date is the date stated in the cited HHS news release.

<sup>158</sup> American Hospital Association, “FEMA Implements Ventilator Request Process,” April 1, 2020; U.S. House Committee on Oversight, “SNS PPE Distribution Report,” April 6, 2020.

<sup>159</sup> For some contracts, only the value of the contract is available and not the number of ventilators. HHS, “HHS Announces Ventilator Contract with GM,” April 8, 2020; HHS, “HHS Announces New Ventilator Contracts,” April 13, 2020; Moreno, “HHS: Ventilator Stockpile Is Full,” September 2, 2020; HHS, “HHS Announces Ventilator Contract,” April 16, 2020; HHS, “HHS Announces Ventilator Contract with Philips,” April 8, 2020; USASpending.gov Website (accessed November 18, 2020).

<sup>160</sup> USASpending.gov Website (accessed November 18, 2020).

<sup>161</sup> Biesecker, “HHS Canceling Ventilator Contracts,” September 2, 2020; HHS, “HHS Announces Ventilator Contract with Philips,” April 8, 2020; Philips, “Philips EV300 Ventilator Supply Contract,” August 31, 2020; Philips, “Philips and the U.S. Government Collaborate,” April 8, 2020; Stein et al., “U.S. Will Have Enough Ventilators,” September 4, 2020.

<sup>162</sup> AdvaMed, “Principles for Preparedness,” written submission to USITC, August 28, 2020, 17; Biesecker, “HHS Canceling Ventilator Contracts,” September 2, 2020; Slabodkin, “HHS Terminates Hamilton, Vyair Ventilator Contracts,” September 2, 2020; Whooley, “HHS Ends More Ventilator Contracts,” September 2, 2020.

**Box 3.1** Use of the Defense Production Act (DPA) for U.S. ventilator production

DPA provides the President authority to expedite and expand the supply of materials and services from the U.S. industrial base in response to certain critical national needs.<sup>a</sup> On March 13, 2020, the President declared a national emergency with respect to COVID-19.<sup>b</sup> On March 18, 2020, the President issued an executive order giving the U.S. Department of Health and Human Services (HHS) use of his authority “to determine, in consultation with the Secretary of Commerce and the heads of other executive departments and agencies as appropriate, the proper nationwide priorities and allocation of all health and medical resources, including controlling the distribution of such materials (including applicable services) in the civilian market, for responding to the spread of COVID-19 within the United States.”<sup>c</sup> In light of the massive spike in demand for ventilators due to COVID-19, the President invoked DPA on March 27, 2020, to require automaker GM to “accept, perform, and prioritize” contracts with HHS for ventilators.<sup>d</sup> The President again invoked DPA on April 2, 2020, to facilitate the supply of materials to specific firms to aid domestic ventilator production.<sup>e</sup> Using its authority under DPA, HHS contracted with a number of U.S. manufacturers to produce ventilators for the SNS.<sup>f</sup>

<sup>a</sup> The Defense Production Act of 1950, as amended (DPA), 50 U.S.C. §§ 4501 et seq; FEMA, “Defense Production Act,” July 30, 2020.

<sup>b</sup> Proclamation No. 9994, 85 Fed. Reg. 15337 (March 18, 2020).

<sup>c</sup> Executive Order 13909 of March 18, 2020, 85 Fed. Reg. 16222 (March 23, 2020).

<sup>d</sup> There is a substantial amount of synergy between medical device and automotive manufacturing. Production and assembly for both require highly skilled labor to work with and assemble the advanced electronic components, and controlled manufacturing environments that maintain the quality of the air and the cleanliness of surfaces and equipment. Both use automated manufacturing production processes to achieve detailed and high-precision products, although ventilator production is more manual than the highly automated automotive assembly process. Albergotti and Siddiqui, “Ford and GM,” April 4, 2020; Clough, “Trump’s Ventilator Demands,” March 27, 2020; Ulrich, “Automakers Pivot to Produce,” April 1, 2020.; White House, “Memorandum on Order,” March 27, 2020.

<sup>e</sup> White House, “Memorandum on Order,” April 2, 2020; White House, “Statement from the President,” April 2, 2020.

<sup>f</sup> Not all government ventilator contracts were under the DPA. HHS, “HHS Announces New Ventilator Contracts,” April 13, 2020.

## U.S. Manufacturing Industry

### Finished Ventilators

U.S. ventilator manufacturers in 2019 included a mix of large U.S. and foreign-headquartered multinational firms, each with thousands of U.S. employees, and small domestic SMEs with less than 500 employees. U.S. ventilator production before the pandemic was more than 800 ventilators per week. A significant portion of production, on a unit basis, was portable ventilators, such as those used by emergency medical services. The U.S. industry also produces high-end devices for ICUs.<sup>163</sup> Identified U.S. ventilator manufacturers, as of 2019, and their U.S. production locations are shown in table 3.3. Employment at these plants totals more than 3,000.<sup>164</sup>

<sup>163</sup> Information on the types of ventilators produced in the United States is based on a review of company websites. AdvaMed, written submission to USITC, August 28, 2020, 17; Soderstrom, “Coronavirus: Local Manufacturer,” April 10, 2020; Twedt, “Murrysville-based Philips,” March 31, 2020; McFadden et al., “A Small Seattle Firm,” March 17, 2020; WHDH, “Chelmsford Manufacturing Company,” March 23, 2020; Asplund, “Local Ventilator Maker,” March 30, 2020.

<sup>164</sup> These data were compiled in September 2020 and may not include all increases in plant employment at the height of production in 2020. Manufacturers News Inc., IndustrySelect database, <https://www.industryselect.com> (accessed September 4, 2020) and publicly available data sources.

**Table 3.3** Identified ventilator manufacturers in the United States, 2019

Manufacturer	U.S. production location(s)
Airon	Melbourne, FL
GE Healthcare	Madison, WI
Philips Healthcare	Carlsbad, CA; Murrysville, PA
Ventec Life Systems	Bothell, WA
Vyaire Medical	Palm Springs, CA
Zoll Medical	Chelmsford, MA

Sources: Soderstrom, “Coronavirus: Local Manufacturer,” April 10, 2020; Twedt, “Murrysville-based Philips,” March 31, 2020; Noon and Merrick, “All Hands on Deck,” March 26, 2020; WHDH, “Chelmsford Manufacturing Company,” March 23, 2020; McFadden et al., “A Small Seattle Firm,” March 17, 2020; Vyaire Medical, “Vyaire Announces HHS Contract,” April 16, 2020; Philips, “Philips Details Plans,” April 14, 2020. Note: This table includes three firms with foreign headquarters or foreign parents: Philips Healthcare (Netherlands), Vyaire Medical (United Kingdom), and Zoll Medical (Japan). Philips started production of a new ventilator model at a plant in New Kensington, PA in 2020.

The domestic industry responded to the urgent need for ventilators early in the pandemic by quickly ramping up production.<sup>165</sup> AdvaMed members, for example, reported a combined 600 to 900 percent increase in weekly ventilator production in the second quarter of 2020.<sup>166</sup> Manufacturers added workers, increased work hours, increased the number of shifts (including moving to 24/7 production), added production lines, and invested in new equipment.<sup>167</sup> To supplement their existing production capacity some firms engaged contract manufacturers.<sup>168</sup>

The urgency of the pandemic, government ventilator purchases, and the use of the DPA, also spurred new partnerships and production arrangements.<sup>169</sup> These partnerships to produce ventilators during the pandemic included the following:

- In March 2020, GE Healthcare announced a partnership with automaker Ford to manufacture a simplified design of an FDA-cleared life support device by manufacturer Airon at Ford’s facility in Ypsilanti, Michigan. Airon licensed its pNeuton Model A ventilator design to GE Healthcare for the contract. Their goal was to produce 50,000 ventilators for the SNS by July under the contract, and potentially produce 30,000 ventilators per month as needed thereafter. By September 2020, press reports indicate that the companies had completed delivery of their 50,000 contracted ventilators.<sup>170</sup>
- Ventec Life Systems, which produces an FDA-approved critical care ventilator, partnered with automaker GM to deliver 30,000 ventilators to HHS. GM used its facility in Indiana to scale up

<sup>165</sup> Whooley, “GE Healthcare Quadruples,” March 27, 2020; NPR, “CEO Of Ventilator-Making Company,” March 18, 2020; Roy, “Philips to Up Hospital Ventilator Production,” April 15, 2020.

<sup>166</sup> AdvaMed, written submission to USITC, August 28, 2020, 17.

<sup>167</sup> Erdley, “Philips Respironics Hiring,” March 20, 2020; Twedt, “Murrysville-based,” March 31, 2020; Whooley, “GE Healthcare Quadruples,” March 27, 2020; Roy, “Philips to Up Hospital Ventilator Production,” April 15, 2020; WHDH, “Chelmsford Manufacturing Company,” March 23, 2020.

<sup>168</sup> Hale, “Philips Debuts,” April 14, 2020.

<sup>169</sup> See table 3.2 for a list of selected HHS ventilator contracts in 2020.

<sup>170</sup> According to Airon, its proprietary pneumatic technology does not require electricity or batteries and provides oxygen with pressure to keep the lungs open and assist breathing for critically ill patients. Airon, “Ford to Produce 50,000 Ventilators,” March 30, 2020; GE, “Teaming Up,” March 24, 2020; Airon, “Airon Corp Teams With Ford and GE Healthcare,” March 30, 2020; Korosec, “GM, Ford Wrap Up Ventilator Production,” September 1, 2020; Stein et al., “U.S. Will Have Enough Ventilators,” September 4, 2020; Wayland, “GE, Ford Sign \$336 Million Federal Contract,” April 16, 2020.



production of the Ventec ventilators. GM reported all 30,000 contracted ventilators were delivered to HHS by September 1, 2020.<sup>171</sup>

- Following the announcement of its contract to produce 25,574 ventilators for the SNS, Hamilton Medical started a new critical care ventilator production line in Nevada with assistance from GM. Press reports indicate that Hamilton Medical was expected to deliver 4,518 of the originally contracted ventilators before HHS’s early termination of the contract.<sup>172</sup>
- Vyaire announced a contract with HHS for 22,000 ventilators. Vyaire subsequently announced collaboration with Spirit AeroSystems, a manufacturer of aerostructures for commercial and defense aircraft. Spirit AeroSystems was to add its industrial capacity and large-scale manufacturing expertise to further accelerate ventilator production at Spirit’s Wichita facility, along with 700 of its employees. Press reports indicate that by the end of October 2020, Vyaire was expected to deliver 4,000 of the contracted ventilators before HHS’s early termination of the contract.<sup>173</sup>
- Medtronic partnered with Foxconn, a global electronics contract manufacturer, and initiated plans to produce 10,000 ventilators over 12 months at Foxconn’s facilities in Wisconsin. The two companies announced in June 2020 that Foxconn had successfully completed Medtronic’s regulatory and quality requirements necessary to begin manufacturing the ventilators.<sup>174</sup>

## Inputs

U.S. manufacturers supply a significant share of the components and parts used to produce ventilators in the United States, although some key components are imported, as discussed above.<sup>175</sup> To ramp up ventilator production, manufacturers expanded their supply chains in response to COVID-19 by bringing

<sup>171</sup> GM, “Ventec Life Systems and GM Partner,” March 27, 2020; Stein et al., “U.S. Will Have Enough Ventilators,” September 4, 2020.

<sup>172</sup> Hamilton Medical, “Hamilton Medical Announces,” April 14, 2020; Howard, “GM Quietly Helped,” July 3, 2020; Slabodkin, “HHS Terminates Hamilton, Vyaire Ventilator Contracts,” September 2, 2020; Stein et al., “U.S. Will Have Enough Ventilators,” September 4, 2020.

<sup>173</sup> FDA, “Ventilators and Ventilator Accessories” (accessed November 13, 2020); Slabodkin, “HHS Terminates Hamilton, Vyaire Ventilator Contracts,” September 2, 2020; Stein et al., “U.S. Will Have Enough Ventilators,” September 4, 2020; Vyaire, “Vyaire Announces HHS Contract,” April 16, 2020; Vyaire, “Vyaire Medical and Spirit,” May 4, 2020; Vyaire, “Vyaire Medical Begins,” May 5, 2020.

<sup>174</sup> In addition, Medtronic made the design specifications for the 2010 model of its Puritan Bennett 560 ventilator—a compact, lightweight, and portable device—publicly available to help boost ventilator production worldwide. The unit reportedly already sold in 35 countries at the time at an average selling price of under \$10,000. Medtronic made service manuals, design requirement documents, manufacturing documents, schematics, software code, and other information for the device publicly available on its website. The company reported that the device can be used for both adult and pediatric patients, and can be used in clinical, mobile transport, and home settings. Chesbrough, “To Recover Faster from Covid-19, Open Up,” April 16, 2020; Medtronic, “Medtronic Shares,” March 30, 2020; Medtronic, “Medtronic and Foxconn Partner,” June 18, 2020; Medtronic, “Medtronic Provides,” April 8, 2020; USITC, hearing transcript, September 23, 2020, 160 (testimony of Lori Wallach, Public Citizen).

<sup>175</sup> Industry representatives, telephone interview by USITC staff, September 14, 2020; Ferek, “GM Seeks Tariff Relief,” April 3, 2020.

in new suppliers for ventilator components and parts.<sup>176</sup> In addition, FDA's March 24, 2020 EUA temporarily relaxed certain policies and guidelines to allow automakers and part suppliers not usually part of medical goods supply chains to mobilize for manufacturing ventilators.<sup>177</sup>

## U.S. Imports

U.S. imports of ventilators and parts<sup>178</sup> averaged more than \$200 million annually during 2018–19.<sup>179</sup> In comparison, imports under the broader HTS subheading that includes ventilators as well as other ozone therapy, oxygen therapy, aerosol therapy, artificial respiration and other therapeutic respiration apparatus increased from \$2.4 billion in 2018 to \$2.7 billion in 2019. Imports of ventilators and parts accounted for only a small share of the broader subheading.<sup>180</sup> U.S. imports of ventilators and their parts in HTS 9019.20.00 enter duty free and are not subject to section 301 duties.

There are a number of major global ventilator manufacturers that supply the U.S. market from their foreign plants, such as Getinge (manufacturing in Sweden), Hamilton Medical (Switzerland), Medtronic (Ireland), Dräger (Germany), and ResMed (Australia). Imports from some of these companies include high-end ICU ventilator units.<sup>181</sup> Owing to the global footprint of many medical device companies, including U.S.-headquartered companies, U.S. imports of ventilator parts originate from many countries, although certain specialty components and parts may be sourced from just a few countries or even sole-sourced.<sup>182</sup>

U.S. imports in the broader HTS heading containing ventilators provides some insight into import trends in 2020. The large increase in imports overall and the significant increase in the value of products arriving by air freight indicates that ventilator imports likely started to significantly increase in April 2020 and remained at higher than normal levels through September 2020 (figure 3.9).<sup>183</sup>

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<sup>176</sup> Honda, "Honda Begins Making," April 30, 2020; Nielsen, "Traverse City Company," March 26, 2020.

<sup>177</sup> FDA, "Ventilators and Ventilator Accessories EUAs," March 24, 2020.

<sup>178</sup> U.S. imports of ventilators and parts are included in the same statistical reporting number of the Harmonized Tariff Schedule of the United States (HTS). As a result, unlike other case studies in the report, they will be discussed in the same section.

<sup>179</sup> Staff estimates based on proprietary records and official import statistics.

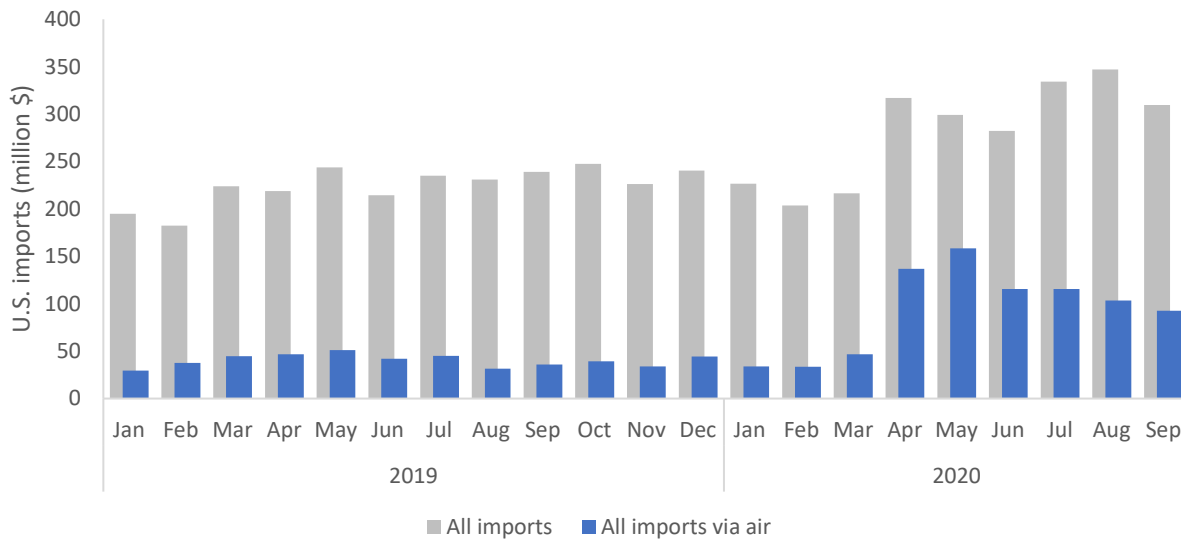
<sup>180</sup> USITC DataWeb/USDOC, HTS 9019.20 (accessed November 17, 2020).

<sup>181</sup> Hamilton Medical produced about 15,000 ventilators in 2019, Getinge produced about 10,000, and Medtronic produced around 8,000. Getinge, "Getinge Increases Production," March 17, 2020; Grand View Research, "U.S. Mechanical Ventilators," 2020, 92; Folmer, "Race Against Time," March 20, 2020; Trade Data Information Services Inc., Import Genius database (accessed September 6, 2020); Carswell, "Medtronic Aiming," April 6, 2020; Risher, "Ventilators Among Life-saving Gear," April 14, 2020; Dräger, "FAQ (Questions from Journalists)," July 2020; Roberts, "ResMed Delivers," April 21, 2020; ResMed, "Form 10-K," June 30, 2020, 34; USASpending.gov Website (accessed November 19, 2020).

<sup>182</sup> Industry representatives, telephone interview by USITC staff, September 14, 2020; Trade Data Information Services Inc., Import Genius database (accessed September 6, 2020).

<sup>183</sup> USITC DataWeb/USDOC, HTS 9019.20.0000 (accessed October 20, 2020); IHS Market, Global Trade Atlas database, HTS 9019.20.0000 (accessed November 2020).

**Figure 3.9** U.S. imports of ventilators and other goods in the broader HTS subheading, all transportation modes and air freight, January 2019–September 2020 (in million dollars)



Source: USITC DataWeb/USDOC, HTS 9019.20.00 (accessed November 2020); IHS Market, Global Trade Atlas database, HTS 9019.20.0000 (accessed November 2020).

Note: Underlying data for this figure can be found in [appendix table E.10](#).

## Supply Chain Challenges and Constraints

Several challenges and constraints hampered the ventilator supply chain throughout the course of the pandemic. U.S. ventilator manufacturers were able to expand their internal production capacity, but faced shortages of key inputs, some of which are only available from sole-source suppliers. Further, transportation bottlenecks for inputs were significant impediments to domestic manufacturers. U.S. imports of finished ventilators were constrained by the fact that global demand significantly exceeded supply, that many foreign-made ventilators were not suitable for use in the U.S. market, and that severe reductions of air- and ocean-going transportation reduced the availability and increased the cost of international cargo transport to the United States.

### Factors Affecting U.S. Production

#### Product to Market

Shortages of certain components were a challenge for some ventilator producers, who sole source some components and are locked into specific suppliers in the short term. Bringing a product to the market with components from a different supplier takes time, as design changes may be needed and the new components need to be tested.<sup>184</sup> Usually the producer would also need to schedule time to get FDA

<sup>184</sup> ResMed, “Form 10-K,” June 30, 2020, 29; industry representatives, telephone interview by USITC staff, September 14, 2020.

approval, but this approval was not necessary in the case of certain COVID-19 related devices subject to FDA’s umbrella EUA for ventilators, ventilator tubing connectors, and ventilator accessories.<sup>185</sup>

## Production and Delivery

The market for ventilators before the pandemic was relatively stable and small, due to the large, slow-growing U.S. market for medical devices. The sudden increase in demand for ventilators during the early months of the pandemic put a significant strain on the supply chains of domestic ventilator manufacturers. Many ventilator manufacturers were able to ramp up their production capacity relatively quickly, but not all suppliers could move with equal speed.<sup>186</sup> There were challenges in sourcing certain medical-grade parts, such as sensors, compressors, control valves, printed circuit boards, and battery cells. Several factors constrained the sourcing of these parts, particularly those from overseas. These included:

- **Shutdowns:** In some instances, when countries instituted shutdowns to reduce the spread of COVID-19, key supplier production facilities were also closed for some time.<sup>187</sup>
- **Export restrictions:** Export restrictions and procedures, such as customs inspections in China, delayed imports of key parts.<sup>188</sup>
- **Reduction in trans-oceanic cargo and higher air freight rates:** Ventilator manufacturers transport many parts by air, often on passenger flights, and with a reduction in passenger flights<sup>189</sup> and competition for limited capacity, it became more difficult to move parts. Air freight capacity constraints were particularly acute regarding any parts sourced from China and India. Early in the pandemic, this contraction of passenger air travel in and out of India and China created a bottleneck for parts like circuit boards.<sup>190</sup>

Production costs increased for some firms, as they had to modify their manufacturing facilities to prevent the spread of COVID-19—for example, by establishing separate or remote production lines. Providing PPE for employees and investing in other protective measures to lessen the chance of spreading the virus, like plexiglass dividers, also added to the production costs.<sup>191</sup>

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<sup>185</sup> FDA, “Ventilator Umbrella EUA Letter,” March 24, 2020.

<sup>186</sup> Industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>187</sup> Industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>188</sup> Mildner et al., “Export Controls and Export Bans,” April 29, 2020; industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>189</sup> Ocean freight is less commonly used in the shipment of finished medical devices like ventilators due to the cost of storing inventory with a just-in-time supply chain and manufacturing cycle times. Industry representatives, telephone interview by USITC staff, September 14 and October 1, 2020.

<sup>190</sup> USITC, hearing transcript, September 23, 2020, 19, 23–24 (testimony of Abby Pratt, AdvaMed), 227 (testimony of Prashant Yadev, Center for Global Development); USITC, hearing transcript, September 24, 2020, 368 (testimony of David Greer, Techman Sales), 380 (testimony of Robert M. Tobiassen, National Association of Beverage Importers); industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>191</sup> Industry representatives, telephone interview by USITC staff, September 14, 2020.

## Factors Affecting U.S. Imports

### Product Availability

The most significant factor affecting product availability was the substantial increase in global demand, coupled with the shortfall in global production capacity to meet that demand. As discussed above, the production of ventilators and other medical devices is based on efficiently managed global supply chains. Industry sources reported that their supply chains are resilient and capable of handling demand spikes associated with transitory healthcare crises, but COVID-19 caused an unprecedented demand surge beyond any reasonable industry forecast.<sup>192</sup> Individual country purchases in March 2020 alone amounted to a large share of typical annual production capacity. Germany, for example, purchased 16,000 ventilators in March 2020.<sup>193</sup> This strained not only ventilator assembly, but also the supply of parts. As with the U.S. industry, some foreign manufacturers rely on imports of components and at times had difficulty securing enough supplies in the early months of the pandemic.<sup>194</sup>

The high demand for ventilators led to reports of some fraudulent broker transactions, whereby sellers or brokers claimed to have access to such goods and, in some instances, asked for advance payment for them. Although such fraud was not limited to foreign countries, media reports identified multiple instances of such fraud related to China. These activities made it more difficult for U.S. purchasers to find and procure legitimate foreign-manufactured ventilators.<sup>195</sup>

### Market Entry and Acceptance

A significant volume of foreign-manufactured ventilators is not suitable for use in the U.S. market. For example, although there are a large number of ventilator manufacturers in China, few meet U.S. requirements or have gone through the process of securing FDA authorization or approval.<sup>196</sup> Further, some firms cannot produce ventilators that have the features or meet the quality requirements for use in ICUs in the United States. This was somewhat mitigated by EUAs, combined with successful

<sup>192</sup> AdvaMed, “Principles for Preparedness,” written submission to USITC, August 28, 2020, 5, 12.

<sup>193</sup> *The Economist*, “Companies Are Scrambling to Build More Ventilators,” March 19, 2020; Rowland, “More Lifesaving Ventilators Are Available,” March 18, 2020; Baldwin, “Ventilator Maker: We Can Ramp Up Production Five-Fold,” March 14, 2020; Miller and Pollina, “Army Joins the Production Line,” March 21, 2020.

<sup>194</sup> *The Economist*, “Companies Are Scrambling to Build More Ventilators,” March 19, 2020; He and Lu, “China Can’t Make,” April 10, 2020; Bloomberg, “China’s Factories Work 24/7,” March 23, 2020; Vanderklippe, “China’s Manufacturing Industry,” March 23, 2020; *Global Times*, “Chinese Ventilator Makers,” March 23, 2020; Yibing and Hao, “Chinese Ventilator Manufacturers,” April 9, 2020; industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>195</sup> The FBI noted that for ventilators and PPE, these “brokers and sellers included both domestic and foreign entities.” Shivers, “COVID-19 Fraud,” June 9, 2020; FBI, “FBI Warns,” April 13, 2020; HIDA, “What Happens When Brokers Get Involved?” written submission to USITC, October 7, 2020; Hong, “Ventilators in High Demand,” April 29, 2020; Walsh and Murphy, “Coronavirus: Face Masks, Ventilators,” May 20, 2020.

<sup>196</sup> Vanderklippe, “China’s Manufacturing Industry,” March 23, 2020; *Global Times*, “Chinese Ventilator Makers,” March 23, 2020; Ma, “China’s Ventilator Firms,” March 3, 2020; Yibing and Hao, “Chinese Ventilator Manufacturers,” April 9, 2020.

adaptation of other respiratory products and techniques, which brought more ventilators and other respiratory devices into the U.S. market.<sup>197</sup>

### Prices and Delivery Costs

Like with the sourcing of inputs, air freight constraints made it harder to import ventilators. With the onset of the pandemic, securing air cargo space became difficult as passenger travel declined.<sup>198</sup> As a result, shipping costs for ventilators, ventilator parts, and other related medical devices spiked in April compared to the previous month and stayed at high levels in May before dropping to a relatively normal level in June.<sup>199</sup>

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<sup>197</sup> Industry representatives, telephone interviews by USITC staff, September 14, 2020, and October 1, 2020; Kaiser Health News, “With Stockpile Full,” September 2, 2020; Medical Product Outsourcing, “HHS Terminates,” September 1, 2020; Stein, “HHS Terminating,” August 31, 2020.

<sup>198</sup> Supply Chain Dive, “Inside Ceva Logistics’ Approach” (accessed August 24, 2020). Industry representatives, telephone interview by USITC staff, September 14, 2020 and October 1, 2020; IHS Markit, Global Trade Atlas database (accessed October 20, 2020).

<sup>199</sup> IHS Markit, Global Trade Atlas database (accessed October 20, 2020); Supply Chain Dive, “Inside Ceva Logistics’ Approach” (accessed August 24, 2020); industry representatives, telephone interview by USITC staff, September 14, 2020 and October 1, 2020; USITC DataWeb/USDOC (accessed October 20, 2020).

# Chapter 4

## Personal Protective Equipment (PPE)

Personal protective equipment (PPE)—clothing and equipment worn to shield the wearer from injury or exposure to hazardous or infectious substances—is critical to protecting healthcare professionals, as well as workers in the construction, manufacturing, and mining industries.<sup>200</sup> The United States is both a domestic producer and an importer of PPE, with most imports (except rubber gloves) produced in China. In the spring of 2020, U.S. demand for PPE substantially increased as a result of the COVID-19 pandemic, outstripping the ability of both domestic and international suppliers to meet demand.<sup>201</sup> As a result, many healthcare facilities have been unable to maintain more than a few weeks’ worth of PPE supplies, far below the levels that some states recommend.<sup>202</sup> While a number of domestic firms increased or pivoted to start PPE production, as of the fall of 2020, demand remained high across almost all segments of PPE used in the response to COVID-19. For some products, PPE supply shortages continue to exist and are projected to continue well into the future.

U.S. PPE producers confront numerous supply chain challenges, including difficulty in acquiring sufficient inputs, particularly nonwoven fabrics (“nonwovens”) used in manufacturing N95 respirators, surgical masks, and medical gowns (see box 4.1, “Nonwovens,” at the end of the Overview section). Firms looking to increase capacity or enter the market face uncertainty over future PPE demand, which, coupled with a high cost of machinery, raises concerns on whether the investment will produce a sufficient return.<sup>203</sup> The U.S. supply chain for PPE is further constrained by obstacles faced by U.S. importers, which particularly center around product availability factors such as foreign export restrictions and global demand and supply imbalances. In addition, U.S. importers must contend with differences in quality and the possibility that the imported product will not meet U.S. standards.

The remainder of this chapter discusses the U.S. PPE industry and trade, with a focus on the period that includes full-year 2019 and January–September 2020. The first part of the chapter gives an overview of the U.S. PPE industry, with information on production, employment, and trade. It then offers three case studies on PPE products that were affected by significant shortages in the first half of 2020: (1) N95 respirators, (2) surgical and isolation gowns, and (3) medical and surgical gloves. Finally, the chapter presents a condensed case study on surgical masks.

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<sup>200</sup> PPE used in the response to COVID-19 is a subset of all PPE. Masters, “Personal Protective Equipment Manufacturing,” May 2020; Asian Development Bank, “Global Shortage of Personal Protective Equipment,” April 2020.

<sup>201</sup> Wan, “America is Running Short on Masks, Gowns,” July 8, 2020; Masters, “Personal Protective Equipment Manufacturing,” May 2020.

<sup>202</sup> Hufford, “Face Masks Are Again in Short Supply,” November 4, 2020. As of July 2020, the Department of Homeland Security reported that more than 25 percent of U.S. states had less than a 30-day supply of PPE. ISEA, written submission to USITC, October 2, 2020, 6; Allen, “Federal Stockpile is Thin Amid Coronavirus Surge,” July 14, 2020.

<sup>203</sup> Industry representative, telephone interview by USITC staff, October 7, 2020; Sparrow, “PPE Industry Experiences Turbulence in Wake of COVID-19,” July 13, 2020.

# Overview of the U.S. PPE Industry and Trade

## Introduction

The U.S. PPE industry includes products intended for industrial applications as well as healthcare applications. U.S. demand for PPE rapidly increased in 2020.<sup>204</sup> Industry sources estimate that 26 billion units of PPE were sold in the first half of 2020 through distributors, representing a 24 percent increase over the same period in 2019.<sup>205</sup> In addition to healthcare demand, as businesses and offices in many states prepared to reopen after the March 2020 lockdown, demand for PPE grew from nontraditional customers such as prisons, airlines, grocery stores, and the construction sector.<sup>206</sup> Moreover, there has been increased need for PPE to replenish and/or create stockpiles at the local and national levels to avoid a recurrence of the extreme shortages of PPE experienced in the spring of 2020.<sup>207</sup> The Commission estimates that U.S. healthcare demand for the PPE products covered by the case studies in this chapter—N95 respirators, surgical masks, surgical and isolation gowns, and medical and surgical gloves—totaled \$2.7 to \$3.0 billion in 2019.<sup>208</sup> There are a number of other critical PPE products used in healthcare and the response to COVID-19 that are not included in this estimate, including coveralls, other respirators, face shields, goggles, other eye protection, and the like that are also experiencing increased demand.<sup>209</sup>

Global production of PPE for healthcare use is characterized by high-volumes and low profit margins for PPE producers, with much of that production occurring in Asia.<sup>210</sup> There is limited U.S. production of certain major PPE products such as medical and surgical gloves, and surgical and isolation gowns, with imports dominating the U.S. market for these major PPE products.<sup>211</sup> However, U.S. producers have traditionally supplied a majority of the domestic market for other products, such as N95 respirators.

Given the low profit margins for PPE products, pricing is a significant factor affecting U.S. PPE demand and supply. U.S. healthcare facilities are highly cost-sensitive customers due to their low revenue

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<sup>204</sup> Wan, “America Is Running Short on Masks, Gowns and Gloves,” July 8, 2020.

<sup>205</sup> This does not represent the total increase in demand, as extensive purchases took place outside of the normal distribution channels in the first half of 2020. USITC, hearing transcript, September 24, 2020, 357 (testimony of Linda O’Neill, HIDA).

<sup>206</sup> Medline, written submission to USITC, September 14, 2020; Wan, “America is Running Short on Masks, Gowns,” July 8, 2020; Dall, “As Pandemic Rages, PPE supply Remains a Problem,” July 29, 2020; Finkenstadt, Handfiled, and Guinto, “Why the U.S. Still Has a Severe Shortage of Medical Supplies,” September 17, 2020.

<sup>207</sup> Industry representatives, interviews by USITC staff, September 28, 29, and 30, 2020.

<sup>208</sup> This market size estimate is based on the estimates presented in the individual case studies below. The size of the overall PPE market is substantially larger. For example, this estimate only includes the \$25 million in N95 respirators used in the healthcare sector in 2019, whereas the entire N95 respirator market was approximately \$600 million.

<sup>209</sup> MSA written submission to USITC, October 2, 2020; ISEA, written submission to USITC, October 2, 2020; AdvaMed, written submission to USITC, September 23, 2020; industry representatives, interviews by USITC staff, September 17 and October 6, 2020.

<sup>210</sup> AdvaMed, “Principles for Preparedness,” written submission to USITC, August 28, 2020, 8; Medline, written submission to USITC, September 14, 2020.

<sup>211</sup> USITC, hearing transcript, September 24, 2020, 357 (testimony of Michael Einhorn, Dealmed Medical Supplies); AdvaMed, written submission to USITC, August 24, 2020, 8; industry representative, telephone interview by USITC staff, September 30, 2020.



margins.<sup>212</sup> Most PPE purchases for healthcare are made directly by hospitals or are negotiated by group purchase organizations (GPOs) on behalf of hospitals. Purchases are made through distributors, who have long-term contracts with healthcare providers, guaranteeing steady prices for PPE.<sup>213</sup> Industry representatives stated that the U.S. medical reimbursement system incentivizes GPOs and distributors to contract with manufacturers offering the lowest prices.<sup>214</sup>

Healthcare providers also use just-in-time supply chains to keep their costs low, with distributors holding varying levels of inventory depending on the company and product.<sup>215</sup> In cases of public health emergencies, when demand for PPE surges, contracts between healthcare providers and distributors establish an allocation system that ensures healthcare providers receive a percentage of their historical PPE purchase volumes, while distributors are typically not permitted to sell to healthcare providers outside their current customer base.<sup>216</sup> Industry sources report that this type of purchasing system is designed to minimize hoarding and stabilize prices in times when PPE is in short supply.<sup>217</sup>

The pandemic caused demand for PPE to surge globally, quickly drawing down available inventories. Population lockdowns and factory closures worldwide in response to the pandemic disrupted PPE production and global shipments.<sup>218</sup> Industry sources indicated that the severity of shortages led to allocation levels never seen before, with the number of items on allocation peaking at over 10,000 items.<sup>219</sup> As of October 2020, one large medical distributor listed face masks, isolation and surgical

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<sup>212</sup> Healthcare facilities are reimbursed the same set price from insurance companies whether they purchase higher-priced, higher-quality U.S.-made PPE products or lower-cost imports. Healthcare providers' revenue margins were estimated to be a relatively low 8 percent for hospitals in 2019, which was the highest margin in decades. Gee, "The High Cost of Hospital Care," June 26, 2019; industry representative, telephone interview by USITC staff, September 30, 2020.

<sup>213</sup> Medline, written submission to USITC, September 14, 2020; industry representative, telephone interview by USITC staff, September 2, 2020.

<sup>214</sup> Medline, written submission to USITC, September 14, 2020; USITC, hearing transcript, September 23, 2020, 203 (testimony of Scott N. Paul, Alliance for American Manufacturing); industry representative, telephone interview by USITC staff, September 2, 2020. In regard to federal government procurement, industry representatives specifically cited the lack of Buy American provisions as a challenge for the domestic industry during COVID-19. See the statements submitted to the Commission by NCTO and Vidalia Mills in appendix D for additional information. Vidalia Mills, written submission to USITC, September 23, 2020, 2; NCTO, written submission to USITC, September 3, 2020, 2; Gilman, written testimony to the United States Senate Committee on Commerce, Science, and Transportation, November 17, 2020, 2.

<sup>215</sup> USITC, hearing transcript, September 24, 2020, 358–61, 395–96 (testimony of Michael Einhorn, DealMed Medical Supplies); September 24, 2020; industry representative, telephone interview by USITC staff, September 2, 2020; industry representative, telephone interview by USITC staff, October 2, 2020; O'Leary, "The Modern Supply Chain Is Snapping," March 19, 2020; Vinoski, "Post-COVID Supply Chain Changes," June 17, 2020.

<sup>216</sup> Medline, written submission to USITC, September 14, 2020; HIDA, written submission to USITC, "What Does 'Allocation' Mean," October 2, 2020.

<sup>217</sup> Medline, written submission to USITC, September 14, 2020; industry representative, telephone interview by USITC staff, September 2, 2020; Medline, written submission to USITC, "What Does Allocation Mean," October 7, 2020.

<sup>218</sup> CRS, "COVID-19: China Medical Supply Chains," October 8, 2020, 14; Johns Hopkins University of Medicine, "Hubei Timeline" (accessed November 6, 2020); WHO, "Modelling the Effects of Wuhan's Lockdown During COVID-19," May 28, 2020; WHO, "Report of the WHO-China Joint Mission," February 2020, 16; Ranney, Griffeth, and Jha, "Critical Supply Shortages," April 30, 2020; Xinhuanet, "Enterprises Producing Personal Protective Equipment," March 6, 2020.

<sup>219</sup> Industry representative, telephone interview by USITC staff, September 28, 2020.

gowns, and gloves, as well as other products, on its allocation list.<sup>220</sup> Another large medical distributor stated that many products, including PPE, are on allocation from the manufacturer and that product availability is “extremely volatile.”<sup>221</sup> Furthermore, industry representatives reported that brokers—who do not use long-term contracts—sold PPE outside of normal supply chains under short-term contracts, leading to substantially inflated prices and even some transactions unknowingly made for counterfeit products.<sup>222</sup>

The PPE industry is expansive and includes many products beyond what is urgently needed by healthcare professionals responding to COVID-19. The focus of this report is on PPE used specifically in the healthcare setting, which includes the most pertinent items used to fight COVID-19 (table 4.1). A wealth of qualitative evidence suggests that the healthcare-related PPE market is expanding in 2020, while the non-healthcare market (industrial PPE) is experiencing a decline of 3 to 6 percent due to the overall slowdown in the economy.<sup>223</sup> However, there is no consistent and recognized source that collects and makes available quantitative data on U.S. production or demand for this industry. Therefore, the Commission relied on multiple data sources to determine PPE trends from 2019 to 2020.

**Table 4.1** Personal protective equipment (PPE) industry coverage

NAPCS code		Description	Examples
2050375000		Manufacturing of personal safety equipment and clothing, industrial and nonindustrial	Respirators, masks, gloves, helmets, protective clothing, eye protection and goggles, face shields and masks
HTS for January 2019 to September 2020 data	HTS for July to September 2020 data	Description	Examples
3926.20.1010	3926.20.1010	Gloves, of various materials, disposable and non-disposable	Surgical and medical gloves
3926.20.1020	3926.20.1020		Seamless disposable gloves
4015.11.0110	4015.11.0110		Other seamless rubber gloves
4015.11.0150	4015.11.0150		Gloves impregnated or covered with plastics or rubber
4015.19.0510	4015.19.0510		
4015.19.0550	4015.19.0550		
4015.19.1010	4015.19.1010		
3926.20.9010	3926.20.9010	Aprons, of plastic and rubber	Protective aprons
4015.90.0010	4015.90.0010		
3926.20.9050	3926.20.9050	Other articles of apparel and clothing accessories, of plastic and vulcanized rubber other than hard rubber	Polyethylene isolation gowns
4015.90.0050	4015.90.0050		Plastic sleeve protectors Protective unisex garments

<sup>220</sup> Medline Industries, “Supply Access Update” (accessed November 8, 2020).

<sup>221</sup> Concordance Healthcare Solutions Website, “About” (accessed November 9, 2020).

<sup>222</sup> HIDA, written submission to USITC, “Building a More Robust Supply Chain,” September 2020; Medline, written submission to USITC, September 14, 2020; 3M, “Fraudulent Activity, Price Gouging, and Counterfeit Products,” May 18, 2020; industry representative, telephone interview by USITC staff, September 2, 2020.

<sup>223</sup> Brinkley, “Frost & Sullivan Presents the Unprecedented Opportunities in the Personal Protection Equipment Industry,” April 29, 2020; industry representative, telephone interview by USITC staff, October 7, 2020.

NAPCS code		Description	Examples
4818.50.0000	4818.50.0020	Certain articles of paper, including articles of apparel and clothing accessories	Hospital/medical gowns or scrubs
4818.50.0020			Paper shoe covers
4818.50.0080			
	4823.90.8620	Shoe covers	Shoe covers
6113.00.1012	6113.00.1012	Certain garments and apparel articles, of various materials	Unisex surgical gowns
6210.10.2000	6210.10.2000		Protective garments
6210.10.5000	6210.10.5000		Coveralls and overalls
6210.10.9010	6210.10.9010		Patient gowns
6210.10.9040	6210.10.9040		
6210.50.5555	6210.50.5555		
6211.42.1081	6211.42.1081		
6211.43.1091	6211.43.1091		
6307.90.9889 (part)	3926.90.9950	Masks, respirators, and face shields	N95 and other respirators
6307.90.9845	6307.90.9845		Powered air purifying respirators (PAPRs)
6307.90.9850	6307.90.9850		Reusable masks
6307.90.9870	6307.90.9870		Surgical and disposable masks
6307.90.9875	6307.90.9875		
9020.00.6000	9020.00.6000		
9020.00.9000	9020.00.9000		
6505.00.0100	6505.00.0100	Hair nets	Disposable hair nets

Sources: Census Bureau, "2017 NAPCS-Based Collection Code" (accessed December 4, 2020); USITC, *COVID-19 Related Goods: U.S. Imports and Tariffs*, June 2020.

Note: Product codes are from the North American Product Classification System (NAPCS) and the Harmonized Tariff Schedule of the United States (HTS). HTS subheadings are primarily the same as those defined as PPE in the Commission's June 2020 report, although they have been refined to better represent trade patterns in COVID-19 related PPE. In addition, a number of new statistical reporting numbers were added in July 2020 that are specific to COVID-19 related PPE, which allow more precise estimates of trade. For time series data from January 2019 through September 2020, both the PPE and non-PPE breakouts were retained to ensure data consistency. However, for respirators and masks the Commission used the new specific HTS data after July 2020 and an estimate of imports for the previous months. The value of imports each month prior to July 2020 was estimated based on Mexican and Taiwanese export data (which can be narrowed to certain COVID-19 related goods), official U.S. import statistics for air freight, shipping manifest data, and the average unit value of imports from trade statistics (which was used to convert import volumes to values).

## U.S. Industry

### Overview of the U.S. Industry and Employment

The U.S. industry produces a range of PPE products for healthcare applications, including N95 respirators, protective apparel, and surgical masks.<sup>224</sup> There were almost 300 establishments engaged in U.S. PPE production in 2017.<sup>225</sup> U.S. PPE manufacturing establishments employed more than 15,000

<sup>224</sup> Industry representatives, interviews by USITC staff, October 2 and 7, 2020.

<sup>225</sup> Census Bureau, Economic Census data (accessed December 4, 2020).

workers, according to data compiled as of September 2020.<sup>226</sup> The largest concentration of employment is in the South, followed by the Northeast, Midwest, and the West.<sup>227</sup>

The U.S. PPE industry comprises a mix of U.S. and foreign-based multinationals, and small and medium-sized enterprises (SMEs). Some of the large U.S. firms making PPE (such as 3M and Owens and Minor) are integrated along all parts of the supply chain, from the manufacture of raw materials to distribution to the end user.<sup>228</sup>

## U.S. Production

U.S. shipments of personal safety equipment and clothing (which includes major PPE products) totaled \$3.5 billion in 2017, the most recent year for which data are available.<sup>229</sup> There are no separate data on current U.S. PPE production specifically for the healthcare market. However, according to industry representatives, U.S. PPE production related to the healthcare segment vastly increased in 2020 in response to the pandemic, while PPE production related to industrial applications declined.<sup>230</sup>

Existing U.S. PPE manufacturers began ramping up production in order to meet surging domestic demand owing to the COVID-19 pandemic in the first half of 2020, leading to significant growth.<sup>231</sup> U.S. manufacturers added extra shifts, began running existing PPE production lines around the clock, and repurposed production lines for PPE production.<sup>232</sup> Further, the U.S. industry hired additional workers and has been retraining existing workers to focus exclusively on the development of PPE supplies.<sup>233</sup>

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<sup>226</sup> These data are based on a list of manufacturing plants identified as producing goods for each of the products covered in the case studies below, as well as a list of plants from Manufacturers News. The Manufacturers News data were filtered by industry code and the description of activities at the location. Therefore, although these data were downloaded in September 2020, they likely do not capture all of the firms that pivoted into PPE production in 2020 as their primary industry code would not have changed. For example, an automotive plant would remain classified as such, even after starting PPE production, and would not be captured in these data. Employment at each plant is based on data from several databases (including Manufacturers News, Dun & Bradstreet, Nexis Dossier, and Orbis), as well as publicly available information sources such as media reports. Manufacturers News Inc., IndustrySelect database, <https://www.industryselect.com> (accessed September 4, 2020); Nexis Dossier database (accessed various dates); Orbis database (accessed various dates); D&B Duns Market Identifiers Plus (US) database, Lexis Advance (accessed various dates), and data compiled from company Websites and media reports.

<sup>227</sup> Based on Census regions. Manufacturers News Inc., IndustrySelect database, <https://www.industryselect.com> (accessed September 4, 2020); Nexis Dossier database (accessed various dates); Orbis database (accessed various dates); D&B Duns Market Identifiers Plus (US) database; Lexis Advance (accessed various dates); data compiled from company Websites and media reports.

<sup>228</sup> Grandview Report, "Healthcare Personal Protective Equipment Market Size, Share & Trends," 2020; Dmitry, "Surgical Apparel Manufacturing," March 2020.

<sup>229</sup> U.S. shipments of personal safety equipment and clothing, industrial and nonindustrial, which does not include certain apparel items and medical and surgical gloves. Census Bureau, Economic Census data (accessed December 4, 2020).

<sup>230</sup> Masters, "Personal Protective Equipment Manufacturing," May 2020; Iyer, "Personal Protective Equipment Industry," May 13, 2020; Medline, written submission to USITC, September 14, 2020; industry representatives, telephone interview by USITC, October 7, 2020.

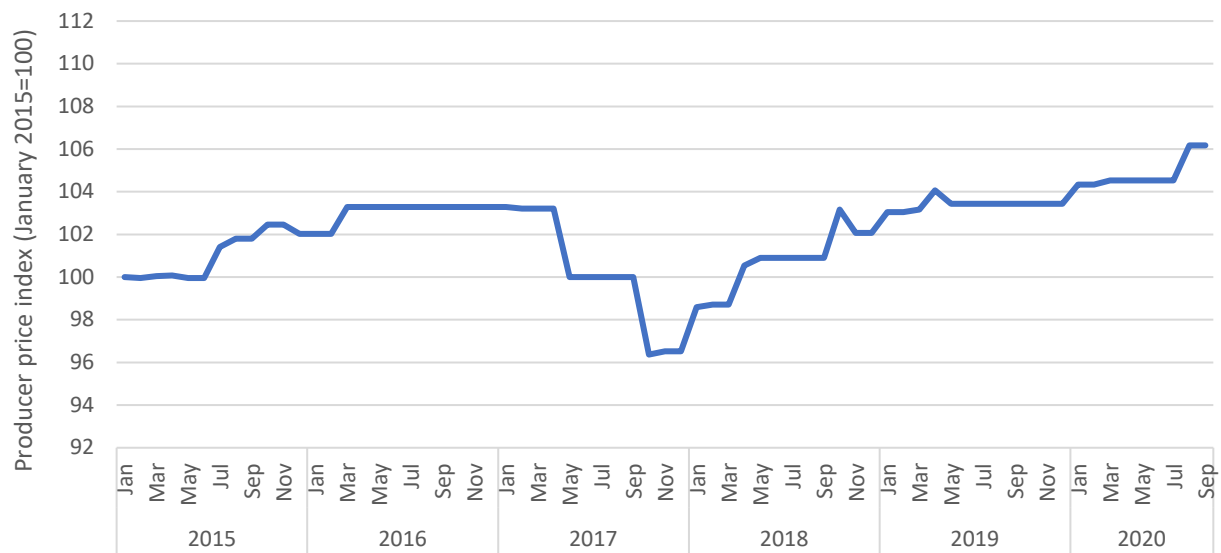
<sup>231</sup> Bhaskar, "Impact of COVID on Demand for PPE in the Healthcare Industry," April 2020; Masters, "Personal Protective Equipment Manufacturing," May 2020; Iyer, "Personal Protective Equipment Industry," May 13, 2020.

<sup>232</sup> AdvaMed, written submission to USITC, September 23, 2020.

<sup>233</sup> AdvaMed, written submission to USITC, September 23, 2020.

There have been widespread reports of price increases for PPE, but these have generally not been the result of U.S. producers raising their prices. The U.S. producer price index for personal safety equipment increased by less than 1 percent in January 2020 (compared to December 2019) and then remained relatively flat through July 2020 (figure 4.1). In August 2020, U.S. producers increased prices by an average of 1.6 percent.<sup>234</sup> These data support what numerous U.S. PPE manufacturers have said—that they are not changing prices in response to the COVID-19 pandemic (except with respect to increased raw material costs), and some continue to honor the prices cited in contracts concluded before the pandemic.<sup>235</sup> 3M, a U.S. multinational corporation that is a major manufacturer of respirators, stated that it would actively work to eliminate price gouging by resellers.<sup>236</sup>

**Figure 4.1** U.S. producer index for personal safety equipment and clothing, January 2015–September 2020 (Index, January 2015 = 100)



Source: BLS, Producer Price Indexes, Series Id WPU1571 (accessed November 8, 2020).

Note: Data for June–September 2020 are preliminary. Underlying data for this figure can be found in [appendix table E.11](#).

## U.S. Imports

U.S. imports of PPE reportedly surged in 2020 due to increased purchases from healthcare customers, nontraditional consumers (dental offices, first responders, schools, airlines, and grocery stores), and federal and state governments.<sup>237</sup> While precise data on PPE imports are not available, these trends are

<sup>234</sup> The producer price index measures the prices received by U.S. producers from the first point of sale and would not include any markups thereafter. BLS, Producer Price Indexes, Series Id WPU1571 (accessed November 8, 2020); SHOPP, Letter to All Post-Acute Care Provider Advocates from the Society of Healthcare Procurement Professionals, April 7, 2020.

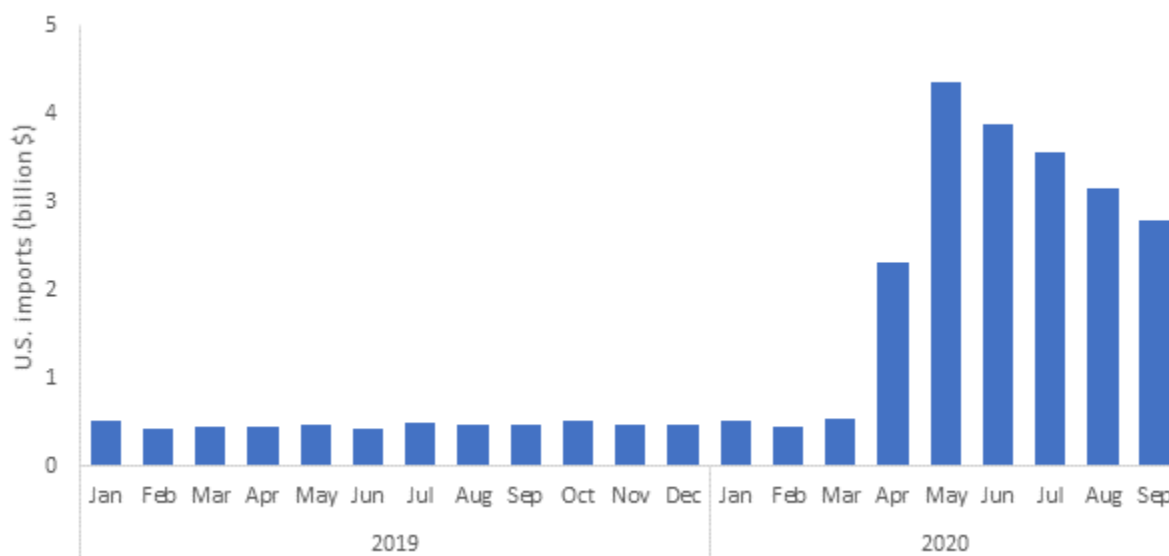
<sup>235</sup> Industry representative, telephone interview by USITC staff, September 30, 2020, October 2, 2020, and October 16, 2020; 3M, “3M Introduces Hotline,” March 31, 2020.

<sup>236</sup> 3M, “3M Introduces Hotline,” March 31, 2020; 3M, “Fighting Fraud and Counterfeit Activity” (accessed November 13, 2020).

<sup>237</sup> Medline, written submission to USITC, September 14, 2020; Wan, “America Is Running Short on Masks, Gowns and Gloves,” July 8, 2020; Dall, “As Pandemic Rages, PPE supply Remains a Problem,” July 29, 2020.

reflected in data that serve as a proxy for U.S. PPE import trends (figure 4.2).<sup>238</sup> These data indicate that U.S. imports started to significantly increase in April 2020, peaked in May, and then declined through September.<sup>239</sup> It is important to note, however, that these are value trends and not volume trends, and patterns of imports by volume in 2020 may have differed given the large fluctuations in prices, including significant price increases, reported by several industry representatives.<sup>240</sup>

**Figure 4.2** U.S. imports of selected PPE products (gloves, surgical and isolation gowns, other garments, masks, respirators, hair nets, and shoe covers), January 2019–September 2020



Source: Trade Data Information Services Inc., Import Genius database (accessed November 8, 2020); USITC DataWeb/USDOC (accessed November 8, 2020); IHS Global Trade Atlas database (accessed November 8, 2020); information compiled by USITC staff.  
 Note: See table 4.1 for additional information on HTS numbers and methodology.

The U.S. market relies heavily on PPE imports from a few foreign suppliers to meet demand for certain products, and this import reliance has continued during the pandemic.<sup>241</sup> Imports supply an estimated 80 to 90 percent of the U.S. PPE market directed toward healthcare applications, with imports primarily originating in China for certain major PPE products, including surgical masks and surgical and isolation gowns. Similarly, medical glove imports originate mainly in Malaysia.<sup>242</sup> N95 respirators, on the other hand, were mostly supplied by domestic production before the onset of the pandemic (see the N95 respirator case study in this chapter). Over the past two decades, cost pressures for healthcare providers

<sup>238</sup> See table 4.1 and the notes to the table for more information on the methodology and the HTS statistical reporting numbers used in this calculation.

<sup>239</sup> Trade Data Information Services Inc., Import Genius database (accessed November 8, 2020); USITC DataWeb/USDOC (accessed November 8, 2020); IHS Global Trade Atlas database (accessed November 8, 2020); information compiled by USITC staff.

<sup>240</sup> USITC, hearing transcript, September 23, 2020, 53 (testimony of Joe Nadler, ArmouRX, Inc.), 241 (testimony of Valerie Karplus, Carnegie Mellon University); USITC, hearing transcript, September 24, 2020, 358, 455 (testimony of Michael Einhorn, Dealmed Medical Supplies), 517 (testimony of Richard Renehan, Renco Corp.).

<sup>241</sup> Industry representatives, interviews by USITC staff, September 29 and 30, and October 2, 2020.

<sup>242</sup> Industry representatives, interviews by USITC staff, September 29 and 30, and October 2, 2020.

have led to a concentration of PPE production among the lowest-cost providers.<sup>243</sup> Foreign suppliers, mainly in Asia, are competitive in PPE production, given the abundant supply of low-cost labor within their countries.<sup>244</sup>

China is the largest supplier of U.S. PPE imports, providing 75 percent of imports in July–September 2020 (figure 4.3). Vietnam emerged in 2020 as a large PPE supplier to the United States, providing 6 percent of total PPE imports, up from 1 percent in 2019.<sup>245</sup> Vietnam responded early to contain the COVID-19 pandemic and fared better than many higher-income economies, and therefore had less demand for PPE in its own domestic market.<sup>246</sup> In addition, Vietnam is a leading apparel exporter and had an established manufacturing infrastructure in place, which facilitated pivoting to the manufacture of certain PPE goods.<sup>247</sup> The Vietnamese government collaborated with local businesses to ramp up PPE production for export, especially with respect to masks, gloves, hair covers, and gowns, and many of these products were ultimately shipped to the United States.<sup>248</sup>

Factory closures and lockdown restrictions in key supplier countries coupled with export restrictions and a disruption of air- and ocean-going cargo shipments made it more difficult and costly to import PPE. With the onset of the pandemic, supply was disrupted for some of the PPE imported from China because the initial outbreak of COVID-19 was concentrated in that country’s Hubei Province (where the city of Wuhan is located), the region housing both significant nonwoven fabric production as well as the largest concentration of global PPE producers.<sup>249</sup> Further, as described in chapter 2, a number of countries imposed export restrictions, and China implemented new rules that slowed or delayed the export of PPE. The pandemic also severely hampered international freight shipments. With the onset of the pandemic, securing air cargo space became difficult as passenger travel plummeted, the number of shipping containers in rotation declined, and costs for all modes of transportation (air, ocean, and ground) rose to exorbitant rates.<sup>250</sup> This had the effect of further squeezing already constrained supply lines and firms having to spend millions of dollars on shipping costs alone to secure needed supplies.<sup>251</sup>

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<sup>243</sup> Asian Development Bank, “Global Shortage of Personal Protective,” April 2020; Ishii, “Surgical Gowns Cost My Hospital 40 Cents Before the Pandemic,” July 29, 2020; Medline, written submission to USITC, September 14, 2020.

<sup>244</sup> Industry representatives, telephone interview by USITC staff, October 2, 2020.

<sup>245</sup> U.S. International Trade Commission, “COVID-19 Related Goods: U.S. Imports and Tariffs (Updated),” Investigation No. 332-576, June 2020.

<sup>246</sup> Delteil, Francois, and Nguyen “Emerging from the Pandemic,” July 1, 2020.

<sup>247</sup> Fibre2Fashion, “Vietnamese Garment Makers,” April 29, 2020.

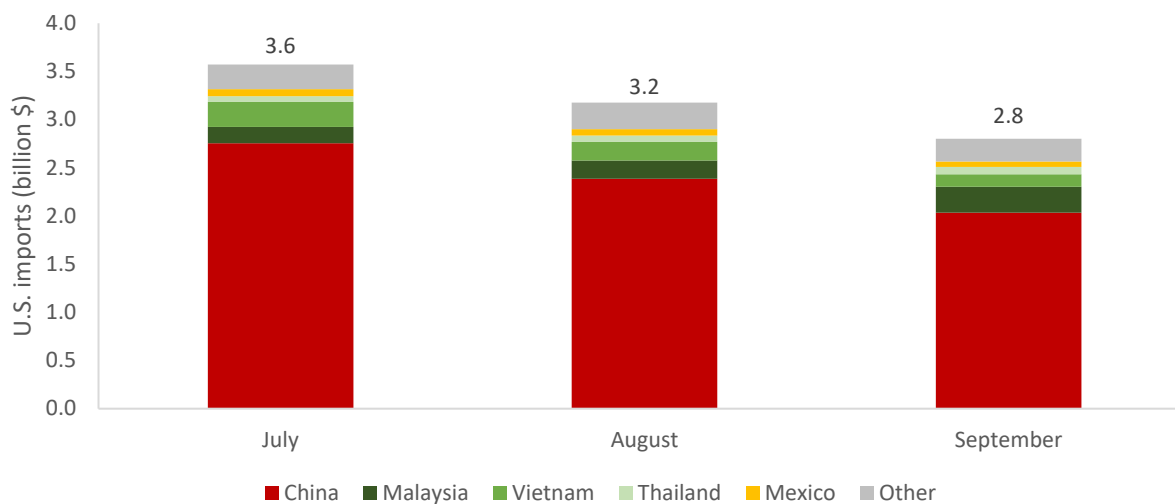
<sup>248</sup> Delteil, Francois, and Nguyen, “Emerging from the Pandemic” July 1, 2020; Suvannaphakdy, “PPE and Free Trade to Better Tackle COVID-19 in ASEAN,” May 7, 2020.

<sup>249</sup> The province was placed in lockdown in late January 2020, and most economic activity ceased; PPE production resumed in March 2020. CRS, “COVID-19: China Medical Supply Chains,” October 8, 2020, 14; Johns Hopkins University of Medicine, “Hubei Timeline,” (accessed November 6, 2020); WHO, “Modelling the Effects of Wuhan’s Lockdown During COVID-19,” May 28, 2020; WHO, “Report of the WHO-China Joint Mission,” February 2020, 16; Ranney, Griffith, and Jha, “Critical Supply Shortages,” April 30, 2020; Xinhuanet, “Enterprises Producing Personal Protective Equipment,” March 6, 2020; Medline, written submission to USITC, September 14, 2020; Industry representatives, interviews by USITC staff, September 2 and 29, 2020.

<sup>250</sup> USITC, hearing transcript, September 23, 2020, 19 (testimony of Abby Pratt, AdvaMed), 80 (testimony of Wesley Cline, Zurn Industries), 242 (testimony of Valerie Karplus, Carnegie Mellon University); industry representatives, interviews by USITC staff, September 4, 15, 28, and 30, October 2 and 20, and November 10, 2020.

<sup>251</sup> USITC, hearing transcript, September 24, 2020, 428 (testimony of Michael Einhorn, Dealmed Medical Supplies).

**Figure 4.3** U.S. imports of selected personal protective equipment (PPE), by country, July–September 2020 (in billion dollars)



Source: USITC DataWeb/USDOC (accessed November 8, 2020).

Note: See table 4.1 for HTS numbers. Underlying data for this figure can be found in [appendix table E.12](#).

Many HTS-8 subheadings covering PPE are subject to NTR duties, although certain gloves, gowns, and shoe covers enter duty free. Ad valorem rates for dutiable items range from 2.5 percent to 16.0 percent. The highest duties are on imports of PPE apparel-related products, such as medical and surgical gowns.<sup>252</sup> Some PPE items are subject to additional section 301 duties on products from China of 7.5 percent to 25 percent.<sup>253</sup> Industry representatives assert that tariffs have a direct impact on PPE costs that are passed on to the consumer.<sup>254</sup>

PPE production and the raw materials used in production tend to be geographically clustered, which enables suppliers to procure inputs more quickly and spend less on shipping costs.<sup>255</sup> For example, nonwoven fabrics, particularly meltblown, spunbond, and spunbond-meltblown-spunbond (SMS)

<sup>252</sup> U.S. International Trade Commission, “COVID-19 Related Goods: U.S. Imports and Tariffs (Updated),” Investigation No. 332-576, June 2020.

<sup>253</sup> Section 301 provides authority for the Office of the U.S. Trade Representative (USTR) to take certain actions after an investigation finding among other things that “an act, policy, or practice of a foreign country is unreasonable or discriminatory and burdens or restricts U.S. commerce.” Those actions include imposing duties or other import restrictions on goods of the foreign country that is the subject of the finding.” Trade Act of 1975, 19 U.S.C. §§ 2411–2417, section 301(b) and 301(c). In a series of notices beginning in August 2018, the U.S. Trade Representative imposed additional duties on certain products from China as a result of a section 301 investigation of China’s acts, policies, and practices related to technology transfer, intellectual property, and innovation. In October 2019, the U.S. Trade Representative additionally established a process by which U.S. stakeholders could request exclusion of particular products classified within an eight-digit HTS subheading of goods subject to the additional duties. See 84 FR 57144.

<sup>254</sup> Medline, written submission to USITC, September 14, 2020; USITC, hearing transcript, September 23, 2020, 54 (testimony of Wesley Cline, Zurn Industries), 238 (testimony of Valerie Karplus, Carnegie Mellon University); USITC, hearing transcript, September 24, 2020, 499 (testimony of Beth Hughes, American Apparel & Footwear Association).

<sup>255</sup> Medline, written submission to USITC, September 14, 2020; industry representatives, telephone interview by USITC staff, October 20, 2020.



fabrics, are major raw material inputs for respirators, masks, and gowns.<sup>256</sup> For the PPE produced in China that incorporate nonwoven fabrics, those fabrics are also predominantly produced in China. For gloves, the final product is also produced where the raw material, historically rubber, is primarily produced—in Malaysia.<sup>257</sup>

## U.S. Exports

U.S. export data for most types of PPE are not available, but U.S. firms do export products to overseas markets, including Canada, Mexico, and a variety of other countries. 3M, for example, typically exports about 25 percent of its domestic respirator production, primarily to Canada and Latin America.<sup>258</sup>

### Box 4.1 Nonwovens

Nonwoven fabrics or “nonwovens” are a critical input in a wide variety of PPE and a product for which there were reported supply chain constraints during 2020.<sup>a</sup> Nonwovens are a key component in N95 respirators, surgical masks, medical gowns and other protective garments, surgical drapes, disposable head and foot covers, and other medical products (e.g., surgical packs, sterilization wrap, and wound care). In 2019, the medical market was the destination for about 5 percent of domestically made nonwovens.<sup>b</sup> Nonwovens are used in a wide variety of applications and for a myriad of other end uses, including personal hygiene products (e.g., diapers), automotive, filtration, packaging, and construction. Nonwovens are also used as the substrate (base) for sanitizing wipes—widely in demand in medical and nonmedical settings. They are also used to meet the growing demand for building air filters, used to improve air filtration in public spaces such as schools and businesses.<sup>c</sup> With the onset of the COVID-19 pandemic, domestic and global demand increased for certain types of nonwovens in response to both PPE shortages and demand for nonwovens from other markets, such as diapers and incontinence products.<sup>d</sup>

Nonwovens can be classified into four major groups differentiated by production process—drylaid, airlaid short fiber, wetlaid, and spunlaid.<sup>e</sup> Drylaid, airlaid short fiber, and wetlaid nonwovens use staple (short) fibers that undergo different processes to create a fabric composed of a web of fibers. Spunlace (also called hydroentangled nonwovens, as the fabric is produced using water jets to entangle the fibers) is a type of drylaid nonwoven that is commonly used in wipes as well as in surgical gowns.<sup>f</sup> However, wipes can be made from a variety of different types of nonwovens, depending on the end-use application.<sup>g</sup>

Spunlaid nonwovens, which are most commonly used for PPE, are made by extruding liquid polymer to form one or more webs in a continuous process. The types of spunlaid nonwoven fabrics typically used in PPE are meltblown, spunbond, and SMS fabrics. Meltblown fabrics in particular have faced shortages in the United States and globally as demand has increased exponentially for their use in PPE. There are a few other types of spunlaid nonwovens, one of which includes “flashspun” (made by DuPont and commercially known as Tyvek), which are also used in disposable protective apparel, such as coveralls. The following provides a brief overview of meltblown, spunbond, and SMS nonwoven fabrics:

**Meltblown:** Meltblown nonwoven fabrics are the key filtration media used in N95 respirators and surgical masks. They are also used in insulation, wipes, sorbents,<sup>h</sup> and other types of filtration, including

<sup>256</sup> USITC hearing transcript, September 24, 2020, 353-54 (testimony of Linda Rouse O’Neil of HIDA).

<sup>257</sup> Medline, written submission to USITC, September 14, 2020.

<sup>258</sup> Gilles, “3M Fires Back at Trump,” April 3, 2020.

liquid and air filtration. Meltblown nonwoven fabrics are made by melting polypropylene (most common for PPE) or other types of resin and extruding the melted polymer to make a web of fine fibers, which can range from 0.1 microns to 30 microns, depending on the level of filtration required. Meltblown fabrics used as filter media for N95 respirators and surgical masks are made with fine fibers that are also electrostatically charged, which enhances their filtration capabilities. The weight of the fabric can also vary; for example, meltblown intended for use in surgical masks typically weighs 25–30 grams per square meter, whereas fabric used for N95 respirators weighs on average 33 to 41 grams per square meter. Because meltblown fabrics are very fine, they can tear easily, so they are generally used in combination with other nonwoven fabrics, particularly spunbond nonwoven fabrics. For a manufacturer, it is easier to install new capacity for meltblown fabrics (less than \$10 million for a new line) than for spunbond and spunmelt fabrics, but meltblown equipment is more complicated to run and the output is slower.<sup>i</sup>

**Spunbond nonwovens:** Spunbond fabrics are commonly used with meltblown fabrics in N95 respirators and in surgical masks. They are also used in a variety of PPE products, including certain medical gowns and disposable foot covers and headcovers, and for numerous other applications, such as personal hygiene, diapers, automotive, packaging, and carpet backing. Like meltblown nonwoven fabrics, spunbond nonwoven fabrics are produced by melting polypropylene or other resin and extruding it into a web; however, spunbond fabrics have greater tensile strength than meltblown fabrics. The machinery used to make spunbond fabrics is a much larger investment (\$30 million–\$60 million for a new production line) than that for meltblown fabrics; however, the production capacity for a spunbond line can be up to 10 times that of a meltblown production line.<sup>j</sup>

**Spunmelt nonwovens:** Spunmelt nonwovens, also called spunbond-meltblown-spunbond (SMS), consist of multiple layers that include spunbond and meltblown webs. An SMS fabric would include a layer of meltblown nonwoven thermally bonded between two layers of spunbond nonwoven. SMS fabrics are commonly used in isolation and surgical gowns as well as for absorbent hygiene goods, such as diapers and incontinence products. SMS fabrics can also be used in place of spunlace for disinfecting wipes. The machinery used to make SMS fabrics can also be used to make spunbond fabrics or meltblown fabrics by turning off part of the production process (i.e., the spunbond web formation is turned off to make meltblown fabrics). SMS production lines have a large footprint, and investment for a new SMS line can reach \$50 million–\$80 million.<sup>k</sup>

<sup>a</sup> There are essentially three types of fabrics, woven (produced on a loom), knitted (produced on knitting machines), and nonwoven (fibers are bonded together).

<sup>b</sup> INDA, *North American Supply Report–2019*, May 2020, 25.

<sup>c</sup> In 2019, 11 percent of domestically produced nonwovens were used in the wipes market, which covers all types of wipes, including but not limited to baby wipes, industrial wipes, and disinfectant/cleaning wipes. The CDC and the American Society of Heating, Refrigerating and Air-Conditioning Engineers (“ASHRAE”) recommended changes to building, heating, ventilating, and air-conditioning systems to reduce airborne concentrations of COVID-19 including improving central air filtration. INDA, *North American Supply Report–2019*, May 2020, 25; American Air Filter Company, Inc., written submission to USITC, October 2, 2020, 1–3; CDC, “Interim Guidance for Businesses and Employers Responding to Coronavirus Disease 2019 (COVID-19) May 2020,” May 6, 2020; ASHRAE, “Building Readiness, Upgrading and Improving Filtration.”

<sup>d</sup> Price, “Nonwovens 2020: Adjusting to the Health and Hygiene Future,” May 19, 2020.

<sup>e</sup> INDA, *North American Supply Report–2019*, May 2020, 61.

<sup>f</sup> King, “Surgical Gowns Manufacturing Basics,” NC State webinar, June 16, 2020; industry representatives, telephone interview by USITC staff, August 17, 2020.

<sup>g</sup> Industry representatives, telephone interview by USITC staff, August 17, 2020.

<sup>h</sup> Substances that can collect molecules of another substance by sorption.

<sup>i</sup> INDA, *Meltblown Nonwoven Markets: COVID-19 Impact Analysis*, 2020, 22–30; industry representatives, telephone interview by USITC staff, August 17, 2020.

<sup>j</sup> Midha, “Spun bonding technology and fabric properties,” April 17, 2017; industry representatives, telephone interviews by USITC staff, August 17 and September 25, 2020.

<sup>k</sup> INDA, *North American Supply Report–2019*, May 2020, 2; industry representatives, telephone interviews by USITC staff, August 17 and September 22 and 25, 2020.

# N95 Respirators

## Major Findings

- Demand for N95 respirators in the United States far exceeds available supply from both domestic production and imports.
- Domestic production of N95 respirators has more than tripled since 2019, and since the onset of the pandemic, supply has been directed toward the medical market; before the pandemic, most production was destined for industrial end uses.
- Key barriers to increasing production of N95 respirators are a shortage of meltblown fabric, the key filtration material used in the devices, and for new producers, a lengthy and costly approval and certification process. In addition, firms are hesitant to enter the market because of the high cost of investment in production capacity and the uncertainty over future demand (existing firms face similar uncertainty when deciding whether to ramp up production).
- Imports of N95 respirators, which come primarily from China, were unable to significantly alleviate U.S. shortages because global demand exceeded available supply; the high cost and short supply of transportation; export restrictions; and low quality and limited consumer acceptance of certain imports, as well as concerns about counterfeit products.

## Introduction

N95 respirators are a critical type of protective device commonly used to safeguard healthcare providers in the response to COVID-19, and as of November 2020, demand continued to far exceed supply.<sup>259</sup> Global demand has increased multifold from 400–500 million respirators sold annually pre-COVID-19.<sup>260</sup> Some industry representatives indicate that demand is essentially limitless, since the market will consume any amount of N95s that are produced.<sup>261</sup> The global industry producing N95 respirators in 2019 primarily consisted of multinationals, such as U.S.-based 3M and Honeywell; a number of manufacturers in China; and a few companies in Europe.<sup>262</sup> The United States is a significant producer of N95 respirators, as well as a major importer, primarily from China. Both domestic production and imports greatly increased in response to the pandemic despite several challenges, including a shortage of raw materials and global demand that still far outpaces supply.

## Product Overview

Respirators are protective devices designed to fit over the nose and mouth to filter out fine airborne particles. They are designed to primarily protect the user, unlike surgical masks, which are designed to prevent the wearer from contaminating others (a case study on surgical masks is presented later in this chapter). There are a number of different types of disposable respirators for medical use. This case

<sup>259</sup> Hufford, “Face Masks Are Again in Short Supply,” November 4, 2020.

<sup>260</sup> Industry representatives, telephone interview by USITC staff, September 15, 2020.

<sup>261</sup> Industry representatives, telephone interview by USITC staff, October 2, 2020.

<sup>262</sup> CDC, NIOSH, “Approved Particulate Filtering Facepiece Respirators,” June 19, 2020.

study will focus only on N95 respirators, and information and data presented are specific to N95 respirators, unless otherwise noted.<sup>263</sup> N95 respirators are so named because of its non-resistance to oil (“non-oil”) and ability to filter out 95 percent of airborne particles. There can be multiple designs for N95 respirators, such as cup style or duckbill style, as long as they meet the relevant performance standard and are fitted tightly to the face. N95 respirators require two or more elastic bands that keep the mask securely on the face, and are typically not recommended for use of more than eight hours.<sup>264</sup> N95 respirators must be approved by the National Institute for Occupational Safety and Health (NIOSH), a division of the Centers for Disease Control and Prevention (CDC), in order to be commercially available. In addition, N95 respirators intended for use in healthcare settings (called “surgical N95 respirators”) must also be cleared by the Food and Drug Administration (FDA).<sup>265</sup> In response to the pandemic, FDA issued Emergency Use Authorizations (EUAs). These EUAs allowed the importation (and sale) of respirators not approved by NIOSH (for example, certain KN95 respirators produced in China), provided they met certain criteria and are included on FDA’s list of respirators authorized under the EUA.<sup>266</sup> However, as of October 15, 2020, FDA announced that it will neither continue to review requests nor add new respirator models made in China to the list of non-NIOSH-approved respirators.<sup>267</sup>

Production of respirators tends to be highly automated. Respirators are composed of several layers of meltblown and spunbond fabric, which are fed into machinery and then molded and cut into the desired mask shape (figure 4.4). The nose bridge and the straps are then attached, usually by machine although occasionally by hand, before they are packaged. There are different degrees of vertical integration in respirator production, with some companies (such as 3M) making many components in-house and others outsourcing inputs.<sup>268</sup> The main filtering material used in the N95 respirator is polypropylene meltblown nonwoven fabric; spunbond fabric is also an important component. A number of other inputs are needed, such as steel staples and aluminum nose clips, as well as raw materials for the inputs, such as polypropylene for the shell, polyurethane for the nose foam, and polyisoprene for the straps.<sup>269</sup>

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<sup>263</sup> The category of disposable respirators, also called filtering facepiece respirators (FFRs), covers a variety of respirators including N95, Surgical N95, N99, N100, R95, P95, P99, and P100. Such respirators have different characteristics based on the share of airborne particles they filter out, whether they are approved by FDA for surgical use, and the extent to which they are resistant to oil (R masks are somewhat oil resistant and P masks are strongly oil resistant). Other forms of respirators include non-disposable respirators which are typically used for more industrial purposes. CDC, NIOSH, “Approved Particulate Filtering Facepiece Respirators,” June 5, 2020.

<sup>264</sup> CDC, NIOSH, “Recommended Guidance for Extended Use,” March 27, 2020.

<sup>265</sup> FDA, “N95 Respirators, Surgical Masks, and Face Masks,” August 20, 2020.

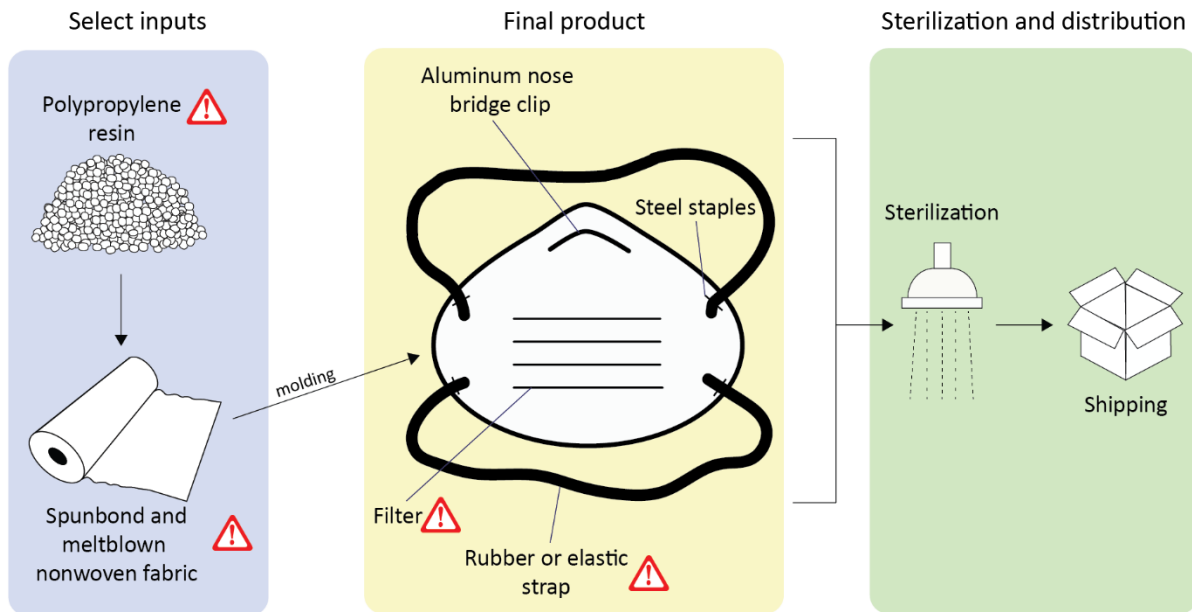
<sup>266</sup> The KN95 is a filtering facepiece respirator similar to the N95 in that it filters 95 percent of airborne particles and is approved by the Chinese National Products Administration. FDA, “Personal Protective Equipment EUAs” accessed October 22, 2020; Hufford, “Face Masks Are Again in Short Supply,” November 4, 2020; FDA, “Letter to Manufacturers of Imported, Non-NIOSH-Approved,” October 15, 2020.

<sup>267</sup> FDA, “Personal Protective Equipment EUAs” accessed October 22, 2020.

<sup>268</sup> Hufford, “Critical Components of Protective Masks,” March 7, 2020.

<sup>269</sup> 3M, “3M Aura Particulate Respirators” (accessed September 2, 2020).

**Figure 4.4** N95 respirators: identifying key inputs and components that have caused supply chain challenges and constraints up through packaging



Source: Compiled by USITC staff.

Note: Red exclamation points indicate supply chain challenges and constraints.

## U.S. Market

The U.S. market for N95 respirators before the COVID-19 pandemic was estimated at about 445 million units in 2019,<sup>270</sup> with the vast majority of these goods designated for industrial end uses, such as mining, fire control, and construction.<sup>271</sup> In the healthcare sector, N95 respirators were used primarily when attending to patients with respiratory illnesses such as influenza or tuberculosis.<sup>272</sup> Estimates on the pre-pandemic number of N95 respirators the U.S. healthcare sector purchased range from about 22 million to 42 million units annually.<sup>273</sup> In value terms, the 2019 market was estimated at \$600 million, with an estimated \$25 million intended for healthcare markets.<sup>274</sup>

U.S. demand for N95 respirators rose sharply in response to COVID-19 as both traditional and nontraditional consumers—such as emergency responders and employees in doctors’ offices and long-term care facilities—required protection from the virus. Hospitals and healthcare systems increased their purchases by 400 percent in January 2020 and an additional 585 percent in February.<sup>275</sup> By March 2020, N95 respirator use in hospitals was reportedly up 1,700 percent compared with normal

<sup>270</sup> AdvaMed, written submission to USITC, September 30, 2020, 10.

<sup>271</sup> Industry representatives, telephone interview by USITC staff, September 15, 2020.

<sup>272</sup> Industry representatives, telephone interview by USITC staff, September 15, 2020.

<sup>273</sup> Premier, “Premier Inc. Survey Finds 86 Percent,” Premier, March 2, 2020; industry representative, email message to USITC staff, October 8, 2020.

<sup>274</sup> Industry representatives, email messages to USITC staff, October 8, 9, and 13, 2020.

<sup>275</sup> Premier, “Premier Inc. Survey Finds 86 Percent,” March 2, 2020.

volumes.<sup>276</sup> Supply shortages led to the use of expired respirators or to the re-use of respirators. To ease the demand, the Centers for Disease Control and Prevention (CDC) relaxed the guidelines for recommended use of N95 respirators from a single use to extended or repeated use and provided promising methods to decontaminate the N95 respirators.<sup>277</sup> By August 2020, 68 percent of nurses reported using N95 respirators for five days or more.<sup>278</sup> Despite these practices and the large increase in supply in the market, industry sources indicate that they are still not able to purchase as many N95 respirators as desired.<sup>279</sup> Industry sources reported estimates of the U.S. market for N95 respirators in 2020 of approximately 1.5 billion to 1.7 billion units.<sup>280</sup> However, U.S. imports of N95 respirators in July–September 2020 alone totaled 1.6 billion units, on average over 500 million per month, indicating that the market for all end uses is likely larger.<sup>281</sup> By comparison, at the start of the pandemic, between 18 and 30 million N95 respirators were reported to be stored in the HHS Strategic National Stockpile (SNS) for emergency medical situations, representing a fraction of current demand.<sup>282</sup> By the end of October, the supply of N95 respirators in the SNS had grown to more than 122 million.<sup>283</sup>

## U.S. Manufacturing Industry

### Finished Goods

There are several firms producing N95 respirators in the United States (table 4.2). Total U.S. production in 2019 was estimated at approximately 30 million N95 respirators per month, accounting for roughly

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<sup>276</sup> USITC, hearing transcript, September 24, 2020, 352 (testimony of Linda O’Neill, HIDA).

<sup>277</sup> Reuse refers to “using the same N95 respirator for multiple encounters with patients but removing . . . it after each encounter.” “Extended use refers to the practice of wearing the same N95 respirator for repeated close contact encounters with several patients, without removing the respirator between patient encounters.” CDC, NIOSH, “Recommended Guidance for Extended Use,” March 27, 2020; FDA, “N95 Respirators, Surgical Masks, and Face Masks,” August 20, 2020. Promising methods for decontaminating N95 respirators include: ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat. CDC, “Decontamination & Reuse of N95 Respirators,” updated October 19, 2020.

<sup>278</sup> N95 respirators are not designed for extended use or multiple uses as they become contaminated and wear down. An American Nurses Association survey of 20,000 nurses conducted between July 24 and August 14 found that 68 percent of nurses responded that they were required to reuse N95 respirators in the two weeks before taking the survey, compared with 62 percent who responded in the May survey, and 58 percent were reusing respirators for five days or more compared with 43 percent in May. American Nurses Association, “Updates on Nurses and PPE” (accessed September 22, 2020).

<sup>279</sup> Industry representatives, telephone interviews by USITC staff, September 28 and October 2, 2020.

<sup>280</sup> AdvaMed, written submission to USITC, September 30, 2020, 10; industry representative, email message to USITC staff, October 8, 2020.

<sup>281</sup> USITC DataWeb/USDOC, HTS 6307.90.9845 (accessed November 8, 2020). In addition to healthcare and industrial uses, imports may also be intended for general consumer use.

<sup>282</sup> According to a GAO report, the Department of Defense reported that prior to the pandemic the SNS contained less than 18 million N95 respirators and Health and Human Services reported that the SNS contained 30 million. The stockpile was depleted during the H1N1 pandemic in 2009, when 75 percent of the stockpile’s N95 respirators were deployed. In addition, many of the respirators in the SNS were past their expiration date. In March 2020, NIOSH completed a study of stockpiled respirators and found that 98 percent of the N95 respirators passed filtration performance standards. GAO, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, GAO-20-625, June 25, 2020, 20; Greenawald, Moore, and Yorio, “Inhalation and Exhalation Resistance,” March 25, 2020, 36; Patel et. al, “Personal Protective Equipment Supply Chain,” June 2017, 244–52.

<sup>283</sup> HHS, “Procurement of N95 Respirators” (accessed November 18, 2020).

80 percent of the U.S. market.<sup>284</sup> Domestic production was primarily oriented toward industrial applications, with medical use respirators accounting for a smaller share. 3M, the original manufacturer of disposable respirators, was the largest producer, with a capacity of 22 million respirators per month in 2019.<sup>285</sup> In 2020, in response to higher demand, U.S. firms significantly increased production and capacity for N95 respirators; annual production is estimated to be three to four times greater than in 2019.<sup>286</sup> U.S. production for September 2020 alone was estimated to be at least 110 million N95 respirators.<sup>287</sup> 3M indicated it will be producing more than 95 million respirators a month starting in October 2020 (up from 50 million per month in June).<sup>288</sup> By the end of 2020, domestic production is expected to reach 160–180 million N95 respirators per month.<sup>289</sup> Several U.S. firms typically maintain the ability to increase production in response to health-related emergencies, and in response to COVID-19, the U.S. industry has made use of this reserve capacity while also adding new capacity. For example, Honeywell, which previously made most of its N95 respirators outside of the United States, made substantial investments in domestic N95 respirator production and expanded U.S. production to 20 million N95 respirators per month.<sup>290</sup> In addition, there have been several new entrants to N95 respirator manufacturing, such as PandMedic Solutions Inc. and Protective Health Gear.<sup>291</sup> U.S. employment at respirator manufacturing plants for the companies identified in table 4.2 totaled more than 3,000, according to data available as of September 2020.<sup>292</sup>

**Table 4.2** Selected U.S. respirator manufacturers

Company (global headquarters)	U.S. production location(s)
3M (U.S.)	Aberdeen, SD, and Omaha, NE
Alpha Pro Tech (Canada)	Salt Lake City, UT
Honeywell (U.S.)	Smithfield, RI, and Phoenix, AZ
Louis M. Gerson (U.S.)	Middleboro, MA
Moldex-Metric (U.S.)	Los Angeles, CA
Owens & Minor (U.S.)	Del Rio, TX, and Lexington, NC
Prestige Ameritech (U.S.)	North Richland Hills, TX

Sources: 3M; Honeywell; Hufford, “3M CEO on N95 Masks: ‘Demand Exceeds Our Production Capacity,’” April 2, 2020; Browne, “DoD Invests in Fight Against COVID-19,” April 23, 2020; Hufford and Evans, “Coronavirus Outbreak Strains Global Medical-Mask Market,” February 6, 2020; Alpha Pro Tech, “Alpha Pro Tech Announces,” February 13, 2020.

Note: Alpha Pro Tech is incorporated in Delaware, with its principal executive offices in Canada.

<sup>284</sup> Estimated by Commission staff based on industry sources.

<sup>285</sup> 3M, “COVID-19 (Novel Coronavirus)” (accessed September 21, 2020); Freedman, “How 3M Blew Its Reputation,” August 19, 2020; Hufford, “3M CEO on N95 Masks,” April 2, 2020; industry representatives, telephone interview by USITC staff, September 15, 2020.

<sup>286</sup> ISEA, written submission to USITC, September 30, 2020, 1; Garflex Inc. dba Fulflex, written submission to USITC, September 30, 2020, 2.

<sup>287</sup> Estimated by Commission staff based on industry sources.

<sup>288</sup> 3M, “3M Awarded Department of Defense Contracts,” May 7, 2020.

<sup>289</sup> Estimated by Commission staff based on industry sources.

<sup>290</sup> Honeywell, “Honeywell Further Expands N95 Face Mask Production,” March 30, 2020; Hufford, “Face Masks Are Again in Short Supply,” November 4, 2020.

<sup>291</sup> Hufford, “Face Masks Are Again in Short Supply,” November 4, 2020.

<sup>292</sup> This estimate is based on the latest available data, with the latest update varying by company and location. Based on data compiled by USITC staff and Manufacturers News Inc., IndustrySelect database, <https://www.industryselect.com> (accessed September 4, 2020).

## Inputs

Meltblown fabric is the key critical filtration component used in N95 respirator production. In 2019, there were 23 companies with 85 production lines making meltblown fabric in the United States, and U.S. production capacity totaled 198 million kilograms, representing 41 percent of global capacity.<sup>293</sup> In 2019, most U.S. production of meltblown was intended primarily for non-N95 respirator markets: sorbents (used to absorb liquid, such as for diapers); insulation; and all filtration products, of which N95 respirators and surgical masks compose a small part. The Association of the Nonwoven Fabrics Industry (INDA) estimated that before the pandemic, U.S. production of meltblown for N95 respirators was about 860,000 kilograms, or less than 1 percent of U.S. domestic production capacity.<sup>294</sup> Nonwoven fabrics are generally sold under long-term contracts, and production is customized according to the intended end-use requirements.<sup>295</sup> Nevertheless, to the extent feasible, U.S. producers of meltblown fabric have switched their production from fabrics for nonmedical applications to fabrics for use in N95 respirators and surgical masks.<sup>296</sup>

In addition to product switching by existing firms, since the onset of the pandemic there has been significant new investment in production capacity for meltblown fabrics for use in U.S. respirator and surgical mask production.<sup>297</sup> A significant portion of the production was spurred by federal contracts.<sup>298</sup> According to industry sources, production capacity for meltblown fabric in the United States is projected to increase by about 25 million kilograms by the end of 2020, and by an additional 11 million kilograms by the end of 2021. Most of the new capacity will be capable of making the fine-fiber meltblown needed for N95 respirators.<sup>299</sup>

Similar to meltblown fabrics, most U.S. production of spunbond fabrics before the pandemic was intended for nonmedical markets; the medical market accounted for only about 5 percent of spunbond production in the United States.<sup>300</sup> In 2019, there were 17 U.S. firms with 53 production lines making spunbond fabrics, and they were operating at over 90 percent capacity utilization.<sup>301</sup> As with meltblown

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<sup>293</sup> INDA, *Meltblown Nonwoven Markets: COVID-19 Impact Analysis*, 2020, 55; industry representatives, telephone interview by USITC staff, October 1, 2020.

<sup>294</sup> INDA, *Meltblown Nonwoven Markets: COVID-19 Impact Analysis*, 2020, 49; industry representatives, telephone interview by USITC staff, October 1, 2020.

<sup>295</sup> INDA, *Meltblown Nonwoven Markets: COVID-19 Impact Analysis*, 2020, 26–27; industry representatives, telephone interview by USITC staff, September 25, 2020.

<sup>296</sup> Industry representatives, telephone interviews by USITC staff, September 25 and October 6, 2020.

<sup>297</sup> Hufford and Evans, “Critical Component of Protective Masks in Short Supply,” March 7, 2020; industry representatives, telephone interviews by USITC staff, August 17, September 30, and October 1 and 5, 2020.

<sup>298</sup> For example, in June, DOD awarded Lydall, Inc., a \$13.5 million contract to increase domestic capacity of meltblown fabric capable of supplying fabric for 1.7 billion N95 respirators or 6.5 billion surgical masks per year. Other DOD contracts include \$2.75 million to NPS Corporation to install a new meltblown line scheduled to start in November 2020, which should support the annual production of up to 720 million N95 respirators or 2.0 billion surgical masks, and \$2.2 million to Hollingsworth & Vose to increase production of meltblown for use N95 respirators. DOD, “DOD Awards \$13.5 Million Contract,” July 2, 2020; Lydall, Inc., “Lydall Breaks Ground,” July 31, 2020; DOD, “DOD Awards \$2.75 Million Contract,” July 25, 2020; DOD, “DOD Announces Defense Production Act,” May 28, 2020.

<sup>299</sup> Industry representatives, telephone interview by USITC staff, October 1, 2020.

<sup>300</sup> Industry representatives, telephone interviews by USITC staff, August 17, 2020 and October 1, 2020.

<sup>301</sup> Kalil, “The State of the North American Nonwoven’s Market and Its Response to COVID-19,” September 29–30, 2020.



production, industry sources stated that after the pandemic started they used their equipment to expand production of spunbond fabrics. To the extent feasible, firms shifted some production from nonmedical applications to medical applications.<sup>302</sup> In addition, one new spunbond line is expected to begin production in the United States by mid-2021.<sup>303</sup>

## U.S. Imports

### Finished Goods

Specific data on U.S. imports of N95 respirators are not available from before July 2020 because respirators were classified in the HTS under a subheading that covered numerous miscellaneous textile products (including many non-PPE products). The HTS did not break out specific tariff lines for respirators until July 2020. However, shipment volumes by ocean and air freight provide some insights into the U.S. import trend in 2020 compared to prior years.<sup>304</sup> Data from ocean freight shipping manifests show that U.S. monthly imports of respirators (including N95 and KN95) via ocean freight remained stable during January 2019–February 2020 (figure 4.5), fell sharply during March and April 2020, and then saw strong growth between May and September 2020 (including a more than 400 percent increase from July to September).<sup>305</sup>

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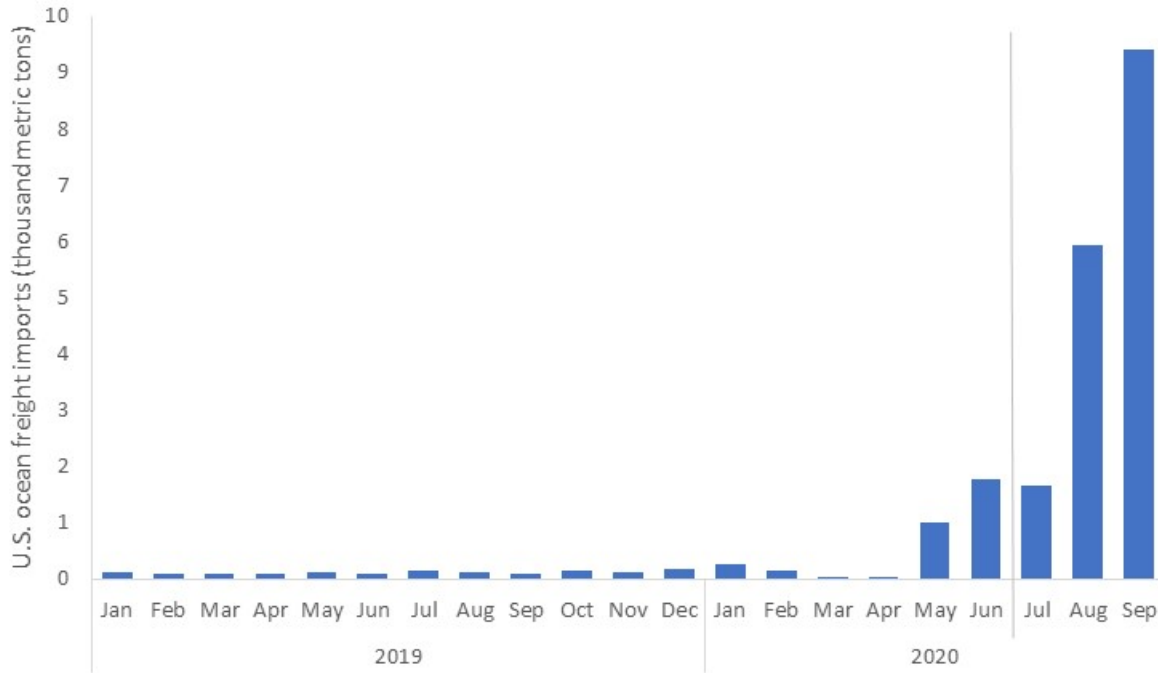
<sup>302</sup> Industry representatives, telephone interviews by USITC staff, September 22 and 25, 2020.

<sup>303</sup> Kalil, “The State of the North American Nonwovens’ Market and Its Response to COVID-19,” September 29–30, 2020; Nonwovens Industry, “PF Nonwovens Adds,” December 4, 2020.

<sup>304</sup> The HTS statistical reporting number that covered respirators and other face masks (as well as a mix of other PPE and non-PPE products) was 6307.90.9889 until June 30, 2020. The description for this code in the HTS was “other made up articles, not elsewhere specified or included.” On July 1, 2020, new breakouts were established for N95 and other respirators. This report therefore uses shipping manifest data (figure 4.5), which show bill of lading information, to identify imports of respirators in 2019 and the first half of 2020. The report also uses air freight data (figure 4.6) to identify imports of respirators and other masks in 2019 and through September 2020.

<sup>305</sup> Trade Data Information Services Inc., Import Genius database (accessed September 2020); IHS Markit, Global Trade Atlas database (accessed September 2020).

**Figure 4.5** U.S. imports of respirators (including N95 and KN95) by ocean freight, January 2019–September 2020 (in thousand metric tons)



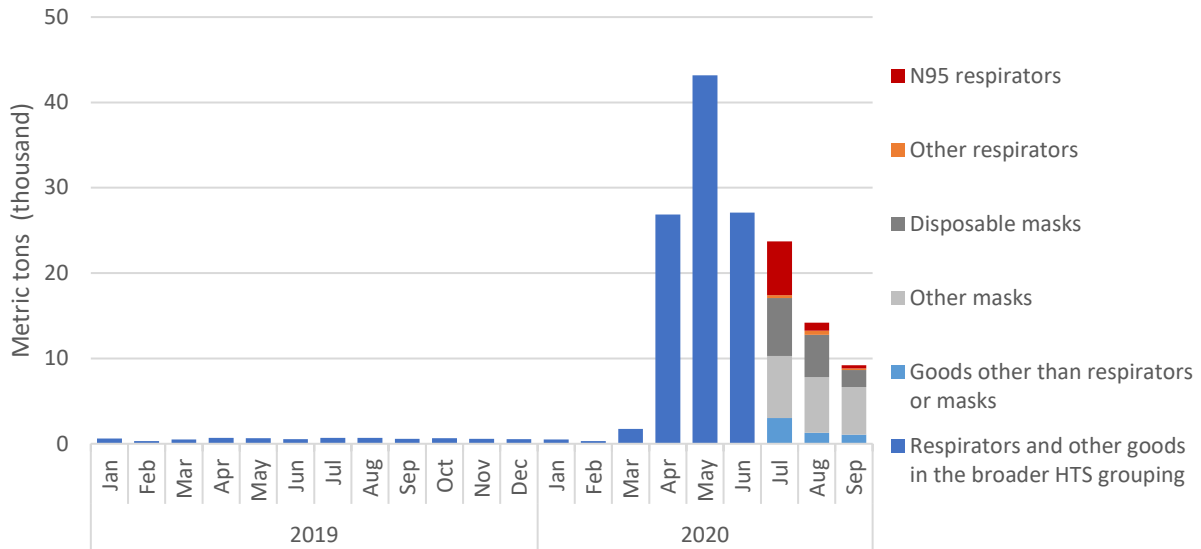
Source: Trade Data Information Services Inc., Import Genius database (accessed November 8, 2020); IHS Markit, Global Trade Atlas database, HTS 6307.90.9845 and 6307.90.9850 (accessed November 8, 2020).

Note: January 2019 to June 2020 data are from shipping manifest data. These data only include those goods in shipping manifest records that could specifically be identified as respirators. Further, records that included both respirators and other items were excluded. Data from July to September 2020 are based on official import statistics.

In addition to ocean freight, starting in March 2020 there was a significant increase in the use of air freight to expedite imports of respirators and other products included in the broader HTS groupings that include respirators (figure 4.6). It is not possible to break out the precise quantity of respirator imports in these data before July 2020. (Also, given that demand for surgical masks rose sharply during this time, it is unclear what share of these imports was respirators as opposed to other products.) In August 2020, when expedited shipping became less critical, the primary shipping method switched back to ocean freight.<sup>306</sup>

<sup>306</sup> IHS Markit, Global Trade Atlas database (accessed September 2020).

**Figure 4.6** U.S. imports of respirators and other goods included in the broader HTS grouping, by air freight, January 2019–September 2020 (in thousand metric tons)

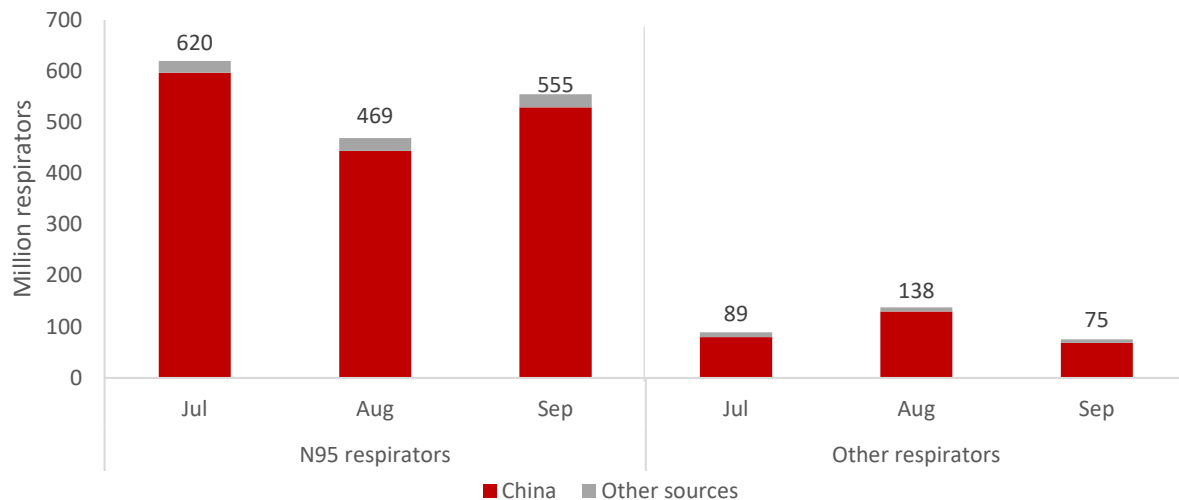


Source: Official U.S. trade statistics from IHS Markit, Global Trade Atlas database, HTS 6307.90.9845, 6307.90.9850, 6307.90.9870, 6307.90.9875, 6307.90.9891, 6307.90.9889 (accessed September–November 2020).

Note: Underlying data for this figure can be found in [appendix table E.13](#).

The new HTS breakout introduced in July 2020 allows for a clearer picture of U.S. import trends in N95 respirators (figure 4.7). Specifically, U.S. imports of N95 respirators in July 2020 totaled 620 million respirators (\$1.1 billion), falling in August to 469 million respirators (\$798 million), and then rebounding to 555 million respirators (\$828 million) in September 2020 (figure 4.6). Imports of other types of respirators totaled 89 million (\$46.9 million) in July, 138 million (\$78.5 million) in August, and 75 million (\$29 million) in September.

**Figure 4.7** U.S. imports of N95 respirators, by country, July–September 2020 (in million respirators)



Source: USITC DataWeb/USDOC, HTS 6307.90.9845 and 6307.90.9850 (accessed November 2020).

Note: Underlying data for this figure can be found in [appendix table E.14](#).

China was the primary source of imports of respirators before the pandemic, supplying more than 80 percent of ocean freight imports in 2019, and continues to be the leading source of U.S. imports in 2020.<sup>307</sup> China supplied 95 percent of N95 respirator imports in July–September 2020 (1.6 billion units). Mexico was the second-largest source, supplying 4 percent of imports (63 million units). U.S. imports of N95 respirators are subject to a 7 percent normal trade relations (NTR) duty rate; these products are excluded from section 301 tariffs on imports from China.<sup>308</sup>

The leading overseas suppliers to the U.S. market in 2019 included firms such as Makrite Industries, Jinfuyu Industrial, Shanghai Masco Nonwoven Products, Aswan International, and AOK Tooling.<sup>309</sup> All of these firms continued to supply the U.S. market in 2020, along with a large number of new entrants and substantial imports from 3M plants outside of the United States.<sup>310</sup> As of June 2020, only about 10 overseas companies had received FDA and NIOSH clearance for surgical N95 respirators for the U.S. market. Although, as discussed above, imports of non-approved respirators from other firms were allowed under Emergency Use Authorizations (EUAs) implemented by FDA.<sup>311</sup>

## Inputs

Meltblown and spunbond fabrics of the type typically used in N95 respirators are generally classified in HTS subheadings 5603.11 and 5603.12,<sup>312</sup> which also include other types of nonwoven fabrics, such as the SMS used in isolation and surgical gowns.<sup>313</sup> U.S. imports of these fabrics totaled \$541 million in 2019.<sup>314</sup> January–September 2020 imports were up 18 percent compared to the same period in 2019.<sup>315</sup> China, Turkey, and Israel were the largest suppliers to the U.S. market in 2019 and 2020, accounting for 14 percent (\$78 million), 12 percent (\$65 million), and 10 percent (\$54 million), respectively, of U.S. imports in 2019.<sup>316</sup> These fabrics are duty free under NTR status.<sup>317</sup>

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<sup>307</sup> Trade Data Information Services Inc., Import Genius database (accessed September 2020).

<sup>308</sup> HTS chapter 99 subchapter 3 note 20; 85 FR 15244 (March 17, 2020).

<sup>309</sup> Trade Data Information Services Inc., Import Genius database (accessed September 2020).

<sup>310</sup> In July 2020, 3M announced it had supplied the U.S. government with 166.5 million respirators from its plants in Asia. Trade Data Information Services Inc., Import Genius database (accessed September 2020); 3M, “COVID-19 (Novel Coronavirus)” (accessed September 21, 2020).

<sup>311</sup> CDC, NIOSH, “Surgical N95 Respirators,” May 12, 2020.

<sup>312</sup> INDA, *Meltblown Nonwoven Markets: COVID-19 Impact Analysis*, 2020, 48; industry representatives, telephone interviews by USITC staff, August 17 and September 25, 2020.

<sup>313</sup> Note these HTS subheadings cover a broader group of fabrics than meltblown and spunbond fabrics (such as flashspun) and the nonwoven fabrics imported under these provisions cover other end-uses, such as N95 respirators, face masks, and nonmedical end uses.

<sup>314</sup> Import data include imports under HTS subheadings 5603.11 (weighing not more than 25g/m<sup>2</sup>) and 5603.12 (weighing more than 25g/m<sup>2</sup> but not more than 70 g/m<sup>2</sup>). USITC/DOC DataWeb (accessed October 8, 2020).

<sup>315</sup> USITC/DOC DataWeb (accessed October 8, 2020).

<sup>316</sup> USITC/DOC DataWeb (accessed October 8, 2020), USITC/DOC DataWeb (accessed October 24, 2020).

<sup>317</sup> U.S. imports from China under HTS statistical suffix 5603.12.0090 are exempt from Section 301 tariffs; all other imports from China under HTS subheadings 5603.11 and 5603.12 are subject to a Section 301 tariffs of 25 percent ad valorem. 83 Fed. Reg. 47974 (September 21, 2018); 84 Fed. Reg. 20459 (May 9, 2019); 85 FR 48600 (March 16, 2020); 85 FR 48600 (August 11, 2020).

## Supply Chain Challenges and Constraints

Even though U.S. production of N95 respirators increased significantly since the onset of the pandemic, U.S. demand still outpaces available supply from both domestic production and imports. A key barrier to increasing U.S. production of N95 respirators is a continuing shortage of the filtration media used in N95 respirators; however, this shortage is expected to ease by 2021. Other barriers to increasing production include the cost of investing in new equipment to expand or establish new capacity without guaranteed long-term demand through which to recoup the investment. Producers must also obtain regulatory approval for new devices, which can be a lengthy process for new producers of any medical device, including N95 respirators.

Importing N95 respirators to fulfill demand has also been fraught with numerous challenges. In the early months of the pandemic, respirators were not available from China, the leading global producing country. Chinese producers that temporarily shut down for the Chinese New Year stayed shuttered due to the pandemic. Further, export restrictions limited the ability of U.S. importers to source from overseas suppliers. Once N95 respirators became available, importers faced challenges in shipping the articles to the United States. Air freight, the preferred method to get product to the U.S. market quickly, was severely limited in the early days of the pandemic. U.S. importers also faced intense competition from other global buyers, and many countries placed controls on the export of N95 respirators. All these factors had the effect of further limiting the supply of N95 respirators available for the U.S. market. Finally, the demand/supply imbalance has led to imports of fraudulent and counterfeit products, which in turn has increased costs for U.S. firms having to verify the legitimacy of supply from foreign producers.

### Factors Affecting U.S. Production

#### Market Size

Although U.S. firms responded to the call for more N95 respirators by increasing or initiating production, capacity was nevertheless insufficient to meet demand throughout the response. The potential for a sharp drop in demand after the pandemic is a significant factor that U.S. firms consider when investing in domestic production. U.S. production capacity is oriented toward supplying a typical level of annual demand (although some firms maintain idle capacity that can be brought online quickly). Respirator production is also focused on industrial applications, which historically accounted for most U.S. demand. With significant expenditures required to ramp up production, the investment may be cost prohibitive without some certainty of future demand that would cover the costs of the investment.

Vidalia Mills, a domestic firm that invested in new N95 respirator production after the onset of the pandemic stated that “one of the greatest challenges facing manufacturers interested in onshoring a viable PPE industry is the need to mitigate investment risk.”<sup>318</sup> Prestige Ameritech, a domestic producer of N95 respirators and face masks, increased production in response to the H1N1 virus (“swine flu”) in 2009 without a guarantee of future demand. Later, the firm encountered financial difficulties when demand suddenly dropped off after that pandemic ended.<sup>319</sup> Likewise, with the current pandemic,

<sup>318</sup> USITC, hearing transcript, September 24, 2020, 508 (testimony of Dan Feibus, Vidalia Mills).

<sup>319</sup> Frontline, “America’s Medical Crisis,” October 6, 2020.

industry sources note that firms that have initiated or expanded face mask production with the expectation that the public and private sector will buy U.S.-made products stand to lose millions in investment if there is no follow through on U.S. purchasing.<sup>320</sup>

## Product to Market

Barriers to entry for new firms include meeting industry standards, the federal certification process, and determining the best design and methods to use to achieve the N95 filtration without violating intellectual property rights. One new U.S. producer of N95 respirators noted that the “heroic efforts” of firms to bring new production to market have been hindered by their difficulty in understanding the “lengthy and confusing” certification process.<sup>321</sup> FDA, through NIOSH, must approve all respirators designed for healthcare use.<sup>322</sup> Typically, NIOSH approval processes take an average of three months from beginning to end, and longer for surgical N95s.<sup>323</sup> Additionally, FDA requires a 90-day notification—known as an FDA 510(k) premarket notification<sup>324</sup>—before producers can market a new device.<sup>325</sup> While NIOSH is expediting reviews for established manufacturers, industry representatives reported that the process is still arduous for new manufacturers and involves significant time and cost.<sup>326</sup> The optimal processes to produce N95 respirators may also be covered by intellectual property rights, requiring new entrants to create their own design that achieves the required filtration level (or to license from the intellectual property rights holder).<sup>327</sup> This can add time to the process to start production of N95 respirators. It is also difficult for new entrants to the market to gain trust or to get a foothold in the healthcare distribution system.<sup>328</sup> Typically, hospitals and healthcare systems that require N95 respirators work with established suppliers, and extensive verifications of new suppliers may be needed.<sup>329</sup> One industry representative suggested that such challenges make it more appealing to skip the approval processes and regulatory hurdles altogether and sell to the consumer market instead of the healthcare sector.<sup>330</sup>

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<sup>320</sup> Industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>321</sup> USITC, hearing transcript, September 24, 2020, 509 (testimony of Dan Feibus, Vidalia).

<sup>322</sup> Government officials, telephone interview by USITC staff, September 10, 2020.

<sup>323</sup> Government officials, telephone interview by USITC staff, September 10, 2020; Birkner, “Detailing the Process for NIOSH Respirator Approval,” March 1, 2006.

<sup>324</sup> A premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective—that is, substantially equivalent to—a legally marketed device that is not subject to premarket approval. FDA, “510(k) Premarket Notification,” November 9, 2020. See appendix F for an explanation of the FDA 510(k) premarket notification process.

<sup>325</sup> Yang, “Importing Masks and Respirators,” April 28, 2020.

<sup>326</sup> Hufford, “Face Masks Are Again in Short Supply,” November 4, 2020; industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>327</sup> Contrera, “N95 Masks Save Lives,” September 21, 2020; USITC, hearing transcript, September 23, 2020, 160 (testimony of Lori Wallach, Global Trade Watch); Clark, “Inside the Chaotic, Cutthroat Gray Market for N95 Masks,” November 17, 2020.

<sup>328</sup> USITC, hearing transcript, September 24, 2020, 467 (testimony of David Greer, Techman Sales, Inc.); industry representatives, telephone interview by USITC staff, October 20, 2020.

<sup>329</sup> USITC, hearing transcript, September 23, 2020, 151 (testimony of Prashant Yadav, Center for Global Development).

<sup>330</sup> Industry representatives, telephone interview by USITC staff, September 14, 2020.

## Production and Delivery

Obtaining the necessary machinery is also a barrier to starting new production. Beginning production of N95 respirators can take six months or more, as it takes time to acquire the machinery and set it up.<sup>331</sup> The machinery can cost between \$125,000 and nearly \$300,000 and produce respirators at the rate of 25-50 units per minute, depending on the style of respirator.<sup>332</sup> Once the machines are installed, workers must be trained to operate them, a process that can take an additional 10 to 15 days.<sup>333</sup> N95 respirator machinery is primarily made in Asia, and when demand rose steeply in March, foreign manufacturers of the machines reported that they would be unable to fill orders for three to six months.<sup>334</sup> Subsequently, some U.S. companies such as Craig Machinery & Design in Louisville, Kentucky, began to make the machines to manufacture N95 respirators, allowing several new companies to procure the machinery necessary to start producing the respirators.<sup>335</sup>

A key barrier to increasing production of N95 respirators is a continuing shortage of meltblown fabric used as the filtration media in N95 respirators.<sup>336</sup> Starting in February 2020, many U.S. manufacturers of meltblown fabrics were reportedly sold out of materials for respirators, as only a small portion of their business was devoted to respirator or mask production.<sup>337</sup> Meltblown fabric was also in short supply globally, and although China reportedly substantially increased its capacity for meltblown fabrics, the quality does not meet the standard required for N95 respirators.<sup>338</sup> Moreover, current producers of meltblown cannot easily switch from producing meltblown intended for other applications to producing meltblown for N95 respirators because the change can require upgrades or alterations to the machinery.<sup>339</sup> New investment in meltblown production can cost up to \$10 million; further, it can take nine months or longer to obtain the machinery, which must be imported (primarily from Germany), and get it up and running.<sup>340</sup> The leading global producer, the German company Reicofil, reported that it was receiving nearly 50 requests a day for its machines and meltblown fabric, mostly from China. Reicofil also stated that it turned down most of the requests because a single machine takes at least five to six months to produce.<sup>341</sup> Despite challenges in acquiring machinery, there is significant new investment in meltblown production capacity. However, U.S. industry sources indicated that as of early October 2020,

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<sup>331</sup> Hufford, “New Manufacturers Jump into Mask Making,” March 21, 2020; Feng, “COVID-19 Has Caused a Shortage,” March 16, 2020; industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>332</sup> Yin USA, “N95 Automatic Mask Machine” (November 24, 2020); industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>333</sup> Industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>334</sup> Hufford, “New Manufacturers Jump into Mask Making,” March 21, 2020.

<sup>335</sup> Durham, “Louisville Factory Building Machines,” April 10, 2020; WGRZ, “4 Western New York Companies,” July 30, 2020.

<sup>336</sup> Hufford, “New Manufacturers Jump into Mask Making,” March 21, 2020; Hufford, “3M CEO on N95 Masks,” April 2, 2020; industry representative, email message to USITC staff, September 25, 2020.

<sup>337</sup> Industry representatives, telephone interview by USITC staff, August 17, 2020.

<sup>338</sup> Industry representatives, telephone interviews by USITC staff, September 25 and October 5, 2020.

<sup>339</sup> INDA, *Meltblown Nonwoven Markets: COVID-19 Impact Analysis*, 2020, 22; industry representative, telephone interview by USITC staff, September 25, 2020.

<sup>340</sup> Industry representatives, telephone interviews by USITC staff, August 17, September 25, 2020, and October 1 and 5, 2020.

<sup>341</sup> Feng, “COVID-19 Has Caused A Shortage of Face Masks,” March 16, 2020; industry representatives, telephone interview by USITC staff, October 5, 2020.

U.S. demand for meltblown fabrics still far exceeded current domestic capacity.<sup>342</sup> Industry sources, however, predict the domestic shortage of meltblown fabric needed for PPE should be eased somewhat by the end of 2020, and that new U.S. production capacity should be able to meet demand for expanded production of N95 respirators and surgical masks by the end of 2021.<sup>343</sup>

Consistent with the above, the price of meltblown fabrics has increased for sales on the spot market, particularly affecting the costs for new manufacturers of N95 respirators.<sup>344</sup> In addition, the price of polypropylene resin, a key input in meltblown or spunbond fabrics, increased 11 percent in July and an additional 6 percent in August, as a result of increased demand and hurricane activity, which disrupted some U.S. production of polypropylene resin.<sup>345</sup> However, more production is coming online, as construction on a new polypropylene resin plant in La Porte, Texas, was completed in late June, and the plant is expected to produce a billion pounds of polypropylene resin a year.<sup>346</sup> Depending on the contracts between nonwoven producers and their customers, raw material price increases are sometimes passed on to the final customer.<sup>347</sup>

Another challenge for domestic producers of N95 respirators has been the lack of a supply of elastic straps. Respirators require elastic straps that wrap around the head to ensure proper fit. There are very few U.S. manufacturers of elastic; the Vermont-based Fulflex reports that it is the only domestic producer that specializes in making rubber elastic straps for N95 respirators and masks.<sup>348</sup> In September 2020, Fulflex stated that it was operating at full capacity but existing demand not only exceeded that capacity, but is expected to double based on forecasts.<sup>349</sup> The company said that it was considering investing in a new production facility that would increase its capacity so that it could supply straps for an additional 2.5 billion masks annually.<sup>350</sup> Such an investment would take 9–12 months before it would become operational.<sup>351</sup>

## Factors Affecting U.S. Imports

### Product Availability

The most critical supply chain constraint faced by importers of N95 respirators was a sharp contraction in the worldwide supply of N95 respirators, as key producers halted operations in early 2020 and then

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<sup>342</sup> USITC, hearing transcript, September 24, 2020, 578–79 (testimony of Dan Feibus, Vidalia Mills); industry representatives, telephone interviews by USITC staff, September 25 and October 5, 2020.

<sup>343</sup> INDA, *Meltblown Nonwoven Markets: COVID-19 Impact Analysis*, 2020, 55; industry representatives, telephone interviews by USITC staff, August 17, September 25, and October 1, 2020.

<sup>344</sup> Chi, “Price Soars for Core Material of Face Masks,” February 27, 2020; industry representative, telephone interview by USITC staff, September 25, 2020 and October 5, 2020. Goods sold on a spot market are purchased for immediate payment and delivery, as opposed to being purchased under a forward or futures contract.

<sup>345</sup> American Chemistry Council, written submission to USITC, October 2, 2020, 1; industry representatives, telephone interview by USITC staff, October 5, 2020; industry representatives, email message to USITC staff, September 28, 2020.

<sup>346</sup> Esposito, “Commodity Resin Prices Stay Heated in July,” August 10, 2020.

<sup>347</sup> Industry representatives, telephone interview by USITC staff, September 25, 2020.

<sup>348</sup> USITC, hearing transcript, September 24, 2020, 504 (testimony of Pat Curtin, Garflex Inc. dba Fulflex).

<sup>349</sup> USITC, hearing transcript, September 24, 2020, 504 (testimony of Pat Curtin, Garflex Inc. dba Fulflex).

<sup>350</sup> USITC, hearing transcript, September 24, 2020, 505 (testimony of Anand Kulkarni, Garflex Inc. dba Fulflex).

<sup>351</sup> USITC, hearing transcript, September 24, 2020, 576 (testimony of Anand Kulkarni, Garflex Inc. dba Fulflex).



were unable to fulfill the overwhelming global demand upon restarting production. China is one of the major global exporters of respirators, and when the pandemic hit the country, not only was domestic production shut down for a time, but also inventories were drawn down for domestic use, while exports dropped. According to some industry observers, as COVID-19 cases rose worldwide, other countries attempted to purchase more N95 respirators from China, resulting in bidding wars and price gouging.<sup>352</sup>

Export controls limited imports by restricting firms' ability to source from overseas suppliers to attempt to meet demand. Export controls on PPE were in frequent use, especially early in the pandemic, with at least 51 countries maintaining some form of control in June.<sup>353</sup> Such controls included a total ban on PPE exports, license requirements, or spot inspections. China in particular, while never formally announcing export controls, limited exports of N95 respirators from companies producing them in China, including the U.S.-headquartered company 3M for several months.<sup>354</sup> Over time, some countries have removed or lowered these restrictions.<sup>355</sup> China began exporting N95 and equivalent respirators (e.g., KN95) in April; however, the poor quality of some of the products led to a backlash, and the Chinese government stepped in to conduct inspections of the shipments, slowing supply.<sup>356</sup>

Even after N95 respirators became available for shipment to the United States, transportation challenges persisted for importers, largely because of limited air freight capacity resulting from fewer passenger flights. Typically, N95 respirators are imported into the United States via ocean freight. However, in the first few months of the pandemic, importers turned to air freight to get the product as quickly as possible. Unfortunately, the number of flights allowed from China were significantly reduced.<sup>357</sup> There were over 300 flights from China to the United States a week in January 2020, which had been cut to only eight flights a week as of August.<sup>358</sup> The Federal Emergency Management Agency's (FEMA's) Project Airbridge, which chartered air cargo flights to and from China and other countries, helped to mitigate some of the difficulties in finding flights and resulted in the import of nearly 1.5 million N95 respirators.<sup>359</sup> Still, the cost of air freight increased as a result of restrictions on travel. With fewer flights, there were fewer opportunities to ship goods via air, which led to costs that were six to seven times higher than pre-pandemic, according to industry representatives.<sup>360</sup> One firm reported paying freight costs of as much as \$2.00 to \$2.50 per mask to ship via air in late March and April versus 35 cents per mask before COVID-19.<sup>361</sup>

## Market Acceptance

The supply shortage prompted buyers to seek product from abroad. Products manufactured abroad may be different than purchasers are used to purchasing, raising questions about comparability and performance. Although the FDA's EUA allows some non-NIOSH approved respirators, such as KN95

<sup>352</sup> Walsh, "The Only Way We Can," March 18, 2020.

<sup>353</sup> Georgi, Alberda, and Costelloe, "Reference Guide: Worldwide Export Controls on Face Masks," June 3, 2020.

<sup>354</sup> USITC, hearing transcript, September 23, 2020, 59 (testimony of Ralph Ives, AdvaMed); Frontline, "America's Medical Crisis," October 6, 2020.

<sup>355</sup> Georgi, Alberda, and Costelloe, "Reference Guide: Worldwide Export Controls on Face," June 3, 2020.

<sup>356</sup> USITC, hearing transcript, September 23, 2020, 59-60 (testimony of Ralph Ives, AdvaMed).

<sup>357</sup> Chokshi, "China Steps Back in Airline Dispute with the Trump Administration," June 3, 2020.

<sup>358</sup> Lund, "Global Supply Chain and Trade Conference: Logistics and Transportation," August 27, 2020.

<sup>359</sup> FEMA, "FEMA Phasing Out Project Airbridge," June 17, 2020.

<sup>360</sup> Industry representatives, telephone interview by USITC staff, September 15, 2020.

<sup>361</sup> Industry representatives, telephone interview by USITC staff, September 29, 2020.

respirators and other foreign equivalents, to be used in healthcare applications,<sup>362</sup> some healthcare professionals are nonetheless reluctant to accept them. For example, the industry standard in hospitals has been the cup style N95 respirator, and healthcare professionals are reportedly more skeptical of other forms of respirators.<sup>363</sup> Healthcare distributors are therefore hesitant to purchase KN95 respirators without assurance that they will sell.<sup>364</sup>

Another challenge cited by industry sources is the poor quality of some N95 respirators or their equivalent (e.g., KN95). After issuing an EUA authorizing the use of certain Chinese respirators in April 2020, FDA withdrew its authorization with respect to respirators manufactured by more than 60 Chinese companies in May.<sup>365</sup> In a NIOSH report published in August 2020, 40 percent of respirators (including N95 and KN95) that were permitted to be imported under the EUA issued in April did not meet the U.S. filtration standard. Further, the test only assessed filtration efficiency, and many of the products used ear loop attachment rather than the straps designed to wrap around the head, which provide a tighter fit.<sup>366</sup>

Businesses selling substandard or counterfeit products have also made it more challenging to identify and import legitimate products. Hospitals and other healthcare organizations have attempted to obtain these goods outside of their usual supply chains because their typical suppliers have not been able to meet their needs.<sup>367</sup> Industry sources report that customers have incurred significant financial loss due to fraudulent products they procured outside of their normal supply chains in order to obtain high-demand goods.<sup>368</sup> Vetting new vendors not only requires extra time and money, but is difficult during a pandemic for firms that do not have established supply networks in Asia.<sup>369</sup>

### Prices and Delivery Costs

There was a sharp increase in the price of N95 respirators outside of the normal supply chains that made it more challenging to source products. The price of finished respirators reportedly increased from less than \$1.00 per unit to as high as \$12.00 a respirator.<sup>370</sup> Average prices for some imported respirators were particularly high even during the summer of 2020. For example, in July 2020, the unit value of certain N95 respirators imported from China into Seattle, Washington, was \$4.05.<sup>371</sup> The majority of the

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<sup>362</sup> Yang, “Importing Masks and Respirators from Overseas,” April 28, 2020.

<sup>363</sup> Industry representatives, telephone interviews by USITC staff, September 28 and 29, 2020.

<sup>364</sup> Industry representatives, telephone interview by USITC staff, September 29, 2020.

<sup>365</sup> Hufford, “FDA Pulls Dozens of Mask Makers in China,” May 7, 2020.

<sup>366</sup> Powers, “PPE CASE: Filtration Efficiency Performance,” 2020; Keenan and Greenburg, “Imported N95 Masks,” May 5, 2020.

<sup>367</sup> Industry representatives, telephone interviews by USITC staff, September 2 and 28, 2020.

<sup>368</sup> Industry representatives, telephone interview by USITC staff, September 28, 2020.

<sup>369</sup> USITC, hearing transcript, September 23, 2020, 129 (testimony of Abby Pratt, AdvaMed); USITC, hearing transcript, September 24, 2020, 366 (testimony of David Greer, Techman Sales, Inc.).

<sup>370</sup> Industry representatives, telephone interviews by USITC staff, September 15 and 28, 2020.

<sup>371</sup> Imports totaled 1.2 million respirators. The unit value of total imports of N95 respirators in July 2020 was \$2.03 per respirator. Based on U.S. Customs value. USITC DataWeb/USDOC, HTS 6307.90.9845 (accessed October 25, 2020).

increase in price has been attributed to opportunistic businesses and new entrants into the market.<sup>372</sup> In contrast, 3M and other domestic N95 respirator producers did not raise prices on their respirators.<sup>373</sup>

## Surgical Masks

### Major Findings

- With the onset of the pandemic, demand for surgical masks increased substantially, not only from traditional users, such as hospitals, but also from long-term care facilities, medical offices, and others in contact with the public, such as emergency responders.
- Prior to the pandemic, an estimated 85 percent of the domestic market for surgical masks was supplied by imports in 2019, with most coming from China.
- The pandemic has spurred new U.S. investment in surgical mask production by both existing producers and new firms. Challenges reported by domestic producers with respect to scaling up included a lack of (1) multi-year contracts from government or commercial buyers, and (2) incentives for customers to buy U.S.-made PPE, such as under Buy American provisions, which would provide firms some assurance of recouping the multimillion-dollar investment in production. Two additional challenges were a shortage of meltblown fabric, the filtration material used in surgical masks, and the difficulty new suppliers face in gaining market acceptance from the medical community.

### Introduction

U.S. demand for surgical masks quickly outpaced supply with the onset of the pandemic, as their use became more widespread throughout the U.S. healthcare system. Since most of the U.S. market for surgical masks is supplied by imports from China, U.S. importers were facing shortages from the shutdown in Wuhan, where most of the masks are made. At the same time, U.S. importers faced intense global competition for access to the same supply. There has been new U.S. investment in surgical mask production in the United States; however, new entrants have encountered challenges accessing inputs, particularly meltblown fabric, the key filtration material used in surgical masks. However, there has been substantial new investment in meltblown fabric production, which is expected to reduce supply shortages by 2021. New producers also faced a backlog in testing for new face masks in order to meet FDA requirements, although this backlog has reportedly eased. While the supply of surgical face masks available in the U.S. market has increased, as of October 2020, some industry sources state that they are still in short supply.

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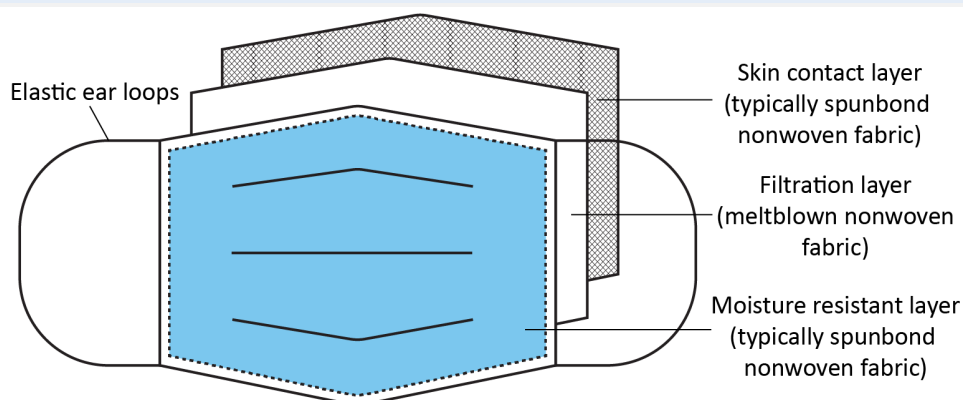
<sup>372</sup> Industry representatives, telephone interviews by USITC staff, September 28, 2020.

<sup>373</sup> 3M, "COVID-19 (Novel Coronavirus)" (accessed December 9, 2020); USITC, hearing transcript, September 23, 2020, 66 (testimony of Ralph Ives, AdvaMed); industry representatives, telephone interviews by USITC staff, September 28 and October 2, 2020.

## Product Overview

Surgical masks,<sup>374</sup> also sometimes referred to as procedural or isolation masks, are used in hospitals and other medical facilities to prevent the transmission of particles from the wearer to others and provide protection to the wearer against large droplets or splashes of bodily or other hazardous fluids.<sup>375</sup> Surgical masks use at least three layers of material (figure 4.8). The middle layer is an electrostatically charged meltblown nonwoven fabric that is the key fabric used for filtration. The inner and outer layers are typically made from spunbond nonwoven fabric. The interior layer is designed to be hydrophilic (with an affinity for water) to absorb moisture from the mouth and breathing, while the outer layer is designed to be hydrophobic (water-repellent) to repel liquid on the outside of the mask.<sup>376</sup> Surgical masks are classified by FDA as class II medical devices that require FDA clearance prior to being placed on the market, unless authorized under an EUA or otherwise exempt.<sup>377</sup> FDA issued an EUA for surgical masks in August 2020.<sup>378</sup>

**Figure 4.8** Components of a surgical mask



Source: Compiled by USITC staff.

<sup>374</sup> This section does not cover face masks like three-layer face masks that may look like surgical masks but are not FDA-cleared. Certified masks are classified as level 1, level 2, or level 3, and reflect the level of protection each provides. Surgical masks that do not obtain third-party certification are classified as “minimal protection.” CDC, “Understanding the Difference Surgical Mask, N95 Respirator” (accessed October 5, 2020); Henneberry, “How Surgical Masks Are Made, Tested and Used,” August 17, 2020; FDA, “Enforcement Policy for Face Masks and Respirators,” May 2020.

<sup>375</sup> A surgical mask differs from a N95 respirator, which fits closely on the face and is primarily intended to protect the wearer by filtering out airborne particles, including small particle aerosols and large droplets. CDC, “Understanding the Difference Surgical Mask, N95 Respirator” (accessed October 5, 2020).

<sup>376</sup> Industry representatives, telephone interview by USITC staff, September 25, 2020.

<sup>377</sup> 21 CFR § 878.4040. See also Appendix F.

<sup>378</sup> Due to the shortage of surgical masks, FDA issued an umbrella EUA in August 2020. The EUA covers surgical face masks intended for use in healthcare settings demonstrated to meet certain criteria. The EUA specifically excludes face masks made in China. As of November 2020, 11 manufacturers of surgical masks were under the umbrella EUA. FDA, “Personal Protective Equipment EUAs” (accessed October 15, 2020); FDA, “Emergency Use Authorization Letter for Face Masks,” April 24, 2020.

## U.S. Market

With the onset of the pandemic, the use of surgical masks became more widespread for all medical and even nonmedical staff in hospitals, as well as in other medical settings such as long-term care facilities, home health care, and doctors' and dental offices.<sup>379</sup> The supply of surgical masks was inadequate to meet the needs of a pandemic in part because of the healthcare just-in-time delivery system, in which distributors typically hold a 30- to 90-day supply from which to service their customers.<sup>380</sup> As is the case with many COVID-19 related goods, as U.S. demand for surgical masks surged during the pandemic, it quickly outstripped available supply. The size of the market for surgical masks in 2019 was estimated at about 108 million to 140 million per month.<sup>381</sup> Beginning in March 2020 and continuing through July, the size of the market for surgical masks is estimated to have increased to roughly 375 million to 425 million masks per month.<sup>382</sup> This total does not include the large number of nonsurgical disposable masks being used by industry and other businesses as well as by the public at large.

China is estimated to supply nearly three-quarters of the U.S. market for surgical masks, and as with other articles of PPE, China's output was disrupted early in the pandemic.<sup>383</sup> When China resumed production, U.S. buyers found themselves competing against other global buyers of surgical masks. Industry sources have mixed views on the current state of product availability; some distributors indicated that in September 2020 they were no longer in short supply, while other distributors indicated they were still unable to purchase as many surgical masks as they need.<sup>384</sup>

## U.S. Manufacturing Industry

Before the pandemic, U.S. production of surgical masks supplied only about 15 percent of the U.S. market demand.<sup>385</sup> Prestige Ameritech claims to be the largest domestic producer of surgical masks.<sup>386</sup> Domestic medical mask production was estimated at 17 million masks per month in 2019.<sup>387</sup> Industry

<sup>379</sup> USITC, hearing transcript, September 24, 2020, 352–53 (testimony of Linda Rouse O'Neill, HIDA); Grandview Research, "U.S. Disposable Face Mask Market Analysis," April 2020, 25; industry representatives, telephone interview by USITC staff, September 28, 2020.

<sup>380</sup> USITC, hearing transcript, September 24, 2020, 348–50 (testimony of Linda Rouse O'Neill, HIDA), 402 (testimony of Michael Einhorn, Dealmed Medical Supplies); industry representatives, telephone interviews by USITC staff, October 2, 2020.

<sup>381</sup> Polowczyk, "White House COVID-19 Supply Chain Task Force Report," June 10, 2020; industry representatives, email messages to USITC staff, October 8 and 9, 2020.

<sup>382</sup> Polowczyk, "White House COVID-19 Supply Chain Task Force Report," June 10, 2020; industry representatives, email messages to USITC staff, October 8 and 9, 2020.

<sup>383</sup> The outbreak in China coincided with closures associated with Chinese New Year and rolled into quarantine within Wuhan. USITC, hearing transcript, September 24, 2020, 354–55 (testimony of Linda Rouse O'Neill, HIDA) and 362 (testimony of Michael Einhorn, Dealmed Medical Supplies); industry representatives, telephone interview by USITC staff, October 2, 2020.

<sup>384</sup> Medline Industries, written submission to USITC, September 14, 2020, 5; Medline Industries, "Supply Access Update" (accessed October 14, 2020); industry representatives, telephone interview by USITC staff, September 30, 2020.

<sup>385</sup> Medline Industries, written submission to USITC, September 14, 2020, 5.

<sup>386</sup> Prestige Ameritech, "About Us" (accessed October 15, 2020).

<sup>387</sup> INDA, *Meltblown Nonwoven Markets: COVID-19 Impact Analysis*, 2020, 49; industry representatives, email message to USITC staff, October 8, 2020.

sources indicate that domestic production has increased since then, due to producers increasing production of surgical masks and new firms entering the market, such as Vidalia Mills.<sup>388</sup> More new production is slated for early 2021. For example, Medline Industries stated it is in the process of establishing one to four new surgical mask production lines, with full production anticipated to be online by early 2021,<sup>389</sup> and Crosstex International, Inc. was awarded a \$3.5 million U.S. Department of Defense contract to increase domestic production of face masks, with expanded capacity expected to come online starting in May 2021.<sup>390</sup>

## U.S. Imports

Before the pandemic, imports were estimated to supply 85 percent of the market for surgical masks, with China accounting for most of the imports.<sup>391</sup> Official data on U.S. imports of face masks were not available until July 2020 when new HTS breakouts were introduced.<sup>392</sup> Data for July–September 2020 show that imports of all disposable masks, including surgical masks but excluding N95 and other respirators, totaled 10.8 billion units (\$1.5 billion).<sup>393</sup> China supplied 92 percent of the volume and value of such imports. The NTR ad valorem<sup>394</sup> rate of duty on surgical masks is 7 percent; these products are excluded from section 301 tariffs on imports from China.<sup>395</sup>

## Supply Chain Challenges and Constraints

The supply of surgical masks in the United States was severely constricted early in the pandemic by the shutdown of production in China, where most surgical masks that are used in the U.S. market are made. When production in China resumed, there was heightened global competition for these products. There has been new investment in the United States to produce surgical masks. However, one of the key inputs used in surgical face mask production, meltblown fabric, has been in short supply, especially for new producers that do not have established relationships with meltblown suppliers. New producers also faced delays in completing the necessary tests required to obtain FDA approval. Finally, firms that have invested in, or are considering investing in, surgical mask production in the United States are concerned that there may not be sufficient long-term demand to recover the expense of the new investment.

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<sup>388</sup> Cantel International, “Cantel Announces Initiatives to Help Fight COVID-19,” April 1, 2020; Businesswire.com, “Premier Inc. and 15 Leading Health Systems Invest,” May 26, 2020; Freeman, “Vidalia Mills Receives New PPE,” June 17, 2020; industry representatives, telephone interview by USITC staff, October 2, 2020.

<sup>389</sup> Medline Industries, Inc., written submission to USITC, September 14, 2020, 5.

<sup>390</sup> DOD, “DOD Awards \$3.5 Million Contract,” July 19, 2020.

<sup>391</sup> Medline Industries, written submission to USITC, September 14, 2020, 5; USITC, hearing transcript, September 24, 2020, 350 (testimony of Linda Rouse O’Neill, HIDA); industry representatives, telephone interviews by USITC staff, September 30 and October 2, 2020.

<sup>392</sup> Starting in July 2020, disposable face masks were covered by a new HTS statistical suffix, 6307.90.9870; before July, disposable face masks were covered by HTS statistical suffix 6307.90.9889, which covers a large basket of miscellaneous textile articles.

<sup>393</sup> This covers all disposable non-respirator masks, not just surgical masks. Unless otherwise noted, trade data in this paragraph are based on USITC DataWeb/USDOC (HTS 6307.90.9870, accessed October 2020).

<sup>394</sup> Ad valorem is a rate of duty expressed as a percentage of the appraised customs value of the imported good.

<sup>395</sup> HTS chapter 99 subchapter 3 note 20; 85 Fed. Reg. 15244 (March 17, 2020).

## Factors Affecting U.S. Production

New U.S. entrants to domestic surgical face mask production face several challenges, including regulatory approval. Producers must meet the requirements for FDA’s 510(k) clearance. The process can take six months or longer and cost up to \$65,000 in legal fees and testing costs, although FDA issued an EUA for surgical masks on August 5, 2020, that may help expedite getting new products to market.<sup>396</sup> In addition, although surgical masks do not require approval through NIOSH (as N95 respirators do), they do require testing by an independent laboratory. At its peak, the only laboratory testing these products in the United States experienced a backlog of two to three months; however, by the beginning of October 2020 the backlog reportedly had been reduced to less than one month.<sup>397</sup>

The cost of starting up a new surgical mask manufacturing facility is a multimillion-dollar process including the costs of machinery, outfitting buildings, and training.<sup>398</sup> To recoup the cost of investment, industry representatives stated they need a guaranteed long-term market, which could include “Buy American” provisions for U.S. government contracts and longer-term contracts that go beyond the current 90 to 120 days.<sup>399</sup> This guarantee will be particularly critical when demand returns to pre-pandemic levels. In addition, one industry source stated that before the onset of the pandemic, domestic production costs for surgical masks were typically at least twice those of China.<sup>400</sup> There is concern that once the demand for surgical masks declines, U.S. producers’ products may not be cost competitive against imported masks.<sup>401</sup> Other impediments to expanding production are the amount of time needed to import the machinery from overseas (6–8 months) and uncertainty about access to necessary service and technical support.<sup>402</sup> In addition, industry sources report it can also be difficult for a new supplier to gain trust and market acceptance from the medical community.<sup>403</sup>

As with other PPE, manufacturers face obstacles concerning the availability of materials. The filtration material (meltblown nonwoven fabric) used in surgical masks has been in short supply as U.S. and foreign producers increase production of surgical masks and N95 respirators, which both use this product. Nevertheless, there has been significant new investment to increase production of meltblown

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<sup>396</sup> For example, Premium PPE is a domestic producer of disposable face masks that received an EUA for surgical masks on October 15, 2020. USITC, hearing transcript, September 24, 2020, 364–65 (testimony of David Greer, Techman Sales, Inc.); FDA, “Personal Protective Equipment EUAs,” November 10, 2020; industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>397</sup> Nelson Labs is the only laboratory conducting the ASTM testing standards for surgical masks in the United States. Industry representatives, telephone interview by USITC staff, October 1, 2020.

<sup>398</sup> Industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>399</sup> Frontline, “America’s Medical Crisis,” October 6, 2020; USITC, hearing transcript, September 24, 2020, 533–34, 543 (testimony of Daniel Feibus, Vidalia Mills) and 520, 522–25 (testimony of Kim Glas, NCTO).

<sup>400</sup> Industry representatives, telephone interviews by USITC staff, September 29 and October 2, 2020.

<sup>401</sup> USITC, hearing transcript, September 24, 2020, 360 (testimony of Michael Einhorn, Dealmed Medical Supplies); Frontline, “America’s Medical Crisis,” October 6, 2020; industry representatives, telephone interview by USITC staff, October 2, 2020.

<sup>402</sup> Industry representatives, telephone interview by USITC staff, September 14, 2020.

<sup>403</sup> USITC, hearing transcript, September 24, 2020, 466–67 (testimony of David Greer, Techman Sales, Inc.) and 467 (testimony of Linda Rouse O’Neill, HIDA).

nonwoven fabric, both in the United States and globally.<sup>404</sup> (See the “production and delivery” section of the previous case study on N95 respirators for additional information on the shortage of meltblown fabric.) Several industry sources indicated that even though face mask production is more automated than that of some products, such as medical gowns, the cost of production is still higher in the United States than in China or other Asian countries.

## Factors Affecting U.S. Imports

Industry sources cited three main factors affecting the availability of imports of surgical masks. First, early in the pandemic, the general lack of PPE available from China, the largest source of surgical masks for the U.S. market, combined with intense global demand competition worked to limit the supply available for U.S. importers.<sup>405</sup> Second, industry sources reported that transportation logistics both within China and shipping surgical masks out of China were particularly difficult early in the pandemic.<sup>406</sup> For instance, the cost of airfreight increased nearly 10-fold compared with pre-pandemic costs.<sup>407</sup> Third, some foreign countries manufacturing surgical masks, including Thailand, Malaysia, South Korea, Vietnam, and India, imposed export restrictions.<sup>408</sup> One industry representative stated that foreign export controls were the reason for shortages of surgical face masks and, in particular, that there have been long delays in obtaining export approvals for surgical masks from Thailand.<sup>409</sup> In China, changing requirements on the documentation required for surgical masks added to significant logistics challenges firms already faced in exporting the product.<sup>410</sup>

## Surgical and Isolation Gowns

### Major Findings

- The United States began 2020 with an existing shortage of surgical and isolation gowns due to a recall by a major U.S. supplier. With the onset of the pandemic, the shortage has grown, especially for isolation gowns. Demand is driven not only by traditional customers like hospitals, but also by nontraditional customers such as primary care facilities and dental offices.
- The United States relies heavily on imports to supply the U.S. market. There is little medical gown production capacity in the United States because gown production is a labor-intensive

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<sup>404</sup> INDA, *Meltblown Nonwoven Markets: COVID-19 Impact Analysis, 2020*, 54; Medline Industries, written submission to USITC, September 14, 2020, 7; industry representatives, telephone interview by USITC staff, August 17, 2020.

<sup>405</sup> USITC, hearing transcript, September 24, 2020, 350, (testimony Linda Rouse O’Neill, HIDA), 356–58 (testimony of Michael Einhorn, Dealmed Medical Supplies); industry representatives, telephone interview by USITC staff, September 15, 2020.

<sup>406</sup> Industry representatives, telephone interviews by USITC staff, September 28, 2020 and October 2, 2020.

<sup>407</sup> Industry representatives, telephone interviews by USITC staff, September 28, 2020. See chapter 2 for additional information on the reduction in air cargo capacity and the increase in air freight costs.

<sup>408</sup> AdvaMed, written submission to USITC, October 7, 2020; USITC, hearing transcript, September 24, 2020, 351–52 (testimony Linda Rouse O’Neill).

<sup>409</sup> Medline, written submission to USITC, September 14, 2020, 5.

<sup>410</sup> Industry representatives, telephone interview by USITC staff, November 10, 2020.



process, and U.S. labor rates are relatively higher than those in other major supplying countries, including China and Vietnam.

- In response to the supply shortage, existing U.S. firms pivoted to making disposable and reusable gowns, although they faced numerous constraints. In addition to a shortage of the nonwoven fabrics used in disposable gowns, new U.S. producers reported facing two other obstacles: demand uncertainty stemming from a lack of guaranteed orders by customers or the U.S. government; and difficulties in understanding, designing to, and manufacturing in accordance with FDA standards.

## Introduction

The COVID-19 pandemic has contributed to a severe shortage of surgical and isolation gowns in the U.S. market. In January 2020, Cardinal Health (which produces mainly in China) recalled 9.1 million gowns from the U.S. market, causing the United States to face a deficit in the supply of surgical and isolation gowns even before the pandemic was declared in March. The shortage was worsened by additional demand pressure, as nontraditional customers (such as first responders and primary care offices) requested supplies of gowns to protect themselves against exposure to the virus. U.S. firms tried to address the demand surge by beginning and expanding production but were hampered by shortages of SMS fabrics. Also, U.S. firms hesitated to invest in expensive machinery due to uncertainty about future demand and return on investment.<sup>411</sup> The United States continues to rely on imports of isolation and surgical gowns, mainly from China, Vietnam and Turkey, to satisfy demand, with imports continuing to account for the vast majority of the market.<sup>412</sup> However, imports were constrained by restrictions placed in China on medical protective clothing exports and by U.S. purchasers' concerns about the quality of gown imports.

## Product Overview

Surgical and isolation gowns are used in healthcare settings to protect wearers from infection or illness.<sup>413</sup> Surgical gowns are intended to be worn by healthcare personnel during surgical procedures to protect both the patient and the health care personnel from the transfer of microorganisms, bodily fluids, and particulate matter. Isolation gowns, which offer a higher level of protection, are designed to protect the back as well as the front of the body; they are used in situations where there is a medium to high risk of contamination.<sup>414</sup> FDA considers both types of gowns Class II medical devices. They must meet several FDA requirements, including standards relating to their liquid barrier performance.<sup>415</sup>

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<sup>411</sup> Industry representatives, telephone interview by USITC staff, September 17, 2020.

<sup>412</sup> USITC DataWeb/USDOC (accessed November 2020); industry representatives, telephone interview by USITC staff, October 2, 2020.

<sup>413</sup> FDA, "Personal Protective Equipment for Infection Control: Medical Gowns," March 11, 2020.

<sup>414</sup> According to FDA, the critical zones of protection for isolation gowns do not include bindings, cuffs, and hems; gowns (including seams) must meet the highest liquid barrier protection level for which the gown is rated. The surgical gown has a lower level of protection because its critical zones only include the front of the body from top of shoulders to knees, and the arms from the wrist cuff to above the elbow. FDA, "Personal Protective Equipment for Infection Control: Medical Gowns," March 11, 2020.

<sup>415</sup> FDA, "Personal Protective Equipment for Infection Control: Medical Gowns," March 11, 2020.

Standards for surgical gowns and isolation gowns are based on standards of the Association for the Advancement of Medical Instrumentation (AAMI)<sup>416</sup> and the American National Standards Institute (ANSI) that cover four levels of liquid barrier protection, with level 1<sup>417</sup> being the lowest level and level 4 the highest.<sup>418</sup> FDA adopted these standards and they must be met before surgical gowns can obtain the required FDA clearance for sale into the U.S. market. In addition to liquid barrier protection, the ANSI and AAMI standards also describe testing requirements for surgical gowns to evaluate tear resistance, seam strength, lint generation, evaporative resistance, and water vapor transmission.<sup>419</sup> Further, level 4 surgical gowns must pass an ASTM standard requiring a viral penetration resistance test before obtaining FDA clearance.<sup>420</sup>

There are both disposable gowns and reusable gowns, which are made of different fabrics (figure 4.9).<sup>421</sup> Disposable gowns, made from nonwoven materials, are designed to be used once.<sup>422</sup> Reusable gowns, which may be made from polyester or cotton woven or knit fabrics,<sup>423</sup> can be laundered from 25 to 100 times before their shelf life expires, and as such are a better financial alternative for hospitals.<sup>424</sup> Due to the shortage of disposable surgical gowns during the COVID-19 pandemic, FDA issued an Emergency Use Authorization (EUA) for the use of level 1 and level 2 reusable gowns that were not otherwise authorized for use as surgical gowns, provided they contain a label with instructions for cleaning, disinfecting, and sterilizing them according to the standards of the Occupational Safety and Health Administration (OSHA).<sup>425</sup>

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<sup>416</sup> Specifically, ANSI (American National Standards Institute)/AAMI PB70:2012 is the standard that establishes a classification system (levels 1–4) for surgical gowns, based on liquid barrier performance using standardized test methods.

<sup>417</sup> Level 1 gowns are used in minimal-risk settings such as during basic care or standard isolation, as a cover gown for visitors, or in a standard medical unit and nursing homes. Level 2 gowns are used in low-risk settings, such as during blood draws, suturing, in the intensive care unit (ICU), or a pathology lab. FDA, “Personal Protective Equipment for Infection Control: Medical Gowns,” March 11, 2020.

<sup>418</sup> Level 3 gowns are used in moderate-risk settings, whereas level 4 gowns, which prevent virus penetration for up to one hour, are used in high-risk situations when pathogen resistance is needed or infectious diseases are suspected. FDA, “Personal Protective Equipment for Infection Control: Medical Gowns,” March 11, 2020.

<sup>419</sup> FDA, “Personal Protective Equipment for infection control: Medical Gowns,” March 11, 2020.

<sup>420</sup> CDC, “NIOSH Personal Protective Equipment Information (PPE-Info),” November 15, 2015.

<sup>421</sup> Grandview Research, “Hospital Gowns Market Size, Share and Trends,” August 2020.

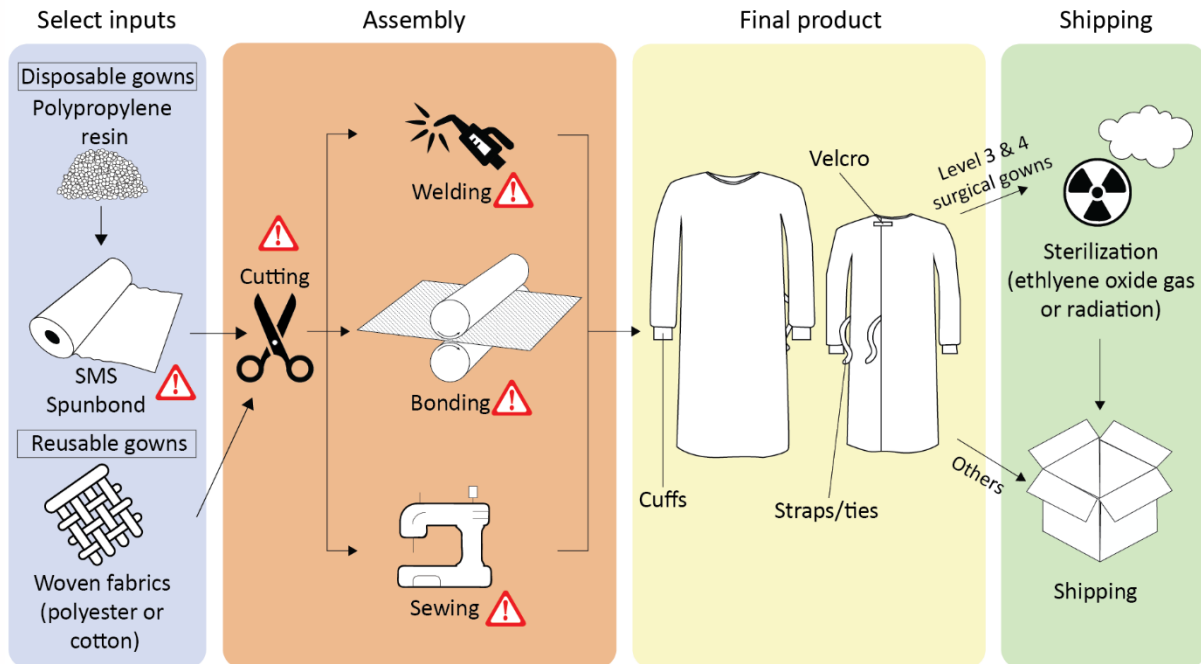
<sup>422</sup> Grandview Research, “Hospital Gowns Market Size, Share and Trends,” August 2020.

<sup>423</sup> Chaion, “Science behind Surgical Gowns,” August 2020.

<sup>424</sup> FABRIC, “What We Are Doing to Solve the Problem” (accessed November 2, 2020); USITC, hearing transcript, September 24, 2020, 549 (testimony of Kim Glas of NCTO).

<sup>425</sup> FDA, “FAQs on Shortages of Surgical Masks and Gowns,” June 19, 2020; FDA, “Emergency Use Authorization Letter for Gowns,” May 22, 2020.

**Figure 4.9** Surgical and isolation gowns: identifying key inputs and components that have caused supply chain challenges and constraints up through packaging



Source: Compiled by USITC staff.

Note: Red exclamation points indicate supply chain challenges and constraints; SMS = Spunbond meltblown spunbond.

Disposable surgical and isolation gowns are primarily made of two nonwoven fabrics, SMS nonwoven fabric and spunbond fabric (see nonwovens box 4.1), depending on the level of protection required and the intended end use.<sup>426</sup> Level 1 isolation gowns can also be made of polyethylene (plastic) materials.<sup>427</sup> Level 1 or level 2 surgical and isolation gowns may be made from spunbond nonwoven fabric or a lighter-weight SMS fabric, which does not offer as high a level of liquid barrier protection.<sup>428</sup> In contrast, level 3 or level 4 surgical and isolation gowns require a higher level of fluid barrier protection, and are often produced with denser SMS fabric which offers healthcare workers the highest level of protection from contact with body fluids or bacteria.<sup>429</sup> Other inputs to gowns include knit cuffs, closures such as hook-and-loop (Velcro), and trim.

Reusable gowns are generally made from tightly woven plain weave fabrics, normally polyester or cotton. These gowns are chemically finished or coated and often pressed through rollers to enhance the

<sup>426</sup> Kilinc, "A Review of Isolation Gowns," September 2015; Grandview Report, "Healthcare Personal Protective Equipment Market Size, Share & Trends," April 2020; Fashion for the Frontlines, "Medical Gown Requirements," (accessed October 23, 2020).

<sup>427</sup> Medline, written submission to USITC, September 14, 2020, 6.

<sup>428</sup> The spunbond nonwoven fabric outer layer gives the gown increased tensile strength which prevents ripping and tearing of the fabric. The spunbond layer that is worn closest to the skin allows for a highly breathable environment and helps to keep the wearer cool. Biotextiles 2016, "Introduction to Biotextiles: Surgical Gowns," March 14, 2016; Holdsworth, "What Is SMS or Spunbond Meltblown Spunbond?" (accessed November 2, 2020); Blickman, "Personal Protective Equipment" (accessed October 23, 2020).

<sup>429</sup> FDA, "Personal Protective Equipment: Medical Gowns," March 11, 2020.

liquid-barrier properties.<sup>430</sup> Production of reusable gowns is more labor intensive because they are made with woven fabrics that must be cut and then sewn or welded together.<sup>431</sup> For gowns with a high level rating, the surgical gown must be sterilized to kill microorganisms using one of three methods: heating in an autoclave, using ethylene oxide gas, or applying radiation.<sup>432</sup>

## U.S. Market

The U.S. market for surgical and isolation gowns in 2019 was estimated at about 800 million units (valued at roughly \$500 million–\$700 million).<sup>433</sup> Imports supply most of the market, with import penetration rates as high as 99 percent.<sup>434</sup> Disposable gowns are far more common than reusable gowns, accounting for more than 90 percent of the U.S. gown market in 2019; the share of reusable gowns is growing, however, with new U.S. production following the start of the pandemic.<sup>435</sup>

Since March 2020, there have been severe shortages of surgical and isolation gowns.<sup>436</sup> Industry representatives estimated that in 2020 the U.S. market has more than tripled, based on data provided in October 2020, to an estimated 2.9 billion gowns over the full year 2020.<sup>437</sup> Increased demand from both traditional (e.g., hospitals) and nontraditional customers (e.g., doctors' offices, dental and ophthalmologist practices, police departments, and rescue workers) contributed to the rapid growth in the market.<sup>438</sup> Distributors, which were hesitant to order thousands of gowns owing to sales uncertainty prior to the pandemic, were soon placing orders for millions of units, and ultimately had to place customers on allocation.<sup>439</sup> To combat the surging demand for medical gowns, FDA relaxed some of its standards to facilitate supply during the COVID-19 pandemic, including allowing the use of expired medical gowns if they exhibited no visible tears or degraded fibers.<sup>440</sup>

During 2020, demand pressures and shortages were greater for isolation gowns, which are more widely used for the treatment of COVID-19 patients, than for surgical gowns.<sup>441</sup> For example, in June 2020, Premier, a leading healthcare group purchase organization (GPO), surveyed 100 U.S. health systems and

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<sup>430</sup> Kilinc, "A Review of Isolation Gowns," September 2015.

<sup>431</sup> Google Patents, "Surgical Gown and Method of Manufacturing the Surgical Gown," 2012.

<sup>432</sup> Google Patents, "Surgical Gown and Method of Manufacturing the Surgical Gown," 2012.

<sup>433</sup> Commission estimates based on industry interviews, email messages to USITC staff, October 8 and 9, 2020.

<sup>434</sup> Industry representatives, interviews by USITC staff, September 30 and October 2, 2020; Webber, "High Demand for Medical Gowns," August 2, 2020.

<sup>435</sup> Based on 2019 data. Grandview Research, "Hospital Gowns Market Size, Share & Trends," August 2020; USITC, hearing transcript, September 24, 2020, 578 (testimony of Kim Glas, NCTO); industry representatives, interviews by USITC staff, September 29 and October 2, 2020.

<sup>436</sup> One U.S. firm noted that there is currently no shortage of gowns made from polyethylene material (which are not certified to AAMI standards) but noted a shortage in gowns made from nonwoven materials. Medline, written submission to USITC, September 14, 2020; Wan, "America Is Running Short on Masks, Gowns," July 8, 2020.

<sup>437</sup> These data are based on reported numbers by traditional participants in the healthcare sector, and there may be new manufacturers or other applications not fully captured in the data. Industry representative, email message to USITC staff, October 8, 2020.

<sup>438</sup> Webber, "High Demand for Medical Gowns," August 2, 2020; Wan, "America is Running Short on Masks, Gowns," July 8, 2020.

<sup>439</sup> Industry representatives, telephone interviews by USITC staff, September 2 and 28, 2020.

<sup>440</sup> FDA, "FAQs on Shortages of Surgical Masks and Gowns," June 19, 2020.

<sup>441</sup> Industry representatives, telephone interview by USITC staff, October 2, 2020.

found that isolation gowns were being consumed at five times the normal rate.<sup>442</sup> Industry sources claim that demand for isolation gowns remained high from spring through fall 2020, while traditional demand for surgical gowns dropped slightly over the same timeframe because fewer surgical procedures occurred during the pandemic.<sup>443</sup> When isolation gowns cannot be sourced, industry has indicated that surgical gowns are being used as a substitute, although they are more expensive.<sup>444</sup> In general, health systems faced supply shortages for both types due to pending backorders starting in the spring 2020.<sup>445</sup>

Healthcare systems, either on their own initiative or as directed by states, have been increasing their stockpiles of PPE, including medical gowns, which has further exacerbated the supply shortage.<sup>446</sup> In addition, the federal government has issued requests for proposals for the purchase of isolation gowns. The U.S. government signed contracts with nine U.S. firms in September 2020 for at least 73 million disposable isolation gowns (expandable to 275 million gowns if needed for the SNS) and 15 million reusable gowns.<sup>447</sup>

## U.S. Manufacturing Industry

### Finished Goods

The value of U.S. surgical and isolation gown production is estimated at about \$70 million in 2019.<sup>448</sup> Prior to the pandemic, there were very few U.S. producers of disposable and reusable surgical and isolation gowns, with the two most prominent being Merrow Manufacturing and Standard Textile Co. (table 4.3).<sup>449</sup> However, there have been a number of new entrants, and since March 2020, many U.S. apparel and textile firms have added domestic capacity by altering their product lines to include surgical and isolation gowns. Newer entrants include companies such as 99 Degrees and Keep It Here.<sup>450</sup> Many of these companies already had cut and sew capabilities but did not produce apparel domestically.<sup>451</sup>

<sup>442</sup> Premier, "Premier Inc. Survey of Covid-19," April 1, 2020; USITC, hearing transcript, September 24, 2020, 352 (testimony of Linda O'Neill, HIDA).

<sup>443</sup> Industry representatives, telephone interview by USITC, October 2, 2020.

<sup>444</sup> Industry representatives, interviews by USITC staff, September 29 and 30, 2020.

<sup>445</sup> Premier's survey consisted of 100 health systems representing 2,026 total facilities across 48 states in the United States. The Premier Survey found that 49 percent of respondents cited isolation gowns as heavily back ordered, while 35 percent of respondents found that surgical gowns were heavily backordered as of June 2020. *LABline*, "Survey Shows Supply Chain Shortages Persist," July 1, 2020.

<sup>446</sup> *LABline*, "Survey Shows Supply Chain Shortages Persist," July 1, 2020; industry representatives, telephone interview by USITC staff, September 28, 2020.

<sup>447</sup> DOD, "DOD Awards Contracts for COVID-19 Disposable Isolation Gowns," September 14, 2020; DOD, "DOD Awards Contracts for COVID-19 Reusable Isolation Gowns," September 11, 2020.

<sup>448</sup> Industry representatives, email messages to USITC staff, October 8 and 9, 2020; industry representatives, telephone interview by USITC staff, October 2, 2020.

<sup>449</sup> Diment, "Surgical Apparel Manufacturing," March 2020; Scientect, "Surgical Gowns Market 2020," August 17, 2020.

<sup>450</sup> Mathieu, "Local Manufacturer Shifts Production," April 17, 2020; Friedman, "Denim Firms Vidalia Mills," May 12, 2020; Grandview Research, "Hospital Gowns Market Size, Share & Trends," August 2020; U.S. Chamber of Commerce, "Tracker: How Businesses Are Accelerating Production" (accessed September 14, 2020); Quito, "Ford is Using Airbag Material to Make Hospital Gowns," April 13, 2020.

<sup>451</sup> Webber, "High Demand for Medical Gowns," August 2, 2020.

**Table 4.3** Selected U.S. surgical and isolation gown manufacturers

Company (global headquarters)	U.S. production location(s)
Merrow Manufacturing (U.S.)	Fall River, MA
Standard Textile Co. Inc. (U.S.)	Thomaston, GA, and Union, SC
99 Degrees (U.S.)	Lawrence, MA
Shawmut Corp. (U.S.)	West Bridgewater, MA

Sources: Merrow Manufacturing, “Merrow Manufacturing Becomes Largest Producer Of USA-Sourced PPE,” May 21, 2020; Wade, “Lawrence Company Making Gowns for Health Care Workers,” April 13, 2020; Ebben, “Shawmut Corporation Joins Coronavirus Fight By Making Hospital Gowns,” April 30, 2020; Standard Textile Co. Inc. “Standard Textile Increases Production of Healthcare Products to Support Medical Workers,” March 31, 2020.

## Inputs

As noted in box 4.1, most U.S. production of nonwoven fabrics is not supplied to the PPE market.<sup>452</sup> In 2019, U.S. production capacity for SMS and spunbond fabrics totaled about 1.1 billion kilograms.<sup>453</sup> About 20 percent of SMS and 5 percent of spunbond production are estimated to have been for medical end uses, which, in addition to medical gowns and surgical masks, includes products used for wound care and surgical drapes.<sup>454</sup> Domestic production of spunbond and SMS fabrics was already operating at more than 90 percent capacity before the pandemic and had little room to expand further.<sup>455</sup> However, industry sources indicated that firms optimized their equipment to expand production and, to the extent feasible, shifted some of their production from nonmedical to medical applications.<sup>456</sup> For example, Berry Global Group, Inc., announced an \$8 million investment to optimize its U.S. production of SMS fabrics used in medical gowns, face masks, and other PPE; its expanded capacity is expected to be operational in December 2021.<sup>457</sup> Despite increased U.S. nonwoven production, several industry representatives noted that as of September 2020 it is difficult to obtain SMS fabric, and many companies that produce these fabrics are fully booked with orders until at least early 2021.<sup>458</sup>

Several firms make nonwoven fabric domestically for disposable medical gowns, including Berry Global Group, PF Nonwovens, and Owens & Minor, a vertically integrated medical gown producer.<sup>459</sup> Precision Fabrics Group makes nonwoven and woven fabrics for disposable and reusable protective apparel and has traditionally served nonmedical applications. In response to COVID-19, the company has

<sup>452</sup> Kalil, “The State of the North American Nonwoven’s Market and Its Response to COVID-19,” September 29–30, 2020; industry representatives, telephone interviews by USITC staff, August 17 and October 1, 2020.

<sup>453</sup> INDA, *North American Supply Report–2019*, May 2020, 12; industry representatives, telephone interview by USITC staff, October 1, 2020.

<sup>454</sup> Industry representatives, telephone interviews by USITC staff, August 17 and October 1, 2020.

<sup>455</sup> Kalil, “The State of the North American Nonwoven’s Market and Its Response to COVID-19,” September 29–30, 2020; industry representatives, telephone interview by USITC staff, August 17, September 25, and October 1, 2020.

<sup>456</sup> Industry representatives, telephone interview by USITC staff, September 22 and 25, 2020.

<sup>457</sup> The upgrade is in its Statesville, NC plant. Berry Global Group, Inc., “Berry Announces Capacity Enhancements,” May 20, 2020.

<sup>458</sup> Industry representatives, interviews by USITC staff, September 17, 22, and 29, 2020.

<sup>459</sup> Berry Global Group, Inc., “COVID-19” (accessed October 24, 2020); Andes, “Hazle Township Plant Making Materials Needed,” April 17, 2020; Christian and Prober, “Letter to Senator Warren and Senator Blumenthal on behalf of Owens & Minor,” May 18, 2020.

transitioned to supplying fabric for healthcare use.<sup>460</sup> Other domestic producers of woven medical fabrics for use in reusable gowns include Milliken & Company and Standard Textile, the latter producing fabrics as part of its vertically integrated reusable gown operation.<sup>461</sup>

## U.S. Imports

### Finished Goods

In 2019, U.S. imports of products classified under a broader HTS grouping that includes surgical and isolation gowns, as well as other garments,<sup>462</sup> totaled 2.4 billion garments valued at \$1.7 billion, of which surgical and isolation gowns were estimated at between \$500 and \$700 million.<sup>463</sup> U.S. imports of this broader HTS grouping increased almost 150 percent by quantity to 4.4 billion units and almost 300 percent in value terms in January to September 2020 compared to the same period in 2019. Imports in June 2020 alone exceeded total imports by value in the first half of 2019. Imports under HTS 6210.10.5000, the primary HTS number for gowns,<sup>464</sup> increased more than 200 percent by volume from January–September 2019 to the same period in 2020, rising from 1.0 billion garments to 3.1 billion garments. The value of imports increased more than 500 percent, from \$593 million in January to September 2019 to \$3.6 billion during the same time period in 2020. The number of garments imported per month peaked in June 2020 at 792 million garments (figure 4.10).<sup>465</sup>

<sup>460</sup> Precision Fabrics, “Protective Apparel Fabrics” (accessed October 24, 2020); Adams, “PFG on the Front Lines in the Coronavirus Fight,” March 26, 2020.

<sup>461</sup> Milliken & Company, “Milliken & Company Increases Inventory of Reusable Protective,” July 27, 2020; Standard Textile, written submission to USITC, October 2, 2020, 1; Standard Textile.

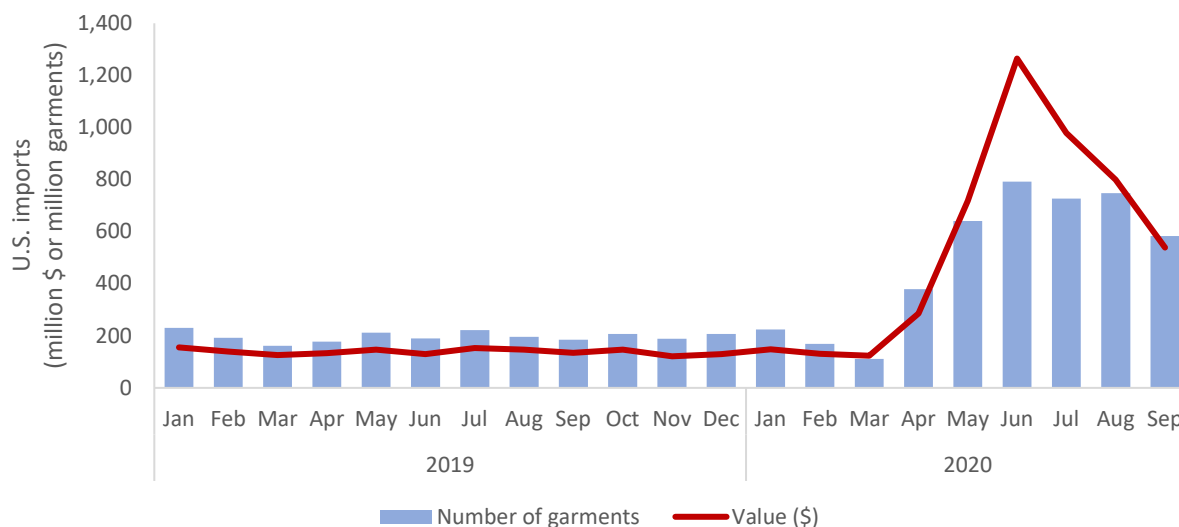
<sup>462</sup> Imported surgical and isolation gowns are generally classified in chapter 62 of the international Harmonized Commodity Description and Coding System (HS). The exact HTS number depends on the type of material used, and they are included under numbers that cover other apparel items. See figure 4.8 for HTS numbers. Duty rates for medical gowns range from 0 to 16 percent ad valorem for surgical and isolation gowns. Surgical or isolation gowns included in HTS 6113.00.1012 and 6210.10.5000 are not subject to section 301 tariffs, while the section 301 tariffs on surgical and isolation gowns classified under HTS 6210.10.2000, and 6210.10.9040 were suspended on December 15, 2019. Section 301 tariffs of 25 percent ad valorem are levied on U.S. imports from China under HTS 3926.20.9050 and 7.5 percent ad valorem on imports under 6210.50.5555, 6211.42.1081, and 6211.43.1091. USITC, Harmonized Tariff Schedule of the United States (2020) Revision 22.

<sup>463</sup> Industry representative, email to USITC staff, October 8, 2020.

<sup>464</sup> HTS 6210.10.5000 covers nonwoven disposable apparel designed for use in hospitals, clinics, laboratories or contaminated areas.

<sup>465</sup> Official trade statistics, DataWeb, accessed September 10, 2020; industry representative, telephone interview by USITC staff, October 2, 2020.

**Figure 4.10** U.S. imports of medical gowns and other goods in the broader HTS grouping, January 2019–September 2020 (in million garments and million dollars)



Source: USITC DataWeb/USDOC, HTS 3926.20.9050, 6113.00.1012, 6210.10.2000, 6210.10.5000, 6210.10.9040, 6210.50.5555, 6211.42.1081, and 6211.43.1091 (accessed November 12, 2020).

Note: These import numbers are likely overstated for medical gowns as they include nonmedical gown apparel as well. Underlying data for this figure can be found in [appendix table E.15](#).

Industry representatives indicate that 80 to 90 percent of surgical and isolation gown imports are from China, while the remaining imports are primarily sourced from the rest of Asia, including Cambodia, Vietnam, Thailand, Myanmar, and Bangladesh.<sup>466</sup> China remained the major source of imports in 2020, despite stricter export requirements, with U.S. imports from China increasing from 1.5 billion to 3.5 billion garments during January to September 2020 compared with the same period in 2019.<sup>467</sup> China accounted for 69 percent of the value, and 80 percent of the volume, of U.S. surgical and isolation gown imports in the broader HTS grouping from January to September 2020 (figure 4.11).<sup>468</sup> Other suppliers of medical gowns during January–September 2020 were Vietnam (10 percent by value, 6 percent by volume), and Mexico (6 percent by value, 3 percent by volume). Among the leading import sources, Turkey had the most growth in the HTS grouping containing U.S. medical gown imports from 2019 to 2020.<sup>469</sup> An industry representative stated that Turkey has been gaining a larger share of the medical gown market because producers are price competitive and have high quality standards.<sup>470</sup>

<sup>466</sup> Industry representatives, telephone interview by USITC staff, September 30, 2020; Medline, written submission to USITC, September 14, 2020.

<sup>467</sup> China imposed restrictions on medical protective clothing stemming from maintaining the quality of exports of medical products, which were rescinded on April 26, 2020 provided the gowns met the requirements of the importing country. USITC DataWeb/USDOC (accessed September 10, 2020); Hawes, “New Challenges of Medical Sourcing,” June 12, 2020; Sandler, Travis, and Rosenberg. “China Tightens Export Requirements,” May 1, 2020.

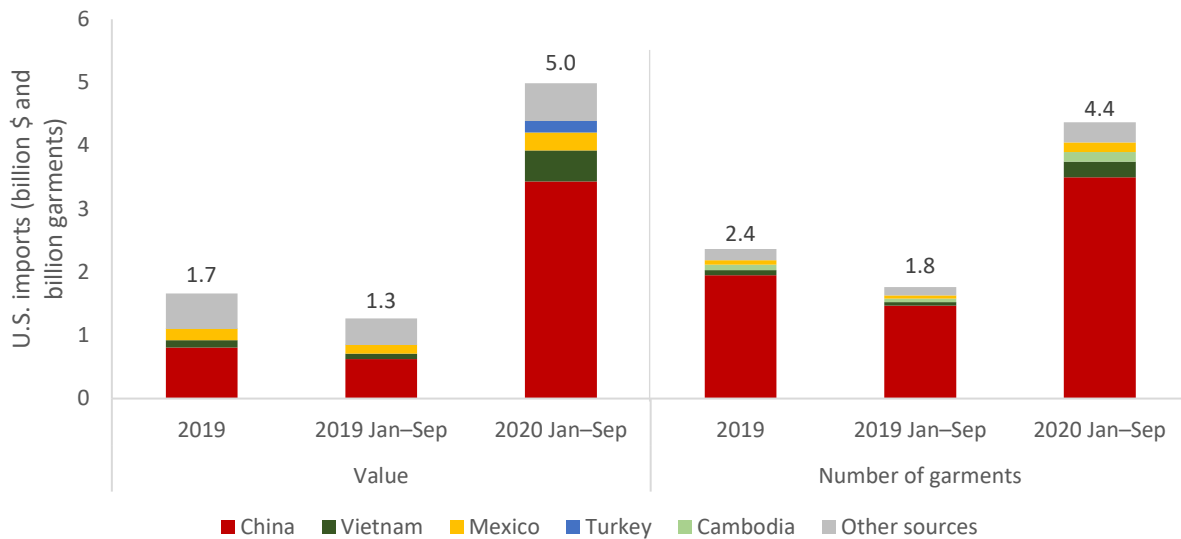
<sup>468</sup> USITC DataWeb/USDOC (accessed September 10, 2020).

<sup>469</sup> USITC DataWeb/USDOC (accessed September 10, 2020).

<sup>470</sup> Industry representatives, telephone interview by USITC staff, September 29, 2020.



**Figure 4.11** US imports of medical gowns and other goods in the broader HTS grouping, by country, 2019, January–September 2019, and January–September 2020 (in billion dollars and billion garments)



Source: USITC DataWeb/USDOC, HTS 3926.20.9050, 6113.00.1012, 6210.10.2000, 6210.10.5000, 6210.10.9040, 6210.50.5555, 6211.42.1081, and 6211.43.1091 (accessed November 12, 2020).

Note: These import numbers are likely overstated for medical gowns as they include nonmedical gown apparel as well. Countries shown for value are the top four import sources by value, and countries shown by volume are the top four import sources by volume. Underlying data for this figure can be found in [appendix table E.16](#).

## Inputs

SMS and spunbond fabrics of the types typically used in surgical and isolation gowns are generally classified in HTS subheadings 5603.11 and 5603.12,<sup>471</sup> which also cover other types of nonwoven fabrics, including, but not limited to, meltblown fabrics. U.S. imports of these fabrics totaled \$541 million in 2019 (figure 4.12).<sup>472</sup> January–August 2020 imports totaled \$487 million, up 18 percent from the same period in 2019.<sup>473</sup> China and Turkey were the largest suppliers to the U.S. market in 2019, accounting for 14 percent (\$78 million) and 12 percent (\$65 million), respectively, of U.S. imports.<sup>474</sup> These fabrics enter the United States duty-free under NTR status.<sup>475</sup>

<sup>471</sup> Industry representatives, email message to USITC staff, October 8, 2020.

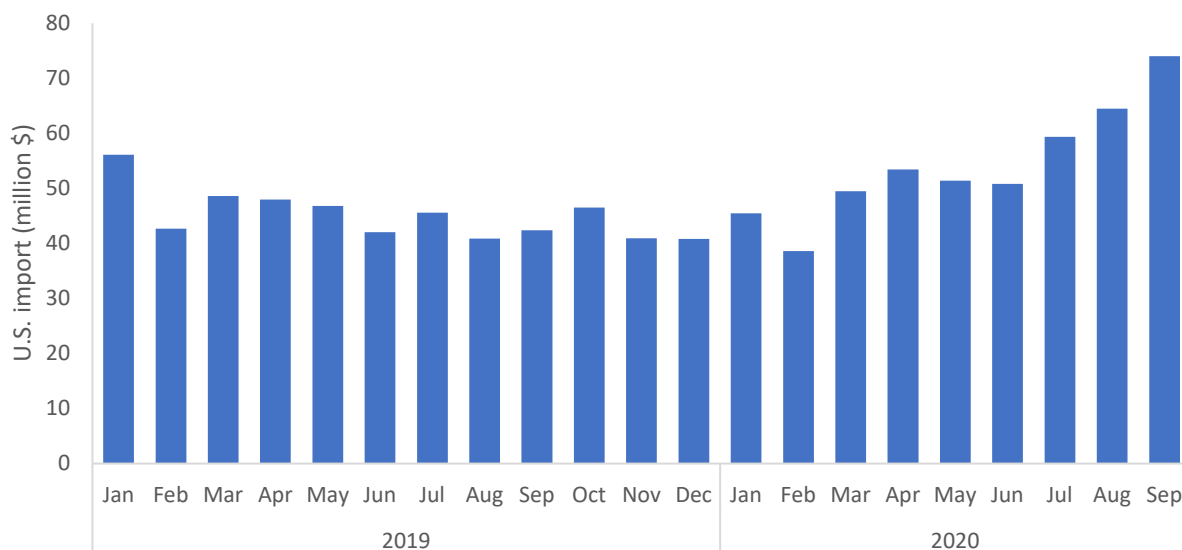
<sup>472</sup> Import data include imports under HTS subheadings 5603.11 (weighing not more than 25g/m<sup>2</sup>) and 5603.12 (weighing more than 25g/m<sup>2</sup> but not more than 70 g/m<sup>2</sup>). USITC/DOC DataWeb (accessed October 8, 2020).

<sup>473</sup> USITC/DOC DataWeb (accessed October 8, 2020).

<sup>474</sup> USITC/DOC DataWeb (accessed October 8 and 24, 2020).

<sup>475</sup> U.S. imports from China under HTS statistical reporting number 5603.12.0090 are exempt from section 301 tariffs; all other imports from China under these subheadings are subject to section 301 tariffs of 25 percent ad valorem. 83 FR 47974 (September 21, 2018); 84 FR 20459 (May 9, 2019); 85 FR 48600 (March 16, 2020); 85 FR 48600 (August 11, 2020).

**Figure 4.12** U.S. imports of selected nonwovens of the type used in surgical and isolation gowns and other goods, January 2019–September 2020, by value (in million dollars)



Source: USITC DataWeb/USDOC, HTS 5603.11 and 5603.12 (accessed November 2020).

Note: Underlying data for this figure can be found in [appendix table E.17](#).

## Supply Chain Challenges and Constraints

Even before the declaration of a pandemic, the supply chain for surgical and isolation gowns in the United States faced several challenges and constraints. As noted above in the introduction to Surgical and Isolation Gowns, Cardinal Health’s recall of 9.1 million level 3 surgical gowns from the U.S. market in January 2020 had already created a shortage before the onset of the pandemic. With the U.S. gown supply temporarily constricted by this gown recall, Chinese export restrictions began in April 2020 after concerns were raised about the quality of Chinese products, further tightening U.S. supply. In response, new U.S. firms entered the market to produce disposable and reusable gowns. However, the firms faced numerous constraints, including shortages of SMS fabrics and the high costs of such fabrics due to the short supply globally as well as high labor costs associated with cutting and assembly in the United States. Also, U.S. firms have been reluctant to purchase costly machinery to automate production because of uncertainty about long-term demand for gowns and return on their investment, especially as gown production is characterized by low profit margins.

### Factors Affecting Domestic Production

#### Market Size

Although U.S. production capacity rose in response to the pandemic, several U.S. producers and industry representatives expressed concern over entering the market owing to uncertainty about future demand and sales, the ability to recoup their investment in expensive machinery, and the availability of additional workers. The lack of demand certainty was cited by one gown manufacturer as the main hinderance to a more robust U.S. production response, as firms are unwilling to make substantial

investments without long-term contracts and predictability.<sup>476</sup> Some U.S. firms reported that the uncertainty of future demand stems, in part, from the lack of Buy American provisions and guaranteed orders from the U.S. government as well as their own customer base.<sup>477</sup> Healthcare facilities purchase gowns through distributors or a group purchase organization (GPO), and rarely go to the manufacturers directly to purchase gowns.<sup>478</sup> With a lack of guaranteed orders and contracts for purchase, some U.S. firms have reduced production, while others have stopped production altogether, resulting in idled capacity in the late summer through fall 2020.<sup>479</sup> U.S. firms stated that global manufacturers have ramped up global gown production in response to the pandemic, resulting in U.S. customers purchasing more gowns from importers and less from U.S. manufacturers, compared to their purchases in the spring of 2020.<sup>480</sup>

According to some industry representatives, another challenge for U.S. firms has been changes in government contracts that have led to confusion and a lack of demand visibility for certain types of surgical and isolation gowns. U.S. medical gown producers, especially those that are new entrants to the market, stated that bidding for U.S. government contracts is not a transparent process and can lead bidding firms to waste expenses trying to meet vague requirements in the request for proposal (RFP).<sup>481</sup> U.S. medical gown producers noted an instance where the U.S. government issued an RFP for level 1 isolation gowns, but then abruptly decided to change the RFP to purchase 250 million units of disposable level 2 through level 4 isolation gowns instead.<sup>482</sup> According to industry representatives, this incident was a source of confusion and frustration for U.S. producers because they had produced millions of yards of fabric at considerable expense to meet the original proposal for level 1 isolation gowns with reusable materials.<sup>483</sup> Another firm noted that its bid for the same RFP was rejected, along with those of five other U.S.-based firms, based on price alone.<sup>484</sup> Concerns were raised that some of the firms that were awarded federal government contracts to produce medical gowns might not have the capabilities and proficiencies to manufacture U.S.-made gowns for the federal stockpile.<sup>485</sup>

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<sup>476</sup> Concern over the ability to spread out costs and recoup investment also forced some firms to charge higher prices. Industry representative, telephone interview by USITC staff, September 17, 2020.

<sup>477</sup> Industry representatives, telephone interview by USITC staff, September 17, 2020; Vidalia Mills, written submission to USITC, September 23, 2020, 2; NCTO, written submission to USITC, September 3, 2020, 2; Gilman, written testimony to the United States Senate Committee on Commerce, Science, and Transportation, November 17, 2020, 2.

<sup>478</sup> Industry representatives, telephone interview by USITC staff, September 17, 2020.

<sup>479</sup> Industry representatives, telephone interview by USITC staff, September 17 and 22, 2020; USITC hearing transcript, September 24, 2020, 522–23 (testimony of Kim Glas of NCTO).

<sup>480</sup> Industry representatives, telephone interview by USITC staff, September 17, 2020.

<sup>481</sup> USITC hearing transcript, September 24, 2020, 522–23 (testimony of Kim Glas of NCTO).

<sup>482</sup> USITC hearing transcript, September 24, 2020, 522–24 (testimony of Kim Glas of NCTO); industry representatives, telephone interviews by USITC staff, September 17 and 22, 2020.

<sup>483</sup> USITC hearing transcript, September 24, 2020, 523–24 (testimony of Kim Glas of NCTO).

<sup>484</sup> TSG Finishing, written submission to USITC, September 11, 2020.

<sup>485</sup> NCTO, “Multi-Association Response to New York Times Report,” October 7, 2020; Gelles and Abrams, “The Trump Administration Awarded P.P.E. Contracts,” October 7, 2020; Gelles and Abrams, “An Arms Dealer, an Ex-N.F.L. Player and Huge Federal Contracts,” October 7, 2020.

## Product to Market

New U.S. entrants find it difficult to understand the FDA standards that they must follow to make their products compliant for U.S. sale. In addition, these firms do not understand if any exemptions have been made by FDA for these gowns and what they are.<sup>486</sup> Some U.S. companies have incurred additional costs to hire consultants to explain FDA standards or conduct testing in laboratories to ensure that the fabric they purchased meets quality standards for certain level gowns.<sup>487</sup> In addition, new entrants to the U.S. medical gown market must apply for 510(k) clearance for level 3 and level 4 gowns. Firms must also comply with labeling requirements before they can sell medical gowns commercially, which adds to the time required to get the product to market.<sup>488</sup>

Some firms were still unable to acquire the necessary premarket clearance approvals and not able to obtain SMS fabric (which has viral barrier properties) which are required by the FDA in order to produce level 3 and level 4 surgical gowns, and instead shifted to level 1 and level 2 reusable gown production.<sup>489</sup> In contrast, other new U.S. entrants to the production of medical gowns stated that FDA approvals for level 1 to level 2 gowns were relatively easy to obtain, often taking only two to four weeks for approval.<sup>490</sup>

## Production and Delivery

Labor costs (especially for reusable gowns) are the main barrier to producing medical gowns in the United States.<sup>491</sup> One industry representative stated that the cost for a level 3 surgical gown, for example, ranges from \$4 to \$7 out of Asia, versus \$17 to \$20 for a U.S.-made gown.<sup>492</sup> Surgical gowns require labor-intensive processes such as stitching or welding around the seams, adding elastic at the cuffs, or incorporating ties or belts, providing lower-cost Asian suppliers such as China, Thailand, and Vietnam with an advantage.<sup>493</sup> Most medical gown production takes place in China.<sup>494</sup> Reportedly, China has been producing PPE, including medical gowns, using the forced labor of Uighurs in western China, which may drive down the costs of U.S. imports of PPE from China.<sup>495</sup>

Industry representatives stated that one reason for the shortfall in U.S. medical gown production is that SMS fabrics are not available in the quantities needed to fulfill current demand.<sup>496</sup> Global SMS fabric

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<sup>486</sup> Industry representatives, telephone interviews by USITC staff, September 17 and 22, 2020.

<sup>487</sup> Industry representatives, telephone interview by USITC staff, September 22, 2020.

<sup>488</sup> Industry representatives, telephone interview by USITC staff, September 29, 2020.

<sup>489</sup> FABRIC, "What We Are Doing to Solve the Problem" (accessed November 2, 2020).

<sup>490</sup> Industry representatives, telephone interview by USITC staff, September 17, 2020.

<sup>491</sup> Medline, written submission to USITC, September 14, 2020; industry representatives, telephone interview by USITC staff, September 29, 2020.

<sup>492</sup> USITC hearing transcript, September 24, 2020, 476-77 (testimony of Michael Einhorn, Dealmed Medical Supplies).

<sup>493</sup> Industry representatives, telephone interview by USITC staff, September 17, 2020; Diment, "Surgical Apparel Manufacturing," March 2020.

<sup>494</sup> Medline, written submission to USITC, September 14, 2020, 6; industry representatives, interviews by USITC staff, September 29 and October 2, 2020.

<sup>495</sup> Xiao et al., "China Is Using Uighur," July 20, 2020; Evans, "China Uses Forced Uighur Labor," July 20, 2020.

<sup>496</sup> Wan, "America is Running Short on Masks, Gowns," July 8, 2020; Przybyla, "Medical Companies Warn PPE, Critical Equipment Shortage," July 2, 2020; industry representatives, telephone interview by USITC staff, September 22 and 25, 2020.

supply was constrained early in the pandemic, when much of the SMS fabric capacity in China was converted to producing meltblown fabrics, resulting in a shortage of SMS fabric for isolation gown manufacturers in Asia.<sup>497</sup> Domestically produced SMS is backlogged, and it is difficult for U.S. SMS producers to add more production. The machinery required for production is expensive and new capacity takes time to set up and implement.<sup>498</sup> For example, a machine to produce SMS reportedly costs between \$50 to \$60 million, and it takes at least 18 months to get a line up and running, from production to delivery.<sup>499</sup> After the COVID-19 pandemic began, SMS capacity was being used to produce inputs for face masks and respirators, instead of isolation gowns, as these items were more in demand and production was being prioritized over medical gowns.<sup>500</sup> Soon, however, new gown producers started production to try to alleviate the shortage of isolation gowns in the United States, driving up demand for SMS fabrics.<sup>501</sup> This led to a tightening of the supply chain, as SMS fabrics were unavailable or customers faced waiting lists that extended into 2021.<sup>502</sup> SMS fabric supply is still tight, although there was some recovery of this supply in fall 2020 from peak constraints in spring 2020.<sup>503</sup>

SMS fabric shortages are leading to higher SMS prices, resulting in higher production costs for U.S. firms. There has been a surge in global prices for spot buying of SMS fabric.<sup>504</sup> Industry representatives have indicated that prices for SMS fabrics on the spot market have increased to four to seven times the 2019 price.<sup>505</sup> New producers of surgical gowns were especially affected by the shortage of available supplies because they did not have long-term contracts with existing nonwoven fabric suppliers and had to buy fabrics on the spot market at inflated prices.<sup>506</sup>

## Factors Affecting U.S. Imports

### Product Availability

There was a demand-supply imbalance for surgical and isolation gowns, particularly level 3 and 4 gowns needed for the treatment of COVID-19 patients, which were already in short supply at the onset of the pandemic.<sup>507</sup> As noted above in the introduction to “Surgical and Isolation Gowns,” in January 2020, Cardinal Health (which produces mainly in China) recalled 9.1 million level 3 surgical gowns from the U.S. market after its Chinese supplier shifted production to unauthorized sites, leading to concerns

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<sup>497</sup> Industry representatives, telephone interview by USITC staff, September 30, 2020.

<sup>498</sup> Industry representatives, telephone interview by USITC staff, September 22 and 25, 2020.

<sup>499</sup> INDA, North American Supply Report–2019, May 2020, 2; industry representatives, telephone interviews by USITC staff, August 17 and September 22 and 25, 2020.

<sup>500</sup> Healthcare Purchasing News, “Premier Survey Shows Isolation Gowns Replacing N95 Masks,” April 20, 2020.

<sup>501</sup> Industry representatives, telephone interview by USITC staff, September 17 and 22, 2020.

<sup>502</sup> Industry representatives, telephone interview by USITC staff, September 22, 2020; Healthcare Purchasing News, “Premier Survey Shows Isolation Gowns Replacing N95 Masks,” April 20, 2020; industry representatives, telephone interview by USITC staff, September 17, 2020.

<sup>503</sup> Industry representatives, telephone interview by USITC staff, September 30, 2020.

<sup>504</sup> Industry representatives, telephone interview by USITC staff, September 30, 2020.

<sup>505</sup> Industry representatives, telephone interview by USITC staff, September 30, 2020 and October 20, 2020.

<sup>506</sup> Industry representatives, telephone interview by USITC staff, September 22, 2020.

<sup>507</sup> Armstrong and Sanders, “One Reason Caregivers Are Wearing Trash Bags,” April 3, 2020.

about product quality.<sup>508</sup> Coupled with the gown shortages, beginning April 1, 2020, the Chinese government imposed restrictions on exporting PPE, which included medical protective clothing.<sup>509</sup> The Chinese government stated that only those companies in China that were accredited to sell Chinese products within China could export medical protective gowns.<sup>510</sup> Most of these export restrictions on gowns were changed on April 26, 2020, allowing for protective apparel and other PPE to be exported if they met either FDA or EU requirements.<sup>511</sup> However, industry sources reported that changing customs documentation requirements caused delays and confusion and were an additional impediment to getting product out of China.<sup>512</sup>

## Medical and Surgical Gloves

### Major Findings

- Gloves are one of the most highly constrained COVID-19 related products. Global demand for gloves has increased monumentally, exceeding global production capacity, and a glove shortage is expected to continue through 2021 and into 2022. Virtually all medical gloves are imported; there is little domestic production of gloves because it is a labor-intensive process. Most U.S. imports of medical gloves are from Malaysia (primarily nitrile gloves) and China (primarily vinyl gloves).
- Global production is running at full capacity, and adding new capacity requires substantial investment and time (about one year). Production of gloves is also limited by a scarcity of the inputs used in nitrile gloves.
- Industry sources have stated that prices have been increasing steadily since spring 2020.

### Introduction

U.S. demand for medical and surgical gloves rapidly increased in response to the pandemic, but an increase in supply was much slower to materialize than for many other PPE products. As a result, in early November, there was an estimated global shortage of 200 billion gloves,<sup>513</sup> and gloves are expected to be in short supply well into 2021 and possibly in 2022. Global demand for 2020 is estimated at approximately 600 billion gloves, while total global production capacity can only supply approximately

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<sup>508</sup> Cardinal recalled certain level 3 surgical gowns after discovering that their FDA-authorized supplier (Siyang HolyMed) had shifted production of some gowns to unapproved sites. As a result, Cardinal could not assure the sterility of the gowns. Cardinal later terminated its contract with Siyang HolyMed. In order to address the supply shortage, Cardinal Health increased production of similar products, offered level 4 protective gowns to bolster the supply, and worked with other suppliers who offered substitute products. Cardinal Health, “Cardinal Health Announces Voluntary Field Actions,” January 30, 2020.

<sup>509</sup> Werner et. al, “PPE Shortages: FDA and Chinese Government Issue New Policies,” April 6, 2020.

<sup>510</sup> Wu and Bermingham, “Coronavirus: China’s New Export Restrictions,” April 3, 2020.

<sup>511</sup> Sandler, Travis, & Rosenberg, “China Tightens Export Requirements,” May 1, 2020; Hawes, “New Challenges of Medical Sourcing in China,” June 12, 2020.

<sup>512</sup> Industry representatives, telephone interview by USITC staff, November 10, 2020.

<sup>513</sup> Strickler et al., “Trump Admin is ‘Woefully Behind’ in Stockpiling,” October 29, 2020.

60 percent of that amount.<sup>514</sup> The United States has limited manufacturing of medical and surgical gloves, and almost all U.S. demand is met by imports, primarily from Malaysia. The ability of foreign suppliers to ramp up production, at least in the short term, is limited by both shortages of raw materials and production capacity constraints.

## Product Overview

Gloves used in the healthcare sector fall into four groups based on constituent material—latex, vinyl, nitrile, and other rubber synthetics (e.g., neoprene and polyisoprene). This case study focuses primarily on nitrile medical gloves. Nitrile gloves are used for a wide range of purposes and industries, including both food service and medical fields, to protect against contamination and the spread of disease. Nitrile gloves are the most common type of glove used in the medical field, including by doctors, nurses, emergency medical technicians, and technicians prepping patients, because of their cost, hypoallergenic properties, and sturdiness.<sup>515</sup> By comparison, vinyl gloves are reportedly less durable than other types of gloves, and neoprene gloves are the most expensive (due to their higher input costs and frequent use in surgical settings).<sup>516</sup> Production of nitrile gloves requires nitrile butadiene rubber (NBR) and the machinery necessary to manufacture the gloves (figure 4.13).<sup>517</sup> In the production process, ceramic hand formers are cleaned and coated before being dipped into vats of hot liquid NBR.<sup>518</sup> After drying, the finished gloves are removed from the molds and tested for quality.

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<sup>514</sup> Industry representative, telephone interview by USITC staff, October 16, 2020; Strickler et al., “Trump Admin is ‘Woefully Behind’ in Stockpiling,” October 29, 2020.

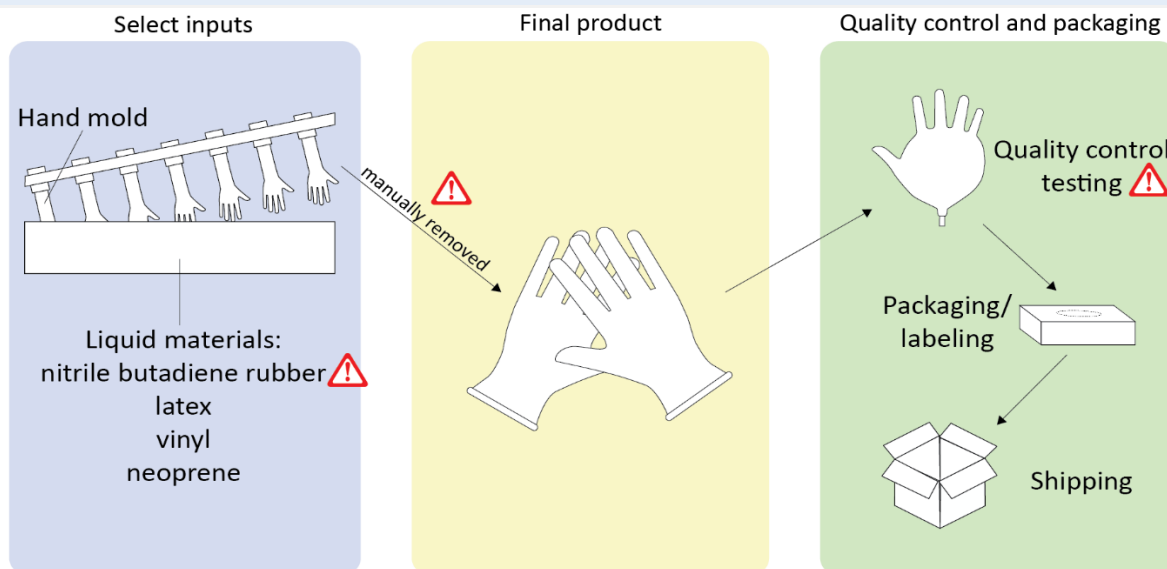
<sup>515</sup> Industry representatives, telephone interviews by USITC staff, September 29 and 30, and October 2 and 16, 2020.

<sup>516</sup> Ochs, “Tips for Choosing the Best Disposable Gloves,” November 30, 2017.

<sup>517</sup> NBR is produced through the copolymerization of butadiene and acrylonitrile.

<sup>518</sup> The formers are coated in a salt bath, which improves the coagulation of NBR around the hand former, allowing the glove to be easily removed.

**Figure 4.13** Medical and surgical gloves: identifying key inputs and components that have caused supply chain challenges and constraints up through packaging



Source: Compiled by USITC staff.

Note: Red exclamation points indicate supply chain challenges and constraints.

Gloves for medical purposes are typically divided into two groups, medical and surgical. Both medical and surgical gloves are Class I medical devices under FDA and require 510(k) premarket notification to allow FDA to review the glove for leak resistance, tear resistance, and biocompatibility (to ensure the glove will not harm the wearer). Only gloves that have received FDA 510(k) clearance can be offered for sale.<sup>519</sup> In the United States, the difference between the two glove types is that surgical gloves must be sterile and meet a third-party ASTM International (ASTM) standard, while medical gloves do not.<sup>520</sup>

According to FDA guidance, medical gloves are intended for a single use (i.e., they are changed after each patient).<sup>521</sup> However, when medical glove supplies are critically low, due to either high demand or unavailability (such as during a pandemic), FDA can offer guidance to ease supply shortages. To alleviate the shortage, on March 30, 2020, FDA authorized the use of nonmedical gloves<sup>522</sup> that closely align with FDA and ASTM standards.<sup>523</sup> Since April 27, 2020, FDA has also allowed for the reuse of medical gloves between patients with no known infectious disease as long as the gloved hands are cleaned between patients.<sup>524</sup>

<sup>519</sup> FDA, CDRH, “Medical Gloves,” June 12, 2020, 10–12.

<sup>520</sup> HTS Subheading explanatory note for HTS 4015.11 specifies: Surgical gloves are thin, highly tear-resistant articles manufactured by immersion, of a kind worn by surgeons. They are generally presented in sterile packs; Explanatory Note to 4015.11, Harmonized Commodity Description and Coding System. 2017; FDA, “Enforcement Policy for Gowns, Other Apparel, and Gloves,” March 31, 2020; FDA, “Guidance for Industry and FDA Staff,” January 22, 2008, 2–4. Government officials, telephone interview by USITC Staff, October 5, 2020.

<sup>521</sup> FDA, “Medical Glove Guidance Manual,” August 22, 2018.

<sup>522</sup> Defined here as gloves that have not met the 510(k) premarket notification requirement.

<sup>523</sup> FDA, “Enforcement Policy for Gowns, Other Apparel, and Gloves,” March 31, 2020.

<sup>524</sup> FDA, “Medical Glove Conservation Strategies,” April 27, 2020.



## U.S. Market

There was a substantial increase in U.S. glove demand following the onset of the pandemic that could not be met by existing supply sources to the U.S. market. The glove shortage was reported to still be a major concern as of November 2020.<sup>525</sup> Virtually all medical and surgical gloves in the U.S. market are supplied by imports. Based on import data, the U.S. market for medical and surgical gloves was approximately 78 billion gloves in 2019.<sup>526</sup> U.S. imports totaled 66.7 billion gloves during January–September 2020, up about 17 percent from the same period in 2019. Nitrile gloves account for most of the gloves used in the medical sector.<sup>527</sup>

Industry sources indicate that global demand for nitrile gloves has significantly exceeded supply since the onset of the pandemic, and that the global shortage of gloves is expected to last until late 2021 or early 2022.<sup>528</sup> One firm estimated that current U.S. glove demand is twice as high as in 2019.<sup>529</sup> Moreover, it is expected that the administration of vaccinations for COVID-19 will continue to put strain on the supply chain for medical gloves into 2021.<sup>530</sup>

## U.S. Manufacturing Industry

### Finished Goods

U.S. production of gloves is limited.<sup>531</sup> There are three U.S. glove producers—the Showa Group (Showa), Renco Corporation (Renco), and Rhino Health, Inc. (Rhino)—employing a combined 840 workers (table 4.4).<sup>532</sup> Showa, a domestic producer since 1951, produces 400 million gloves annually, a mix of medical and nonmedical gloves.<sup>533</sup> In December 2019, Showa announced a \$20 million expansion that is expected to double its domestic glove capacity to 800 million gloves when it comes online in April 2021.<sup>534</sup> A second expansion would bring production to 1.2 billion gloves annually, but additional details

<sup>525</sup> Industry representatives, telephone interview by USITC staff, November 10, 2020.

<sup>526</sup> USITC DataWeb/USDOC, HTS 3926.20.1010, 4015.11.0110, 4015.11.0150, 4015.19.0510, and 4015.19.0550 (accessed September 9, 2020).

<sup>527</sup> USITC hearing transcript, September 24, 2020, 472 (testimony of Michael Einhorn, Dealmed Medical Supplies, LLC); industry representatives, telephone interviews by USITC staff, September 15 and 29 and October 2, 2020.

<sup>528</sup> Medline, written submission to USITC, September 14, 2020, 4; industry representatives, telephone interviews by USITC staff, September 15, 2020; USITC hearing transcript, September 24, 2020, 472 (testimony of Michael Einhorn, Dealmed Medical Supplies); Ansell, “Edited Transcript of ANN.AX Earnings Conference Call,” August 24, 2020.

<sup>529</sup> Industry representatives, telephone interview by USITC staff, October 16, 2020.

<sup>530</sup> USITC, hearing transcript, September 24, 2020, 544 (testimony of Richard Renehan, Renco Corp.); industry representatives, telephone interview by USITC staff, October 16, 2020.

<sup>531</sup> USITC, hearing transcript, September 24, 2020, 542 (testimony of Richard Renehan, Renco Corp.); industry representatives, telephone interview by USITC staff, September 15, 2020.

<sup>532</sup> Showa Group, “SHOWA, CABVI Address Critical COVID-19 PPE Gloves Supply Needs,” July 22, 2020; USITC, hearing transcript, September 24, 2020, 527 (testimony of Richard Renehan, Renco Corp.); Quintero, “Glove Company,” March 26, 2020.

<sup>533</sup> There is U.S. production of other types of rubber gloves, but these firms do not produce the standard medical and surgical gloves discussed here. Showa, “Showa’s Investment,” October 23, 2020.

<sup>534</sup> Showa, “Showa’s Investment,” October 23, 2020; West, “Showa Group Expansion,” October 21, 2020.

on this expansion are not available.<sup>535</sup> With the onset of the pandemic, Renco, traditionally a U.S. producer of sleeve gloves<sup>536</sup> used in chemical laboratories, announced that it was expanding its operations to include production of nitrile examination gloves. Renco is using a former glove production facility in New Hampshire that it purchased in 2018, and was producing gloves as of September 2020.<sup>537</sup> Renco received \$22.4 million from the U.S. Department of Defense to assist in capacity expansion.<sup>538</sup> Finally, Rhino Health started production in New Mexico around December 2019 using an already existing building, and has an annual production capacity of 60 million gloves. It is planning an expansion that would bring its annual glove production capacity to 1.3 billion gloves.<sup>539</sup>

**Table 4.4** Identified U.S. surgical and medical glove plants, as of September 2020

Company (global headquarters)	U.S. production location(s)
Renco Corp. (U.S.)	New Hampshire
Rhino Health, Inc. (Korea)	New Mexico
Showa Group (Japan)	Alabama

Source: Showa Group, “SHOWA, CABVI Address Critical COVID-19 PPE Gloves Supply Needs,” July 22, 2020; USITC, hearing transcript, September 24, 2020, 527 (testimony of Richard Renehan, Renco Corp.); Quintero, “Glove Company,” March 26, 2020.

## Inputs

There are two companies in the United States producing NBR for gloves: Japanese-owned Zeon Corporation and U.S.-owned Huntsman Corporation.<sup>540</sup> One source indicated that minimal U.S. production of NBR limits the ability to boost domestic production of nitrile gloves.<sup>541</sup>

## U.S. Imports

### Finished Goods

U.S. imports of gloves increased during the first nine months of 2020 across almost all types of gloves, in terms of both end uses and materials.<sup>542</sup> U.S. imports of medical and surgical gloves totaled 78.0 billion (\$2.1 billion) in full-year 2019.<sup>543</sup> During January–September 2020, imports totaled 66.7 billion (\$2.1 billion), up 17 percent by quantity from the same period in 2019 (figure 4.14).<sup>544</sup> There was also an

<sup>535</sup> Showa, “Showa’s Investment,” October 23, 2020.

<sup>536</sup> Sleeve gloves are gloves that extend all the way to the shoulder.

<sup>537</sup> USITC, hearing transcript, September 24, 2020, 512 (testimony of Richard Renehan, Renco Corp.); Richard Renehan, written testimony to USITC, September 14, 2020, 4.

<sup>538</sup> USDOD, “Contracts for July 13, 2020,” July 13, 2020.

<sup>539</sup> *Albuquerque Journal*, “Glove Manufacturer,” December 13, 2018; *Navajo-Hopi Observer*, “Navajo Nation Invests,” November 19, 2019; Quintero, “Glove Company,” March 26, 2020.

<sup>540</sup> Zeon Chemicals, “Nipol NBR,” accessed October 5, 2020; Huntsman, “Nychem Specialty Nitrile Latexes” (accessed October 5, 2020).

<sup>541</sup> Strickler et al., “Trump Admin is ‘Woefully Behind’ in Stockpiling,” October 29, 2020.

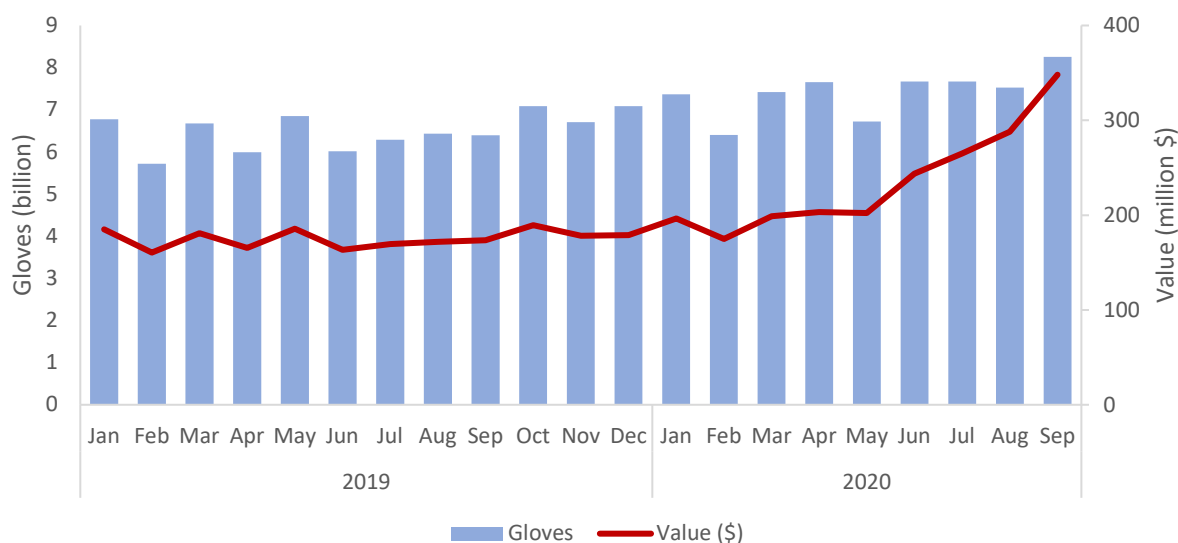
<sup>542</sup> Gloves are classified under HTS 3926.20.1010, 4015.11.0110, 4015.11.0150, 4015.19.0510, and 4015.19.0550.

<sup>543</sup> USITC DataWeb/USDOC (accessed September 1 and 9, 2020), HTS 3926.20.1010, 4015.11.0110, 4015.11.0150, 4015.19.0510, and 4015.19.0550.

<sup>544</sup> USITC DataWeb/USDOC (accessed September 1, 9, and October 8, 2020), HTS 3926.20.1010, 4015.11.0110, 4015.11.0150, 4015.19.0510, and 4015.19.0550.

increase in U.S. imports of products that may temporarily be used as a substitute for surgical and medical gloves. U.S. imports of nonmedical, nonsurgical seamless disposable gloves of rubber and vulcanized rubber gloves rose 22 percent by volume (58 percent by value) to 23.9 billion during January to September 2020 compared with the same period in 2019, while vinyl/plastic gloves rose by 36 percent by volume (163 percent by value) to 41.3 billion.<sup>545</sup>

**Figure 4.14** U.S. imports of medical and surgical gloves, January 2019–September 2020 (in billion gloves and million dollars)



Source: USITC DataWeb/USDOC, HTS 3926.20.1010, 4015.11.0110, 4015.11.0150, 4015.19.0510, 4015.19.0550 (accessed October 2020).  
Note: Underlying data for this figure can be found in [appendix table E.18](#).

With a natural abundance of rubber trees, Malaysia is the main source for rubber and vulcanized rubber medical and surgical gloves, which includes, but is not limited to, nitrile gloves.<sup>546</sup> Malaysia accounted for nearly three-quarters of U.S. imports by volume (74 percent, 48 billion gloves or \$1.3 billion) in 2019.<sup>547</sup> Between January and September 2020, 42.7 billion rubber and vulcanized rubber gloves (75 percent or \$1.2 billion) were imported from Malaysia.<sup>548</sup> China is by far the largest supplier of U.S. imports of vinyl gloves, accounting for 98 percent of vinyl gloves by quantity in full year 2019 and during January to September 2020.<sup>549</sup>

The increase in global glove demand led to a substantial increases in glove prices in 2020.<sup>550</sup> The price increases were particularly pronounced for vinyl gloves (for which data for medical and surgical are not

<sup>545</sup> USITC DataWeb/USDOC, HTS 3926.20.1020 and 4015.19.1010 (accessed October 14, 2020).

<sup>546</sup> For example, it also includes latex and neoprene gloves.

<sup>547</sup> USITC DataWeb/USDOC, HTS 4015.11.0110, 4015.11.0150, 4015.19.0510, and 4015.19.0550 (accessed September 1, and 9, 2020).

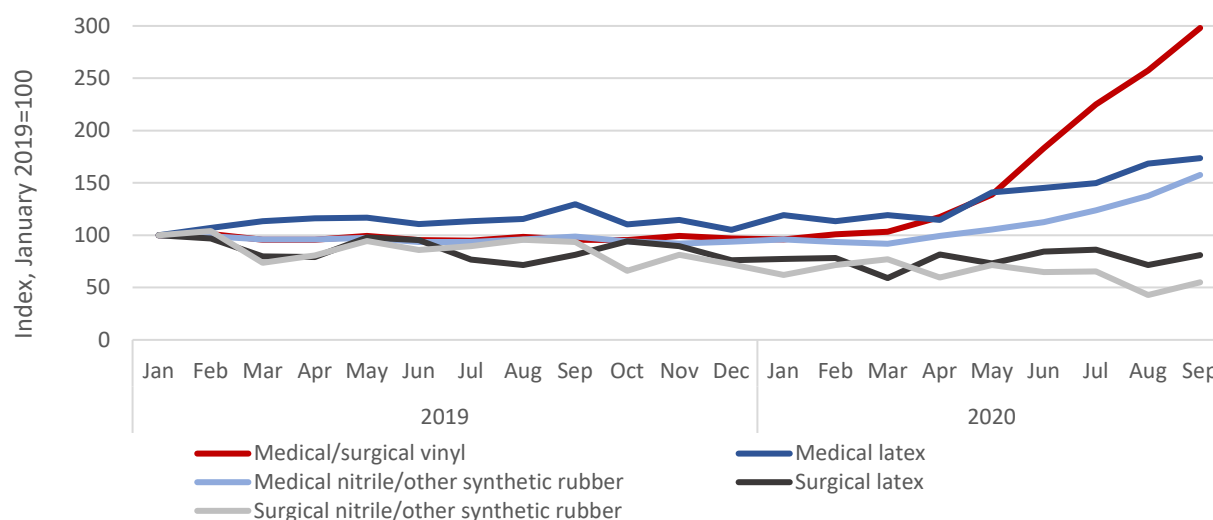
<sup>548</sup> USITC DataWeb/USDOC, HTS 4015.11.0110, 4015.11.0150, 4015.19.0510, and 4015.19.0550 (accessed October 8, 2020).

<sup>549</sup> USITC DataWeb/USDOC, HTS 3926.20.1010 (accessed September 9, and October 13, 2020).

<sup>550</sup> USITC DataWeb/USDOC, HTS 4002.51.0000 (accessed October 13, 2020); industry representatives, telephone interviews by USITC staff, September 30, October 2 and 16, and November 10, 2020.

broken out separately at the HTS 10-digit level) and rubber medical gloves (figure 4.15).<sup>551</sup> Industry sources report wildly fluctuating prices for these gloves, with increases of as high as 500 percent for vinyl and 250 percent for nitrile gloves.<sup>552</sup> Trade data show that the unit value of U.S. imports of latex and synthetic rubber gloves was relatively steady during 2019 through March 2020, and increased by more than 150 percent from April 2020 to September 2020, while the unit value of U.S. imports of vinyl/plastic gloves was up by 185 percent.<sup>553</sup> U.S. rubber and plastic surgical and medical gloves imports enter duty-free at the NTR rate.<sup>554</sup> U.S. imports of rubber medical gloves from China were subject to section 301 duties but subsequently excluded from those duties.<sup>555</sup>

**Figure 4.15** Unit values of U.S. medical and surgical glove imports, January 2019–September 2020 (Index, January 2019 = 100)



Source: USITC DataWeb/USDOC, HTS 3926.20.1010, 4015.11.0110, 4015.11.0150, 4015.19.0510, 4015.19.0550 (accessed October–November 2020).

Note: Underlying data for this figure can be found in [appendix table E.19](#).

## Inputs

U.S. imports of NBR in 2019 totaled 3 million kilograms, valued at \$3 million.<sup>556</sup> During January–September 2020, the quantity of imports for every month, except August, were higher than the imports

<sup>551</sup> USITC DataWeb/USDOC, HTS 3926.20.1010, 4015.11.0110, 4015.11.0150, 4015.19.0510, and 4015.19.0550 (accessed September 1, 9, and October 8, 2020).

<sup>552</sup> Industry representatives, telephone interview by USITC staff, September 29, 2020.

<sup>553</sup> USITC DataWeb/USDOC, HTS 3926.20.1020 and 4015.19.1010 (accessed November 17, 2020).

<sup>554</sup> However, gloves that are not medical or surgical of rubber or vulcanized rubber have duty rates ranging from 3 to 14 percent ad valorem.

<sup>555</sup> HTS statistical reporting numbers 4015.19.0510 (medical gloves, mittens and mitts (except surgical) of natural rubber, other than hard rubber) and 4015.19.0550 (medical gloves, of vulcanized rubber other than hard rubber, not elsewhere specified or included). HTS chapter 99 subchapter 3 note 20; 85 FR 13970 (March 10, 2020).

<sup>556</sup> USITC DataWeb/USDOC, HTS 4002.51.0000 (accessed October 13, 2020).

in the same month in 2019. Imports of NBR, however, are driven by all end uses of the product, such as automotive parts, belts, hoses, and gaskets.<sup>557</sup>

## Supply Chain Challenges and Constraints

Since the onset of the pandemic, global demand for medical gloves has escalated while the global supply chain is running at full capacity. The United States is almost entirely dependent on imports of medical gloves, particularly nitrile gloves from Malaysia and vinyl gloves from China.<sup>558</sup> The ability of imports to meet U.S. demand is constrained by production capacity for NBR, the major raw material used in manufacturing nitrile gloves, and new capacity is not expected to come online until 2022. Restrictions affecting factory operations in the wake of the pandemic also disrupted production in major supplying countries. U.S. imports also have been limited by a Withhold Release Order (WRO) issued by U.S. Customs and Border Protection (CBP) on imports from two producers in Malaysia (among the world's largest glove producers) because of forced labor violations. Prices of nitrile and vinyl gloves increased since the onset of the pandemic and are expected to continue through at least the end of this year.

## Factors Affecting Domestic Production

### Production and Delivery

Due to the labor-intensive nature of glove production, labor costs put U.S. manufacturers at a competitive disadvantage compared with lower labor cost countries, including Malaysia, China, and Thailand. Each glove line has production workers that remove each glove from its mold by hand; in addition, there are several chemists, machinists, and quality assurance personnel totaling 30–40 workers per line.<sup>559</sup> In Malaysia, these labor costs account for a small share of production, around 10 percent of production costs.<sup>560</sup> However, average U.S. monthly manufacturing wages were almost 4 times wages in Malaysia in the first quarter of 2020.<sup>561</sup>

Another major hindrance in increasing domestic production is the length of time involved; it can take up to 18 months to bring new U.S. production capacity online.<sup>562</sup> For example, Showa announced its planned expansion in December 2019, but the production will not be online until April 2021.<sup>563</sup> It took about a year for Rhino Health to bring production online in an existing plant and was expected to take just over a year for the construction and production to start at a new plant.<sup>564</sup> The machinery for these plants is mostly shipped from Asia, with transportation of new production equipment adding to the

<sup>557</sup> Zeon Chemicals, “Acrylonitrile Butadiene Copolymer (NBR) Latex” (accessed October 19, 2020).

<sup>558</sup> Industry representatives cited high labor costs as the primary reason for limited glove production in the United States.

<sup>559</sup> Industry representatives, telephone interview by USITC staff, September 15, 2020; USITC, hearing transcript, September 24, 2020, 409 (testimony of Michael Einhorn, Dealmed Medical Supplies).

<sup>560</sup> Top Glove Corp., Investor Presentation, 12, October 2, 2020; Ansell, “F’20 Full Year Results,” August 25, 2020, 21.

<sup>561</sup> See table 2.1.

<sup>562</sup> Industry representatives, telephone interview by USITC staff, September 15, 2020; Strickler, “Trump Admin is ‘Woefully Behind’ in Stockpiling Medical Gloves as Covid-19 Surges,” October 29, 2020.

<sup>563</sup> Showa, “Showa’s Investment,” October 23, 2020; West, “Showa Group Expansion,” October 21, 2020.

<sup>564</sup> Albuquerque Journal, “Glove Manufacturer,” December 13, 2018; Navajo-Hopi Observer, “Navajo Nation Invests,” November 19, 2019.

amount of time needed to bring production online.<sup>565</sup> Further, setting up a glove dipping plant reportedly costs tens of millions of dollars.<sup>566</sup> In addition to these challenges, a global shortage of NBR will limit the viability of any new production. Industry sources reported that supply constraints for raw materials began in March 2020, leading to delays in deliveries that were exacerbated by interruptions in transportation logistics and overwhelming demand pressures on raw materials producers.<sup>567</sup>

## Factors Affecting Imports

### Product Availability

As the United States is highly dependent on imports of medical and surgical gloves, strong global demand with the onset of the pandemic has severely constricted the available supply of gloves in the United States. Producers are reportedly operating at 100 percent capacity, yet global demand far exceeds global production capacity.<sup>568</sup> Demand has increased in countries that previously had not been large consumers of medical gloves, such as India and China.<sup>569</sup> In addition, the actions of opportunistic buyers are further limiting supply. Industry sources report a buying frenzy, and instances of buyers trying to “corner” the market by making huge purchases of gloves.<sup>570</sup>

Further, disruptions affecting production in key supplying countries, including plant closures, created a product shortage as demand was beginning to escalate rapidly. In mid-March, lockdown orders resulted in factory closures in Malaysia, the leading source for nitrile gloves.<sup>571</sup> Factories remained shuttered until they were able to receive staffing exemptions on the basis that the production of the gloves was “essential.”<sup>572</sup> Factories initially reopened at 50 percent capacity and by the beginning of April received exemptions to fully staff their facilities.<sup>573</sup> Nonetheless, even operating at full capacity, Malaysian producers (who supply more than 60 percent of the global market for rubber medical gloves) are not able to meet current demand; Top Glove Corp Bhd, for example, the world’s largest medical glove manufacturer, which supplies 25 percent of the global market, was reportedly receiving orders that were double its full production capacity.<sup>574</sup> Moreover, in November 2020, Top Glove announced that it would temporarily shut down or reduce capacity at half of its factories due to an outbreak of COVID-19 among its workers.<sup>575</sup>

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<sup>565</sup> Trade Data Information Services, Import Genius database (accessed October 25, 2020).

<sup>566</sup> Strickler, “Trump Admin is ‘Woefully Behind’ in Stockpiling Medical Gloves as Covid-19 Surges,” October 29, 2020.

<sup>567</sup> Industry representatives, telephone interviews by USITC staff, August 20 and September 15, 2020.

<sup>568</sup> Industry representatives, telephone interview by USITC staff, October 16, 2020.

<sup>569</sup> Industry representatives, telephone interview by USITC staff, October 16, 2020.

<sup>570</sup> USITC, hearing transcript, September 24, 2020, 409 and 544 (testimony of David Greer, Techman Sales, Inc., Richard Renahan, Renco Corp.); industry representatives, telephone interview by USITC staff, October 16, 2020.

<sup>571</sup> Yassin, “The Prime Minister’s Special Message on COVID-19,” March 16, 2020.

<sup>572</sup> Ha, “The World’s Hospitals Are Running out,” March 26, 2020; Peter, “Top Maker of Medical Gloves Warns of Dire Global Shortage,” March 26, 2020.

<sup>573</sup> Ha, “The World’s Hospitals Are Running out,” March 26, 2020; Peter, “Malaysia Loosens Lockdown Rules,” April 10, 2020; Medline, written submission to USITC, September 14, 2020, 4.

<sup>574</sup> Ha, “The World’s Hospitals Are Running out,” March 26, 2020.

<sup>575</sup> Ray, “Major PPE Maker Shuts Factories,” *Forbes*, November 24, 2020.

The supply of gloves was further restricted due to forced-labor violations in Malaysian glove factories. U.S. Customs and Border Protection issued a WRO<sup>576</sup> on July 15, 2020, against two subsidiaries of Top Glove, because of forced labor violations.<sup>577</sup> This is not the first time a Malaysian glove manufacturer has faced a WRO. From September 2019 through the end of March 2020, WRP Asia Pacific Sdn. Bhd. had a WRO on its products for a forced-labor violation.<sup>578</sup>

In addition, a scarcity of NBR, a key input in nitrile gloves, has had a severe impact on the ability to expand nitrile glove production and is cited by some industry sources as the most significant constraint affecting the supply chain.<sup>579</sup> There are a limited number of global producers of NBR.<sup>580</sup> Global production of NBR was reportedly at capacity before the onset of COVID-19, and producers are unable to meet the increased demand.<sup>581</sup> New capacity for NBR production is not expected to come online globally until late 2021 or early 2022.<sup>582</sup>

## Market Acceptance

Despite the increase in demand seen across almost all types of gloves, medical professionals have been hesitant to switch to the use of non-nitrile gloves in medical settings.<sup>583</sup> Although the FDA's guidance on using nonmedical gloves in medical settings was implemented to help reduce the glove shortage, medical personnel reportedly prefer not to use the FDA-authorized substitutes because they are labeled as not FDA-approved for medical use.<sup>584</sup>

## Prices and Delivery Costs

Numerous cost increases affecting multiple factors of production (e.g., labor and shipping) and higher demand have led to significant increases in the price of gloves. Since the onset of the pandemic, the price of gloves sold by foreign producers has increased multifold—according to industry sources, by as much as 4 to 7 times the price pre-pandemic.<sup>585</sup> Another industry source stated that some large Malaysian glove producers have increased the price of gloves by about 10–20 percent each month, and Chinese glove producers have increased the price of gloves by about 50 percent.<sup>586</sup>

<sup>576</sup> A WRO is the facility by which CBP does not allow items produced using forced labor into the United States. 19 CFR §12.42.

<sup>577</sup> Top Glove produces nitrile, latex, and vinyl gloves. Customs and Border Protection, “Withhold Release Orders,” July 15, 2020; Lee, “Amid Virus Crisis, U.S. Bars Imports,” July 16, 2020.

<sup>578</sup> CBP Office of Trade, “CBP Revokes Withhold Release Order,” March 24, 2020.

<sup>579</sup> Industry representatives, telephone interview by USITC staff, October 16, 2020.

<sup>580</sup> Industry representatives, telephone interview by USITC staff, September 15, 2020; Zeon Chemicals, “Nipol NBR” (accessed October 5, 2020); Huntsman, “Nychem Specialty Nitrile Latexes” (accessed October 5, 2020).

<sup>581</sup> USITC, hearing transcript, September 24, 2020, 445 (testimony of Michael Einhorn, Dealmed Medical Supplies); industry representatives, telephone interview by USITC staff, September 15, October 2 and October 16, 2020.

<sup>582</sup> Industry representatives, telephone interview by USITC staff, September 15, 2020.

<sup>583</sup> Industry representatives, telephone interviews by USITC staff, September 29 and October 16, 2020.

<sup>584</sup> FDA, “Enforcement Policy for Gowns, Other Apparel, and Gloves,” March 31, 2020; industry representatives, telephone interviews by USITC staff, September 29 and October 16, 2020.

<sup>585</sup> Industry representatives, telephone interviews by USITC staff, September 15 and 30, 2020.

<sup>586</sup> Medline Industries, Inc., written submission to USITC, September 14, 2020, 4.

One of the factors affecting glove prices, starting in the summer of 2020, is the increase in the cost of nitrile glove inputs, spurred in part by a lack of supply.<sup>587</sup> As a result of shortages, prices for NBR—which decreased in the initial months of the pandemic—started to rise in the summer of 2020. The U.S. price per kilogram of NBR imports reflects this trend, increasing 25 percent from July to August.<sup>588</sup> Even with increased prices, some glove producers are reportedly running their lines at a loss due to the higher input costs.<sup>589</sup> Firms also experienced increases in labor costs beginning in March, because factory hours were expanded at production facilities abroad; these added costs trickled down to U.S. glove importers.<sup>590</sup>

Freight costs, as with other PPE, were also an issue in shipping gloves, but the problem was more temporary than for other products.<sup>591</sup> Gloves are typically shipped via ocean freight, but with the need for PPE on an expedited basis, some gloves were imported using air freight.<sup>592</sup> Air freight shipments peaked in April 2020 and quickly dropped off, although they did result in temporary large increases in shipping costs. Insurance and freight costs for U.S. imports of nitrile and other synthetic gloves from Malaysia were 74 percent higher in April 2020 than in January 2020, and costs for U.S. imports of vinyl gloves from China were 168 percent higher.<sup>593</sup>

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<sup>587</sup> USITC, hearing transcript, September 24, 2020, 445 (testimony of Michael Einhorn, Dealmed Medical Supplies); industry representatives, telephone interviews by USITC staff, September 15 and October 2 and 16, 2020.

<sup>588</sup> USITC, hearing transcript, September 24, 2020, 445 (testimony of Michael Einhorn, Dealmed Medical Supplies); industry representatives, telephone interviews by USITC staff, September 15 and October 2 and 16, 2020; USITC DataWeb/USDOC, HTS 4002.51.0000 (accessed October 13, 2020).

<sup>589</sup> Industry representatives, telephone interview by USITC staff, October 16, 2020.

<sup>590</sup> Ansell, “Edited Transcript of ANN.AX Earnings Conference Call,” August 24, 2020.

<sup>591</sup> Industry representatives, telephone interviews by USITC staff, September 15 and October 1, 2020.

<sup>592</sup> USITC, hearing transcript, September 24, 2020, 368 (testimony of David Greer, Techman Sales, Inc.); USITC, hearing transcript, September 24, 2020, 427–29 (testimony of Michael Einhorn, Dealmed Medical Supplies); industry representatives, telephone interviews by USITC staff, September 29 and October 2, 2020.

<sup>593</sup> IHS Markit, Global Trade Atlas database, HTS 3926.20.1010, 4015.19.0550 (accessed October 25, 2020); USITC DataWeb/USDOC, HTS 3926.20.1010, 4015.19.0550 (accessed October 25, 2020).



# Chapter 5

## Pharmaceuticals

Testing, therapeutic treatments, and development of vaccines have been at the forefront of efforts to combat COVID-19. Pharmaceuticals (e.g., antivirals, antibiotics, hormones, and vaccines) prevent, diagnose, treat, or cure diseases in humans. As of October 2020, remdesivir was the only drug approved by the U.S. Food and Drug Administration (FDA) for use in the prevention or treatment of COVID-19.<sup>594</sup> However, other pharmaceuticals are available—some under FDA Emergency Use Authorizations (EUAs)—that may reduce the severity or length of symptoms. In addition, pharmaceuticals are used to treat many of the secondary conditions stemming either directly from the virus (e.g., abnormal blood clotting, respiratory conditions, and organ damage and failure) or from treatment protocols (e.g., sedatives needed for critically ill patients on ventilators).<sup>595</sup> Each test, drug, and therapeutic protocol represents a different area of pharmacological development and treatment; some of these are intended to protect the general population (e.g., testing and vaccines), while others are intended to give those infected with the virus a higher chance of survival (e.g., drug-based therapies).

The need for testing supplies, therapeutics, and vaccines put unprecedented stress on the supply chain. While pharmaceutical manufacturers were able to ramp up production, there have been challenges in getting medicines to the right locations, at high enough volumes, and in the needed dosage forms. Ramping up production and delivery of testing supplies was even more challenging, as tests for a new virus had to be created and delivered in a short time frame, and the related testing consumables needed to be ones that worked on existing laboratory equipment. Finally, additional challenges lie ahead in the ongoing development and delivery of a vaccine.

The first part of this chapter provides an overview of the U.S. pharmaceutical industry. This overview includes all pharmaceuticals and, except as noted, does not specifically address pharmaceuticals used in the response to COVID-19. The second part of the chapter presents a case study describing COVID-19 test kits and another describing the ongoing efforts and potential supply chain challenges to developing and bringing to market vaccines for the prevention of COVID-19.

## Overview of the U.S. Pharmaceutical Industry and Trade

### Introduction

The United States has a large, geographically diverse pharmaceutical industry with established supply chains that proved resilient during the first half of 2020. The flexibility and number of manufacturing sites inherent in the global footprint of the pharmaceutical sector allowed firms to respond relatively quickly to demand and deliver additional medicines to aid in the response to the pandemic (see box

<sup>594</sup> FDA, “Coronavirus Treatment Acceleration,” September 30, 2020; FDA, “FDA Approves First,” October 22, 2020.

<sup>595</sup> WHO, “Naming the Coronavirus Disease” (accessed September 6, 2020); Weill Cornell Medicine, “What Is Known about COVID-19,” July 2, 2020; FDA, “Understanding Investigational Drugs,” April 2, 2019.

5.1).<sup>596</sup> The U.S. industry, which comprises companies ranging from large multinational firms to small and medium-sized firms (SMEs), was operating at almost full capacity in the second quarter of 2020 to meet demand. These supplies were delivered via the existing wholesale distribution network, which is heavily concentrated; three companies (AmerisourceBergen, Cardinal Health, and McKesson Corporation) reportedly distribute about 90–95 percent of pharmaceuticals consumed in the United States.<sup>597</sup>

### **Box 5.1** COVID-19 Related Pharmaceuticals

Pharmaceuticals related to COVID-19 are a subset of all pharmaceuticals covered in this chapter. FDA has issued eight Emergency Use Authorizations (EUAs) as of November 2020 for pharmaceuticals used in the treatment of COVID-19 and related symptoms: (1) casirivimab and imdevimab (2) baricitinib in combination with remdesivir (3) bamlanivimab; (4) COVID-19 convalescent plasma (CCP); (5) remdesivir; (6) Fresenius Propoven 2 percent emulsion; (7) Regiocit (used as a replacement solution); and (8) multiBic/multiPlus solutions.<sup>a</sup> Some of the EUAs are for drugs and treatment protocols that have been around for decades, while other EUAs are for relatively new small-molecule or biologic drugs.<sup>b</sup> There are still over 260 treatments in late-stage trials,<sup>c</sup> which include antivirals, cell and gene therapies, immunomodulators (immune system regulators), neutralizing antibodies, and combinations thereof.<sup>d</sup>

While the drugs are under an EUA they continue to undergo clinical trials to obtain FDA approval, and many firms are scaling up production. During the pandemic, producers have reduced the time needed to start commercial production, and generic drug producers, among others, have been providing contract manufacturing services to supplement production of some of the products currently used to treat patients with COVID-19.<sup>e</sup>

Beyond drugs that are being studied to specifically treat COVID-19, there are several existing approved drugs that are instrumental in life-support treatment protocols, such as those used when a patient is placed on a ventilator. These protocols necessitate the use of several drugs to facilitate the safe use of the device and the comfort of the patient and include the use of sedatives, analgesics (pain relievers), paralytics, and vasopressors (which raise blood pressure).<sup>f</sup> Certain antacids and steroids have also been used in the treatment of patients receiving ventilation.<sup>g</sup> Each drug has an important role in the different stages of patient ventilation.<sup>h</sup>

In the early months of the pandemic, some of these drugs were in short supply due to the sudden spike in ventilator use that accompanied the spread of the COVID-19 virus.<sup>i</sup> Reports indicate that, although these drugs have been on FDA's drug shortage list, the shortage was largely alleviated as of September.<sup>j</sup> The limited duration of the shortage can likely be attributed to the lower-than-anticipated need for ventilators, evolving treatment methods of COVID-19 patients, and an easing of restrictions by various regulatory authorities.<sup>k</sup>

<sup>a</sup> Remdesivir is still on an EUA, as its approval is more limited in scope. Both Regiocit and multiBic/multiPlus are solutions authorized to use as part of continuous renal replacement therapies (CRRT). FDA, "Emergency Use Authorizations," updated November 10, 2020.

<sup>b</sup> FDA, "Emergency Use Authorizations," updated December 8, 2020.

<sup>596</sup> Industry representatives, telephone interview by USITC staff, September 28 and 29, and October 14 and 21, 2020.

<sup>597</sup> The distribution network's customers include retail sites, pharmacies, and hospitals. Industry representatives, telephone interview by USITC staff, September 29, 2020; Fein, "The Big Three Wholesalers," October 2, 2019; McKesson, "Deliver Therapies Accurately," (accessed October 18, 2020).

<sup>c</sup> Late stage = Phase 2, 2/3, 3, 4. Late-stage trials assess safety and establish whether the treatment is effective. They may generate enough evidence to support the statutory standards for EUA or approval. FDA Website, “Coronavirus Treatment Acceleration Program,” updated September 30, 2020.

<sup>d</sup> FDA, “Coronavirus Treatment Acceleration Program,” updated September 30, 2020.

<sup>e</sup> Gilead Sciences, “Working to Supply Remdesivir for COVID-19,” October 5, 2020; USITC, hearing transcript, September 23, 2020, 291 (testimony of Jonathan Kimball, Association for Accessible Medicines); Gilead, “Voluntary Licensing Agreements for Remdesivir” (accessed October 1, 2020).

<sup>f</sup> Rosenthal, “COVID-19 Slowing,” June 17, 2020.

<sup>g</sup> Hartford HealthCare, “Hartford Hospital Study,” September 2, 2020; Prescott and Rice, “Corticosteroids in COVID-19 ARDS,” September 2, 2020.

<sup>h</sup> Sedatives are typically used to ease patients into ventilation. Analgesics (pain relievers) address the pain and physical discomfort resulting from intubation of the ventilator. Paralytics keep the patient in a state amenable to treatment with a ventilator. Vasopressors, antacids, and steroids address other issues related to the treatment regimen. For more information on the treatment of patients receiving ventilation related to COVID-19, see Anesi, “Coronavirus Disease 2019,” September 14, 2020.

<sup>i</sup> As of September 30, 2020, drugs classified by FDA as “currently in shortage” and that are used in the treatment of ventilated patients include cisatracurium (paralytic); dexmedetomidine (sedative); dexamethasone (steroid); famotidine (antacid); fentanyl (analgesic/sedative); midazolam (sedative); propofol (anesthetic); and vecuronium (paralytic). Note, some shortages are dosage specific. USITC, hearing transcript September 24, 2020, 372 (testimony of Jonathan Kimball, Association for Accessible Medicines); FDA, “FDA Drug Shortages” (accessed September 30, 2020) [Cisatracurium, Dexmedetomidine, Dexamethasone, Famotidine, Fentanyl, Midazolam, Propofol, Vecuronium]; see also “Hartford Hospital Study” (accessed September 30, 2020).

<sup>j</sup> USITC, hearing transcript September 24, 2020, 372 (testimony of Jonathan Kimball, Association for Accessible Medicines).

<sup>k</sup> Begley, “Ventilators Are Overused for Covid-19 Patients,” April 8, 2020; Thompson, Ranard, and Wei, “Prone Positioning in Awake, Nonintubated Patients with COVID-19,” June 17, 2020; and see 85 Fed. Reg. 20302 (April 10, 2020).

Broadly speaking, pharmaceuticals may be placed within two distinct categories: (1) small-molecule drugs and (2) biological products (biologics).<sup>598</sup> Traditionally, small-molecule drugs have been the cornerstone of modern medicine, and account for a large share of the pharmaceuticals currently marketed.<sup>599</sup> Small-molecule drugs generally have more predictable actions, involve simpler manufacturing processes, and are often administered as oral formulations.<sup>600</sup> Conversely, biologics are a relatively newer field of drugs and therapies that currently represent a smaller share of pharmaceuticals available on the market. However, the share of the market accounted for by biologics is growing as new technologies reach the market.<sup>601</sup> Biologics are typically more expensive due to more complex manufacturing processes, are more fragile to store and transport, and are available solely as intravenous injections.<sup>602</sup> Small-molecule drugs can be novel (also referred to as innovative) or generic, while biologics are generally classified as novel or biosimilar.<sup>603</sup>

<sup>598</sup> Generally, small molecules are simple, in terms of chemical structure and production, while biologics are inherently complex, in both structure and manufacturing processes. Ngo and Garneau-Tsodikova, “What Are the Drugs of the Future?” 2018, 757.

<sup>599</sup> Examples of small-molecule drugs include aspirin, penicillin, and atorvastatin (also sold under the brand name Lipitor). Ngo and Garneau-Tsodikova, “What Are the Drugs of the Future?” 2018, 757.

<sup>600</sup> Industry representatives, telephone interview by USITC staff, October 14, 2020; Ngo and Garneau-Tsodikova, “What Are the Drugs of the Future?” 2018, 757.

<sup>601</sup> Biologics are derived from naturally occurring sources: human, animal, or microorganism. Biologics can be living entities such as cells and tissues, and are commonly comprised of sugars, proteins, nucleic acids, or combinations thereof. FDA, “What Are “Biologics” Questions and Answers” (accessed December 6, 2020).

<sup>602</sup> Ngo and Garneau-Tsodikova, “What Are the Drugs of the Future?” 2018, 757; industry representatives, telephone interview by USITC staff, October 14, 2020. The manufacturing complexity makes it difficult to scale up biologics while maintaining batch-to-batch equivalence.

<sup>603</sup> Although both are approved through abbreviated pathways, generics are not the same as biosimilars because the approval requirements are different. A generic drug must have the same characteristics as an existing approved brand-name drug (i.e., dosage, administration, safety, strength, quality, and performance). A biosimilar is a biological product that must be “highly similar” to an existing, already approved, reference product and must

Despite the differences between small-molecule drugs and biologics, all drugs (novel, generic, and biosimilar) have an active pharmaceutical ingredient (API) that is the basis of the finished dosage product. For generics, the data and rights to produce the APIs are available to all, but novel drugs are typically under patent for several years, precluding competition from generics while the patents are in force.<sup>604</sup> FDA approves pharmaceuticals for human use in the U.S. market based on their proven safety and efficacy profiles; as discussed in more detail below, FDA also maintains continued regulatory oversight of pharmaceuticals (also see chapter 1 and appendix F).<sup>605</sup>

The pharmaceuticals described in this chapter include products of four industry groups, as classified by the North American Industry Classification System (NAICS), shown in table 5.1. The NAICS industries selected for inclusion are the primary NAICS classification codes for pharmaceuticals identified by the Commission in its June 2020 report on COVID-19 related goods.

**Table 5.1** Pharmaceutical industry coverage

NAICS	Description	Examples
325411	Medicinals and botanicals	Uncompounded medicinal and botanical chemicals and their derivatives (i.e., generally for use by pharmaceutical preparation manufacturers). These are typically bulk active pharmaceutical ingredients (APIs).
325412	Pharmaceutical preparations	In vivo diagnostic substances and pharmaceutical preparations (except biological) intended for internal and external consumption in dose forms (e.g., ampoules, tablets, capsules, vials, ointments, powders, solutions, and suspensions).
325413	In vitro diagnostic substances	In vitro (i.e., not taken internally) diagnostic substances (e.g., chemical, biological, or radioactive substances) used for diagnostic tests that are performed in test tubes, petri dishes, machines, etc.
325414	Biological products (except diagnostic)	Vaccines, toxoids, blood fractions, and culture media of plant or animal origin (except diagnostic).

Source: NAICS Association, <https://www.naics.com/>; SICCODE Business Data, <https://siccode.com/>.

## U.S. Industry

### Overview of the U.S. Industry

The U.S. pharmaceutical industry comprises nearly 5,000 establishments, with manufacturing concentrated in areas with significant production of upstream chemicals (e.g., Texas and New Jersey) or with significant biotechnology/biomedical clusters (e.g., California, Florida, Massachusetts, New York, and Texas) (figure 5.1).<sup>606</sup> The U.S. facilities generally include production sites engaged in various steps in pharmaceutical production, including API (also known as drug substance), formulation, and fill and

also have no meaningful differences from the existing product. FDA, “Biosimilar and Interchangeable Products,” updated October 23, 2017; FDA, “Novel Drugs 2015 Summary,” January 2016; FDA, “Novel Drug Approvals for 2020,” September 16, 2020.

<sup>604</sup> FDA, “Generics: Overview and Basics,” September 13, 2017; FDA, “Generic Drug Facts,” June 1, 2018.

<sup>605</sup> FDA, “Types of Applications,” October 23, 2014; FDA, “New Drug Application (NDA),” June 10, 2019.

<sup>606</sup> The U.S. in vitro diagnostics industry is heavily concentrated (25 percent) in California. BLS, “Quarterly Census of Employment and Wages,” first quarter 2020; Swindell, “Sun, Sand and Drugs,” June 15, 2017; Philippidis, “In Praise of Lesser-Sung Life Sciences Clusters,” June 5, 2020; BioFlorida, “State of the Life Sciences Industry” (accessed September 16, 2020).

finish.<sup>607</sup> There is significant variation in the extent of vertical integration at each plant: some perform operations ranging from R&D to formulation, while others fulfill only one or more of the specific steps in the production process.<sup>608</sup> The industry also includes establishments that engage in contract manufacturing for other firms.<sup>609</sup> Production facilities take an average of five years to start up, although the amount of time varies depending on the final drug formulation and form of administration (e.g., oral versus intravenous).<sup>610</sup> Once the facilities are established, capacity is not necessarily dedicated to a specific drug, and the amount of capacity (as well as production level) is product dependent (e.g., small-molecule versus biological products, generic versus novel).<sup>611</sup>

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<sup>607</sup> Companies routinely evaluate the economics and location of existing production capacity, assessing factors such as market access; location(s) of drug approvals; employee skills, availability, and labor costs; financial incentives; and duty rates, among others. Many firms have several production facilities within the United States. PricewaterhouseCoopers, “Pharma 2020” (accessed June 16, 2020). *Pharmaceutical Business Review*, “Eli Lilly to Build,” January 22, 2020; Pfizer, “U.S. Manufacturing Sites” (accessed September 29, 2020).

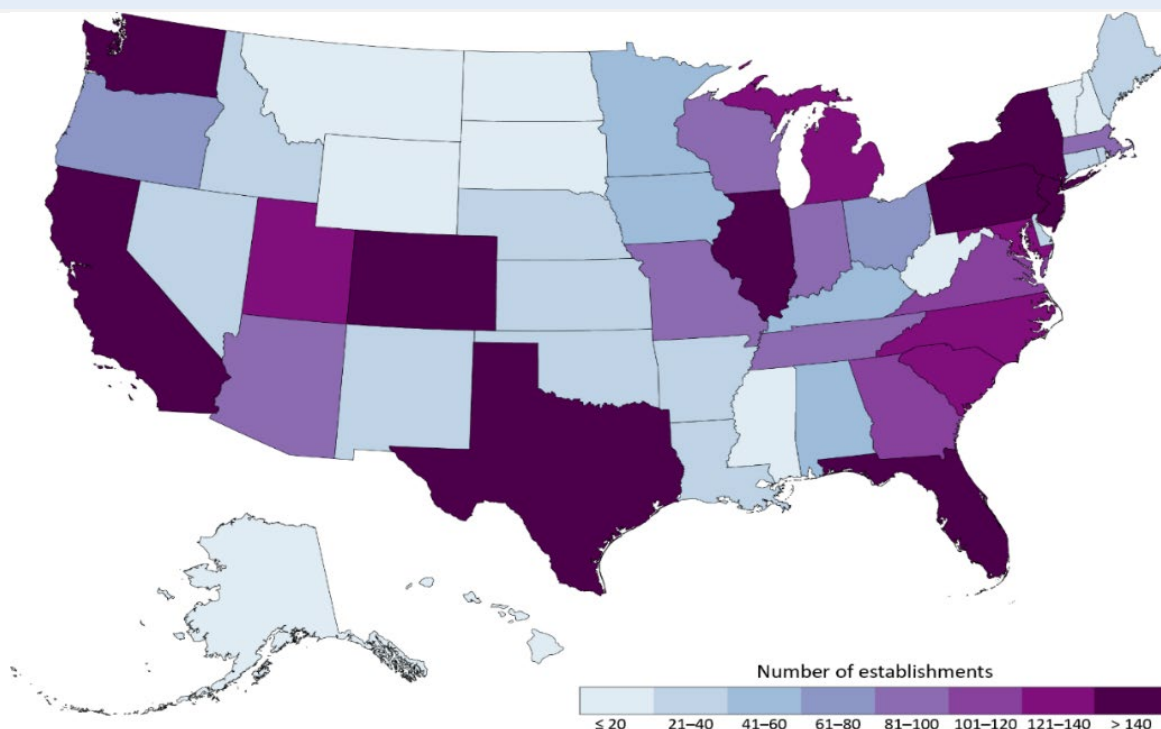
<sup>608</sup> In general, in vitro diagnostic establishments are concentrated in advanced biotechnology R&D areas for access to skilled labor and intellectual property. *Pharmaceutical Technology*, “The Top Ten Pharmaceutical Companies,” updated January 24, 2020; Rees, “Top Five Generic Drug Makers,” July 12, 2019; IMARC Group, “Global Generic Drugs Market” (accessed September 16, 2020); Lee, “Modernizing the Way Drugs Are Made,” FDA, May 11, 2017; Eli Lilly and Company, “What Does It Take to Manufacture,” October 7, 2020; FDA, “Contract Manufacturing Arrangements,” November 2016, 3; Alcami Website, “About” (accessed October 19, 2020).

<sup>609</sup> See, for example, AbbVie Inc. Website, “About” (accessed October 19, 2020); Aenova Website, “About” (accessed October 19, 2020); ANI Pharmaceuticals, Inc. Website, “About” (accessed October 19, 2020).

<sup>610</sup> PhRMA, pre-hearing brief, September 14, 2020, 4; industry representative, telephone interview by USITC staff, October 14, 2020.

<sup>611</sup> Traditionally, small-molecule drugs are manufactured via batch processing, but some manufacturers have adopted continuous processing, reducing time from API production to final formulation from months to days. By comparison, going from API production to formulation for a batch of monoclonal antibodies (biologic) can take anywhere from 30 to 90 days. Industry representatives, telephone interview by USITC staff, October 14, 2020; Lee, “Modernizing the Way Drugs Are Made,” FDA, May 11, 2017; Deloitte, “Advanced Biopharmaceutical Manufacturing,” 2015; Johnson, “These Laboratory-Made Antibodies,” September 30, 2020; Eli Lilly and Company, “What Does It Take to Manufacture,” October 7, 2020.

**Figure 5.1** Geographical distribution of establishments, pharmaceutical manufacturing, first quarter 2020



Source: Bureau of Labor Statistics (BLS), Quarterly Census of Employment and Wages, January–March 2020, NAICS 3254 (accessed October 2020).

Note: An establishment is defined as a single physical location at which business is conducted or services or industrial operations are performed. For more information, see Census Bureau, “Glossary” (accessed August 13, 2020). Underlying data for this figure can be found in [appendix table E.20](#).

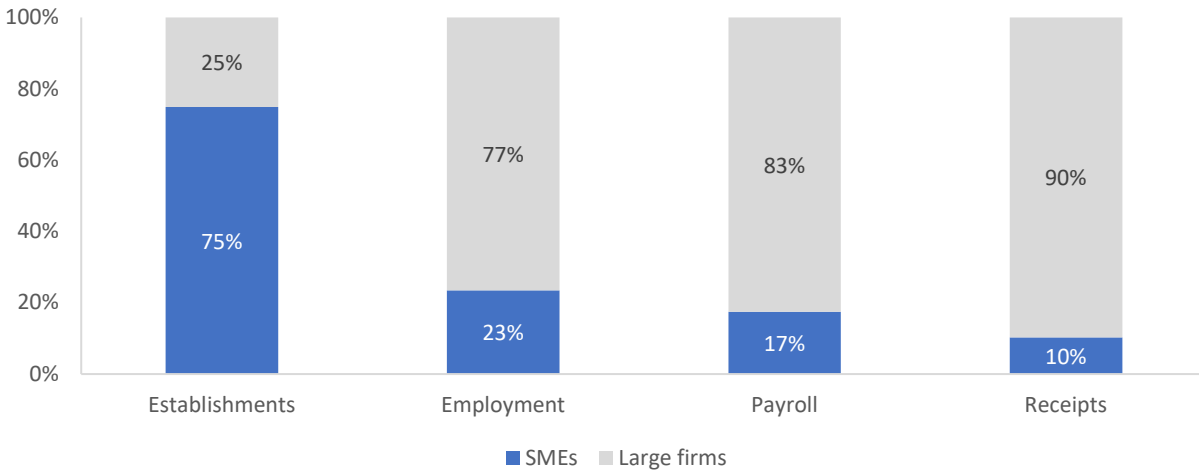
Although large firms accounted for 90 percent of pharmaceuticals receipts in 2017, SMEs accounted for 75 percent of the establishments (figure 5.2). Smaller biopharmaceutical companies developing pipelines of drug candidates are often acquisition targets for larger firms.<sup>612</sup> Also, in some instances, biotechnology SMEs have teamed up with larger firms in strategic alliances to develop and/or market their products.<sup>613</sup> These consolidations and agreements are intended to help ensure a pipeline of new products, extend product portfolios, reduce risk for the developing company, diversify geographic reach, and mitigate losses from patent expirations.<sup>614</sup>

<sup>612</sup> Bansal, De Backer, and Ranade, “What’s Behind the Pharmaceutical Sector’s M&A Push,” October 10, 2018; Parrish, “What’s Behind All the M&A Deals,” July 31, 2019.

<sup>613</sup> Hess and Evangelista, “Pharma-Biotech Alliances,” August 23, 2005; *Inside Informatics*, “SMEs in Pharma and Biotech—Size Matters,” December 2, 2015.

<sup>614</sup> Bansal, De Backer, and Ranade, “What’s Behind the Pharmaceutical Sector’s M&A Push,” October 10, 2018; Arnum, “2019,” December 4, 2019; Parrish, “What’s Behind All the M&A Deals in Pharma?” July 31, 2019. The drug pipeline refers to the drug candidates a company has under development. Crowe, “The Drug Pipeline,” December 21, 2016.

**Figure 5.2** Pharmaceutical establishments, employment, payroll, and receipts, by enterprise size, 2017



Source: Census Bureau, Statistics of U.S. Businesses data, NAICS 3254 (accessed August 2020).

Note: Data for receipts are preliminary data. “Receipts (net of taxes collected from customers or clients) are defined as operating revenue for goods produced or distributed, or for services provided.” Business size is based on the size of the enterprise. “An enterprise (or ‘company’) is a business organization consisting of one or more domestic establishments that were specified under common ownership or control.” For more information, see Census, “Glossary” (accessed August 13, 2020). Underlying data for this figure can be found in [appendix table E.21](#).

## U.S. Production

The United States is a significant producer of both APIs and finished dosage products, including generics and novel drugs.<sup>615</sup> The value of U.S. shipments of pharmaceuticals increased by 25 percent during 2015–19 to a high of \$268.7 billion in 2019, largely driven by rising prices rather than higher volumes.<sup>616</sup> U.S. pharmaceutical shipments in 2018 were primarily pharmaceutical preparations (73 percent). The remainder were biologics (15 percent), of which vaccines, toxoids, and antigens accounted for nearly one-third; in vitro diagnostic substances (6 percent); and medicinal and botanical manufacturing (6 percent).<sup>617</sup> For pharmaceutical preparations, value added totaled \$122.8 billion in 2018, equivalent to 78 percent of the value of domestic pharmaceutical preparation shipments.<sup>618</sup>

U.S. manufacturers responded to the pandemic by substantially increasing pharmaceutical shipments (figure 5.3). Domestic shipments of pharmaceuticals reached \$221 billion during January–September 2020, up 11 percent from the same period in 2019, and capacity utilization at domestic plants reached 87 percent in the second quarter of 2020 (higher than any other time during January 2015–June 2020).<sup>619</sup> This growth can be attributed to sustained demand from healthcare providers, an uptick in personal prescription refills as consumers sought to stock up in light of the pandemic, and several new late-phase clinical trials.<sup>620</sup> The industry was able to continue ramping up shipments during the pandemic—even while working on bringing new COVID-19-specific products to the market—largely because firms maintain emergency plans that they deployed as needed. Some of the steps included (1) drawing down significant available inventories, (2) tapping into a diverse range of production sites, and (3) employing a range of contract manufacturers.<sup>621</sup>

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<sup>615</sup> An August 2019 review of FDA’s inspection program indicated that the United States accounted for 28 percent of worldwide registrations for API plants and 47 percent of finished dosage manufacturing facilities, but these statistics represent the number of registered facilities that FDA inspected, not production capacity nor the specific type of product manufactured at the facility. USITC, hearing transcript, September 23, 2020, 185 (testimony of Prashant Yadav, Center for Global Development), 188 (testimony of Lori Wallach, Public Citizen), 264–65 (testimony of Jonathan Kimball, Association for Accessible Medicines); Woodcock, written testimony, Subcommittee on Oversight and Investigations Committee on Energy and Commerce, December 10, 2019, 3; PhRMA, written submission to the USITC, September 14, 2020, 4.

<sup>616</sup> Producer prices for pharmaceuticals increased 21 percent during 2015–19, largely driven by an increase in prices for pharmaceuticals and biologic preparations. BLS, Producer Price Indexes, NAICS 3254 (accessed December 7, 2020).

<sup>617</sup> Census, “Annual Survey of Manufactures,” NAICS 325412, 325414, 325413, 325411 (accessed August 2020).

<sup>618</sup> Census, “Annual Survey of Manufactures,” NAICS 325412 (accessed October 2020).

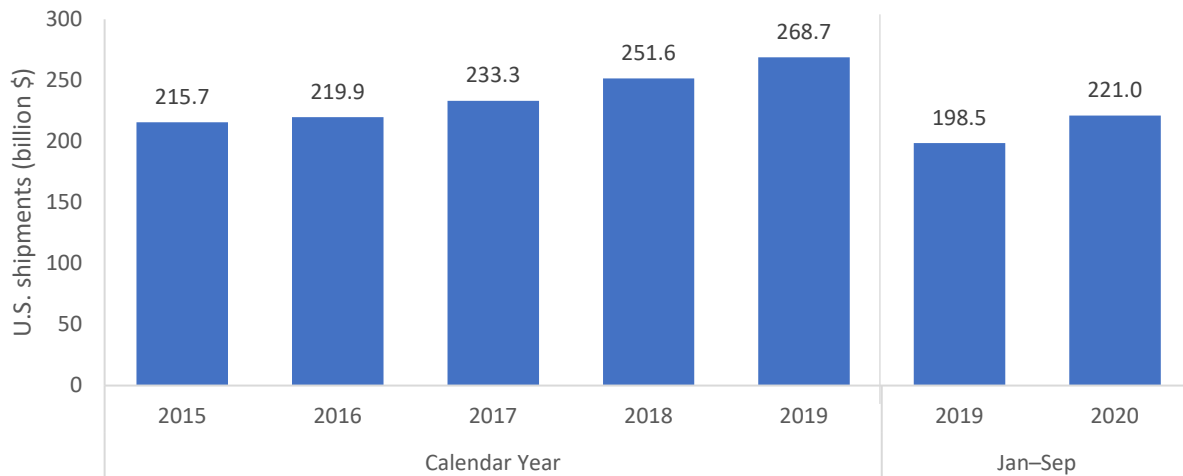
<sup>619</sup> Census, “Manufacturers’ Shipments, Inventories, and Orders” (accessed August–October 2020); Census, Quarterly Survey of Plant Capacity Utilization data, NAICS 3254 (accessed August–October 2020).

<sup>620</sup> Cerullo, “2020 Is Three Days Old,” January 3, 2020; Bunis, “Companies Raise Prices,” June 30, 2020; Harston, “How the U.S. Compares,” October 12, 2020; Advanced Medical Reviews, “The Rising Costs of Specialty Drugs,” January 15, 2020; Marsh, “Live Updates,” June 16, 2020.

<sup>621</sup> PhRMA, pre-hearing statement, September 14, 2020, 5–6; USITC, hearing transcript, September 23, 2020, 262–63 (testimony of Jonathan Kimball, Association for Accessible Medicines); industry sources, telephone interviews by USITC staff, September 28, 29, and 30, 2020.



**Figure 5.3** Pharmaceutical shipments, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)



Source: Census, “Manufacturers’ Shipments, Inventories, and Orders,” Series U25BVS (NAICS 3254) (accessed August–October 2020).

Note: Includes all NAICS in 3254, including 325413 (In-Vitro Diagnostic Substance Manufacturing). Underlying data for this figure can be found in [appendix table E.22](#).

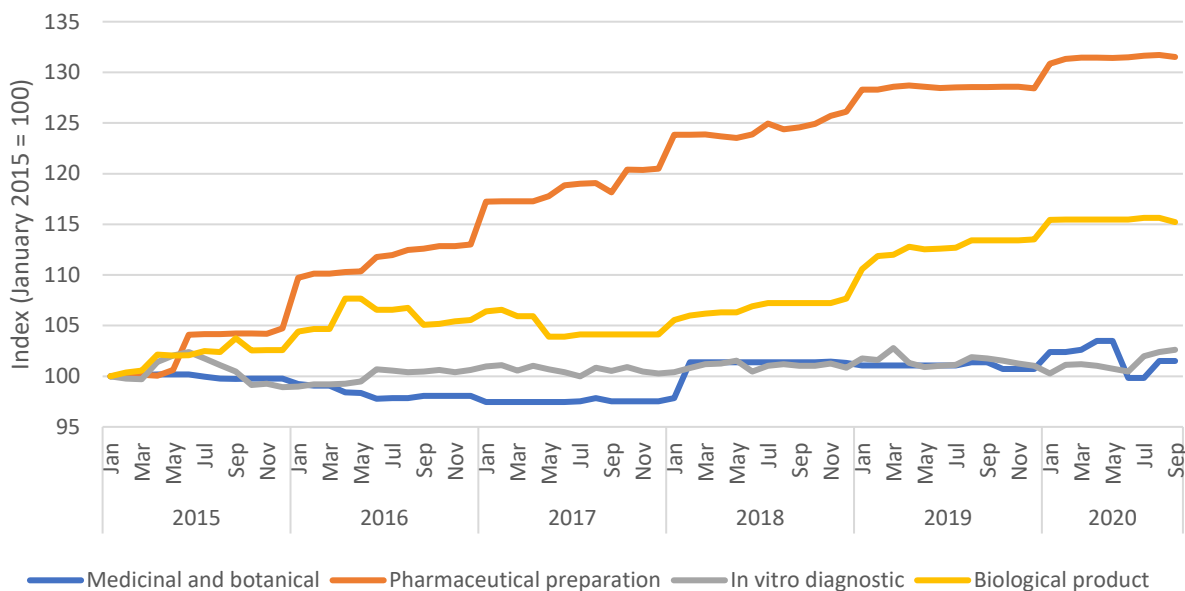
U.S. producer prices for pharmaceutical preparations increased more than 30 percent from January 2015 to January 2020, while biologic prices rose more than 15 percent (figure 5.4). Prices for medicinal and botanical products (APIs), on the other hand, were relatively flat.<sup>622</sup> U.S. pharmaceutical companies have largely maintained their prices during the pandemic, although drug price increases most commonly occur in January.<sup>623</sup> In general, novel drugs are produced at lower volumes and are of higher value than generics, in part because of their proprietary nature, while generics are typically produced at high volumes and are sold at prices that are as much as 40 to 95 percent lower than novel products.<sup>624</sup>

<sup>622</sup> BLS, “Producer Price Indexes” (accessed October 16, 2020).

<sup>623</sup> Keown, “Despite Calls to Lower Drug Prices,” February 7, 2020; Marsh, “Live Updates: January Drug Price Hikes,” February 4, 2020.

<sup>624</sup> FDA, “Generic Drug Facts,” June 1, 2018. See also FDA, “Generics,” September 13, 2017; FDA, “FDA In Brief,” December 13, 2019; FDA, “Novel Drugs,” January 2016; FDA, “Novel Drug Approvals for 2020,” September 16, 2020; USITC, hearing transcript, September 23, 2020, 286 (testimony of Jonathan Kimball, Association for Accessible Medicines).

**Figure 5.4** U.S. producer price index for four pharmaceutical industry groups, January 2015–September 2020 (Index, January 2015 = 100)



Source: BLS, Producer Price Indexes, <https://www.bls.gov/ppi/>, NAICS 325411, 325412, 325413, 3254214 (accessed October 21, 2020).  
 Note: Data are for primary products. Underlying data for this figure can be found in [appendix table E.23](#).

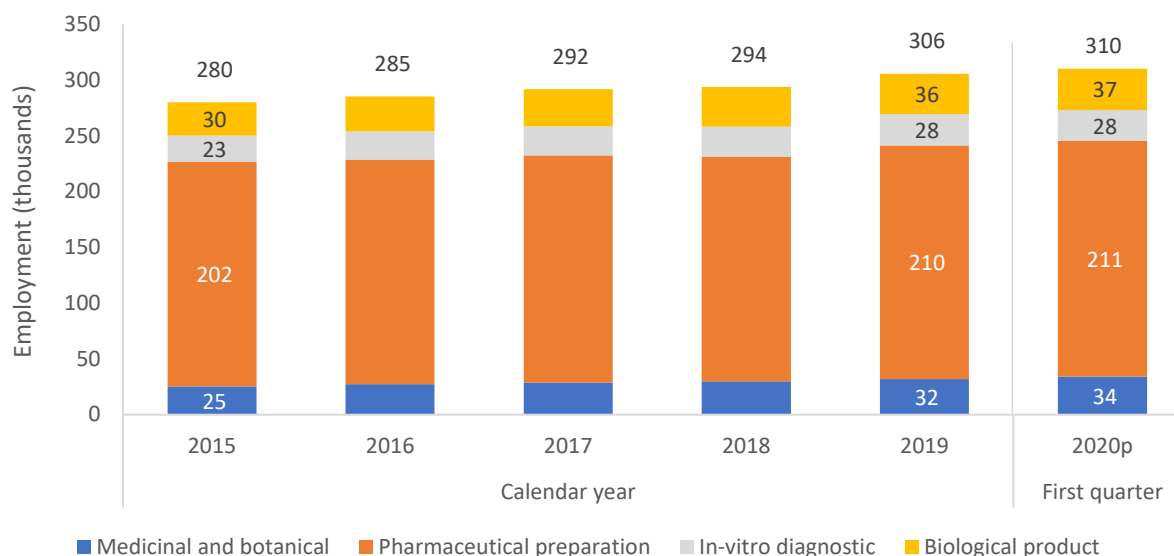
## U.S. Employment

Employment in U.S. pharmaceutical manufacturing totaled approximately 306,000 workers in 2019, up 9 percent from 2015, and reached 310,000 in the first quarter of 2020 (figure 5.5).<sup>625</sup> Production of pharmaceutical preparations employed the majority of workers, 211,000 (68 percent of pharmaceutical employment), followed by biological products (37,000, 12 percent), medicinal and botanical products (34,000, 11 percent), and in-vitro diagnostics (28,000, 9 percent). As of May 2019, less than one-third of employees within this industry were involved in physical production of pharmaceuticals, which is a small share compared with U.S. manufacturing overall.<sup>626</sup>

<sup>625</sup> BLS, Quarterly Census of Employment and Wages, NAICS 3254 (accessed September 9, 2020).

<sup>626</sup> In contrast, the pharmaceutical industry has higher employment percentages than U.S. manufacturing overall with respect to life, physical, and social science occupations (15 percent of employment), management occupations (13 percent), business and financial operations occupations (8 percent), and sales and related occupations (6 percent). BLS, “Occupational Employment Statistics,” May 2019.

**Figure 5.5** U.S. employment, pharmaceutical manufacturing, by industry, 2015–19 and first quarter 2020 (in thousand employees)



Source: BLS, Quarterly Census of Employment and Wages, NAICS 325411, 325412, 325413, 325414 (accessed November 2020).

Note: 2015–19 data are annual averages. Data for 2020 are from the first quarter. p=preliminary. Underlying data for this figure can be found in [appendix table E.24](#).

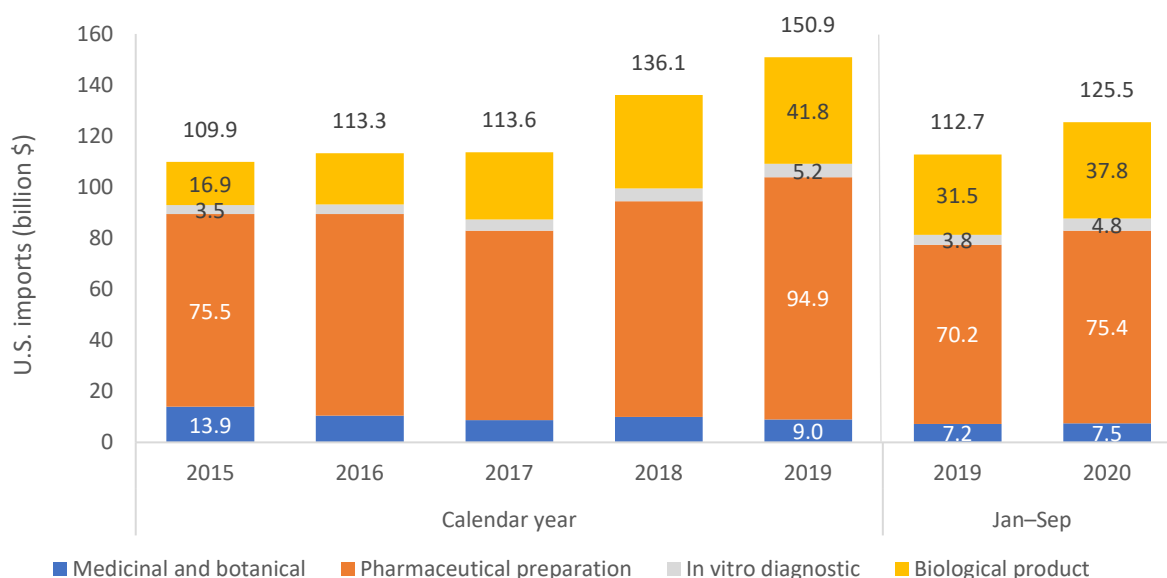
## U.S. Imports

U.S. imports of pharmaceuticals remained relatively constant during 2015–17 and grew during 2018–19 to \$150.9 billion (11 percent) (figure 5.6). During this period, the values of U.S. imports of both pharmaceutical and biological preparations increased. The increase in imports was driven largely by growth in U.S. biologics imports, which is the fastest-growing segment of the U.S. market.<sup>627</sup> IQVIA estimates that biologics, including vaccines, accounted for about 42 percent of U.S. spending on pharmaceuticals in 2018.<sup>628</sup>

<sup>627</sup> IQVIA, “Biologics Market Dynamics,” March 9, 2020, 2.

<sup>628</sup> IQVIA, “Biologics Market Dynamics,” March 9, 2020, 2.

**Figure 5.6** U.S. imports of pharmaceuticals, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)



Source: USITC DataWeb/USDOC, NAICS 325411, 325412, 325413, 325414 (accessed November 2020).

Note: Underlying data for this figure can be found in [appendix table E.25](#).

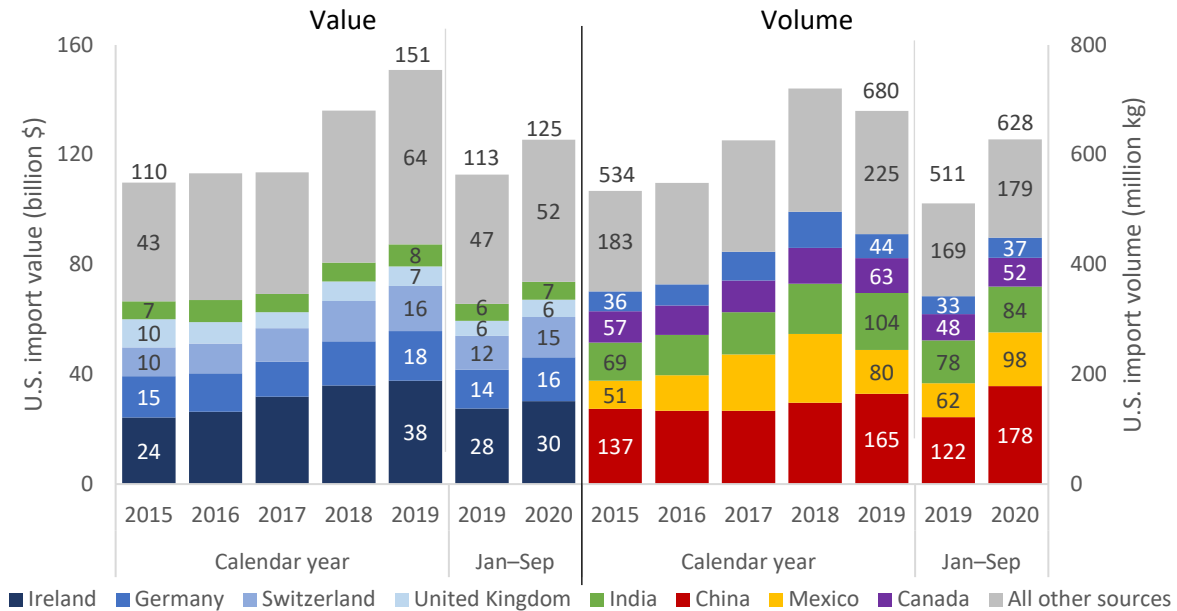
The leading suppliers of pharmaceuticals to the U.S. market, by value, in 2019 were in Europe (Ireland, Germany, and Switzerland), while the leading suppliers by volume were in Asia (China and India) and North America (Canada and Mexico) (figure 5.7). In general, higher unit-value products (usually novel products)—some around \$3,000 per kilogram—are imported from Europe and often involve related-party trade.<sup>629</sup> Lower-valued products—with average unit values around \$20–100 per kilogram—are predominantly sourced from China and India.<sup>630</sup> The lower value implies that U.S. imports of products from China and India are largely generic pharmaceuticals and commodity chemicals used in a variety of pharmaceuticals (including generics), which are significantly lower in value than brand-name novel APIs and formulations. U.S. pharmaceutical imports from China increased 46 percent by volume from January–September 2020 compared to the same period in 2019. U.S. imports from China, by volume, were primarily medicinal and botanical products (69 percent of imports) and, to a lesser extent,

<sup>629</sup> Related-party trade is defined as an import transaction where one party owns at least 10 percent of the other party. Germany, Switzerland, and the United Kingdom (UK) have large pharmaceutical industries, with many companies in these countries having significant operations in the United States, including through acquisitions. Examples include Bayer, Boehringer Ingelheim, and Merck (Germany); Novartis (Switzerland); and GlaxoSmithKline and AstraZeneca (UK). USITC DataWeb/USDOC (accessed October 2020); Census, related-party trade database, NAICS 3254 (accessed September 2020); Census, “Trade Definitions” (accessed November 4, 2020).

<sup>630</sup> USITC DataWeb/USDOC, for commodity group CH019 “Medicinal Chemicals” (accessed October 14, 2020).

pharmaceutical preparations (27 percent).<sup>631</sup> U.S. imports from India, by comparison, were primarily pharmaceutical preparations (94 percent of imports).<sup>632</sup>

**Figure 5.7** U.S. imports of pharmaceuticals, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars and million kilograms)



Source: USITC DataWeb/USDOC, NAICS 3254 (accessed November 2020).

Note: The countries presented are in the top five in total value during January 2015–September 2020 and top five by volume during January 2015–September 2020. Underlying data for this figure can be found in [appendix table E.26](#).

U.S. pharmaceutical import prices, excluding tariffs, increased by 12 percent from January 2015 to January 2020, and have been largely stable in 2020.<sup>633</sup> Relatively few U.S. imports of pharmaceuticals are dutiable, primarily because of the WTO Agreement on Trade in Pharmaceutical Products.<sup>634</sup> In addition to immediate duty-free entry for formulated products, the agreement provided duty-free treatment for certain U.S. imports of bulk APIs.<sup>635</sup> This duty-free treatment has shifted U.S. imports from

<sup>631</sup> The primary medicinal and botanical products imported from China, by volume, during January–September 2019 were vitamins and supplements, with vitamin C, lysine, and vitamin E accounting for 79 percent of imports (up from 72 percent in all of 2019). USITC DataWeb/USDOC, NAICS 325411, 325412, 325413, 325414 (accessed November 2020).

<sup>632</sup> USITC DataWeb/USDOC, NAICS 325411, 325412, 325413, 325414 (accessed November 2020).

<sup>633</sup> BLS, “Import/Export Price Indexes” (accessed September 2020).

<sup>634</sup> The WTO Agreement on Trade in Pharmaceutical Products entered into force on January 1, 1995 and was last updated in 2010.

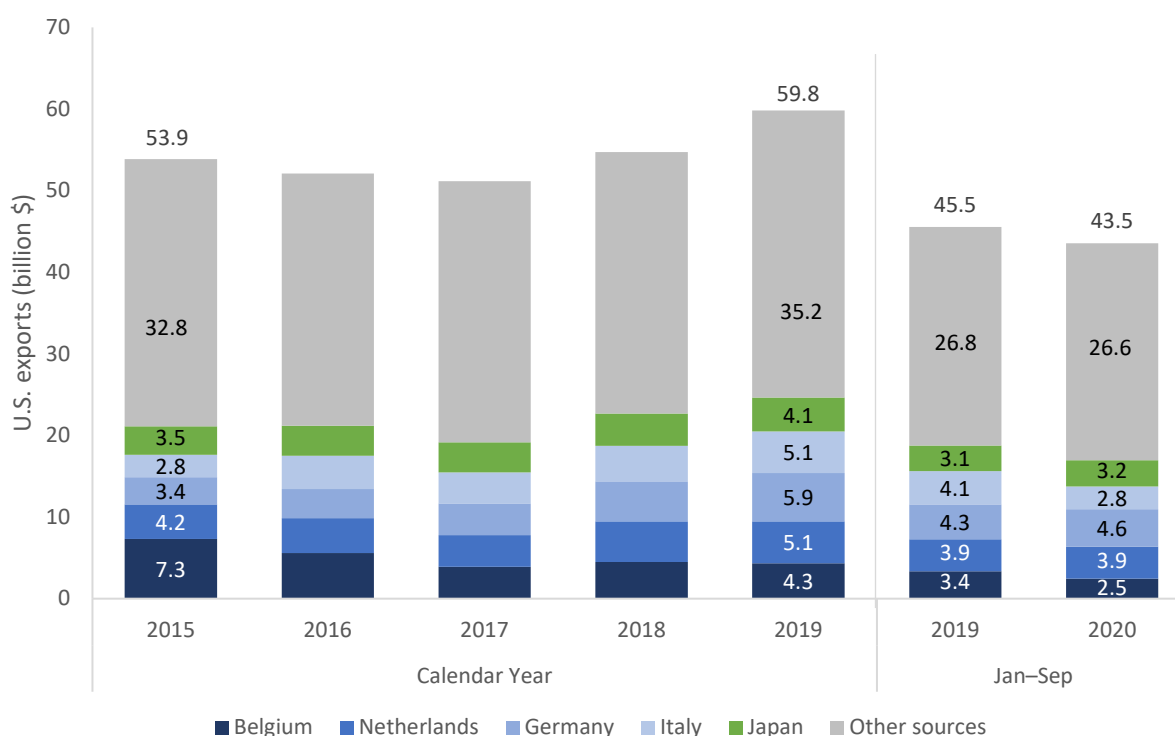
<sup>635</sup> It also provided duty-free entry for U.S. imports of certain bulk pharmaceuticals under the agreement’s Pharmaceutical Appendix. USITC, *Pharmaceutical Products and Chemical Intermediates, Fourth Review*, September 2010, 2-1.

APIs towards formulated dosage-form products,<sup>636</sup> and has prompted increased usage of foreign trade zones to process APIs into formulated products.<sup>637</sup>

## U.S. Exports

Growth in pharmaceutical exports, which rose to \$59.8 billion in 2019, largely reflects growing exports of biologics, and, in part, related-party trade between firms operating in the United States and their overseas units (figure 5.8). Exports are primarily split between formulated products and biologics, with the top five export market destinations being Germany, the Netherlands, Italy, Belgium, and Japan.<sup>638</sup>

**Figure 5.8** U.S. exports of pharmaceuticals, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)



Source: USITC DataWeb/USDOC, NAICS 3254 (accessed November 2020).

Note: The countries presented are in the top five in value during January 2015–September 2020. Underlying data for this figure can be found in [appendix table E.27](#).

<sup>636</sup> Nesbitt, “Changes in the U.S. Pharmaceutical Import Mix,” August 2017; USITC, *Pharmaceutical Products and Chemical Intermediates, Fourth Review*, September 2010, 2-1.

<sup>637</sup> Use of FTZs helps remedy some tariff inversions that result between APIs and final formulated products. Nesbitt, “Changes in the U.S. Pharmaceutical Import Mix,” August 2017.

<sup>638</sup> Harston, “How the U.S. Compares to Europe,” October 12, 2020; industry representatives, telephone interviews by USITC staff, October 14 and 21, 2020.

# COVID-19 Test Kits

## Major Findings

- The rapid onset and spread of COVID-19 led to a sharp increase in demand for COVID-19 test kits. Shortages of test kits and related supplies have continued throughout the pandemic, as demand has remained high and certain diagnostic testing materials and laboratory supplies made by different manufacturers are not interchangeable.
- The initial rollout of tests kits was delayed due to contamination. Once new commercial tests were authorized, U.S. firms quickly brought them to the market, and production of sample collection supplies and test kits substantially increased during 2020.
- There have been several challenges that have impacted domestic production, including the time required to design the tests, shortages of key inputs, the time needed to bring new machinery online, and difficulties in recruiting new workers. Finally, the sterilization capacity required for some products has been a challenge for some firms.
- The rise in global demand exceeded the global supply of key goods used in diagnostic testing, some of which were only produced by a handful of firms before the pandemic. Further, many supplies can be used only on certain types or brands of laboratory equipment. A decline in air freight capacity also made it harder and more expensive to import products.

## Introduction

Since the beginning of the pandemic, the United States has faced shortages in diagnostic COVID-19 test kits as well as a range of other products needed for testing, such as additional reagents, swabs, and ribonucleic acid (RNA) extraction kits.<sup>639</sup> A test kit for the purposes of this case study refers to a kit that consists of a variety of protocol specific reagents to test for COVID-19 including primer-probes mixes and positive controls. Challenges for U.S. producers range from developing and launching an entirely new product (diagnostic tests) to bringing additional production capacity online for products required for testing, such as swabs. Testing for COVID-19 has also been hampered by shortages of lab capacity and the machinery needed to run tests. While U.S. producers of diagnostic tests ramped up production between March and September 2020, allowing many more tests to be run, constraints persist throughout the diagnostic test supply chain.

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<sup>639</sup> Reagent is a generic term for a substance or mixture used in chemical reactions and analysis. There are multiple types of reagents used in COVID-19 testing, as will be explained below. RNA stands for ribonucleic acid. RNA performs the same function as DNA in humans insofar as it carries the genetic information of the virus.

## Product Overview

### Description

This case study covers diagnostic tests and related key consumables needed for COVID-19 testing. There are two types of tests relevant to detecting COVID-19: diagnostic tests to reveal whether an individual is currently infected, and antibody tests to determine whether a person was previously infected.<sup>640</sup> There are two types of diagnostic tests—molecular and antigen tests.<sup>641</sup> This case study focuses on standard molecular tests, unless noted otherwise, because during the first half of 2020 those were the tests that experienced the most significant supply chain issues.

Molecular tests<sup>642</sup> were the first type approved for detecting COVID-19 and continue to be central to domestic testing infrastructure.<sup>643</sup> Molecular tests return a positive result when there is genetic material (RNA) from the virus present (i.e., an active infection). Molecular tests can be either rapid tests (results in less than one hour) or standard tests that take longer to process.<sup>644</sup> By October 2020, there were hundreds of molecular tests authorized by FDA.<sup>645</sup>

The first step in COVID-19 testing is to develop and approve a test (figure 5.9). The next step is to collect samples from patients at testing sites. Several consumable products are used for sample collection (also referred to as specimen collection, test collection, or media kits), including swabs and vials filled with a transport medium to preserve the sample on the way to the laboratory.<sup>646</sup>

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<sup>640</sup> Antibody tests detect past infection by looking for the COVID-19 specific proteins produced as part of the human body's immune system response to infection. Evidence of past infection is found in the patient's blood, necessitating a blood draw to isolate the relevant disease markers.

<sup>641</sup> Both diagnostic tests provide the current infection status of a patient, but they look for different viral markers. Antigen tests look for viral proteins, while molecular tests look for viral RNA (genetic material). Of the two, antigen tests have generally lower sensitivity and specificity. Test sensitivity describes how often a positive case is correctly identified, while specificity describes how often a negative case is correctly identified. As a result, a negative test does not definitively confirm that there is no active infection. By October 2020, there were seven FDA-authorized antigen tests. NIH, "NIH Delivering," July 31, 2020; industry representatives, telephone interview by USITC staff, September 22, 2020; FDA, "Coronavirus Disease 2019 Testing Basics" (accessed October 24, 2020).

<sup>642</sup> Other names for molecular tests include viral tests, nucleic acid amplification tests (NAAT), real-time polymerase chain reaction (RT-PCR) tests, and loop-mediated isothermal amplification (LAMP) tests. FDA, "Coronavirus Disease 2019 Testing Basics," (accessed October 24, 2020).

<sup>643</sup> CDC, "Diagnostic Testing," August 5, 2020; industry representatives, telephone interview by USITC staff, September 8, 2020.

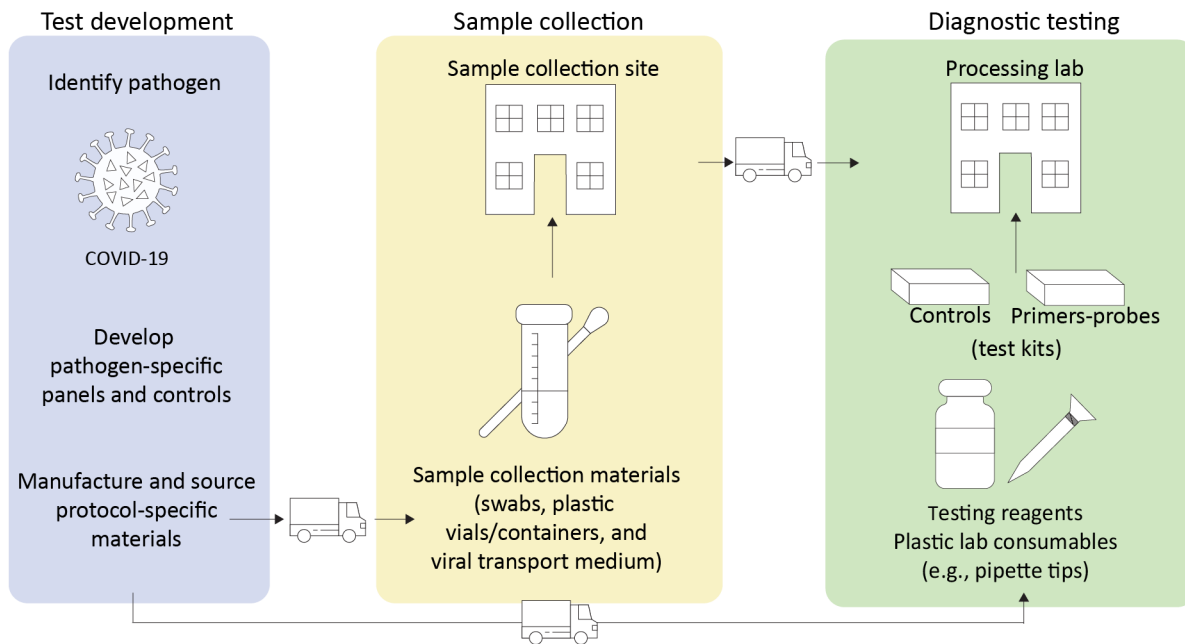
<sup>644</sup> FDA, "Coronavirus Disease 2019 Testing Basics" (accessed October 24, 2020).

<sup>645</sup> This does not include tests developed and authorized for use at a single lab. FDA, "In Vitro Diagnostics EUAs" (accessed October 24, 2020).

<sup>646</sup> Goods may also be shipped separately, rather than as part of a kit.



**Figure 5.9** COVID-19 diagnostic testing—three key stages (test development, sample collection, and diagnostic testing) and materials required



Source: Compiled by USITC staff.

Note: Sample collection materials and diagnostic tests may be sent to separate locations depending on whether (1) the testing site is the point of care (i.e., the diagnostics are run at the same location), or (2) the samples need to be transported to a lab.

Diagnostic testing involves using test kits (also referred to as assays), general testing reagents (including extraction reagents, which are often packaged into RNA extraction kits), and plastic lab consumables. Test kits vary depending on the manufacturer, although all contain primer-probe mixes that are designed to interact with COVID-19 RNA along with positive and negative controls (box 5.2).<sup>647</sup> All diagnostic tests require controls to confirm that the test was performed properly and that the result is reliable.<sup>648</sup>

### Box 5.2 Example of a Diagnostic Test Kit

Test kits, also referred to as assays, are one type of “kit” that has been used to diagnose and track the spread of COVID-19 worldwide (there are also sample collection kits and RNA extraction kits). During the first few months of 2020, as COVID-19 spread around the world, molecular diagnostic tests became the standard, and the protocols for diagnostic tests were published referencing specific test kits. In this report, the discussion of testing has been divided into two areas—the collection of samples and the

<sup>647</sup> Specifically, molecular tests use primers and enzymes that amplify the amount of viral RNA in a sample.

<sup>648</sup> The negative control yields no response to the test, contains no COVID-19 biomarkers, and validates that the process was not inadvertently contaminated or disrupted. The positive control contains the COVID-19 marker that should create a response to the test and shows whether an error occurred during the sample preparation procedure if the test did not yield a positive result. Only one control of each type is required per batch, and the rate of use/depletion of a given lab depends on the capacity of their instruments. Negative controls are substitutable, as they can be any type of cells so long as human DNA is present; however, any substitution of positive controls requires process re-validation. Government officials, telephone interview by USITC staff, September 10, 2020.

processing of samples in the lab—which are both necessary steps in diagnostic testing. The test kits and the materials they contain vary by manufacturer; test kits used at the processing lab always contain primer-probe mixes and controls.

The first authorized COVID-19 test kit in the United States (figure 5.10) is an example of a diagnostic test kit (also referred to as a diagnostic panel), contained in two boxes that include seven vials total. The first box (right) has three vials that each contain primer-probe mixes. The second box (left) includes four vials that each contain materials that act as the positive control to be used to validate the results of the diagnostic panel run on a sample using the primer-probes in the first box. The primer-probe mixes amplify the genetic material present in the sample, and the probes bind to the viral-containing material. If there is no viral-containing material within the sample to amplify (via the primer), then there is nothing for the probe to bind to, yielding a negative test (e.g., the patient does not have COVID-19).

**Figure 5.10** First FDA-authorized diagnostic test kit for COVID-19 in the United States



Sources: Compiled by USITC from CDC, “CDC’s Diagnostic Test for COVID-19 Only and Supplies,” updated October 9, 2020; CDC, “Diagnostic Tests,” updated August 5, 2020; WHO, “Molecular Assays to Diagnose COVID-19,” January 24, 2020.

## Diagnostic Test Development

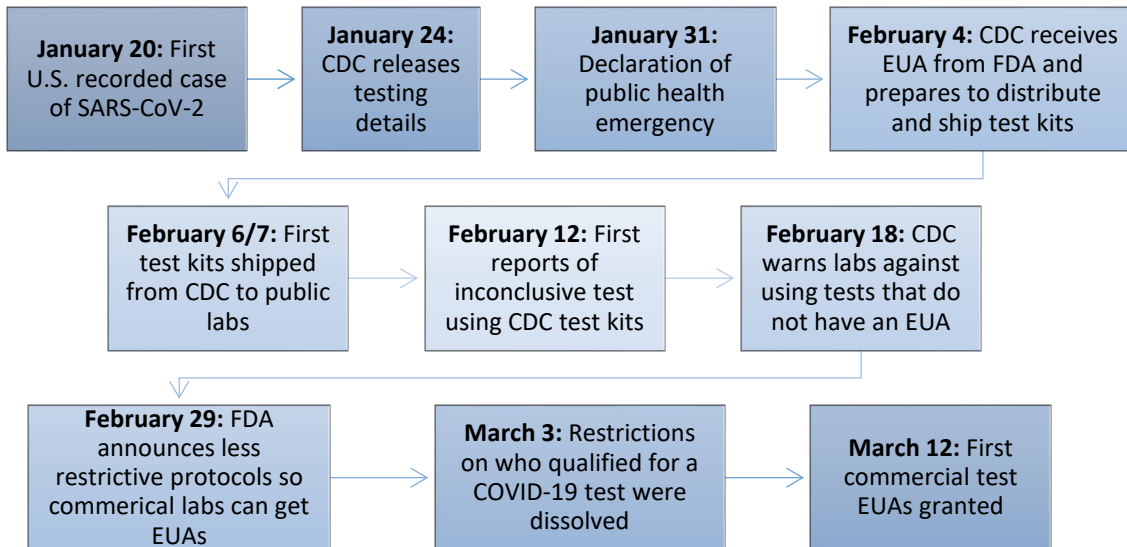
When the United States faces a pandemic, generally the federal government, through CDC, initially takes the lead on developing accurate and reliable diagnostic tests. The first test for COVID-19 was developed and manufactured by CDC, receiving FDA approval on February 4. However, one of the control vials provided by CDC to public health labs as part of the test kit (assay) was found to be contaminated, leading to unreliable results, and this error required three weeks to fully correct.<sup>649</sup> The first commercial test, developed by Roche Molecular Systems Inc., was approved on March 12, 2020 (figure 5.11).<sup>650</sup> The rollout of the diagnostic tests struggled to keep pace with the spread of COVID-19, given that community transmission started in late January to early February.<sup>651</sup>

<sup>649</sup> The HHS Office of Inspector General is conducting an audit “to review CDC’s process of producing and distributing the COVID-19 test kits.” CNN, “Early CDC Test Kits,” June 25, 2020; Chen et. al., “Key Missteps,” February 28, 2020; HHS, Office of Inspector General, “Audit of HHS’s Production” (accessed December 9, 2020).

<sup>650</sup> FDA, “In Vitro Diagnostics EUAs” (accessed October 22, 2020).

<sup>651</sup> CDC, “Community and Close Contact Exposures,” September 11, 2020.

**Figure 5.11** Timeline for authorization of public and commercialized COVID-19 diagnostic tests, January–March 2020



Source: Kelly, Cahlan, and Samuels, “What Went Wrong with Coronavirus Testing in the U.S.,” March 30, 2020; Armour, Abbott, Burton, and McKay, “What Derailed America’s Covid Testing: Three Lost Weeks,” August 18, 2020; GenomeWeb, “FDA Takes Fast Action to Approve Two New Commercial COVID-19 Diagnostic Tests,” March 17, 2020; FDA, “cobas SARS-CoV-2,” October 15, 2020; FDA, “FAQs on Testing for SARS-CoV-2” (accessed September 2, 2020); U.S. Government Accountability Office, “COVID-19: Opportunities to Improve Federal Response and Recovery Efforts,” June 25, 2020, 115.

Note: The less restrictive protocols on February 29 made it so FDA will not object to commercial tests that are distributed and used while the EUA request is pending regulatory approval. Industry has also reported that FDA has been responsive in rendering assistance to increase the availability of test supplies.

All COVID-19 test kits must be submitted to and approved by FDA before they can be used in patient care.<sup>652</sup> However, the declaration of a public health emergency gave the FDA authority to grant Emergency Use Authorizations (EUAs) for expedited processing of test approval applications.<sup>653</sup> At the end of March, FDA also granted EUAs for the use of testing kit supplies that are normally not allowed for diagnosis.<sup>654</sup>

## U.S. Market

In January 2020, the first COVID-19 cases were confirmed in the United States, immediately triggering a rapid rise in the demand for COVID-19 testing that could not be met. The early demand was felt in all areas of diagnostic testing. The supply of diagnostic tests to the U.S. market began to increase steadily, and between March and mid-October 145 million commercial diagnostic tests had been supplied.<sup>655</sup> For sample extraction in the lab (RNA extraction kits), the initial demand was measured in hundreds of

<sup>652</sup> USITC, hearing transcript, September 23, 2020, 74 (testimony of Susan Van Meter, AdvaMed).

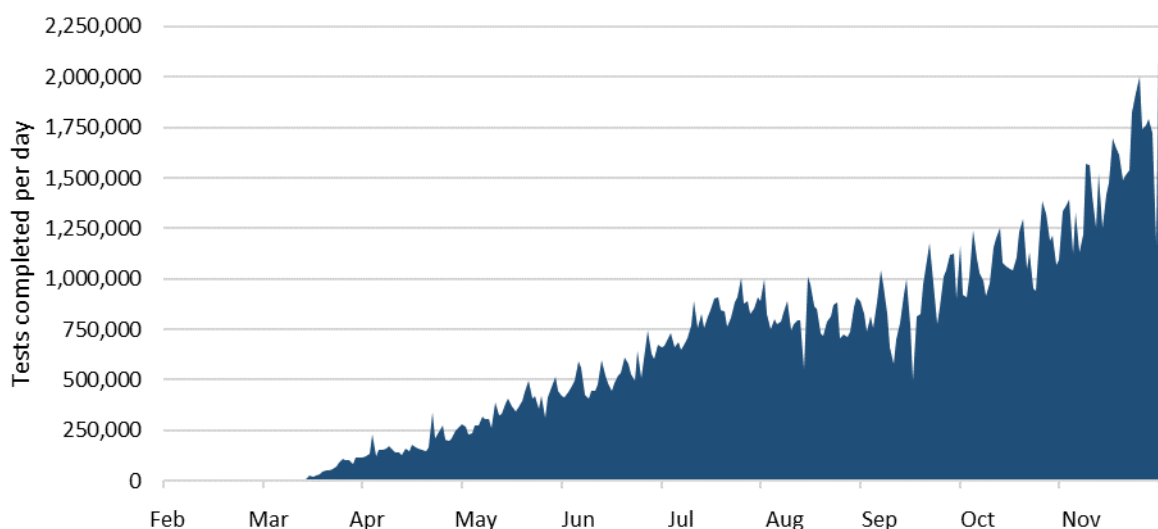
<sup>653</sup> A list of currently approved EUAs for COVID-19 tests may also be found at FDA, “In Vitro Diagnostics EUAs” (accessed August 25, 2020); FDA, “Coronavirus Disease 2019” (accessed August 25, 2020).

<sup>654</sup> Provided the manufacturer provides a letter attesting that the chemical composition is the same. This applies to supplies normally labeled “research use only” (RUO) and “investigational use only” (IUO), which are typically not substitutable with those labeled “in vitro diagnostic” (IVD). Government officials, telephone interview by USITC staff, September 9, 2020.

<sup>655</sup> AdvaMed, “AdvaMed COVID Testing Supply Registry,” October 16, 2020.

thousands per month; by September, demand for these kits had approached tens of millions per month.<sup>656</sup> Between February and November, the number of tests performed per day rose from less than 10,000 to more than 1 million (figure 5.12).<sup>657</sup> However, testing remains well below the hundreds of millions of tests per month that are estimated, by some sources, to be needed for a full reopening of schools and the economy.<sup>658</sup>

**Figure 5.12** U.S. COVID-19 tests completed, per day, February–November 2020



Source: COVID Tracking Project, “National Data” (accessed December 1, 2020).

Note: Test counts are based on the data provided by individual states and territories, covering all test types; additional information on each location’s methods is available at the COVID Tracking Project, “Our Data.”

Further, challenges in the supply of sample collection and diagnostic test materials have persisted throughout the pandemic. An August–September survey of commercial laboratory personnel found that the vast majority of respondents had experienced supply chain interruptions or limits on the availability of supplies and equipment necessary for commercial diagnostic testing (including test kits, reagents, and plastic consumables) and sample collection at some point in time during 2020.<sup>659</sup> At the time of the survey, shortages continued to persist, with a majority of respondents indicating they were experiencing bottlenecks in the supply chain for test kits and certain plastic laboratory consumables.<sup>660</sup> For sample

<sup>656</sup> Industry representatives, telephone interview by USITC staff, September 8, 2020; USITC, hearing transcript, September 23, 2020, 24–25 (testimony of Susan Van Meter, AdvaMed).

<sup>657</sup> Allen, Weyl, and Guthrie, “The Mechanics of the COVID-19 Diagnostic Testing Supply Chain,” April 22, 2020.

<sup>658</sup> Sheridan, “U.S. Needs 193 Million,” September 9, 2020; Allen et al, “Roadmap to Pandemic Resilience,” April 20, 2020 6; Allen, Weyl, and Guthrie, “The Mechanics of the COVID-19 Diagnostic Testing Supply Chain,” April 22, 2020, 13–14.

<sup>659</sup> Association for Molecular Pathology, “Summary of August,” 2020, 7.

<sup>660</sup> Media reports also point to the continuation of shortages in August–September 2020. Association for Molecular Pathology, “Summary of August,” 2020, 7; Frosch, “Covid-19 Testing Is Hampered,” September 22, 2020; Biviano, “Nationwide Shortage,” August 15, 2020.

collection materials, the market for swabs grew almost 300 percent, according to an estimate by one industry representative.<sup>661</sup>

## U.S. Manufacturing Industry

### Diagnostic Tests

Many U.S. producers are able to supply test kits and testing reagents for the domestic market (table 5.2).<sup>662</sup> Roche, Promega, and IDT all provide reagents for molecular diagnostic tests from U.S. facilities.<sup>663</sup> CDC is also a domestic producer and packager of test kits, but only for state public health laboratories; its kits include primers-probes mixes and control samples.<sup>664</sup> Becton Dickinson (BD) and Qiagen (a company headquartered in Europe) also produce various testing reagents domestically.

**Table 5.2** Examples of U.S. test kit and testing reagent producers

Company	U.S. plant locations
CDC	Atlanta, GA
Integrated DNA Technologies	Coralville, IA
Promega	Madison, WI
Qiagen	Boston, MA
Roche	Branchburg, NJ

Source: Industry representatives, telephone interviews by USITC staff, August 25 and 28, and September 22, 2020; Integrated DNA Technologies, “SARS-CoV-2 Probes and Other COVID-19 Research Reagents” (accessed September 29, 2020); Sable-Smith, “Promega Helping Supply materials for COVID-19 Tests,” March 18, 2020.

Note: The information presented does not represent an exhaustive list of every company that produces testing supplies within the United States. The table only includes manufacturers who produce reagents for nucleic acid tests.

The increase in testing demand spurred U.S. manufacturers’ production of testing reagents. Domestic production has primarily been bolstered by increasing capacity utilization of existing production.<sup>665</sup> For example, Qiagen has reportedly begun ramping up production at its Germantown, Maryland, facility,<sup>666</sup>

<sup>661</sup> Industry representatives, telephone interview by USITC staff, August 20 and September 8, 2020; AdvaMed, written submission to the USITC, September 23, 2020, 19; Allen, Weyl, and Guthrie, “The Mechanics of the COVID-19 Diagnostic Testing Supply Chain,” April 22, 2020, 15; USITC, hearing transcript, September 23, 2020, 24–25 (testimony of Susan Van Meter, AdvaMed).

<sup>662</sup> The extent to which the domestic market met demand before 2020 is unknown for two reasons: (1) the wide variety of materials that are used to perform diagnostic tests, and (2) the fact that different tests can use different reagents.

<sup>663</sup> Industry representatives, telephone interviews by USITC staff, August 25 and 28, 2020; government officials, telephone interview by USITC staff, September 9, 2020.

<sup>664</sup> This manufacturing takes place at CDC facilities in Georgia managed by CDC’s Division of Scientific Resources. Further information on the specific materials the CDC provides may be found here: Centers for Disease Control and Prevention, “Diagnostic Test for COVID-19 Only and Supplies,” July 15, 2020; Government officials, telephone interview by USITC staff, September 9, 2020.

<sup>665</sup> In contrast, new capacity is required to meet the demand for rapid tests, which require unique reagents and plastic components. The U.S. Departments of Defense (DOD) and Health and Human Services (HHS) have made investments with Becton Dickinson to increase production of these materials onshore through contract manufacturers in Massachusetts and Pennsylvania. Industry representative, telephone interview by USITC staff, August 25 and September 22, 2020; York, “Meeting Customer Needs,” March 30, 2020; USDOD, “DOD and HHS Invest,” July 31, 2020.

<sup>666</sup> Industry representatives, telephone interview by USITC staff, September 22, 2020.

and Wisconsin-based Promega is reportedly increasing its output and capacity utilization with more shifts and overtime.<sup>667</sup> The domestic industry's response was complicated by the novel nature of the virus. For example, the U.S. market for COVID-19-specific elements of tests did not exist before the pandemic. The unique materials required to test for the disease—the primers, probes, antigens, and antibodies—can be manufactured using some existing techniques and procedures, although these reagents require novel design and development to be pathogen specific.

There are multiple domestic firms that produce plastic lab consumables within the United States, such as Hologic, Jabil, Corning, and Porex.<sup>668</sup> Domestic producers such as Hologic have been boosting production and employment to meet the increased demand for their products.<sup>669</sup> Porex is the sole domestic manufacturer of the filters required for plastic pipette tips.<sup>670</sup>

## Sample Collection

In 2019, few U.S. firms produced components for sample collection for testing (table 5.3). Before the pandemic, Puritan Medical Products (Puritan) was the only U.S. firm producing flocced swabs for diagnostic use.<sup>671</sup> While there are several U.S. producers of viral transport medium, these reportedly do not have enough capacity to meet current demand.<sup>672</sup> Alternative products, such as saline, reportedly are being used as substitutes to expand testing capacity.<sup>673</sup> Finally, there are reportedly plans to onshore additional viral transport medium production capacity in response to the pandemic.<sup>674</sup>

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<sup>667</sup> York, "Meeting Customer Needs," March 30, 2020; industry representatives, telephone interview by USITC staff, August 25, 2020; Sable-Smith, "Promega Heling Supply materials for COVID-19 Tests," March 18, 2020.

<sup>668</sup> Industry representatives, telephone interviews by USITC staff, September 21, 2020; Foo, "San Diego Company," August 6, 2020.

<sup>669</sup> DOD, "DOD, HHS Award \$7.6 Million," July 27, 2020; Foo, "San Diego Company," August 6, 2020; industry representatives, telephone interview by USITC staff, August 25, 2020.

<sup>670</sup> More information on Porex's products can be found here: Porex Filtration Group, "Liquid & Sample Handling" (accessed September 29, 2020). Industry representatives, telephone interview by USITC staff, August 28 and September 21, 2020.

<sup>671</sup> Flocced swabs are the preferred type of swab for COVID-19 testing. Industry representatives, telephone interview by USITC staff, August 20, 2020.

<sup>672</sup> Industry representatives, telephone interviews by USITC staff, September 17 and 22, 2020.

<sup>673</sup> Industry representatives, telephone interview by USITC staff, September 22, 2020.

<sup>674</sup> Thermo Fisher Scientific, "Thermo Fisher Scientific Officially Opens New Site for Manufacturing COVID-19 Sample Collection Products," August 28, 2020.

**Table 5.3** Identified U.S. producers of swab and viral transport medium

Company	U.S. plant locations
<b>U.S. producers of swabs</b>	
FormLabs	Millbury, OH
Microbrush	Grafton, WI
Puritan Medical Products	Guilford, ME
U.S. Cotton	Cleveland, OH
<b>U.S. producers of viral transport medium</b>	
Hardy Diagnostics	Santa Maria, CA; Springboro, OH
Puritan Medical Products	Guilford, ME
Teknova Inc.	Hollister, CA
Thermo Fisher	Lenexa, KS

Source: U.S. Cotton, "Our COVID-19 Response" (accessed September 29, 2020); Industry representatives, telephone interviews by USITC staff, August 20 and September 17, 2020; Lininger, "Concordance Partners," April 20, 2020; Hardy Diagnostics, "Universal Transport Medium" (accessed October 8, 2020); Puritan Medical Company, "Puritan UniTranz-RT" (accessed October 8, 2020); Teknova, "Teknova Scales up Production," September 10, 2020; Thermo Fisher, "Thermo Fisher Scientific," August 28, 2020.

Note: The information presented does not necessarily represent an exhaustive list of every company that produces swabs and viral transport medium within the United States. Three of the listed U.S. swab producers, Microbrush, Puritan, and U.S. Cotton employ more than 600 people combined. Producers of viral transport medium may produce other testing supplies as well.

Since the pandemic began, the U.S. industry has expanded production capacity for swabs used in sample collection. For example, Puritan increased production by building a new facility for foam swab manufacturing using funding provided by the U.S. Department of Health and Human Services (HHS) and is under contract by the federal government to build a new plant to produce flocked swabs.<sup>675</sup> These sites are slated to increase the company's output to 50 million swabs per month by spring 2021.<sup>676</sup> Other subsectors of the swab industry have retooled their production to meet demand for COVID-19 tests.<sup>677</sup> For example, Microbrush switched from making dental applicators to flocked swabs on its existing equipment within a three-month period, and its capacity is now reported to be more than 1 billion swabs per year.<sup>678</sup> Similarly, cotton swab producer U.S. Cotton switched part of its existing manufacturing lines to accommodate the synthetic materials needed for swabs for diagnostic tests.<sup>679</sup> Other firms, such as FormLabs, are using 3D printers to manufacture swabs under FDA EUAs.<sup>680</sup>

<sup>675</sup> These investments are part of the \$627 million disbursed through the Defense Production Act Title III for seventeen manufacturing investments. U.S. Department of Defense, "DOD Details \$75 Million Defense," April 29, 2020; U.S. Government Accountability Office, "COVID-19: Federal Efforts," September 21, 2020, 11.

<sup>676</sup> U.S. Department of Defense, "DOD Awards \$51.15 Million Indefinitized Contract," July 31, 2020.

<sup>677</sup> USITC, hearing transcript, September 23, 2020, 84 (testimony of Susan Van Meter, AdvaMed); AdvaMed, written submission to the USITC, September 23, 2020, 19.

<sup>678</sup> Part of three-month transition required the procurement of new molds from a Proctor and Gamble subsidiary. Microbrush is a subsidiary of Young Innovations, headquartered in Algonquin, IL. Industry representatives, telephone interview by USITC staff, September 17, 2020; Hauer, "A Grafton Company Switched," October 1, 2020; Naczek, "From Dental Products," August 28, 2020.

<sup>679</sup> Industry representatives, telephone interview by USITC staff, September 28 and October 2, 2020; Esposito, "Gaston County Company," April 22, 2020.

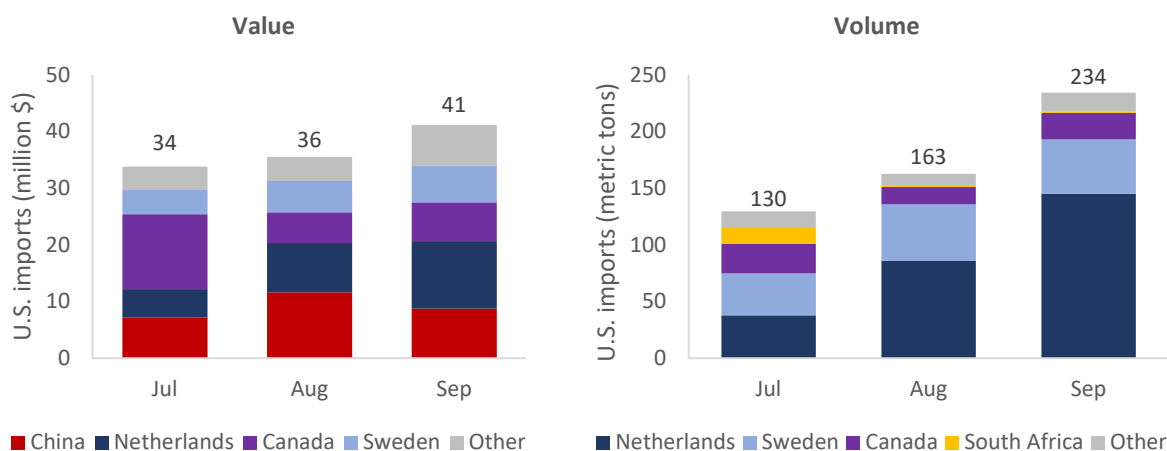
<sup>680</sup> Lininger, "Concordance Partners with NW Ohio Company," April 20, 2020; U.S. Food and Drug Administration, "3D Printing in FDA's Rapid Response to COVID-19," August 3, 2020.

## U.S. Imports

### Diagnostic Tests

U.S. imports of testing reagents for polymerase chain reaction (PCR)-type<sup>681</sup> molecular tests, a commonly employed COVID-19 diagnostic test, increased from \$34 million in July 2020 to \$41 million in September 2020 (the only time period for which data are available), while the volume of imports increased from 130 metric tons in July 2020 to 234 metric tons in September 2020 (figure 5.13).<sup>682</sup> The leading sources of imports by value were China (25 percent of imports July–September 2020), the Netherlands (23 percent), Canada (23 percent), and Sweden (15 percent), while the largest sources by volume were the Netherlands (51 percent), Sweden (26 percent), and Canada (12 percent). China’s absence from the list of top suppliers by volume reflects the higher unit values of its imports.

**Figure 5.13** U.S. imports of reagents for PCR-type molecular tests, July–September 2020 (in million dollars and metric tons)



Source: USITC DataWeb/USDOC, HTS 3822.00.5050 (accessed November 2020).

Note: Underlying data for this figure can be found in [appendix table E.28](#).

The U.S. manufacturing base for extraction reagents is supplemented by many producers overseas.<sup>683</sup> One of the world’s largest producers is Qiagen, a Europe-based producer with facilities in Hilden, Germany, and Barcelona, Spain (with a production facility in Boston, Massachusetts).<sup>684</sup> The German firm Roche also is a producer.<sup>685</sup>

<sup>681</sup> COVID-19 testing polymerase chain reactions (PCR), specifically reverse transcription (RT-PCR), is a process in which the RNA is amplified within a sample. FDA, “Coronavirus Disease 2019 Testing Basics” (accessed October 24, 2020).

<sup>682</sup> PCR-type reagents are the only testing reagents specifically related to COVID-19 testing that have an HTS-10 statistical breakout. USITC DataWeb/USDOC for HTS statistical reporting number 3822.00.5050 (accessed October 2, 2020).

<sup>683</sup> There are no import data specific to many of the reagents used for COVID-19 diagnostic testing (i.e., non-PCR tests) including: test kits (primer-probes and controls), laboratory and extraction reagents.

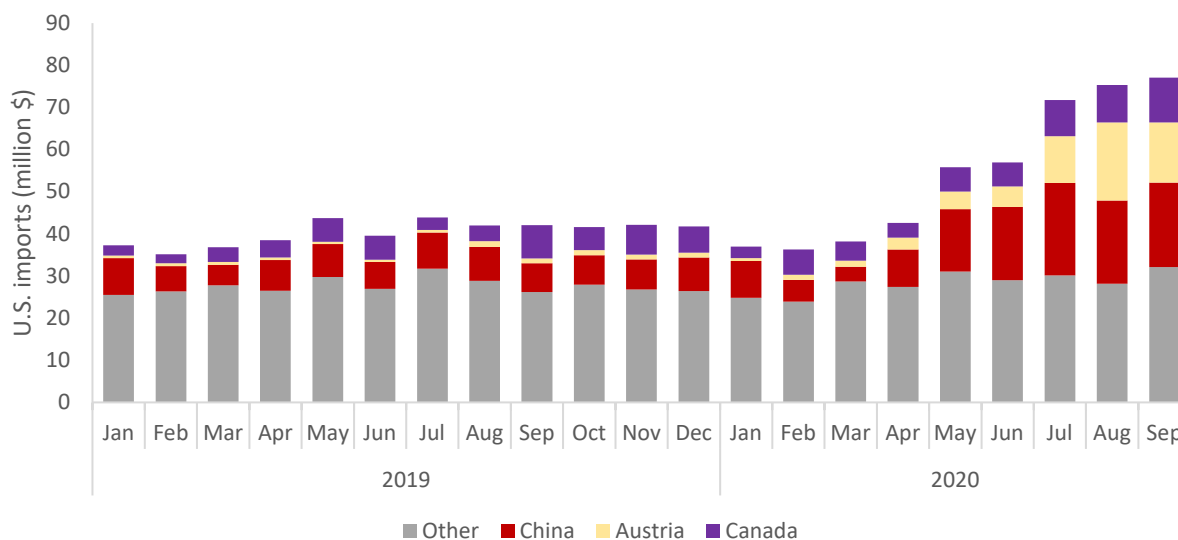
<sup>684</sup> Krieger, “Coronavirus: California Testing Hamstrung by Shortage of Key Chemical,” March 15, 2020.

<sup>685</sup> Industry representatives, telephone interviews by USITC staff, August 28, 2020.



In 2020, U.S. imports of laboratory plastic products, which encompasses a variety of non-COVID-19 related goods as well as COVID-19 related products, were slightly above prior-year levels in February and March, then started to rapidly increase above prior-year levels starting in April (figure 5.14). Most of the increase in imports was supplied by three countries—China, Austria, and Canada.<sup>686</sup> In addition to the imports reflected in figure 5.14, the United States imports significant quantities of plastic pipette tips for automated laboratory equipment that are often machine-specific.<sup>687</sup>

**Figure 5.14** U.S. imports of plastic laboratory ware, by country, January 2019–September 2020 (in million dollars)



Source: USITC DataWeb/USDOC, HTS 3926.90.9910 (accessed November 2020).

Note: Underlying data for this figure can be found in [appendix table E.29](#).

## Sample Collection

U.S. imports of products classified under the HTS statistical reporting number containing swabs started to increase in April 2020 (figure 5.15). Imports from Italy most quickly responded to the surge in U.S. demand, followed by imports from China and South Korea.<sup>688</sup> Several foreign swab producers reportedly sell to U.S. consumers, including European producer Copan-Italia, which is one of the few producers that can supply the flocked swabs needed for the diagnostic test for COVID-19. Firms in China and South Korea can also supply flocked swabs.<sup>689</sup>

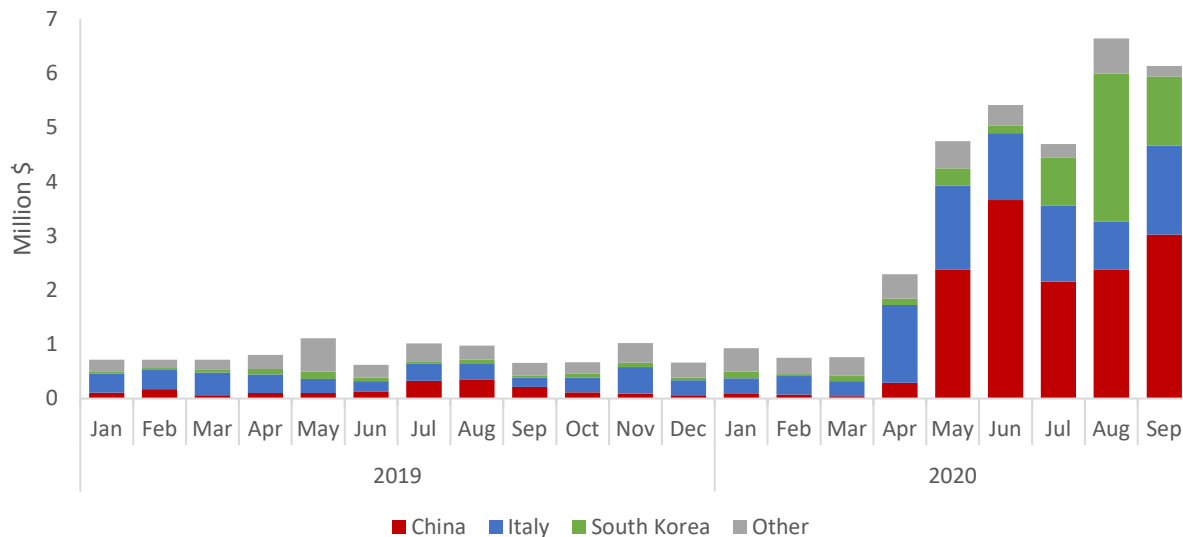
<sup>686</sup> USITC DataWeb/USDOC for HTS statistical reporting number 3926.90.9910 (accessed October 17, 2020).

<sup>687</sup> Pipette tips (HTS 8479.89.9499) are subject to 25 percent section 301 duties, while laboratory ware (HTS 3926.90.9910) is currently excluded from section 301 duties. HTS chapter 99 subchapter 3 note 20; Wu, “It’s Like Groundhog Day,” August 15, 2020; Government officials, telephone interview by USITC staff, September 9, 2020.

<sup>688</sup> Products imported under this HTS number, including swabs, are subject to 25 percent section 301 duties. HTS chapter 99 subchapter 3 note 20; USITC DataWeb/USDOC for HTS statistical reporting number 5601.22.0090 (accessed October 2, 2020).

<sup>689</sup> Copan-Italia was unable to secure a patent in South Korea. Tae-seok and Kwan-kyu, “Corona Diagnosis,” March 9, 2020; Jae-cheol, “Coronavirus Swabs,” April 18, 2020; Kyung-Ho, “Opportunities and Risks,” April 28, 2020; Trade Data Information Services, Inc., Import Genius database (accessed November 15, 2020).

**Figure 5.15** U.S. imports of other articles of wadding of man-made fibers (including swabs), January 2019–September 2020 (in million dollars)

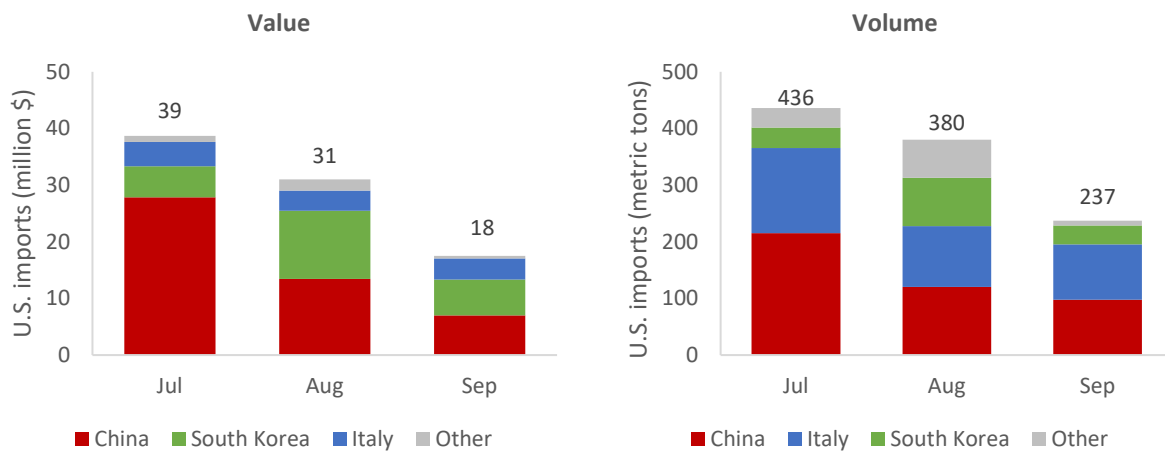


Source: USITC DataWeb/USDOC for HTS statistical reporting number 5601.22.0090 (accessed November 2020).  
 Note: Underlying data for this figure can be found in [appendix table E.30](#).

U.S. imports of viral transport medium appear to have started to increase substantially in April 2020, as imports in the broader HTS subheading containing viral transport medium jumped 82 percent from the prior month. Starting in July 2020, when a tariff line for viral transport medium was broken out separately, U.S. imports of viral transport media peaked in value at \$39 million, exceeding the value of all imports in the broader HTS number (prior to the breakout) in each month during January–June 2020. U.S. imports then dropped to \$18 million in September 2020.<sup>690</sup> By volume, U.S. imports of viral transport medium fell from 436 metric tons in July 2020 to 237 metric tons in September 2020. China was the largest source of imports by both volume and value, while South Korea was the second-largest import source by volume and Italy the second-largest source by value (figure 5.16).<sup>691</sup>

<sup>690</sup> USITC DataWeb/USDOC (accessed November 8, 2020).

<sup>691</sup> Viral transport medium imports are subject to 5 percent general rate of duty. USITC DataWeb/USDOC for HTS statistical reporting number 3821.00.0010 (accessed October 2, 2020).

**Figure 5.16** U.S. imports of viral transport medium, July–September 2020 (in million dollars and metric tons)

Source: USITC DataWeb/USDOC, HTS 3821.00.0010 (accessed November 2020).

Note: Underlying data for this figure can be found in [appendix table E.31](#).

## Supply Chain Challenges and Constraints

At first, reflecting CDC directives, the demand for testing came solely from those who were likely infected (returning from traveling abroad, symptomatic, etc.). During the last week of February 2020, CDC relaxed testing guidelines allowing individuals with severe symptoms and no known exposure to the virus to be tested (previously testing had been limited to those with known exposure to the virus).<sup>692</sup> While the CDC maintained testing recommendations and guidelines, states and localities were primarily responsible for their own policies.<sup>693</sup> Due to the nature of diagnostic testing development and allocations, the demand for COVID-19 diagnostic tests immediately outstripped supply, first because the pathogen (COVID-19) had to be identified; next, because the specific test to detect that pathogen had to be developed. Supply was further constrained by transportation issues and insufficient global capacity for the products needed for testing covered in this case study, specifically test kits, reagents, sample collection supplies (e.g., swabs), and plastic laboratory consumables (e.g., pipette tips). As the number of available test kits grew over the course of summer 2020, states generally relaxed their criteria for who could be tested, a trend that continued through September 2020.<sup>694</sup> Projections of how many tests need to be or should be conducted daily vary, but the supply of diagnostic tests—which include sample collection materials—has yet to fully meet demand.<sup>695</sup>

<sup>692</sup> COVID-19 testing for individuals with no known exposure but severe symptoms were limited to those that had been tested for other infections (i.e., flu). Schive, “COVID-19 (coronavirus disease 2019) February 2020 updates,” February 28, 2020; Kelly, Cahlan, and Samuels, “What Went Wrong with Coronavirus Testing in the U.S.,” March 30, 2020.

<sup>693</sup> Perniciaro, Weinberger, “Variations in State-level SARS-COV-2 Testing,” September 7, 2020, 1.

<sup>694</sup> Perniciaro, Weinberger, “Variations in State-level SARS-COV-2 Testing,” September 7, 2020, Figs. 1-3.

<sup>695</sup> Health Advances, “HA101: Demystifying,” May 7, 2020, 19; Association for Molecular Pathology, “Summary of August,” 2020, 7.

## Factors Affecting U.S. Production

### Product to Market

#### Diagnostic Tests

A major constraint for test kit manufacturers is the time required to develop virus-specific reagents, protocols, and validations.<sup>696</sup> Typically, it takes between two and three years to develop and get approval for a new molecular test, so manufacturers sought to significantly accelerate the steps required to bring a product to market.<sup>697</sup> Firms faced a number of challenges in the initial test design. For example, initial research by manufacturers was hampered by the lack of curated virus samples necessary to complete the design of their materials or to begin production.<sup>698</sup> Further, diagnostics for a new pathogen must begin with CDC. Parallel tests from the private sector are not usually pursued, hampering the early development and authorization of more than one test. FDA's first EUA only authorized CDC's test and protocol. Even when problems occurred with CDC's COVID-19 test, private labs were reminded that they should not use tests that do not have an EUA.<sup>699</sup>

Commercial producers had to bring new COVID-19 diagnostic test production online in a matter of weeks, when the process usually takes months at best.<sup>700</sup> Given the shortened time frame, quality control procedures were incomplete. Further, as commercial producers brought diagnostic tests to market, the firms were competing for a limited number of supplies for certain key diagnostic testing materials.<sup>701</sup> For example, early in the pandemic there were shortages of authorized specimen controls; later, labs were able to develop their own specimen controls with assistance from CDC.<sup>702</sup>

#### Sample Collection

One challenge for new entrants to the swab market is to alleviate concerns within the medical supply chain about the quality of their products.<sup>703</sup> One new entrant, for example, responded to the need for swabs by pivoting to swabs for COVID-19 testing. However, because the company was unknown in the industry and had not sold to the medical market before, the firm was subsequently unable to sell much of that output and found itself sitting on significant inventory.<sup>704</sup> In addition, new swab manufacturers

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<sup>696</sup> USITC, hearing transcript, September 23, 2020, 80–81 (testimony of Susan Van Meter, AdvaMed).

<sup>697</sup> Health Advances, "HA101: Demystifying," May 7, 2020, 69.

<sup>698</sup> Industry representatives, telephone interview by USITC staff, September 8, 2020.

<sup>699</sup> CDC, "Lab Advisory: Reminder: COVID-19 Diagnostic Testing," February 18, 2020.

<sup>700</sup> It usually takes weeks to source the required inputs to produce diagnostic tests, and two to four months to convert a manufacturing line from producing one type of test to making another type of test. It takes three to six months to put a new line into a current plant—or two to three years to build a new plant—followed by the additional time required to distribute the products. Health Advances, "HA101: Demystifying," May 7, 2020, 77.

<sup>701</sup> The majority diagnostic testing reagents are test specific but there is some overlap with other supplies such as extraction reagents. Health Advances, "HA101: Demystifying," May 7, 2020, 78.

<sup>702</sup> Government officials, telephone interview by USITC staff, September 9, 2020.

<sup>703</sup> Some medical providers received poor quality goods early in the pandemic from previously unused sources, which makes them hesitant to accept supplies from companies they haven't dealt with before. Industry representatives, telephone interview by USITC staff, September 17, 2020.; Reinke, "From Dental Tools to Test Swabs," October 8, 2020.

<sup>704</sup> Industry representatives, telephone interview by USITC staff, September 17, 2020.

reported challenges in finding firms offering the sterilization services that are needed for the production of medical-grade swabs.<sup>705</sup> Currently, the two primary domestic firms providing this service are Steris and Sterigenics, and there is increased competition for their capacity.<sup>706</sup>

## Production and Delivery

### Diagnostic Tests

Supply challenges in the production or delivery of any part of the diagnostic chain limits the number of COVID-19 test results that can be obtained on any given day. As mentioned earlier in this chapter, in February 2020, the only authorized test kits were from CDC, and the initial shipments of the kits to the public health labs contained contaminated material. This contamination resulted in unreliable results and required three weeks to fully correct.<sup>707</sup> During this time, the only test kits available were the contaminated CDC test kits, leaving the whole COVID-19 domestic testing infrastructure in limbo and capacity at zero. While such incidence of contamination has not occurred since, it did substantially delay the U.S. COVID-19 response early on.<sup>708</sup>

A shortage of reagents has been a constraint throughout the pandemic, as discussed above. Generally, large testing reagent inventories are not kept because the maximum shelf life for these materials does not exceed one year.<sup>709</sup> The U.S. industry has been able to increase production by using spare capacity in their existing production processes.<sup>710</sup> However, despite these efforts, testing reagents continue to be in short supply.<sup>711</sup> Extraction reagents are commonly used across many of the diagnostic testing protocols, but also have been in short supply.<sup>712</sup> Existing domestic capacity for guanidine salts<sup>713</sup>—a key input to

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<sup>705</sup> Swabs are usually sterilized using ethylene oxide (in gaseous form) because entire pallets of packaged swabs can be sterilized at once. Industry representatives, telephone interview by USITC staff, September 14, 2020; industry representatives, telephone interview by USITC staff, September 17, 2020.

<sup>706</sup> Industry representatives, telephone interview by USITC staff, September 17 and 28, 2020; USITC, hearing transcript, September 23, 2020, 118 (testimony of Abby Pratt, AdvaMed); AdvaMed, written submission to the USITC, September 23, 2020, 10; Baichwal, “Illinois EPA Orders Sterigenics to Cease Operations in Willowbrook until Safety Review Complete,” October 2, 2018; Cobb County Government, “Latest on Sterigenics Plant Situation” (accessed October 1, 2020).

<sup>707</sup> CNN, “Early CDC Test Kits were Delayed because of Contamination Issues, HHS Report Affirms,” June 25, 2020; Chen et al., “Key Missteps at the CDC Have Set Back its Ability to Detect the Potential Spread of Coronavirus,” February 28, 2020.

<sup>708</sup> Sarata, “Development and Regulation of Domestic Diagnostic Testing for Novel Coronavirus (COVID-19): Frequently Asked Questions,” March 9, 2020.

<sup>709</sup> Industry representatives, telephone interview by USITC staff, September 21, 2020.

<sup>710</sup> Industry representatives, telephone interview by USITC staff, August 25, 2020.

<sup>711</sup> A laboratory using one protocol cannot switch to sourcing from a different supplier without completely re-validating its workflow. FDA, “Medical Device Shortages during the COVID-19 Public Health Emergency” (accessed October 20, 2020); U.S. Government Accountability Office, “COVID-19: Federal Efforts Could Be Strengthened,” September 21, 2020, 34–37, 189, 197; industry representatives, telephone interviews by USITC staff, August 25 and September 22, 2020.

<sup>712</sup> These reagents are part of RNA extraction kits commonly used in many of the authorized tests, including the CDC test.

<sup>713</sup> Guanidine thiocyanate and guanidine hydrochloride extract nucleic acids from the virus and prevent the degradation of that genetic material by denaturing sample proteins. Industry representatives, telephone interviews by USITC staff, August 25 and September 22, 2020.

the reagents used for extraction—proved insufficient when demand increased sharply.<sup>714</sup> These inputs need to be imported in order to meet the demand for extraction reagents.<sup>715</sup>

Finally, there are supply chain shortages associated with the availability of many plastic consumables required for diagnostic testing in the lab, ultimately constraining the number of tests that can be performed in a day. For example, industry reports that there has been a shortage of filtered plastic pipette tips,<sup>716</sup> and currently these are available from only one domestic manufacturer, Porex, as noted earlier.<sup>717</sup>

## Sample Collection

Manufacturers of swabs have experienced difficulties in both sourcing manufacturing equipment and bringing it online. Production of medical-grade plastics, such as swabs, requires complex molds and powerful hydraulic presses, both of which necessitate substantial lead times to acquire.<sup>718</sup> Industry reports that the machines used to produce swabs are custom made and typically time-consuming to produce.<sup>719</sup> Plastic swabs must also be produced under extremely clean conditions, and meeting these requirements has reportedly hindered bringing new capacity online.<sup>720</sup> Firms that invest in additional packaging technology for swabs note that expanding capacity—building the machinery, installing it, and bringing it online—takes time.<sup>721</sup>

Finding and training new workers also slows the pace at which the production of sample-collection supplies can be ramped up. For swab production it takes several hundred workers to fully staff a production line, even after upgrading to a more automated process.<sup>722</sup> Reportedly, onboarding has been slowed by the need to train workers in smaller groups to minimize health risks due to the pandemic.<sup>723</sup>

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<sup>714</sup> One of the few facilities globally that could manufacture at the necessary scale is a German-owned company in China. Industry representatives, telephone interview by USITC staff, September 22, 2020; USITC, hearing transcript, September 23, 2020, 118 (testimony of Susan Van Meter, AdvaMed).

<sup>715</sup> Industry representatives, telephone interview by USITC staff, August 25, 2020.

<sup>716</sup> Wu, “It’s Like Groundhog Day,” August 15, 2020; Levenson, “Laboratories Are Rising to the COVID-19 Challenge,” June 2020; government officials, telephone interview by USITC staff, September 9 and November 16, 2020.

<sup>717</sup> More information on Porex’s products can be found here: Porex Filtration Group, “Liquid and Sample Handling” (accessed September 29, 2020). Industry representatives, telephone interview by USITC staff, September 21, and November 16, 2020.

<sup>718</sup> Industry representatives, telephone interview by USITC staff, September 21 and November 16, 2020.

<sup>719</sup> Milliken, “BIW Signs Contract to Build Swab Machines,” May 7, 2020.

<sup>720</sup> Difficulties have been cited that range from process controls to the certifications needed to meet the requirements for clean and sterile production. AdvaMed, written submission to the USITC, September 23, 2020, 20; industry representatives, telephone interview by USITC staff, September 21, 2020.

<sup>721</sup> Industry representatives, telephone interviews by USITC staff, August 20, September 17, and November 16, 2020.

<sup>722</sup> Industry representatives, telephone interview by USITC staff, August 20, 2020.

<sup>723</sup> Industry representatives, telephone interview by USITC staff, August 20, 2020.

## Factor Affecting Imports

### Product Availability

The substantial rise in demand swamped the global supply chain for many of the goods needed for testing, and many countries were competing for the same limited supply.<sup>724</sup> For example, manufacturing capacity of extraction reagents (extraction reagents are often boxed and shipped as a collective unit along with certain plastic consumables, i.e., “kitted”) outside of China was only 4 to 5 million kits per week. While there is substantially more capacity in China, many of its products do not comply with U.S. regulations. In addition, there are few global manufacturers of extraction kits—more than 40 percent of the global market is supplied by two firms.<sup>725</sup> Similarly, there are few global suppliers of sample collection materials, particularly swabs, a situation that led to shortages early in the pandemic.<sup>726</sup>

Further, certain specialized plastic consumables for diagnostic testing are specific to the lab equipment and can only be sourced from a specific foreign manufacturer. For example, there are reported shortages of pipette tips for large, highly automated machines manufactured by Tecan, a Swiss company.<sup>727</sup> Since the tips used in these machines cannot be substituted with tips from other manufacturers, certain labs that use those specific machines may not be able to run at full capacity.<sup>728</sup>

### Market Entry and Acceptance

As outlined earlier, there were not enough domestic test kits (public or commercial) on the market early in the pandemic. Further complicating the matter was that test kits that were imported from abroad could be inaccurate, leading to consumer hesitancy, or inability, to use imported test kits.<sup>729</sup> There are also challenges associated with meeting the specific requirements of the labs performing testing, which require new supply sources to be validated. China is a major global test reagent manufacturer; however, many domestic labs use equipment that requires reagents to be sourced from specific validated manufacturers.<sup>730</sup>

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<sup>724</sup> This forced some state governments to source viable tests from outside the United States. McKinsey, “COVID-19: Overcoming Supply Shortages for Diagnostic Testing,” July 2020, 5–6; Broadwater, Wood, “FDA Approves Use of South Korean Coronavirus Tests,” April 30, 2020.

<sup>725</sup> Qiagen accounts for 22 percent and Thermo Fisher for 20 percent. Kan, “Shortage of RNA,” March 13, 2020.

<sup>726</sup> Webber and Jewett, “Testing Swabs Run,” March 18, 2020.

<sup>727</sup> Wu, “‘It’s Like Groundhog Day,’” August 15, 2020; government officials, telephone interview by USITC staff, September 9, 2020.

<sup>728</sup> Other potential bottlenecks include well plates (used to house and perform assays) produced by Thermo-Fisher and instrument-specific processing cartridges produced by Roche. Government officials, telephone interview by USITC staff, September 9, 2020.

<sup>729</sup> The bad test kits were produced by the company Shenzhen Bioeasy Biotechnology, whose website continues to list testing supplies for sale. The United States has also sourced test kits from South Korea. Liu and Harney, “China Clamps Down,” April 1, 2020; Bioeasy, “Bioeasy” (accessed September 2, 2020); Su, “Faulty Masks. Flawed Tests,” April 10, 2020; Nirappil, Cox, Schneider, “With focus on test, Maryland,” April 20, 2020.

<sup>730</sup> Behnam et al., “COVID-19: Overcoming Supply Shortages for Diagnostic Testing,” July 15, 2020, 5–6.

## Prices and Delivery Costs

Like many other COVID-19 related goods, the transportation of U.S. imports of test kits and supplies has increasingly shifted to, and has been hindered by, air freight's reduced availability and high cost.<sup>731</sup> For example, U.S. imports of swabs from a major supplier in Copan, Italy, have been hampered by border closures and flight cancellations in Europe.<sup>732</sup> Import data for swabs illustrate the high costs of air freight. U.S. importers' insurance and freight costs for products classified in the HTS reporting number containing swabs reached as high as 32 percent of the value of imports from China in March 2020 (and importers paid 31 percent tariffs on imports from China). Insurance and freight costs for imports from Italy reached 19 percent of the value of imports in August and September 2020.<sup>733</sup>

## Vaccines

### Major Findings

- Operation Warp Speed (OWS) awarded billions of dollars to the U.S. vaccine industry to create and produce COVID-19 vaccines that will be free to the public. Major investment, stacking clinical and manufacturing steps to run simultaneously, and new technology have sped up the timeline compared to historical vaccine development.
- The United States is a major vaccine producer and U.S. vaccine imports have historically originated primarily in Europe and Canada.
- Bringing a new COVID-19 vaccine to market presents an enormous set of challenges, from development and testing to readying a new vaccine (or vaccines) for distribution.
- U.S. COVID-19 vaccine demand is expected to be on the order of hundreds of millions of doses. In addition to the vaccine itself, there will be equivalent demand for the ancillary supplies (e.g., syringes, needles, etc.) needed to inoculate people.
- Once a vaccine is authorized, the vaccine and ancillary supplies need to be manufactured on an unprecedented scale. Further, the vaccine needs to be delivered throughout the country while maintaining the storage requirements (e.g., temperature) of the vaccine through transportation and storage.
- Both U.S. manufacturers and foreign suppliers are actively working to meet these challenges, with many already ramping up production and capacity.

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<sup>731</sup> There were some initial issues due to regulatory confusion at Chinese customs, where products were held for two to three weeks before they could be shipped, but this is not reported to be a current problem. Industry representatives, telephone interviews by USITC staff, September 22 and 28, 2020; USITC, hearing transcript, September 23, 2020, 19 (testimony of Abby Pratt, AdvaMed); IHS Markit, Global Trade Atlas database (accessed October 24, 2020).

<sup>732</sup> HHS, "HHS, DOD Coordinate International Airlift Of COVID-19 Supplies," March 20, 2020.

<sup>733</sup> U.S. importers paid 6 percent tariffs on imports from Italy (HTS 5601.22.0090). Costs were not as high for all products; testing reagents enter duty free under 3822.00.5050, and insurance and freight costs were less than 1 percent of the value of the goods imported from China in July and August 2020. USITC DataWeb/USDOC, HTS 5601.22.0090, HTS 3822.00.5050 (accessed October 24, 2020).



## Introduction

Extensive efforts are underway in the United States and around the world to develop and deliver a vaccine for COVID-19. As firms develop their vaccines, they must navigate the current regulatory environment, manufacturing capacity limitations, potential supply constraints, and challenges with scale-up, as billions of doses will be required for the world’s population. To that end, the following discussion provides context through a description of the current U.S. industry and trade, information on the status of vaccine development, and an explanation of challenges that have so far been encountered or forecasted in efforts to develop and distribute a vaccine. These challenges include not only developing the vaccine itself, but the manufacture of myriad related products (e.g., vials, stoppers, syringes, and packaging), plus consumer distribution. As there was no COVID-19 vaccine available for distribution in the United States at the time this report was written, the challenges and constraints outlined in this section reflect anticipated challenges.<sup>734</sup>

## Product Overview

### Description

In discussing supply challenges and constraints for a COVID-19 vaccination program, this case study covers four general subject areas: (1) vaccine development, authorization, and approval; (2) manufacturing, including fill and finish (filling vials with vaccine and finishing by packaging them for distribution);<sup>735</sup> (3) ancillary supplies;<sup>736</sup> and (4) distribution to inoculation sites (figure 5.17).

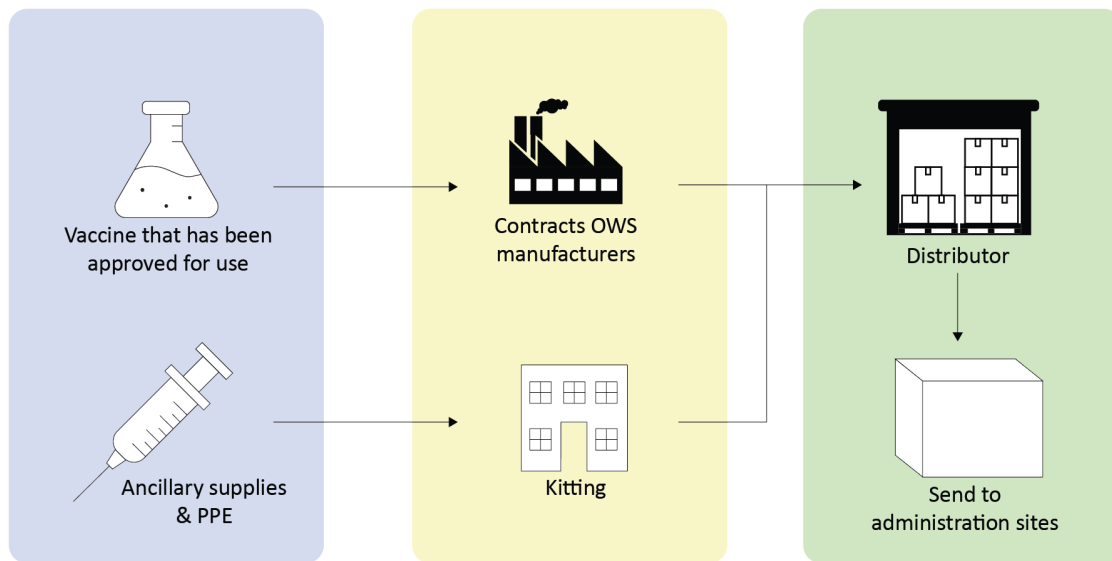
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<sup>734</sup> Note that due to the expedited process for bringing a COVID-19 vaccine to market, the first available vaccines will likely be authorized under an EUA and not through the standard FDA approval process.

<sup>735</sup> During the initial stages of distribution, the majority of vaccines will likely be filled and finished into vials, rather than prepared as prefilled syringes. CDC, “COVID-19 Vaccination Program Interim Playbook,” October 29, 2020, 32, 38; Costas and Hopkins, “Pfizer Sets Up Its “Biggest Ever” Vaccination Distribution,” October 21, 2020; industry representatives, telephone interview by USITC staff, September 10 and October 21, 2020.

<sup>736</sup> Ancillary supplies for COVID-19 vaccine distribution include those in the “vaccine kits” (e.g., needles, syringes, alcohol prep pads, surgical mask, face shields, and vaccination record cards), as well as bandages and gloves. Syringes typically are made of a plastic barrel and plunger that house a needle made of stainless steel. MD Supplies, “Types of Needles” (accessed October 16, 2020); Romanowsk, “Syringe” (accessed October 16, 2020); CDC, “COVID-19 Vaccination Program Interim Playbook,” October 29, 2020, 30.

**Figure 5.17** COVID-19 vaccine development, packaging, and distribution



Source: Compiled by USITC based on HHS and DOD, “From the Factory to the Frontlines” September 2020.  
 Note: OWS = Operation Warp Speed; PPE = personal protective equipment.

A vaccine is a suspension of live or inactivated microorganisms (or fractions of microorganisms) administered to induce immunity and prevent infectious diseases. Types of vaccines are those that prevent disease (prophylactic) and those that are given as treatment after contracting the condition (therapeutic).<sup>737</sup> Broadly speaking, vaccines can be classified into either classical platforms (e.g., whole-inactivated virus, live-attenuated virus, subunit/recombinant or fraction, virus-like particle) or next-generation platforms (e.g., viral vector, DNA, RNA, and antigen-presenting cell).<sup>738</sup> In the current market, different firms have different research strategies for diverse types of vaccines, and the current “front-

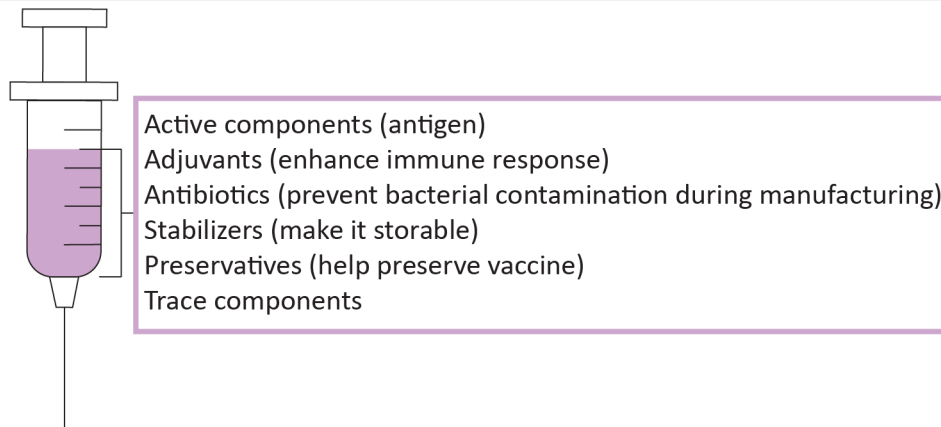
<sup>737</sup> Prophylactic vaccines come in several platforms (types), including (1) live attenuated microorganism (a weakened version of the virus or bacteria), (2) inactivated microorganism or fraction (killed with heat or chemicals), (3) subunit/conjugate microorganism or fraction (a part of a germ is used to elicit immunity), and (4) viral vector (delivers genes to build immunity). As of November 2020, neither deoxyribonucleic acid (DNA) nor ribonucleic acid (RNA) vaccines have been approved for licensure in the United States; currently, messenger RNA (mRNA), a subtype of RNA, is being researched for COVID-19 vaccines. CDC, “Understanding How Vaccines Work,” July 2018; Lee, Loxley, and DiFranco, “A Guide to Vaccine Development and Immunization,” April 27, 2020; HHS, “Vaccine Types” (accessed September 4, 2020); Van Riel, “Next-generation Vaccine Platforms for COVID-19,” July 23, 2020, 811, figure 1.

<sup>738</sup> The general steps of classical vaccine production are as follows: (1) Generate antigen: Grown in eggs or bioreactors; (2) Release and isolate: The antigen is released from the medium in which they are grown; (3) Purify: Separate the antigen from the other components of the medium; (4) Strengthen: Add adjuvants that enhance immune system response, add stabilizers or preservatives to prolong shelf-life; and (5) Package and distribute (also called fill and finish): The vaccine is filled into vial or syringe packages, sealed with sterile stoppers or plungers and labeled for distribution. Note that a potential RNA-platform COVID-19 vaccine does not require the time and complexity involved in generating an antigen and purifying it. The PHG Foundation, “RNA Vaccines: An Introduction” (accessed September 8, 2020); Moderna, “The Advantages of RNA Vaccines” (accessed September 2, 2020); Pardi et al., “mRNA Vaccines—A New Era in Vaccinology,” April 2018; Jackson et al., “The Promise of mRNA Vaccines,” February 2020; College of Physicians of Philadelphia, “How Vaccines are Made” (accessed on September 7, 2020).

runners” are largely next generation prophylactic vaccines (see section below regarding COVID-19 Vaccine Developments).

Common ingredients in U.S.-licensed vaccines include antigens, adjuvants, small amounts of antibiotics, stabilizers, and preservatives, as well as trace components such as formaldehyde and fetal bovine serum (figure 5.18).<sup>739</sup> The human body responds to the antigen by building immunity towards the specific antigen, often with help of an adjuvant, which is an ingredient that helps create a stronger immune response in people receiving the vaccine.<sup>740</sup> The COVID-19 vaccines in Phase 1, 2, and 3 clinical trials currently have most, if not all, of these ingredients.<sup>741</sup>

**Figure 5.18** Common components of classical formulated vaccines



Source: Compiled by USITC staff.

In addition to the vaccine itself, vials are needed to package the vaccine during the “fill and finish” phase of the production process. Typically, vials for vaccines are made of glass, although some are made of

<sup>739</sup> Fetal bovine serum is an animal product commonly used as a nutritional source for the cell cultures used when manufacturing vaccines. ThermoFisher Scientific, “Understand the Basics of Fetal Bovine Serum” (accessed October 14, 2020); FDA, “Common Ingredients in U.S. Licensed Vaccines,” current as of April 30, 2018; Brunning, “A Summary of Common Vaccine Components,” February 10, 2015; CDC, “What’s in Vaccines?” (accessed September 4, 2020).

<sup>740</sup> Adjuvants are considered a component of a vaccine and are not licensed separately. CDC, “Adjuvants and Vaccines” (accessed September 4, 2020); FDA, “Common Ingredients in U.S. Licensed Vaccines” current as of April 30, 2018; CDC, “What’s in Vaccines?” (accessed September 4, 2020); USITC, hearing transcript, September 23, 2020, 154 (testimony of Prashant Yadav, Center for Global Development).

<sup>741</sup> Some vaccines may need a diluent. Most COVID-19 candidates do not have adjuvant. Chung et al., “COVID-19 Vaccine Frontrunners,” October 9, 2020, 12526, Fig. 2; CDC, “COVID-19 Vaccination Program Interim Playbook,” October 29, 2020, 30, 55.

plastic.<sup>742</sup> Rubber stoppers are affixed to the top of the glass vial as barriers between the vaccine material and the air to extend product shelf life.<sup>743</sup>

Most vaccines approved for use in the United States are injected (intramuscularly), typically using a syringe to administer the procedure of immunization.<sup>744</sup> To achieve full immunization, vaccines often require between one and five doses to be administered.<sup>745</sup> Different vaccines have varying dosing schedule recommendations, such as once in a lifetime (e.g., yellow fever), a sequence during childhood (e.g., polio), every 10 years (e.g., tetanus), and once a year (e.g., the flu).<sup>746</sup> The more doses required, the more ancillary supplies are needed.

Once a COVID-19 vaccine is available, reports by CDC, HHS, and DOD indicate that ancillary supplies and certain PPE (excluding gloves and bandages) will be “kitted” (i.e., assembled into vaccine kits). These kits are being prepared for the vaccinators and are set to contain supplies to administer 100 doses of a vaccine.<sup>747</sup>

The authorized or approved vaccine(s) and ancillary supplies will have to be distributed to the vaccine administration sites. For transport of the vaccine(s), many factors that must be considered, including required storage temperature, transport requirements, on-site storage capabilities, and dosage availability.<sup>748</sup> All these factors will be dependent upon the formulations of the specific vaccine.

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<sup>742</sup> Borosilicate glass is a special glass made of boron and silica trioxide that is more resistant to external chemicals and heat shock than common glass, and this makes it a glass of choice for vaccines. Hackett, “Plastic Oral Cholera Vaccine Approved by WHO,” January 10, 2018; EUBiologics, “Euvichol-Plus/Euvichol” (accessed October 24, 2020); Kablo, “What Is Borosilicate Glass?” (accessed October 14, 2020); Tognini, “The COVID Vaccine Will Require Billions of Tiny Glass Vials,” September 3, 2020.

<sup>743</sup> They are able to be sterilized and punctured repeatedly with a needle to retain a seal between the vaccine and the air. Vaccine shelf life generally ranges from one to three years. Future Market Insights, “Sterile Rubber Stopper Market” (accessed November 17, 2020); Plotkin et al., “Complexity and Cost of Vaccine Manufacturing,” June 21, 2017, 4065.

<sup>744</sup> Vaccines are given orally (either tablet or liquid), intranasally, or via injection. Live attenuated influenza vaccine is the only vaccine administered by the intranasal route. Rotavirus, adenovirus, cholera vaccine, and oral typhoid vaccines are the only vaccines administered orally in the United States. CDC, “U.S. Vaccine Names” (accessed September 4, 2020); CDC, “Vaccine Administration” (accessed October 16, 2020).

<sup>745</sup> For example, medical experts recommend that children receive polio vaccinations as children in a four-dose schedule. CDC, “Polio Vaccination: What Everyone Should Know” (accessed October 26, 2020); CDC, “Vaccine and Preventable Diseases” (accessed November 10, 2020); CDC, “Yellow Fever” (accessed November 10, 2020).

<sup>746</sup> CDC, “TDAP” (accessed October 14, 2020); CDC, “Key Facts about Seasonal Flu Vaccine” (accessed October 14, 2020).

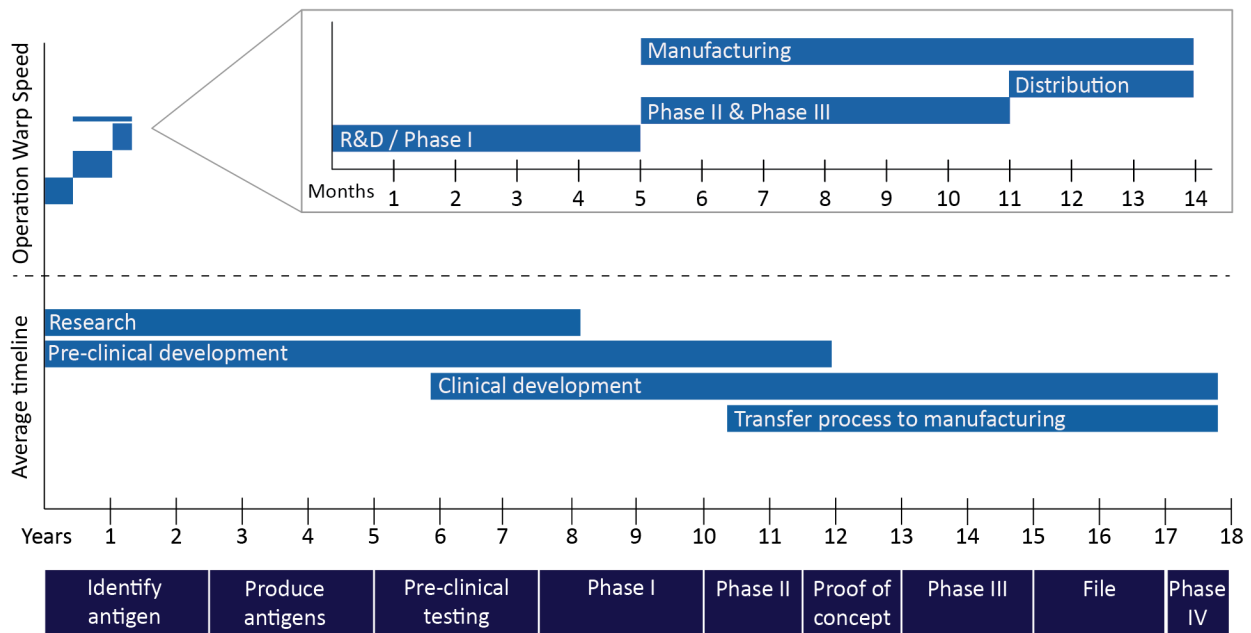
<sup>747</sup> CDC, “COVID-19 Vaccination Program Interim Playbook,” September 16, 2020, 30; HHS and DOD, “From the Factory to the Frontlines,” September 16, 2020, 7.

<sup>748</sup> CDC, “COVID-19 Vaccination Program Interim Playbook,” September 16, 2020, 30.

## Vaccine Development and Manufacturing

Vaccines typically require 10 to 12 years to develop and reach market. The estimated cost for a 10-year timeline starts at \$500 million.<sup>749</sup> A depiction of an industry average is shown in figure 5.19.<sup>750</sup> The stages for vaccine approval are lab research, preclinical, then three clinical stages (known as Phases 1, 2, and 3).<sup>751</sup> The initial research and development may take from 1 to 8 years, preclinical development 1 to 12 years, and clinical development 5 to more than 13 years. During the 2002–03 SARS outbreak, it took about 20 months for research and preclinical development for a vaccine to be ready for testing in people and then to proceed to clinical development.<sup>752</sup>

**Figure 5.19** Vaccine research development cycle (industry average)



Source: Compiled by USITC. Based on GSK, “How We Develop New Vaccines” (accessed August 21, 2020) and DOD, “Developing a Vaccine,” (accessed November 14, 2020).

<sup>749</sup> Gregersen, “What History Tells Us about Vaccine Timetables,” June 9, 2020; Broom, “5 Charts That Tell the Story of Vaccines Today,” June 2, 2020; International Federation of Pharmaceutical Manufacturers and Associations, “The Complex Journey of a Vaccine,” July 2019; Arnold, “Why It Will Still Be a Long Time Before We Get a Coronavirus Vaccine,” April 29, 2020.

<sup>750</sup> GlaxoSmithKline, “How We Develop New Vaccines” (accessed August 21, 2020).

<sup>751</sup> Phase 1: an experimental drug or treatment (“treatment”) is given to a small group of people for the first time to evaluate its safety and to determine a safe dosage range (side effects are identified). Phase 2: the treatment is given to large groups of people to continue to assess effectiveness and evaluate its safety). Phase 3: the treatment is given to larger groups of people. Researchers collect information that will allow the treatment to be used safely (confirm its effectiveness, monitor side effects, compare it to other commonly used treatments). Phase 4: the treatment is registered with FDA, and researchers conduct post-marketing surveillance of effects on users FDA, “What Are the Different Types of Clinical Research?” January 4, 2018.

<sup>752</sup> Radcliff, “How Long Will It Take to Develop a Vaccine” January 30, 2020.

The general to process of bringing a vaccine to market are as follows:<sup>753</sup>

1. Identify the pathogen;
2. Research—determine the mode of action of the pathogen, and researchers determine what platform to use in vaccine development;
3. Development—depending on the vaccine platform this stage can include drug substance (i.e., the active component), adjuvants, stabilizers, preservatives, etc.;
4. Testing—this stage includes testing the vaccine on the population that will receive the vaccine;
5. Process transfer and manufacturing—scale-up (bulk) production to manufacture the vaccine (and overlaps with clinical development).<sup>754</sup> Production includes:
  - active ingredient/drug substance manufacturing;
  - formulation (process where the active ingredient is mixed with all constituents that are part of the final vaccine dosage formulation);
  - fill and finish (aseptically filling and labeling, finishing, the vials);
6. Secondary packaging—packing the vaccine to ship following the necessary storage requirements, such as temperature;
7. Distribution of the vaccine.

## COVID-19 Vaccine Developments

There are significant efforts underway to develop a vaccine in the United States, although a COVID-19 vaccine has not been approved or authorized as of November 2020.<sup>755</sup> As of October 2020, there were more than 40 vaccine candidates that were undergoing clinical trials globally, of which 10 were in Phase 3, including 5 Phase 3 trials in the United States (table 54).<sup>756</sup> Firms enrolling the needed 30,000 volunteers for Phase 3 trials include AstraZeneca (with the University of Oxford), Moderna Therapeutics, and Pfizer and BioNTech.<sup>757</sup>

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<sup>753</sup> Afrin, “Pharmaceutical Formulation,” September 10, 2020; Iqbal, “Production Economics for Vaccines,” 2016, 7.

<sup>754</sup> Depending on the formulation of the vaccine and the capacity of the vaccine developer, many steps of manufacturing may be contracted out (see Table 5.5).

<sup>755</sup> On November 9, 2020, Pfizer announced that its vaccine candidate had 90 percent efficacy and applied for an EUA on November 20, 2020. On November 16, 2020, Moderna announced its vaccine candidate showed it was 94.5 percent effective in preliminary analysis and submitted for an EUA on November 30, 2020. Pfizer, “Pfizer and Biontech Announce Vaccine,” November 9, 2020; Pfizer, “Pfizer and Biontech to submit Emergency Use Authorization,” November 20, 2020; Moderna, “Moderna’s COVID-19 Vaccine Candidate,” November 16, 2020; Moderna, “Moderna Announces Primary Efficacy Analysis,” November 30, 2020.

<sup>756</sup> Rivas et al., “COVID-19 Vaccines: What’s Coming and When?” October 22, 2020; data based on WHO, “Draft Landscape of COVID-19 Vaccine Candidates,” November 3, 2020, attachment 1–2.

<sup>757</sup> Enrollment for the clinical trial is not strictly limited to U.S. populations due to the multinational nature of these manufacturers. Timing between doses for two-dose regimes ranges from 14–56 days. WHO, “Draft Landscape of COVID-19 Vaccine Candidates,” November 3, 2020; STAT COVID-19 Drugs and Vaccines Tracker, “Vaccines” (accessed October 2, 2020); Mitropoulous, “Human Trial for Coronavirus Vaccine,” July 27, 2020.

**Table 5.4** COVID-19 vaccines in Phase 3 clinical trials in the United States and company headquarters locations as of October 31, 2020

COVID-19 Vaccine developer/ manufacturer	Vaccine platform	Doses Required	Contracted Doses through Operation Warp Speed
Pfizer/BioNTech/Fosun Pharma (New Jersey/Germany/China)	RNA-based (next generation)	2	100 million doses (option to acquire up to 500 million additional doses)
Moderna/ NIAID (Massachusetts/Maryland)	RNA-based (next generation)	2	100 million doses (option of acquiring up to 400 million additional doses)
Janssen Pharmaceutical Companies, owned by Johnson & Johnson (Belgium/New Jersey)	Non-replicating viral vector (next generation)	Up to 2	100 million doses (option of acquiring up to 600 million additional doses)
Novavax (Maryland)	Protein subunit (classical)	2	100 million doses
University of Oxford/AstraZeneca (England/England; AZ operations in the US)	Non-replicating viral vector (next generation)	Up to 2	300 million doses

Source: WHO, “Draft Landscape of COVID-19 Vaccine Candidates,” October 2, 2020; AstraZeneca, “Welcome to AstraZeneca United States” (accessed October 15, 2020), Van Riel, “Next-generation Vaccine Platforms for COVID-19,” July 23, 2020, 811, figure 1; HHS, “U.S. Government Engages Pfizer to Produce,” July 22, 2020; HHS, “Trump Administration collaborates with Moderna,” August 11, 2020; HHS, “HHS, DOD Collaborate with Johnson & Johnson,” August 5, 2020; HHS, “HHS, DOD Collaborate with Novavax to Produce,” July 7, 2020; HHS, “Trump Administration’s Operation Warp Speed Accelerates AstraZeneca,” May 21, 2020.

Note: All COVID-19 vaccine candidates, except for Pfizer’s, are being developed as part of Operation Warp Speed (OWS). Fosun Pharma in the United States is a subsidiary of a parent Chinese company.

Several factors have contributed to the rapid development of potential COVID-19 vaccines. First, many organizations were able to build on past work, including efforts to develop vaccines for SARS (Severe Acute Respiratory Syndrome, 2002–03) and MERS (Middle East Respiratory Syndrome, 2012), both coronaviruses.<sup>758</sup> Second, the public release of the virus’ genetic sequence in January 2020 enabled many organizations to quickly start working on a vaccine.<sup>759</sup> Further, as part of Operation Warp Speed (OWS), instead of the approval phases occurring sequentially they are being carried out in tandem (see figure 5.19 and box 5.3).

### Box 5.3 Operation Warp Speed

In April 2020, the U.S. government initiated Operation Warp Speed (OWS), the national program to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.<sup>a</sup> The goal is to deliver 300 million doses, with the initial vaccine doses available in January 2021.<sup>b</sup> It is a public-private partnership that includes several agencies within the U.S. Department of Health and Human Services (HHS)—CDC, FDA, NIH, and BARDA—and the Department of Defense.<sup>c</sup> OWS works with private firms and other federal agencies<sup>d</sup> to coordinate existing HHS-wide efforts to accelerate the development, manufacturing, and distribution of COVID-19 related countermeasures (i.e., vaccines, therapeutics, and diagnostics).<sup>e</sup>

To accomplish this goal, billions of dollars have been directed to support the research, production, and distribution of a COVID-19 vaccine. It is estimated that as of October 2020, \$12 billion had been spent in

<sup>758</sup> Boyle, “Infectious Disease Research Institute Is Working,” June 2, 2020; Taylor, “UK, China Prep Trials,” March 23, 2020; Padron-Regalado, “Vaccines for SARS-CoV-2,” April 23, 2020.

<sup>759</sup> Input knowledge for building a vaccine is the genomic sequence of the microorganism. When this is known, vaccine strategies and innovative products can ensue. Schnirring, “China Releases Genetic Data on New Coronavirus,” January 11, 2020; Arthur, “Virus Change Should Not Affect COVID-19 Vaccine Candidates,” October 15, 2020.

support of OWS efforts.<sup>f</sup> Any vaccine doses purchased through OWS will be made available, at no cost, to the public (table 5.4). Figure 5.19 shows the phases of development, which have been compressed so that many of the clinical phases and steps occur in tandem.<sup>g</sup>

<sup>a</sup> Cohen, “Unveiling ‘Warp Speed,’” May 12, 2020.

<sup>b</sup> Jacobs and Armstrong, “Trump’s ‘Operation Warp Speed,’” April 29, 2020.

<sup>c</sup> HHS, “Fact Sheet: Explaining Operation Warp Speed” (accessed on October 28, 2020).

<sup>d</sup> HHS, “Trump Administration Announces Framework,” May 15, 2020.

<sup>e</sup> HHS, “Fact Sheet: Explaining Operation Warp Speed” (accessed November 6, 2020).

<sup>f</sup> Branswell et al., “Operation Warp Speed Promised to Do the Impossible,” September 8, 2020; Martin, “Inside the Operation Warp Speed Effort,” November 8, 2020.

<sup>g</sup> HHS, “Fact Sheet: Explaining Operation Warp Speed” (accessed November 6, 2020).

## U.S. Market

The U.S. vaccine market was valued at \$18.4 billion in 2019, with 85 vaccines licensed for human use in the United States for 31 different infectious agents.<sup>760</sup> A vaccine for COVID-19, when available, will dramatically change the overall U.S. vaccines market. Industry sources note that 600–700 million units would be needed to inoculate the entire U.S. population by using a two-dose vaccine.<sup>761</sup> Doses of the vaccine will be stored in vials (initially multidose vials); the U.S. market for vials prior to COVID-19 was over 3 billion vials per year.<sup>762</sup> The actual number of doses that will be needed depends on factors such as the dosage required to meet efficacy standards and the length of time achieved immunity persists (i.e., will the vaccine be an annual immunization like a flu shot). In addition, the number of people willing to get the vaccine will impact the number of doses needed.<sup>763</sup> Based on the current makeup of the front-runner vaccines, it is likely that two doses will be needed (see table 5.4).<sup>764</sup>

<sup>760</sup> In the U.S. market, 81.7 percent of the market value is accounted for by human vaccines and 18.3 percent by animal vaccines. Twenty-six of the 85 licensed products are for influenza, the largest category of approved vaccines, with a market value of \$1.6 billion in 2015. FDA, “Vaccines Licensed for Use in the United States” (accessed September 7, 2020); Coherent Market Insights, “U.S. Vaccine Market, 2020–2027,” July 2020; Tirrell, “The \$1.6 Billion Business of the Flu,” October 21, 2015.

<sup>761</sup> Industry representative, telephone interview by USITC staff, September 10, 2020; USITC, hearing transcript, September 23, 2020, 102 (testimony of Abby Pratt, AdvaMed).

<sup>762</sup> Industry representative, telephone interview by USITC staff, November 17, 2020.

<sup>763</sup> Public opinion surveys have shown varying levels of willingness to get vaccinated among health professionals and the general population. If a large share of the population opts not to get the vaccine, the number of needed doses would be much lower. Currently, estimates vary on the share of the population that needs to receive the vaccine in order to achieve herd immunity—the point at which enough people are sufficiently resistant to a disease that an infectious agent is unlikely to spread from person to person. However, all estimates are in agreement that the entire population does not need to be vaccinated to achieve herd immunity. Martin, “Inside the Operation Warp Speed Effort,” November 8, 2020; Fontanet and Cauchemez, “COVID-19 Herd Immunity: Where Are We?” September 9, 2020; Pattani, “Why Herd Immunity Can’t Save Us from COVID-19,” September 29, 2020; Rubin, “Difficult to Determine,” August 25, 2020.

<sup>764</sup> Of the 47 clinical trials currently in Phase 1, 2, or 3 as of November 3, 2020, the highest number of doses reported is three. Only two vaccines currently in trials require 3 doses. None of the vaccines currently in Phase 3 trials in the United States require 3 doses. If the flu vaccine is used as a reference, in the 2019–20 season, 174.5 million doses were distributed in the United States, and the flu is an annual one-dose vaccine. Schwarzenberg and Sutter, “Medical Supply Chains and Policy Options,” September 16, 2020; WHO, “Draft



Demand for ancillary supplies will mirror demand for the vaccine. As all the vaccines currently in Phase 3 clinical trials are administered intramuscularly (given as injections), the more immediate demand will be for syringes and needles. The syringes that will be used will ideally be safety syringes to protect the inoculator, which will be used with hypodermic needles likely ranging in size (gauge and length) based on the patient (i.e., adult versus child).<sup>765</sup> The U.S. market for injection devices is estimated to have been 663 million injection devices per year pre-pandemic and is primarily supplied by six firms: BD, Cardinal Health, Monoject, McKesson, Smiths Medical, and Retractable Technologies Inc. (RTI).<sup>766</sup> The number of syringes needed for a COVID-19 vaccine depends on the formulation of the vaccine in question, which dictates the dosage regime, but it could double the current market for injection devices.

## U.S. Manufacturing Industry

### Vaccines

Vaccine developers<sup>767</sup> are arranging manufacturing capacity in the United States to produce a COVID-19 vaccine as outlined in table 5.5 which highlights examples of reported manufacturing as related to COVID-19 manufacturing.<sup>768</sup> Manufacturing the vaccines involves a variety of laboratory consumables (e.g., glass storage vessels, thermoelastic connectors, etc.).<sup>769</sup> Firms have taken several approaches to U.S. vaccine manufacturing, ranging from vertical integration to contracting with a contract development and manufacturing organization (CDMO), or a combination of both.<sup>770</sup> Pfizer, for example, has a vertically integrated model, as it plans to produce raw materials in St. Louis, Missouri, make drug substances in Andover, Massachusetts, and do formulation and fill in Kalamazoo, Michigan.<sup>771</sup> Some manufacturers planning to produce vaccines internally have reduced production of non-COVID-19 related products to free up capacity for vaccine production. For example, Pfizer is shifting manufacturing of products currently produced in-house to CDMOs.<sup>772</sup>

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Landscape of COVID-19 Candidate Vaccines,” November 3, 2020; CDC, “Historical Reference of Seasonal Influenza Vaccine Doses Distributed,” September 9, 2020.

<sup>765</sup> CDC, “Vaccine Administration,” October 16, 2020. For an explanation of gauges, see Galen, “Choosing the Best Syringe and Needle Size,” June 24, 2020.

<sup>766</sup> Spiro and Emanuel, “A Comprehensive COVID-19 Plan,” July 28, 2020.

<sup>767</sup> The largest firms by global vaccine sales in 2019 were GlaxoSmithKline (\$9.1 billion), Merck (\$8.0 billion), Pfizer (\$6.5 billion), and Sanofi (\$6.3 billion). U.S. shipments of vaccines for human use totaled \$8.5 billion in 2016, the most recent available statistics. Brown, “For a COVID-19 Vaccine,” March 11, 2020; Census, Annual Survey of Manufactures (accessed August 2020).

<sup>768</sup> A firm that is investing or producing at risk makes the investments and/or begins production with no assurance that the final product will be successful. While firms are in fact investing and producing at risk, many frontrunners are doing so with substantial assistance from the federal government. Hargreaves, “Pfizer and BioNTech Work to Scale Up,” May 11, 2020.

<sup>769</sup> Industry representative, telephone interview by USITC staff, November 17, 2020.

<sup>770</sup> A CDMO is a company with which a pharmaceutical firm may contract to outsource any step in the pharmaceutical development and manufacturing process, such as formulation or fill and finish. FDA, “Contract Manufacturing Arrangements,” November 2016, 3.

<sup>771</sup> Hargreaves, “Pfizer and BioNTech Work to Scale Up,” May 11, 2020.

<sup>772</sup> O’Sullivan, “Why Tech Transfer May be Critical,” July 23, 2020.

**Table 5.5** Identified U.S. COVID-19 manufacturing plants for adjuvants, drug substances, formulation, and fill and finish

Manufacturer	Location	COVID-19 vaccine role	Vaccine developer	Capacity/volume (if available)
AGC Biologics	Seattle, WA	Adjuvants	Novavax	Production for Novavax: 1 billion doses (multiyear)
Albany Molecular Research	Albuquerque, NM	Fill-finish	AstraZeneca	Production for AstraZeneca: Millions of doses/year
Avid Bioservices	Tustin, CA	Drug substance	Oragenics	
Catalent	Bloomington, IN	Fill-finish (Moderna, J&J) Formulation (J&J)	Moderna Johnson & Johnson (J&J)	Fill-finish capacity (vials/day): Capacity, one of current lines: 400 vials/minute Adding 3 <sup>rd</sup> line with annual capacity of 80 million vials
Catalent	Harmans, MD	Drug substance	AstraZeneca	
Catalent	Madison, WI	Drug substance (clinical and commercial scale)	Arcturus Therapeutics Spicona	Arcturus: millions (2020), hundreds of millions (2021) Spicona: 2,000 or 4,000 L batch scale
Catalent	Philadelphia, PA	Packaging, labeling, storage, and distribution	Moderna	Initial production for Moderna: 100 million doses
CordenPharma	Boulder, CO	Raw materials (lipids)	Moderna	Enough quantities to create 100 to 200 million doses per month
Endo International	Rochester, MI	Fill-finish	Novavax	
Emergent BioSolutions	Baltimore (Bayview), MD	Drug substance	AstraZeneca J&J Novavax Vaxart	Production capacity: Tens to hundreds of millions of doses annually
Emergent BioSolutions	Baltimore (Camden), MD Rockville, MD	Fill-finish	BARDA investment	
FUJIFILM Diosynth Biotechnologies	Morrisville, NC College Station, TX	Drug substance	Novavax BARDA investment	NC: Doses for up to 30,000 subjects as part of Phase 3 clinical trials TX: 20 million doses a month
GlaxoSmithKline	Not available	Adjuvants	Multiple	
Grand River Aseptic Manufacturing	Grand Rapids, MI	Fill-finish	J&J	Capacity: 200 vials/minute
Kindred Biosciences/Centaur	Burlingame, CA Ellwood, KS	Drug substance	Vaxart	CA: 500-liter scale bioreactors KS: 2,000-liter scale bioreactor
Lonza	Portsmouth, NH	Formulation	Moderna	300 million doses annually between NH and Switzerland
Lonza	Houston, TX	Drug substance (commercial scale)	Altimmune	
Medicago	Durham, NC	Not specified	Medicago	80 million doses annually from 2021 between Durham and Quebec pilot plant
Moderna	Norwood, MA	Drug substance	Moderna	Millions of doses

Manufacturer	Location	COVID-19 vaccine role	Vaccine developer	Capacity/volume (if available)
Novavax	Gaithersburg, MD	Not available	Novavax	
NantKwest	El Segundo, CA	Not specified	ImmunityBio	
Ology Bioservices	Alachua, FL	Drug Substance	Inovio	
Ology Bioservices		Fill-finish	OWS	186.8 million doses of critical vaccines and therapeutics
Pfizer	Andover, MA Kalamazoo, MI St. Louis, MO	Raw materials (MO) Drug substance (MA) Formulation-fill (MI)	Pfizer	MA: Millions of doses MI: 2 lines; (fastest line can fill nearly 600 vials a minute)
Sanofi	Swiftwater, PA	Fill-finish	Sanofi/ GlaxoSmithKline	
Thermo Fisher Scientific	Not available	Drug substance Fill- finish	Inovio	Up to 100 million doses/year
VGXI	Woodlands, TX	Drug Substance Raw Material (DNA plasmid)	Inovio (in dispute)	Thousands of doses
Vigene Biosciences	Rockville, MD	Not specified	Altimune	

Source: Endo International, “Endo Announces Fill-Finish Manufacturing,” September 25, 2020; Emergent BioSolutions, “Emergent BioSolutions Signs Agreement,” April 23, 2020; Emergent BioSolutions, “Emergent BioSolutions Signs Agreement,” July 27, 2020; Emergent BioSolutions, “Emergent BioSolutions Signs Five-Year Agreement,” July 6, 2020; Catalent, “Moderna and Catalent Announce Collaboration,” June 25, 2020; Catalent, “Catalent Signs Agreement,” August 24, 2020; Inovio, “INOVIO Adds Thermo Fisher Scientific,” September 8, 2020; Novavax, “Novavax Announces Facility Expansion,” November 2, 2020; Blankenship, “Emergent BioSolutions, BARDA Reach,” June 1, 2020; Novavax, “Novavax and FUJIFILM Diosynth,” July 23, 2020; Platoff, “Texas Biotech Facility,” July 27, 2020; Keown, “Federal Government Taps,” July 28, 2020; BioSpace, “Vaxart Announces,” March 18, 2020; Grand River Aseptic Manufacturing, “GRAM Partners,” September 25, 2020; Mullin, “Moderna Picks,” May 1, 2020; Stanton, “Inhouse Manufacturing,” May 19, 2020; Avid Bioservices, “Oragenics Signs Process Development,” August 20, 2020; Catalent, “Arcturus Therapeutics and Catalent,” May 4, 2020; Catalent, “Catalent Signs Agreement,” April 29, 2020; Veleta, “Potential Covid Vaccine,” May 28, 2020; Pfizer, “Scaling Up to Manufacture,” May 5, 2020; Contract Pharma, “Kindred, Vaxart Enter COVID-19,” May 22, 2020; Ology Bioservices, “U.S. Army Contracting Command,” August 26, 2020; AGC, “AGC Expands Contract,” August 18, 2020; *Intelligencer*, “Sanofi: COVID-19 Vaccines,” August 4, 2020; GlaxoSmithKline, “GSK Announces Intention,” May 28, 2020; GRAM Website, “Large Scale Filling” (accessed November 15, 2020); Martin, “Inside the Operation Warp Speed Effort,” November 8, 2020; Feingold, “When Vaccine is Ready,” October 2, 2020; Johnson, “A vial, a Vaccine and Hopes,” November 17, 2020; Altimune, “Altimune Announces Manufacturing Agreement,” July 22, 2020; Vigene Biosciences, “Vigene Biosciences Secures Institutional,” April 29, 2019; NantKwest, “ImmunityBio & NantKwest Sign,” May 27, 2020; NantKwest, “Form 10-K, March 25, 2020, 8, 114; Medicago, “Medicago Begins Phase I,” July 14, 2020; Medicago Website, “Frequently Asked Questions” (accessed November 18, 2020); CordenPharma, “Core Capabilities” (accessed November 17, 2020); CordenPharma, “Moderna Extends Lipid Supply,” May 28, 2020.; Centaur Biopharmaceutical Services, “cGMP Manufacturing” (accessed November 18, 2020); KindredBiosciences, “Kindred Biosciences Announces Expansion,” October 7, 2020; Catalant, “Catalent Partners with Spincona,” June 10, 2020; Rodriguez, “Novavax COVID-19 Vaccine Receives,” November 10, 2020; Businesswire, “Moderna and Catalent Announce”, June 25, 2020; Stanton, “Inovio’s COVID-19 vaccine,” April 8, 2020; Blakenship, “Inovio Accuses Manufacturing Partner,” June 5, 2020; Sagonowsky, “Moderna has started turning out COVID-19,” July 15, 2020; Gilgore, “Novavax’s latest win?,” June 5, 2020; Hargreaves, “Altimune Partners with Lonza,” BioProcess International, November 16, 2020; Catalent. “Catalent Biologics Invests \$50 Million,” September 2, 2020; Keller and Krabbe, “ABQ Plant to Play a Role,” September 18, 2020.

Notes: Altimune’s AdCOVID candidate is an intranasal (spray) vaccine candidate. BARDA = Biomedical Advanced Research and Development Authority (HHS). This table only includes plants that are confirmed to be current or planned production locations for COVID-19 vaccines.

CDMOs are also playing a large role in manufacturing vaccines, including the production of inputs, formulation, fill, and/or finish. For example, Johnson & Johnson contracted with Emergent BioSolutions to manufacture the active drug substance for its vaccine.<sup>773</sup> Emergent BioSolutions in turn ships the majority of what they produce to a Catalent-run fill and finish line.<sup>774</sup> CDMOs made large investments in

<sup>773</sup> Emergent BioSolutions, “Emergent BioSolutions,” April 23, 2020.

<sup>774</sup> Martin, “Inside the Operation Warp Speed Effort,” November 8, 2020.

manufacturing capacity in the last decade, with many firms significantly increasing their drug substance and/or fill and finish manufacturing capacity.<sup>775</sup>

Collectively, the industry (developers and CDMOs) has the domestic capacity to produce hundreds of millions of doses annually (as illustrated in table 5.5), although some capacity is contracted to individual manufacturers and, therefore, cannot be readily interchanged. Further, vaccine developers and CDMOs are making significant investments in new production for a COVID-19 vaccine, accelerating existing expansion plans, and planning to hire hundreds of additional workers.<sup>776</sup> These expansions will add production capacity for hundreds of millions of doses annually. Examples of production capacity and capacity expansion for vaccines include:

- Thermo Fisher projects that it could produce up to 100 million doses per year for Inovio's vaccine.<sup>777</sup>
- Emergent's Baltimore Bayview plant has an annual drug substance production capacity, depending on the type of vaccine, of tens to hundreds of millions of doses.<sup>778</sup>
- In terms of fill and finish, one of Catalent's lines can fill and finish 400 vials a minute, with each vial holding 5 to 10 doses; this pace can amount to bottling 2.9–5.8 million doses a day.<sup>779</sup>
- Catalent is investing in a new vial filling line that it expects to bring online by April 2021. It will be able to fill 80 million vials annually, which translates to 400 to 800 million doses (assuming 5- to 10-dose vials).<sup>780</sup>
- Lonza is building production lines at its location in Portsmouth, New Hampshire plant for production of the Moderna vaccines. The firm expected to start production by November.<sup>781</sup>

As part of fill and finish operations, vials are needed to contain the vaccine.<sup>782</sup> The U.S. glass vial industry (including firms making the tubes from which vials are produced) is composed of a mix of U.S.- and

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<sup>775</sup> See, for example, Roots Analysis, "Biologics Fill/Finish Services Market," May 2019; Catalent, "Catalent Invests \$200 Million," January 7, 2019; Contract Pharma, "Emergent Unveils Expanded Facility in Baltimore," May 17, 2017.

<sup>776</sup> See, for example, Catalent, "Catalent Biologics Invests \$50 Million," September 2, 2020; Keller and Krabbe, "ABQ Plant," September 18, 2020; Catalent, "Catalent Signs Agreement," April 29, 2020; Novavax, "Novavax Announces Facility Expansion," November 2, 2020.

<sup>777</sup> Inovio, "INOVIO Adds Thermo Fisher Scientific," September 8, 2020.

<sup>778</sup> Emergent BioSolutions, "Emergent BioSolutions Signs Five-Year Agreement," July 6, 2020.

<sup>779</sup> Martin, "Inside the Operation Warp Speed Effort," November 8, 2020.

<sup>780</sup> Catalent, "Catalent Biologics Invests \$50 Million," September 2, 2020.

<sup>781</sup> Feingold, "When Vaccine is Ready," October 2, 2020.

<sup>782</sup> Each vial is typically sealed with a rubber stopper and covered with an aluminum flip cap. A major U.S. manufacturer of rubber stoppers is West Pharmaceutical Services, based in Pennsylvania. West Pharmaceutical Services, "About West" (accessed November 6, 2020); Open PR, "Medical Rubber Stoppers Market," August 17, 2020; MarketWatch, "Medical Rubber Stoppers Market Size," September 24, 2020; USITC, hearing transcript, September 23, 2020, 278 (testimony of Ed Brzytwa, American Chemistry Council); Hogue, "Vials Vital for COVID-19," September 22, 2020.

foreign-headquartered firms, including Corning, DWK Life Sciences, Gerresheimer, Nipro, and Schott.<sup>783</sup> Some of these firms announced significant investments in production capacity expansions in 2020 as well. Notable developments regarding capacity expansion for vial production include:

- Corning, using a \$347 million government grant, is expanding capacity to reach a target of three to four times existing capacity, which equates to about 10–25 million vials per month by the end of 2020.<sup>784</sup>
- Other domestic producers of vials, such as DWK Life Sciences and Nipro, also invested in expanding capacity, although the public announcements did not specifically link the expansions to vaccine production.<sup>785</sup>
- In June 2020, HHS’s Biomedical Advanced Research and Development Authority (BARDA) awarded SiO<sub>2</sub> \$143 million for the development of three U.S.-based manufacturing systems to produce plastic and glass vials to support the mass production and distribution of COVID-19 vaccines.<sup>786</sup>

## Distribution of Vaccines

Vaccines are delivered to various sites daily, using an established network of storage and transportation. Some manufacturers use in-house distribution services, while others go through third-party distributors to safely store and transport their vaccines.<sup>787</sup> Over the past decade, the sites where individuals receive vaccinations have expanded beyond doctors’ offices to pharmacies and grocery stores, and these locales are increasingly becoming part of the normal vaccine distribution chain.<sup>788</sup>

A primary requirement of vaccine distribution is to keep the product below a certain temperature.<sup>789</sup> In preparation for a COVID-19 vaccine becoming available for distribution, firms such as UPS, DHL, and FedEx have been preparing for an increase in cold-temperature shipping. UPS, for example, is building a “freezer farm” in Louisville, Kentucky, that will store millions of vials of a vaccine at temperatures as low

<sup>783</sup> BusinessWire, “DWK Life Sciences Increases Glass Vial Production,” September 1, 2020; Schott, “Schott to Invest \$1 Billion,” March 25, 2019; Schott, “Location Profile” (accessed November 3, 2020); Gerresheimer, “Vineland (Primary Packaging Glass), USA” (accessed November 3, 2020); Nipro, “Nipro Invests” (accessed November 3, 2020); Corning, “U.S. Departments of Defense,” June 9, 2020.

<sup>784</sup> Corning received a \$204 million government contract to help accelerate construction of a 2,000-degree furnace to produce molten glass for vials. Pfizer signed a long-term agreement with Corning to procure vials. Bostock, “Inside the US Government’s \$347 Million Plan,” June 22, 2020; Rowland, “A Race Is On,” July 13, 2020; HHS, “BARDA’s COVID-19 Domestic Manufacturing and Infrastructure Investments” (accessed on October 19, 2020); Maddipatla and Mishra, “Pfizer Ties Up with Glass Maker Corning,” May 28, 2020.

<sup>785</sup> BusinessWire, “DWK Life Sciences Increases Glass Vial Production,” September 1, 2020; Nipro, “Nipro Invests” (accessed November 3, 2020).

<sup>786</sup> HHS, “BARDA’s COVID-19 Domestic Manufacturing and Infrastructure Investments” (accessed on October 19, 2020).

<sup>787</sup> For example, Pfizer opted out of using the centralized distributor (McKesson) and provided its own plan for distribution in October 2020. The plan is specific to Pfizer’s vaccine candidate. Costas and Hopkins, “Pfizer Sets Up Its ‘Biggest Ever’ Vaccination,” October 21, 2020; USITC, hearing transcript, September 24, 2020, 493–94 (testimony of Michael Einhorn, DealMed Medical Supplies).

<sup>788</sup> Industry sources, telephone interview by USITC staff, September 28, 2020.

<sup>789</sup> Industry representatives, telephone interview by USITC staff, October 21, 2020; USITC, hearing transcript, September 23, 2020, 259 (testimony of Ed Brzytwa, American Chemistry Council).

as minus 80 degrees Celsius.<sup>790</sup> In August 2020, DHL opened a 20,000-square-foot freezer farm in Indianapolis, Indiana, dedicated to life sciences and healthcare logistics.<sup>791</sup> Meanwhile, over the past decade FedEx grew its cold-chain services to include packaging for, among other things, vaccines.<sup>792</sup> The cornerstone of FedEx's network is the Cold Chain Center at the Memphis International Airport, which also has 20,000 square feet dedicated to temperature-controlled storage of healthcare shipments.<sup>793</sup> Within the center, goods can be stored frozen, cold, and at a controlled room temperature; since the center opened in 2014, McKesson, a leading vaccine distributor, has often shipped vaccines through FedEx.<sup>794</sup>

## Distribution of Ancillary Supplies

This discussion focuses on syringes and needles, as many of the other ancillary supplies (such as surgical masks and gloves) needed to administer a vaccine are discussed elsewhere in the report. The domestic industry for syringes and needles primarily consists of firms such as Becton Dickinson (BD) (production in Nebraska), Cardinal Health (Illinois), Smiths Medical (New Hampshire), and Retractable Technologies (headquartered in Texas).<sup>795</sup> The government has made investments aiming to ensure an adequate supply of syringes. Significant developments with respect to syringes and needles as of November 2020 included:

- BD has struck a partnership with BARDA allocating \$70 million to further expand BD's capacity at its Nebraska site by July 2021.<sup>796</sup>
- In May, Retractable Technologies was contracted with an \$83.8 million order, and is expected to increase its capacity by 50 percent in 12 months.<sup>797</sup>
- In mid-July, Smiths Medical received an order from Marathon Medical for 78.6 million syringe and needle units (through BARDA agreement); in addition, BARDA will contribute \$20 million

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<sup>790</sup> Ronan, "UPS, FedEx Gear Up to Ship COVID-19 Vaccine," August 6, 2020; Pharmaceutical Commerce, "Now, 'Freezer Farms' for Potential COVID-19 Vaccine," August 4, 2020.

<sup>791</sup> Pharmaceutical Commerce, "Now, 'Freezer Farms' for Potential COVID-19 Vaccine," August 4, 2020.

<sup>792</sup> FedEx has built 10 freezer facilities within the last three years. Ronan, "UPS, FedEx Gear Up to Ship COVID-19 Vaccine," August 6, 2020; Mui, "UPS Is Building Vaccine Freezer Farms," September 18, 2020; Chen, "From 'Freezer Farms' to Jets," August 28, 2020.

<sup>793</sup> Risher, "FedEx Ramps Up for COVID-19 Vaccine Distribution," October 15, 2020.

<sup>794</sup> As part of OWS, on August 14, 2020, the CDC announced that McKesson, the distributor for the 2009–10 H1N1 vaccine, would be the contracted centralized distributor of the COVID-19 vaccine in the United States. McKesson's responsibilities will include providing services for rapid distribution of doses of both refrigerated (2- to 8-degrees Celsius) and frozen (-20°C) vaccines. HHS and DOD, "From the Factory to the Frontlines" (accessed September 29, 2020), 4; Garland, "COVID-19 Vaccine Distribution," September 27, 2020.

<sup>795</sup> Smiths Medical, "Smiths Medical Partners," July 15, 2020; Rowland, "Cardinal Health's \$6.1 Billion Deal," April 19, 2017; BD, "BD Partners," July 8, 2020; Retractable Technologies, "Form 10-Q," Aug 14, 2020, 6.

<sup>796</sup> The initial order for 50 million syringes was part of a DPA designation allowing priority access to raw materials for manufacturing. BD, "BD Partners with U.S. Government," July 8, 2020.

<sup>797</sup> HHS, "BARDA and JPEO-CBRND Establish Partnership," updated July 9, 2020; Haberkorn, "Syringes Are Key to Coronavirus Vaccine Delivery," July 8, 2020.

toward a \$38 million expansion at Smiths Medical, which will expand production by 125 million units per year.<sup>798</sup>

- The government also funded \$138 million towards the development of a prefilled syringe.<sup>799</sup>

By October 2020, reports indicate that McKesson had produced enough ancillary supply kits, which include syringes, for 88 million doses (approximately 880,000 kits), enough to inoculate 44 million people under a two-dose regime.<sup>800</sup>

## U.S. Imports

### Vaccines and Vials

U.S. imports of vaccines for human use totaled 1,854 metric tons and were valued at \$7.3 billion in 2019 (figure 5.20).<sup>801</sup> U.S. vaccine imports primarily originate in the European Union. The top three countries supplying these imports, by quantity, in 2019 were Belgium (780 metric tons, \$3.7 billion), Germany (254 metric tons, \$209 million), and Ireland (245 metric tons, \$2.1 billion). U.S. imports from Belgium more than doubled from 2015 to 2019, increasing from 363 metric tons to 780 metric tons. Numerous biologics firms are in Belgium, including GlaxoSmithKline (GSK), which has one of the world's largest vaccine manufacturing sites. GSK acquired Novartis Vaccines (excluding influenza vaccines) in early 2015, significantly expanding the number of vaccines it produces.<sup>802</sup> From January to September 2020, there was a significant decrease in imports of vaccines from Ireland compared to the same period in 2019, with imports decreasing from 196 metric tons to 7 metric tons.

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<sup>798</sup> The initial order placed with Marathon Medical Corp. was for \$27.4 million worth of syringes and needles, with an option to go up to \$54 million; Haberkorn, "Syringes Are Key to Coronavirus Vaccine Delivery," July 8, 2020. Smiths Medical also partnered with the U.S. government and received a \$20 million investment. Smiths Medical, "Smiths Medical Partners with U.S. Government," July 15, 2020.

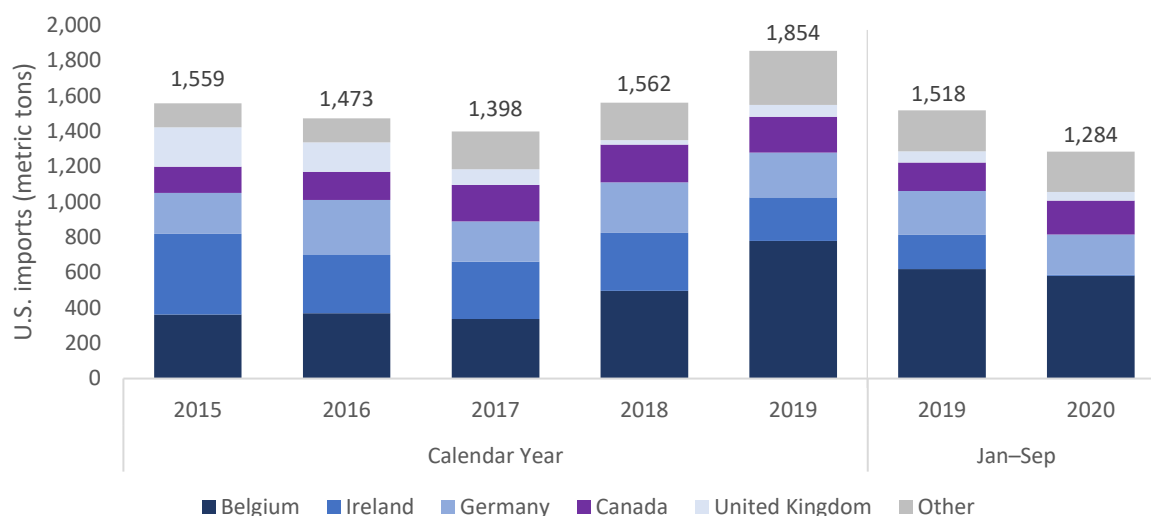
<sup>799</sup> As prefilled syringes for medication and vaccination administrations is relatively new, adoption of this technology varies by manufacturer it is unlikely that the first round of vaccines to come to market will be packaged in prefilled syringes. For example, for the flu vaccine it took years before manufacturers made the change. Fitzpatrick, "Trump Admin Reveals Plan," May 12, 2020; industry representatives, telephone interview by USITC staff, September 10 and October 21, 2020; Mintz, "Prefilled syringes the Next 'Big Thing,'" August 30, 2012.

<sup>800</sup> Martin, "Inside the Operation Warp Speed Effort," November 8, 2020.

<sup>801</sup> U.S. imports of vaccines are duty free. USITC DataWeb/USDOC, HTS statistical reporting number 3002.20.0000 (accessed November 8, 2020).

<sup>802</sup> Sertyn, "Belgium: A Vaccine Country," April 6, 2020; GlaxoSmithKline, "GSK Completes," March 2, 2015; GlaxoSmithKline, "GSK PLC Announces," April 22, 2014; Biopharmguy, "Belgium—Biotech Company List" (accessed October 24, 2020); GlaxoSmithKline, "About Us" (accessed October 24, 2020).

**Figure 5.20** U.S. imports of vaccines for human use, by country, 2015–19, January–September 2019, and January–September 2020 (in metric tons)



Source: USITC DataWeb/USDOC, HTS 3002.20.0000 (accessed November 8, 2020).

Note: Top five countries by total imports for 2015–September 2020. Underlying data for this figure can be found in [appendix table E.32](#).

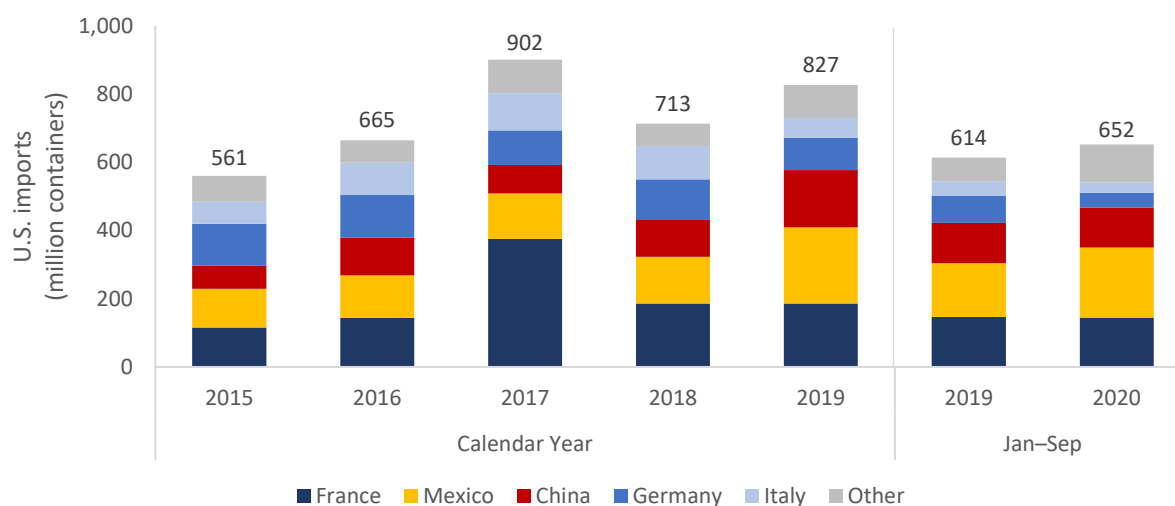
Many vaccines are transported in dosage form in vials.<sup>803</sup> U.S. imports of serum bottles, vials, and other pharmaceutical containers of glass, of a capacity not exceeding 0.15 liter, totaled 827 million containers in 2019 (\$123 million), up from 561 million containers in 2015 (\$95 million), although down from the peak in 2017. The top three countries supplying U.S. imports in 2019 were Mexico (224 million containers, \$20.7 million), France (145 million containers, \$44.1 million), and China (118 million containers, \$6.6 million) (figure 5.21).<sup>804</sup>

<sup>803</sup> Vials in HTS 7010.90.5040 are duty free under normal trade relations (NTR) duty rates. Imports from China are subject to 25 percent section 301 duty rates. Rubber stoppers in HTS 4016.99.1500 used with these vials are subject to 2.7 percent NTR rates and 7.5 percent section 301 duty rates. HTS chapter 99 subchapter 3 note 20. USITC, Harmonized Tariff Schedule of the United States, Revision 22, 2020.

<sup>804</sup> USITC DataWeb/USDOC, HTS 3923.30.0010 (accessed October 14, 2020). Plastic vials, which are currently used less often for vaccines, are imported under a separate HTS number. However, these data are not specific to pharmaceutical applications and are not presented here.



**Figure 5.21** U.S. imports of serum bottles, vials, and other pharmaceutical containers of glass, of a capacity not exceeding 0.15 liter, by country, 2015–19, January–September 2019, and January–September 2020 (in million containers)



Source: USITC DataWeb/USDOC, HTS 7010.90.0540 (accessed November 2020).

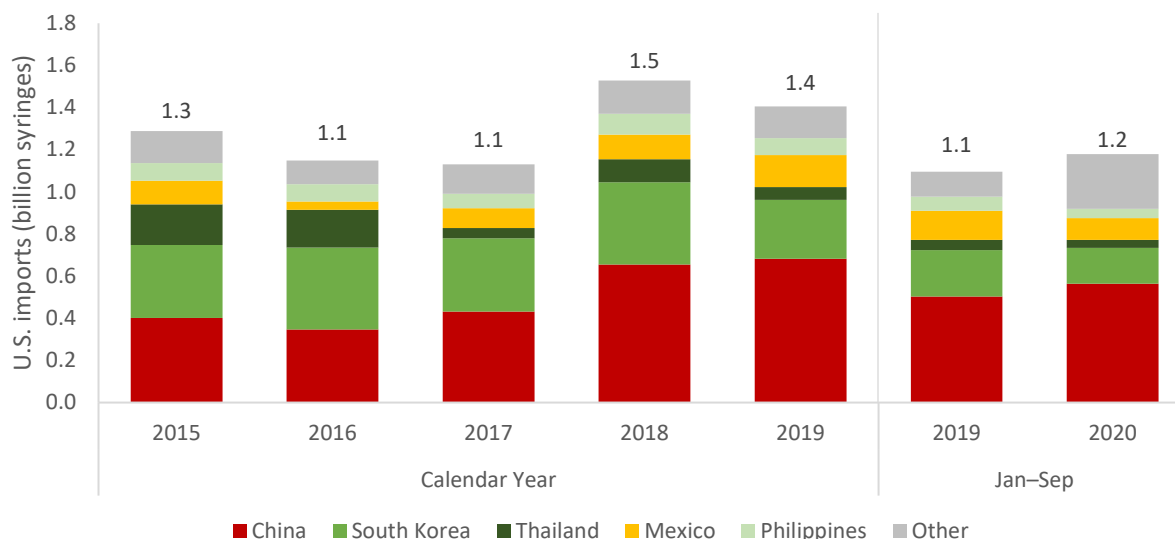
Note: Top five countries by total imports for 2015–September 2020. Underlying data for this figure can be found in [appendix table E.33](#).

## Syringes and Needles

In 2019, 1.4 billion hypodermic syringes were imported into the United States at a value of \$111.4 million. The countries accounting for the highest number of units were China (682.4 million units, \$36.9 million), South Korea (278.8 million units, \$17.0 million), and Mexico (151.3 million units, \$9.4 million) (figure 5.22). Parts and accessories of syringes, with or without their needles, are imported under HTS 9018.31.0090 and had a total value of \$465.0 million in 2019. The countries accounting for the largest values were Taiwan (\$88.8 million), Mexico (\$86.5 million), and Israel (\$50 million).<sup>805</sup>

<sup>805</sup> Hypodermic syringes with or without their needles are imported under HTS 9018.31.0040. Parts and accessories of syringes, with or without their needles, are imported under HTS 9018.31.0090. These products enter duty free. USITC DataWeb/USDOC (accessed October 2020).

**Figure 5.22** U.S. imports of hypodermic syringes, with or without their needles, by country, 2015–19, January–September 2019, and January–September 2020 (in billion syringes)



Source: USITC DataWeb/USDOC, HTS 9018.31.0040 (accessed November 2020).

Note: Top five countries by total imports for 2015–September 2020. Underlying data for this figure can be found in [appendix table E.34](#).

## Supply Chain Challenges and Constraints

Bringing a new COVID-19 vaccine to market presents an enormous set of challenges, starting with developing, testing, and obtaining authorization for a vaccine. Once authorized, the vaccine and ancillary supplies need to be manufactured on an unprecedented scale and delivered throughout the country, putting stress on existing supply networks and available capacity. For COVID-19 vaccines, maintaining the temperature of the vaccines is anticipated to be a key supply chain issue. Both U.S. manufacturers and foreign suppliers are actively working to meet these challenges, with many already ramping up production and capacity.

### Factors Affecting Domestic Production

#### Product to Market

While significant efforts are being made to bring a vaccine to market as quickly as possible, researchers continue to face challenges in meeting requirements for approval set forth by FDA for the clinical trials.<sup>806</sup> As described in figure 5.19, each vaccine has to go through all three phases of clinical trials before it can be distributed to consumers. As of October 20, 2020, vaccine clinical trials that had at one point been paused in the United States included those of AstraZeneca (Oxford), Johnson & Johnson, and

<sup>806</sup> FDA sets the threshold floor standard for a COVID-19 vaccine at 50 percent efficacy. FDA, “Emergency Use Authorization for Vaccines,” October 2020.

Inovio.<sup>807</sup> In October 2020, FDA issued more guidance for industry on receiving an EUA for a COVID-19 vaccine. This guidance recommends that in addition to data from Phase 3 studies, companies should follow up with at least half of vaccine recipients in clinical trials for two months.<sup>808</sup> Despite the challenges, five vaccines have reached Phase 3 clinical trials within nine months of the identification of SARS-CoV-2.<sup>809</sup>

## Production and Delivery

When a vaccine is available, it will take time and increased capacity to ramp up production enough to meet the demand for inoculations, potentially straining the supply chain at multiple points.<sup>810</sup> Bringing additional production capacity online for initial vaccine production is required because the industry was already operating at high capacity utilization before the onset of COVID-19.<sup>811</sup> Firms are planning extensive use of CDMOs, but this entails shortening the time to transfer the necessary technology and manufacturing to CDMOs (and any associated equipment changes or upgrades) down from up to 30 months to a much shorter time period.<sup>812</sup> At the same time, vaccine production is typically a complex process, and the need for consistent quality makes it difficult to boost vaccine production in a short time.<sup>813</sup> Firms also need to find hundreds of workers, some of whom need to be highly skilled, and get production workers trained on new equipment—a process that usually takes up to six months.<sup>814</sup>

Some industry representatives also point to sourcing certain inputs as a potential challenge, depending on the particular vaccine formulation and the extent to which a manufacturer already has a supply chain for a particular product in place.<sup>815</sup> Further, industry indicates that certain laboratory consumables utilized in vaccine manufacturing are in short supply.<sup>816</sup> Vaccine production occurs in clean environment to limit risk of product contamination, and reports indicate that materials used for connections in closed

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<sup>807</sup> Inovio was paused at Phase 2/3, while AstraZeneca and J&J were paused in Phase 3 clinical trials. AstraZeneca's and Johnson and Johnson's trials have since resumed. Whooley, "AstraZeneca Phase III COVID-19 Vaccine Remains on Hold," September 24, 2020; Wamsley, Harris, and Romo, "Johnson & Johnson, Eli Lilly Pause COVID-19 Drug Trials," October 13, 2020; Clinical Trials, "FDA Places Partial Hold on Inovio's Phase II/III," September 29, 2020.

<sup>808</sup> Generally, adverse events linked to vaccination start within six weeks of receiving the vaccine. Krause and Gruber, "Emergency Use Authorization of Covid Vaccines," October 16, 2020.

<sup>809</sup> USITC, hearing transcript, September 23, 2020, 297, (testimony of Jonathan Kimball, Association for Accessible Medicine), 299 (testimony of Katherine Fry, America's Blood Centers).

<sup>810</sup> CDC published interim guidance listing which groups in the population should get priority, and a panel, the Advisory Committee on Immunization Practices, advised CDC in December 2020 that healthcare workers and long-term care facility residents should receive priority. CDC, "COVID-19 Vaccination Program Interim Playbook," September 16, 2020, 12; Dooling et. al, "The Advisory Committee on Immunization," December 3, 2020.

<sup>811</sup> Bringing a new production plant online typically takes three to five years. SAGE, "Pre-empting and Responding," April 2016, 5; Lee, "The Conversation," August 26, 2020.

<sup>812</sup> Barry, "COVID-19 Vaccine Manufacturing," October 19, 2020; O'Sullivan, Rutten, and Schatz, "Why Tech Transfer," July 23, 2020.

<sup>813</sup> SAGE, "Pre-empting and Responding," April 2016, 5; Lee, "The Conversation," August 26, 2020; Avertim, "Top 3 Challenges" (accessed November 3, 2020); O'Sullivan, Rutten, and Schatz, "Why Tech Transfer," July 23, 2020.

<sup>814</sup> Veleta, "Potential Covid Vaccine," May 28, 2020; Sagonowsky, "BIO: Moderna, Merck," June 11, 2020.

<sup>815</sup> Sandburg, "COVID-19 Vaccine Manufacturing," June 11, 2020; Lee, "The Conversation," August 26, 2020; Koerth, "How COVID-19 Is Wreaking Havoc," April 15, 2020; Brennan, "The Next Unprecedented Vaccine," August 12, 2020; Armstrong, "Q&A with Merck," August 6, 2020.

<sup>816</sup> Industry representatives, telephone interview by USITC staff, November 17, 2020.

systems (i.e., the product is not exposed to the surrounding environment) are in extreme shortage.<sup>817</sup> Over the course of 2020, lead time to source these materials is 30 weeks on average, and industry has indicated that as of November 2020 lead time for these materials is as long as 40 weeks.<sup>818</sup>

Another supply chain challenge is fill and finish capacity, which could hamper the delivery of a mass vaccination program for COVID-19, as it did for H1N1 in 2009.<sup>819</sup> Pharmaceutical manufacturers may contract out the fill and finish work to a CDMO. However, even U.S. CDMOs may not have enough capacity, at least in the short run, to fill orders from the upstream firms as part of the COVID-19 vaccine efforts.<sup>820</sup>

A further challenge for delivering a vaccine is increasing the production of vials to meet demand. The global market for medical glass vials is typically about 25 billion vials (with 3.2 billion in the United States), of which about 15–20 billion are borosilicate glass vials for medical use.<sup>821</sup> The incremental demand increase for a vaccine is initially relatively small, as they will be in multidose vials, but there were tight supply and demand conditions even before COVID-19.<sup>822</sup> Expanding vial manufacturing is a highly capital-intensive process, and involves significant lead times to expand.<sup>823</sup> Typical glass vials rated for medical use include specialized borosilicate as a raw material, which could also be in short supply as production ramps up.<sup>824</sup> Further, some of the initial vaccines authorized are likely to require ultra-cold

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<sup>817</sup> Specifically, molded silicone and thermoplastic elastomers used as the connectors within the closed system set-ups. Johnson et al., “Challenging the Cleanroom Paradigm,” August 1, 2011.

<sup>818</sup> Acuity Process Solutions, “Supply Chain Issues,” September 2, 2020; industry representatives, telephone interview by USITC staff, November 17, 2020.

<sup>819</sup> Once produced, vials and syringes will need to be filled with vaccines and packed in highly sterile conditions. Executive Office of the President, President’s Council of Advisors on Science and Technology, “Report to the President on Reengineering the Influenza,” August 2010, 21; Markarian, “CDMOs Build Finish/Fill Capacity,” August 1, 2020; Lawrence et al., “A Strategic Approach to COVID-19 Vaccine R&D,” May 29, 2020; Brennan, “The Next Unprecedented Vaccine,” August 12, 2020; USITC, hearing transcript, September 23, 2020, 313 (testimony of Jonathan Kimball, Association for Accessible Medicine).

<sup>820</sup> Lawrence et al., “A Strategic Approach to COVID-19 Vaccine R&D,” May 29, 2020; Markarian, “CDMOs Build Finish/Fill Capacity,” August 1, 2020.

<sup>821</sup> Burger and Blamont, “Exclusive: Bottlenecks?” June 12, 2020; industry representatives, telephone interview by USITC staff, November 17, 2020.

<sup>822</sup> As of June 2020, Schott, one of the major global producers with an annual production of 11 billion vials, had reached agreements to supply enough vials for 2 billion doses and reportedly had the potential to supply another 1 billion doses (including additional production in the United States) without additional physical infrastructure. Schott did not specify the time frame over which it plans to deliver the vials. Another firm, SGD, reported that it expected additional demand to be equal to about 3 percent of its annual volume. The extent to which a vial shortage will be an issue likely depends on the firm, with large pharmaceutical firms with existing supply chains likely to have better access to vials. The industry is likely to move more toward single dose vials over time. Hopkins and Hinshaw, “Coronavirus Vaccine Makers,” June 16, 2020; Burger and Blamont, “Exclusive: Bottlenecks?” June 12, 2020; industry representatives, telephone interview by USITC staff, November 17, 2020; Schott, “Schott Delivers,” June 26, 2020.

<sup>823</sup> Miller, “The Rollout of a COVID-19 Vaccine,” September 21, 2020.

<sup>824</sup> Griffin, “Fear of Vial Shortage,” June 25, 2020; Hogue, “Vials Vital for COVID-19,” September 22, 2020.

temperature storage, under which standard glass vials have higher breakage rates than under typical storage conditions.<sup>825</sup>

When one or more vaccines become available, hundreds of millions of additional syringes and needles will be required in a short amount of time.<sup>826</sup> BARDA estimates that 650 million to 850 million syringes and needles will be needed for dosing.<sup>827</sup> The current domestic market of 663 million syringes meets current needs, such as flu vaccinations, and the industry will need to supply hundreds of millions of additional syringes for COVID-19 vaccinations alone.<sup>828</sup> The largest domestic producer of safety syringes, BD, stated that capacity to produce 1 billion syringes will likely be demanded in the future.<sup>829</sup> As of July 2020, BD had received orders totaling 330 million needles and syringes, not only from the United States but also from the United Kingdom and Canada.<sup>830</sup> Retractable Technologies, which has been contracted by the federal government to provide syringes, sources more than 80 percent of its products from China. The contract (in dollar terms) is double the company's 2019 revenue. Therefore, it may encounter supply problems until its production expansions are complete.<sup>831</sup>

## Distribution

When a U.S. vaccination program launches, a potential supply chain challenge will be transporting vaccines to inoculation sites.<sup>832</sup> Many vaccines must be kept cold during transport and at the delivery location before injection. Facilities that transport and distribute vaccines will need low-temperature storage, which may pose difficulties for some facilities, particularly for vaccines that require storage lower than -20 degrees Celsius. It is common to store mRNA containing formulations at -80 degrees Celsius, such as Pfizer's vaccine, and as RNA based therapies are comparatively new, ultracold type of freezers that reach these temperatures may not be commonly owned by end-use facilities.<sup>833</sup> For other vaccines it is common to lose 5 to 20 percent or more of vaccines because of a break in the cold chain or other problems with distribution, which poses a challenge to manufacturing, as more doses will then have to be produced.<sup>834</sup> In October 2020, CDC advised jurisdictions not to purchase ultra-cold storage equipment, given the high price and the likelihood that COVID-19 vaccines will become available that

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<sup>825</sup> The Valor glass vials for which Corning, as discussed above, is ramping up production perform better under ultra-cold storage conditions. Popken, "Pfizer Readies 'Herculean Effort,'" November 9, 2020; Hopkins, "Covid-19 Vaccines," November 13, 2020.

<sup>826</sup> These are the same supplies that are needed as part of the COVID-19 clinical trials underway in the United States. Ilancheran, "COVID-19's Impact on the Clinical Trial," September 24, 2020.

<sup>827</sup> Spiro and Emanuel, "A Comprehensive COVID-19 Plan," July 28, 2020.

<sup>828</sup> Spiro and Emanuel, "A Comprehensive COVID-19 Plan," July 28, 2020.

<sup>829</sup> Strickler and Fitzpatrick, "Supply Chain Headache?" May 8, 2020.

<sup>830</sup> In support of OWS, the United States initially ordered 50 million syringes to be completed by December 2020. Hargreaves, "BD Receives Order," July 27, 2020; BD, "BD Partners with U.S. Government on \$70 Million Manufacturing Infrastructure Project," July 8, 2020.

<sup>831</sup> It is worth noting that Retractable was able to quickly and successfully fill a government order worth about \$10 million during the H1N1 pandemic in 2009. Nichols, "Little Elm's Retractable Technologies," July 9, 2020; Haberkorn, "Syringes Are Key to Coronavirus Vaccine Delivery," July 8, 2020.

<sup>832</sup> HHS and DoD, "From the Factory to the Frontlines," 3 (accessed on September 29, 2020).

<sup>833</sup> Steenhuysen and Kelland, "Vaccine Makers Face," June 25, 2020; industry representatives, telephone interview by USITC staff, September 28, 2020.

<sup>834</sup> Steenhuysen and Kelland, "Vaccine Makers Face," June 25, 2020.

will not require such low temperatures.<sup>835</sup> There is reportedly limited supply of ultra-low-temperature freezers in the United States with some suppliers reporting that by December 2020 lead times to complete orders are as long as two months.<sup>836</sup>

Beyond cold chain storage, the distribution of a second dose of a vaccine, for those that that require one, is a substantial logistical challenge.<sup>837</sup> For the vaccines to be most effective, recipients need to comply with vaccine dosing intervals, and the available vaccines will not be interchangeable.<sup>838</sup>

## Factors Affecting U.S. Imports

Factors affecting imports largely mirror the supply chain challenges and constraints that face the U.S. industry. In general, many of the same firms that are establishing U.S. production and supply chains for their products are setting up parallel processes overseas, particularly in Europe. The production ramp-up in foreign locations will encounter the same challenges throughout the supply chain, from the availability of raw materials to fill and finish capacity. Any imported vaccine will have the additional challenge of maintaining the cold chain during transportation from overseas. The extent to which foreign vaccine production will supply the U.S. market is unknown, and depends on which vaccines are authorized, available production capacity, and the contractual obligations of suppliers.<sup>839</sup>

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<sup>835</sup> CDC has advised that most vaccines will not require ultra-cold chain support, although one of the likely first available vaccines (Pfizer) has stringent low-temperature requirements. Goldhill, “We’re Being Left Behind,” November 11, 2020; CDC, “COVID-19 Vaccination Program Interim Playbook,” October 29, 2020, 53.

<sup>836</sup> Reuters, “U.S. States Race to Buy Ultra Cold,” November 13, 2020; Byrne, “Stirling Going the Extra Mile,” October 29, 2020.

<sup>837</sup> Martin, “Inside the Operation Warp Speed Effort,” November 8, 2020.

<sup>838</sup> CDC, “COVID-19 Vaccination Program Interim Playbook,” October 29, 2020, 37.

<sup>839</sup> Some of the more established vaccine manufacturer frontrunners have indicated that they will rely and expand on their regional (i.e., in the U.S.) supply chains (e.g., Pfizer and AstraZeneca), and will employ similar strategies in other regions globally. Even with the expansion of regional supply chains some companies have already started to rely on their global supply chains to supply doses to the United States. Multiple, robust, supply chains help ensure that if there is a challenge or constraint in one then the other can help supplant supply. Newer manufacturers face a larger challenge in growing manufacturing capacity in the U.S. and internationally. House Energy and Commerce Subcommittee, “COVID-19 Vaccine Research and Development Efforts,” July 21, 2020 (testimony of Mene Pangalos, AstraZeneca; Macaya Douoguih, Johnson & Johnson; Julie Gerberding, Merck; Stephen Hoge, Moderna; and John Young, Pfizer). Novavax, “Novavax,” September 15, 2020; Kansteiner, “Signed, Sealed, Delivered: Pfizer,” November 30, 2020.

# Chapter 6

## Soaps and Cleaning Compounds

The soap and cleaning compound industry and supply chain were put under severe strain in the first half of 2020, when a rapid increase in demand exceeded the ability of the domestic supply chain to respond. U.S. manufacturers, which supply most of the domestic market, significantly ramped up production but faced challenges in sourcing key chemical inputs, as well as the nonwoven fabrics needed for products such as disinfecting wipes.<sup>840</sup> In the early phase of the pandemic, some shortages were easier to address. For example, given low barriers to entry into the industry,<sup>841</sup> shortages of hand sanitizer were largely remedied, although there were a number of challenges to overcome such as the sourcing of packaging. On the other hand, the shortage of nonwoven disinfecting wipes is expected to continue into 2021.<sup>842</sup>

## Overview of the U.S. Soap and Cleaning Compound Industry and Trade

### Introduction

The United States has a large industry for manufacturing soaps and cleaning compounds, with most U.S. demand met by domestic production.<sup>843</sup> U.S. imports, to the extent they supply the U.S. market, are primarily from Canada and Mexico, although certain key inputs are supplied from Asia. During the five years before the pandemic, U.S. production, employment, and trade in the industry were fairly stable.<sup>844</sup> Early in 2020, however, after information was widely disseminated to the public that handwashing and disinfecting high-touch surfaces would help to mitigate spread of the virus and offer some protection against COVID-19,<sup>845</sup> U.S. demand for these products saw a sharp increase that led to growth in both domestic production and imports.<sup>846</sup>

Soaps and cleaning compounds are classified into several categories. Soaps are a type of surfactant, and can be natural or synthetic.<sup>847</sup> Hand soaps are primarily sold in bar form (solid) or liquid form, and some

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<sup>840</sup> Bettenhausen and Tullo, “Disinfectant Demand from Coronavirus Concerns,” April 15, 2020; industry representative, telephone interview by USITC staff, November 9, 2020.

<sup>841</sup> FDA Website, “Guidance for Industry,” March 2020.

<sup>842</sup> Gao, “Why Disinfectant Wipes,” July 25, 2020; Kavilanz, “The Clorox Wipes Shortage,” August 4, 2020.

<sup>843</sup> Leggate, “Where to Find Hand Sanitizers,” March 6, 2020.

<sup>844</sup> USITC DataWeb/USDOC (accessed October 2020); BLS, “Quarterly Census of Employment and Wages” (accessed October 18, 2020).

<sup>845</sup> CDC, “Handwashing” (accessed October 19, 2020); CDC “Detailed Disinfection Guidance” (accessed October 23, 2020).

<sup>846</sup> USITC DataWeb/USDOC (accessed October 2020).

<sup>847</sup> Surfactants are surface-active agents that when added to water improve the ability to remove oil, dirt, and grease. Cargill, “Soaps and Surfactants” (accessed October 19, 2020).

formulations contain antibacterial properties.<sup>848</sup> Other disinfecting cleaning compounds contain a variety of active ingredients, including alcohols, reducers, oxidizers, or quaternary ammonium salts.<sup>849</sup> These inputs are found in a variety of consumer products ranging from sprays and wipes to concentrates and hand sanitizers. The soaps and cleaning compounds described in this chapter include one industry, as classified by the North America Industry Classification System (NAICS), shown in table 6.1.<sup>850</sup>

**Table 6.1** Soaps and cleaning compounds coverage

NAICS	Description	Examples
32561	Soap and cleaning compound manufacturing	Household cleaning products like hand soap, laundry detergent and bleach, but also agents for applications like leather finishing, automobile cleaners, and furniture waxes.

Source: NAICS Association, <https://www.naics.com/>; SICCODE Business Data, <https://siccocode.com/> (accessed November 9, 2020).

## U.S. Industry

### Overview of the U.S. Industry

The United States has a large industry producing soaps and cleaning compounds. As of the first quarter of 2020, there were more than 1,700 manufacturing establishments (figure 6.1). The geographical distribution of these establishments correlates with current population distributions, partially due to the economics of transport, which precludes long-distance shipping. Many disinfectants are liquid, making them expensive to transport, and some, like bleach, are classified as dangerous chemicals by the U.S. Department of Transportation, which requires specific certifications when transporting large volumes.<sup>851</sup>

<sup>848</sup> No studies have shown that antibacterial soaps are more effective than plain soap at fighting germs. CDC, “Handwashing” (accessed October 19, 2020).

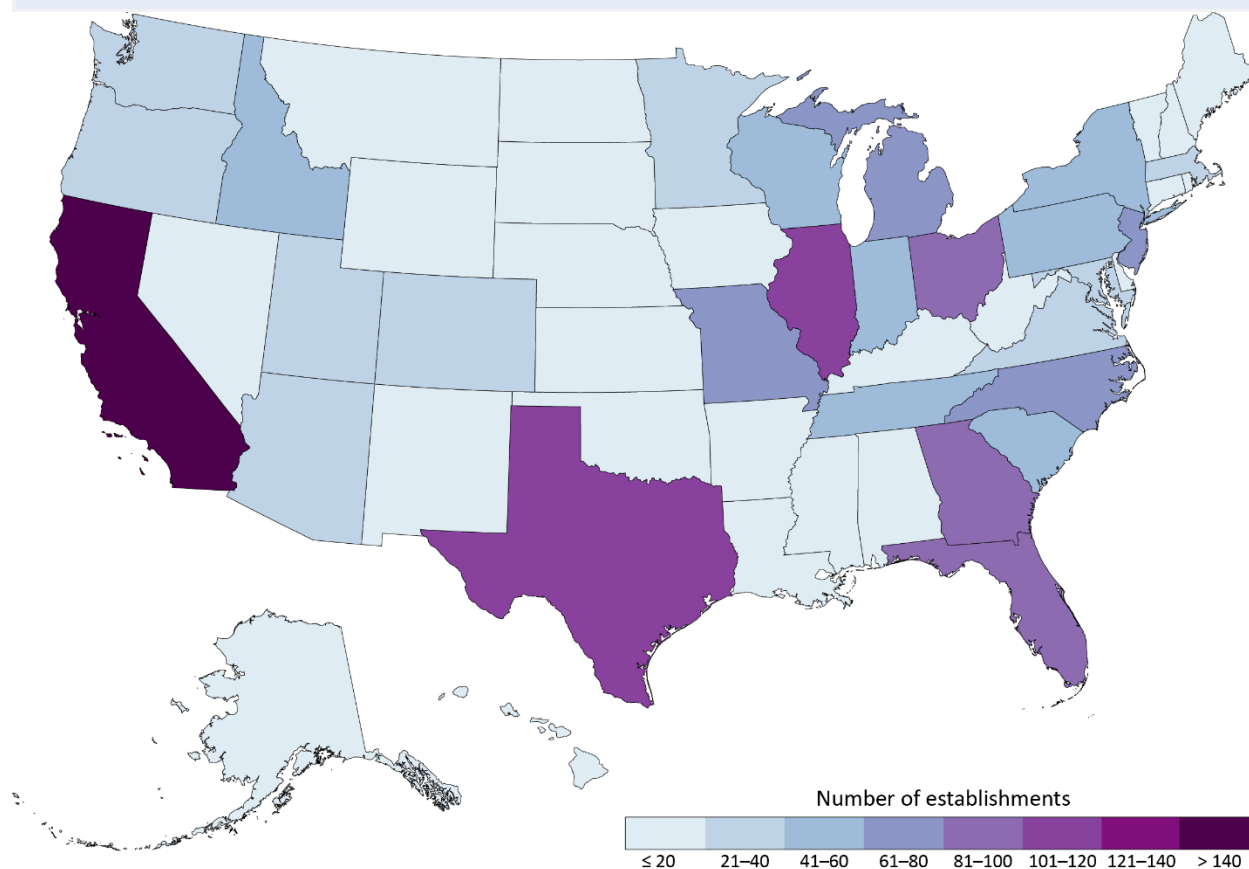
<sup>849</sup> Each class of compound has a different mode of action in which the virus’s lipid (protective) envelope is disrupted. Bettenhausen, “A Chemist’s Guide to Disinfectants,” May 1, 2020.

<sup>850</sup> This code covers a range of goods that are used as cleaning products for personal or commercial use. For the purposes of this discussion, the focus will be on soaps and cleaning compounds; other agents for application are not generally covered in this report.

<sup>851</sup> Beraud et al., “Hypochlorite Bleaches,” September 25, 2019, 39; Chambers, “Why You Cannot Transport Bleach inside Water Tanks,” March 14, 2018; ACC, written submission to USITC, September 21, 2020, Annex 2; industry representative, telephone interview by USITC staff, November 9, 2020.



**Figure 6.1** Geographical distribution of establishments, soap and cleaning compound manufacturing, first quarter 2020



Source: Bureau of Labor Statistics (BLS), Quarterly Census of Employment and Wages, First Quarter 2020, NAICS 32561 (accessed October 2020).

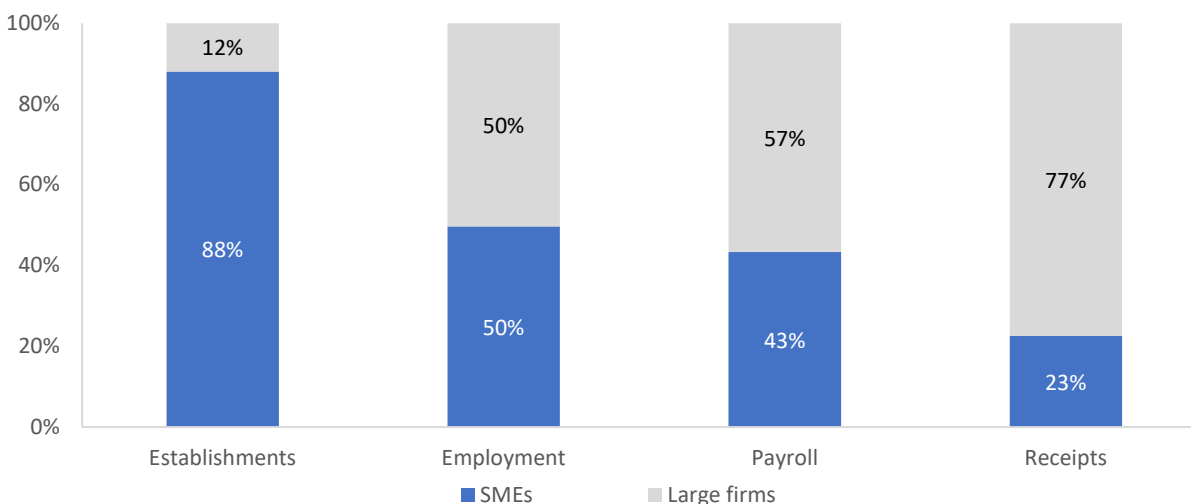
Note: An establishment is “a single physical location at which business is conducted or services or industrial operations are performed.” For more information, see Census Bureau, “Glossary,” <https://www.census.gov/programs-surveys/susb/about/glossary.html> (accessed August 13, 2020). Underlying data for this figure can be found in [appendix table E.35](#).

The U.S. industry producing soaps and cleaning compounds ranges from large consumer product firms, such as Clorox, Colgate-Palmolive, and Procter and Gamble, to specialty chemical manufacturers such as Hocking International Laboratories, Wacker, Solvay, and Arkema.<sup>852</sup> These large firms supplied the majority of U.S. production in 2017, with small firms providing less than a quarter of total shipments (figure 6.2).<sup>853</sup> Cleaning product manufacturers also include small firms making niche products (e.g., artisanal soaps and unique leather cleaning agents) that do not have a large share of the overall market.

<sup>852</sup> See, for example: Terlep, “Why Clorox Wipes,” May 7, 2020; Umstead, “Employment at P&G,” November 13, 2019; Selko, “Colgate-Palmolive Opening,” October 7, 2013; Hocking, “Hocking International COVID-19 Statement,” March 20, 2020; American Chemistry Council, “COVID-19 Member Response” (accessed October 10, 2020).

<sup>853</sup> BLS, “Quarterly Census of Employment and Wages” (accessed October 18, 2020).

**Figure 6.2** Soap and cleaning compound establishments, employment, payroll, and receipts, by enterprise size, 2017



Source: U.S. Census Bureau, Statistics of U.S. Businesses data, NAICS 32561 (accessed August 2020).

Note: Data for receipts are preliminary data. “Receipts (net of taxes collected from customers or clients) are defined as operating revenue for goods produced or distributed, or for services provided.” Business size is based on the size of the enterprise. “An enterprise (or ‘company’) is a business organization consisting of one or more domestic establishments that were specified under common ownership or control.” For more information, see Census, “Glossary” (accessed August 13, 2020). Underlying data for this figure can be found in [appendix table E.36](#).

## U.S. Production

U.S. soap and cleaning compound production and value added were relatively flat from 2015–18, reflecting the mature domestic market.<sup>854</sup> The U.S. industry ships a range of products; detergents accounted for almost half of U.S. shipments in 2016, the latest year for which disaggregated data are available. Other large categories of products shipped included surface-active agents, specialty cleaning and sanitation products, and household soaps and bleaches (figure 6.3). U.S. manufacturers of soaps and disinfectants used in the COVID-19 response generally reported substantially higher sales in the first half of 2020.<sup>855</sup> To meet demand, these firms increased factory hours, added production lines, contracted out additional manufacturing, and focused production capacity on products used in the COVID-19 response.<sup>856</sup> Firms also endeavored to prioritize delivery to healthcare institutions over

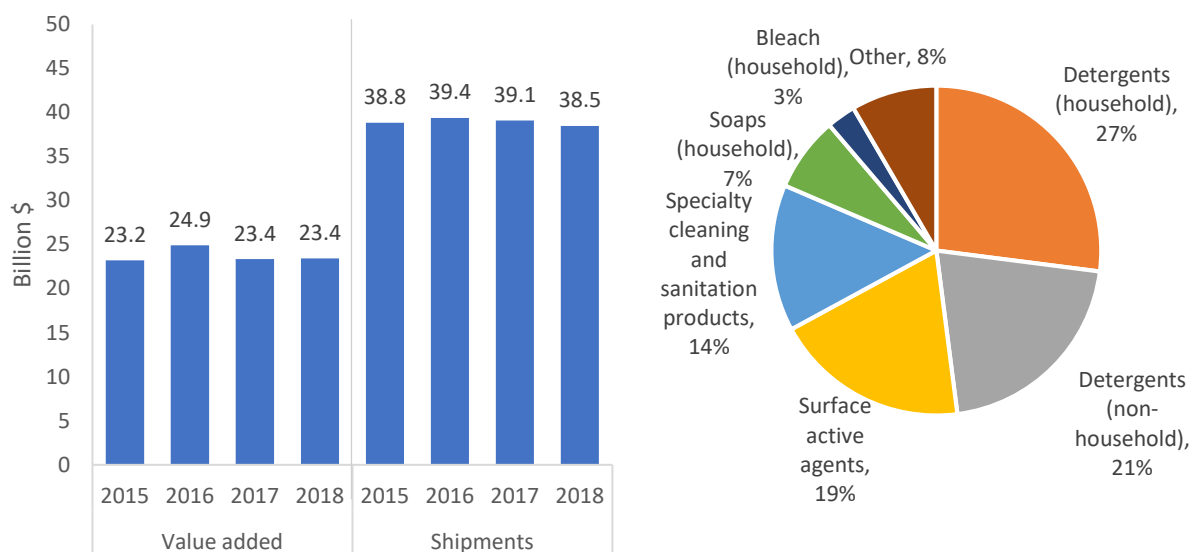
<sup>854</sup> U.S. Census Bureau, Annual Survey of Manufactures and Economic Census data, NAICS 32561 (accessed August 2020); USITC DataWeb/USDOC, NAICS 32561 (accessed October 19, 2020).

<sup>855</sup> Terlep, “Clorox, with Its Sales,” August 3, 2020; Back, “Colgate-Palmolive Signals,” July 31, 2020; Terlep, “Procter and Gamble Posts,” July 30, 2020; Chaudhuri, “Lysol Maker Seeks,” July 28, 2020; Chaudhuri, “Lysol Maker Bets,” April 30, 2020.

<sup>856</sup> Terlep, “Clorox’s New CEO,” September 25, 2020; Terlep, “Clorox, with Its Sales,” August 3, 2020; Terlep, “Why Clorox Wipes,” May 7, 2020; Phillips, “Lysol Factory Job,” April 21, 2020; Hillsborough Beacon, “Hillsborough Is Home,” September 3, 2020; Gao, “Why Disinfectant Wipes,” July 25, 2020; Mak, “Why It’s Still So Tough,” July 21, 2020.

consumers to aid in the response to the pandemic.<sup>857</sup> Nevertheless, they still encountered challenges in sourcing key inputs, such as fabric for wipes, chemical inputs, and packaging materials.<sup>858</sup>

**Figure 6.3** Soap and cleaning compound shipments and value added, 2015–18 (left, in billion dollars) and share of shipments by product type, 2016 (right, percent of shipments)



Source: U.S. Census Bureau, Annual Survey of Manufactures and Economic Census data, NAICS 32561 (accessed August 2020).

Note: Underlying data for this figure can be found in [appendix table E.37](#).

Although most soaps and cleaning compounds are produced domestically, many rely on imported raw material inputs, and increases in input costs can ultimately affect the price of the final formulations. From early 2016 through the end of 2018, the prices of U.S. soap and cleaning compounds increased significantly (about 7 percent), reflecting, in part, increased U.S. tariffs on relevant chemical inputs during that time.<sup>859</sup> Besides the added duties, there was also an increase in the price of certain widely used inputs; notably, coconut and palm oil prices increased during this period.<sup>860</sup> Nonetheless, U.S. manufacturers have largely maintained prices during the pandemic, with the producer price index for these products increasing by less than 0.3 percent during January to September 2020.<sup>861</sup>

<sup>857</sup> Gojo Industries, “Front Lines Prioritized by Purell Brand,” April 13, 2020; industry representative, telephone interview by USITC staff, November 9, 2020.

<sup>858</sup> Terlep, “Clorox, with Its Sales,” August 3, 2020; Chaudhuri, “Soap Makers Are Cleaning Up,” July 10, 2020; Gao, “Why Disinfectant Wipes,” July 25, 2020; Tullo and Bettenhausen, “Disinfectant Demand,” April 15, 2020; Kavilanz, “No One Can Get,” May 1, 2020; Mak, “Why It’s Still So Tough,” July 21, 2020.

<sup>859</sup> A number of chemical inputs were subject to section 301 tariffs as part of tranche 3. ACC, written submission to USITC, September 21, 2020, 11.

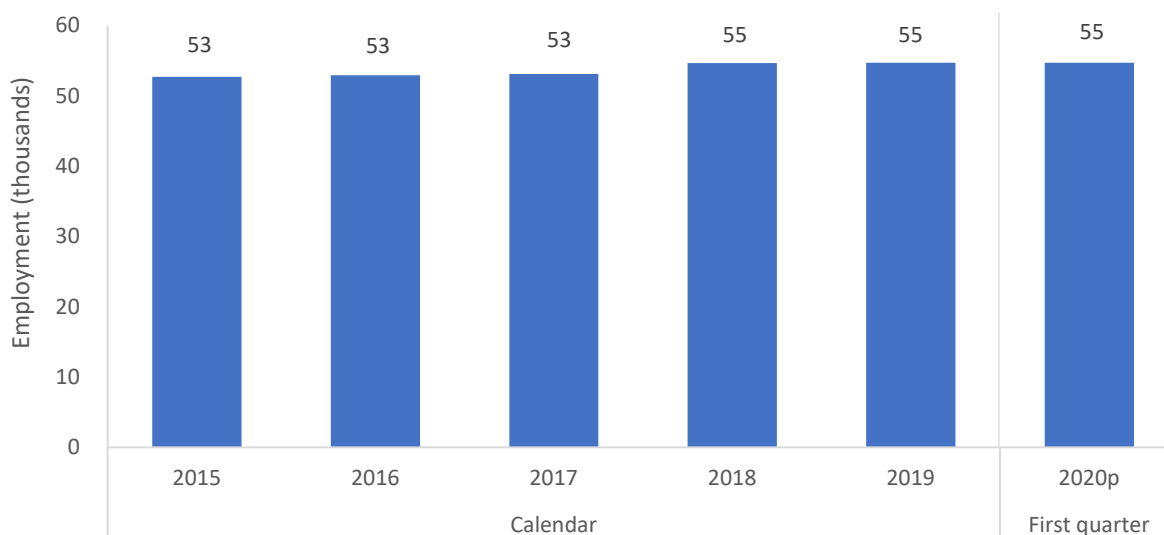
<sup>860</sup> Palm oil prices increased from 2016 to 2017, then declined in 2018; coconut oil prices similarly declined during 2017–18. Plecher, “Average Prices for Palm Oil Worldwide from 2014 to 2025,” August 4, 2020; Plecher, “Average Prices for Coconut Oil Worldwide from 2014 to 2025,” August 4, 2020.

<sup>861</sup> BLS, “Producer Price Indexes,” NAICS 32561 (accessed October 18, 2020).

## U.S. employment

U.S. employment in soap and cleaning compound manufacturing increased modestly during 2015–19, rising by about 4 percent (figure 6.4).<sup>862</sup> In 2019, soap and other detergent manufacturing accounted for the largest share of employment (48 percent), followed by manufacturing of polish and other sanitation goods (43 percent).<sup>863</sup> In response to the increased demand and rise in production, employment in the industry increased by 5 percent in 2020, rising by about 2,800 employees from January to August 2020 on a seasonally adjusted basis (3,400 or 6 percent on a non-seasonally adjusted basis).<sup>864</sup>

**Figure 6.4** U.S. employment, soap and cleaning compound manufacturing, 2015–19 and first quarter 2020 (in thousand employees)



Source: BLS, “Quarterly Census of Employment and Wages,” NAICS 32561 (accessed October 2020).

Note: p=preliminary. Underlying data for this figure can be found in [appendix table E.38](#).

## U.S. Imports

Imports of soap and cleaning compounds marginally increased from 2015–19, averaging 3 percent year-over-year growth (figure 6.5). As noted, most domestic demand was met by U.S. production; what the United States did import was sourced primarily from Canada and Mexico before the pandemic. This situation reflects the generally lower value-to-weight ratio of these commodities, which normally incentivizes shorter trade routes to minimize transportation costs. Even so, U.S. imports from China, the third-largest supplier, increased 39 percent from 2015–18. Imports then fell 15 percent in 2019 following the imposition of section 301 tariffs. Following the onset of the pandemic, U.S. imports of soap and cleaning products rose 30 percent during January–September 2020 compared with the same period

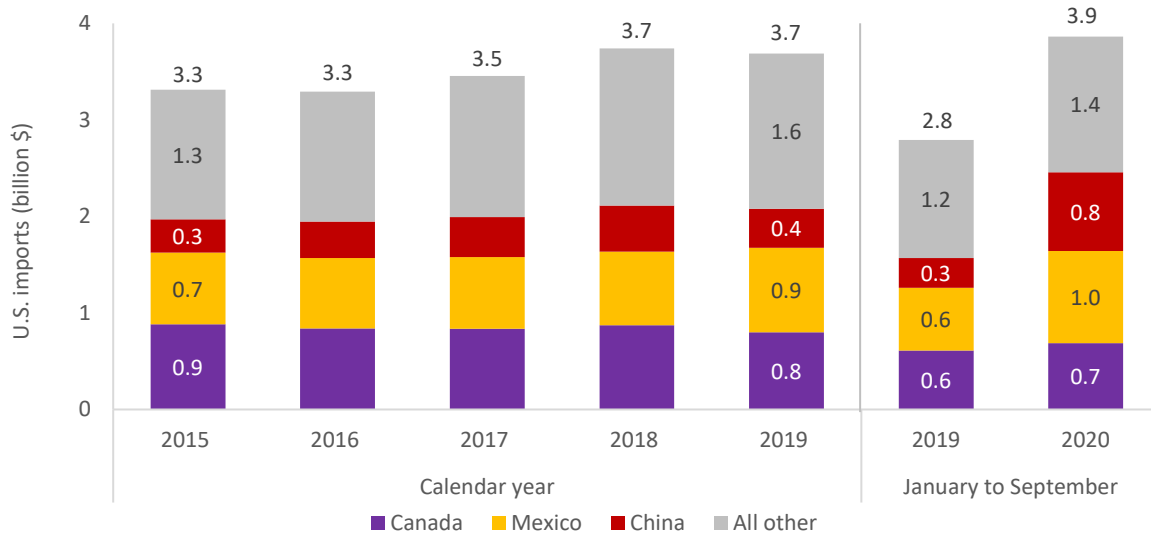
<sup>862</sup> BLS, “Quarterly Census of Employment and Wages” (accessed August 2020).

<sup>863</sup> BLS, “Quarterly Census of Employment and Wages” (accessed August 2020).

<sup>864</sup> These data are from the Current Employment Statistics rather than the Quarterly Census of Employment and Wages generally used in the report, and therefore are not reflected in the figure. BLS, Current Employment Statistics (accessed October 19, 2020).

in 2019; the increase in imports came mostly from China (up \$511 million, 166 percent) and Mexico (\$304 million, 47 percent).<sup>865</sup> According to industry sources, the magnitude of demand compelled traditionally U.S.-centric producers to seek offshore supplies to help fulfill the need for COVID-19 related soaps and cleaning compounds.<sup>866</sup>

**Figure 6.5** U.S. imports of soaps and cleaning compounds, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)



Source: USITC DataWeb/USDOC, NAICS 32561 (accessed November 2020).

Note: Underlying data for this figure can be found in [appendix table E.39](#).

Duties paid on imported soaps and cleaning compounds have increased substantially since 2017. The share of imports subject to duties increased from 23 percent in 2015 to 29 percent in 2019, and the average trade-weighted applied tariff rate for dutiable items increased from 4.6 percent to 13.4 percent. The higher duty rates reflect the imposition of section 301 tariffs on Chinese goods.<sup>867</sup>

## U.S. Exports

Soap and cleaning compound exports were relatively constant from 2015–19 and were just 3 percent higher in January through September 2020 compared to the same period in 2019 (figure 6.6). Canada and Mexico are the largest markets for U.S. soap and cleaning compound exports, together accounting

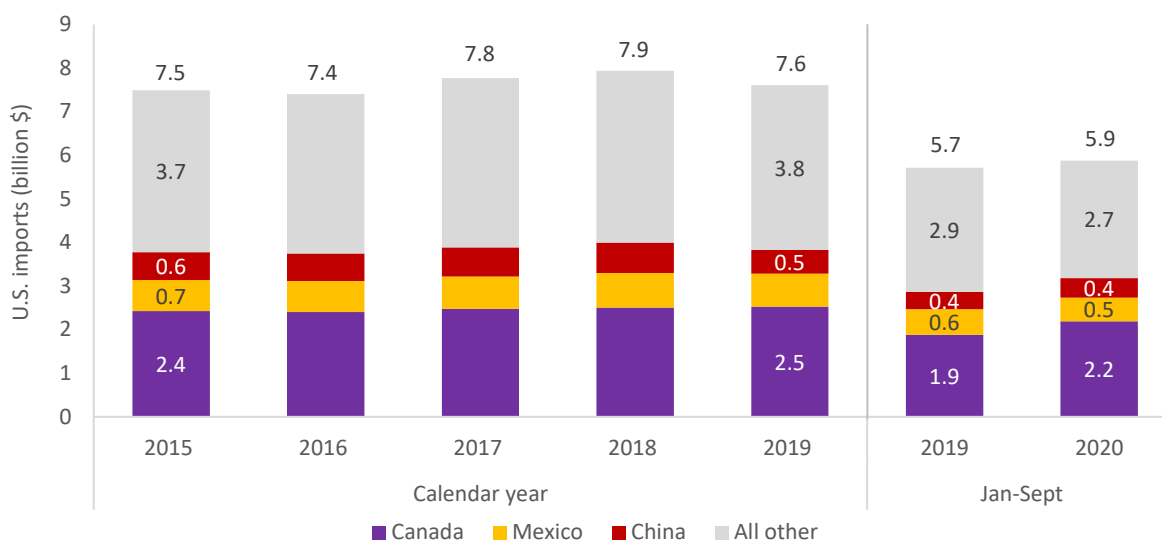
<sup>865</sup> Imports from China increased across all types of soaps and cleaning compounds, with total imports of soaps and other detergents (NAICS code 325611) up 105 percent in January–September 2020 compared to the same period in 2019, imports of surface-active agents (NAICS 325613) up 115 percent, and most substantially, imports of polishes and other sanitation goods (NAICS 325612) up 818 percent. Imports from Mexico also increased across the board, although less so among soaps and other detergents (up 15 percent) and surface-active agents (up 32 percent), compared to polishes and other sanitation goods (up 1,021 percent). USITC DataWeb/USDOC (accessed September 30, 2020).

<sup>866</sup> Industry representative, telephone interview by USITC staff, November 9, 2020.

<sup>867</sup> USITC DataWeb/USDOC (accessed November 2020).

for over 40 percent of U.S. exports in 2019. U.S. export prices, like producer prices, rose from 2015–19.<sup>868</sup>

**Figure 6.6** U.S. exports of soaps and cleaning compounds, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)



Source: USITC DataWeb/USDOC, NAICS 32561 (accessed November 2020).

Note: Underlying data for this figure can be found in [appendix table E.40](#).

## Hand Sanitizer

### Major Findings

- U.S. producers typically supply a significant share of the domestic hand sanitizer market.
- U.S. hand sanitizer demand substantially increased as a result of the pandemic, and by March–April 2020 there were hand sanitizer shortages.
- U.S. producers were able to increase production quickly, aided by the U.S. Food and Drug Administration (FDA) publishing an approved formulation for hand sanitizer and a temporary policy enabling new entrants to make hand sanitizer). This allowed nontraditional producers (e.g., distillers) to more easily step in to make hand sanitizer, since they had access to equipment and alcohol (a primary input).
- U.S. imports started to increase rapidly in April 2020, reaching their peak in July 2020.
- The main challenge for U.S. producers was the sourcing of inputs.

<sup>868</sup> BLS, “Import/Export Price Indexes” (accessed August 2020).

- The main challenge for importers was the proliferation of dangerous products following the relaxation of standards. These products were later recalled.

## Introduction

In January and February 2020, U.S. demand for hand sanitizer rapidly increased as the number of confirmed cases of COVID-19 rose around the world. U.S. imports skyrocketed starting in April 2020, and U.S. production rose as firms entered the market from other industries. The rapid increase in production led to shortages of inputs, initially alcohol and subsequently packaging materials. The main challenges that importers faced was the proliferation of unsafe product (i.e., toxic) that could not be used. The supply of hand sanitizer quickly increased, and many of the new entrants had exited the industry by September 2020.

## Product Overview

Hand sanitizer is a liquid, gel, or foam used to clean the hands and kill infection-causing germs.<sup>869</sup> Most hand sanitizers are alcohol-based, made up largely of alcohol and water. They may also contain other ingredients, such as emollients, fragrances, and colorings (figure 6.7).<sup>870</sup> Most production uses either ethyl alcohol (ethanol) or isopropyl alcohol. Ethanol is made to a variety of grades, and specifications used in a variety of industries (e.g., fuel, food, medical); a distinguishing factor of medical grade ethanol is that it is approved for treatment for the skin.<sup>871</sup> The Centers for Disease Control (CDC) largely endorsed handwashing as the preferred method to control the spread of COVID-19, but recommended the use of hand sanitizers containing at least 60 percent alcohol when handwashing was not possible.<sup>872</sup>

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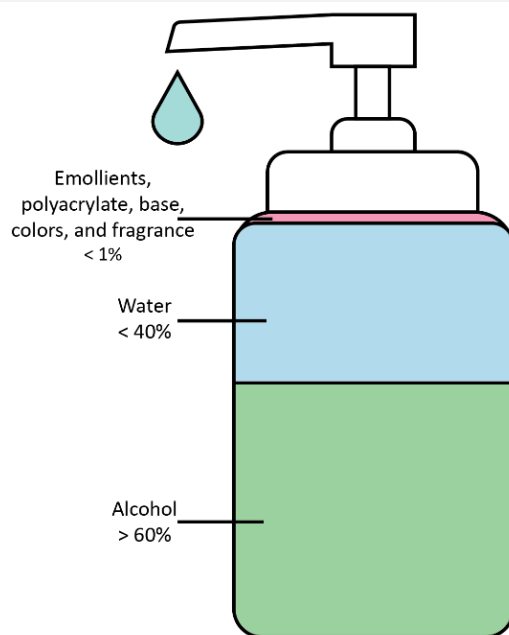
<sup>869</sup> FDA Website, “Guidance for Industry,” March 2020; Murugesu, “Hand Sanitiser [sic]” (accessed November 9, 2020).

<sup>870</sup> Hand sanitizer is manufactured using the following alcohols: alcohol (ethanol) that is not less than 94.9 percent ethanol by volume, or United States Pharmacopeia (USP grade) isopropyl alcohol. FDA Website, “Guidance for Industry,” March 2020.

<sup>871</sup> “Medical grade” is typically high purity ethanol and is USP certified. Grain Processing Corporation, “Alcohol Grades” (accessed October 15, 2020); FDA Website, “Policy for Temporary Compounding,” March 2020; ClearSolv, “Ethyl Alcohol (Ethanol)” (accessed November 9, 2020).

<sup>872</sup> FDA Website, “Guidance for Industry,” March 2020, 2.

**Figure 6.7** Hand sanitizer ingredients



Source: USITC based on *Chemistry and Engineering News*.

## U.S. Market

In 2019, the United States was the largest global hand sanitizer market, with retail hand sanitizer sales of almost \$200 million.<sup>873</sup> Typical channels of distribution for hand sanitizers include retail (for direct sale to consumers), commercial, industrial, and institutional channels, such as hospitals. The top selling hand sanitizer brands in 2019 were Purell and Germ-X; however, private-label brands combined made up 48 percent of consumer sales.<sup>874</sup>

The pandemic resulted in a sharp increase in demand in 2020, with U.S. retail sales of hand sanitizer increasing from \$25 million in February 2020 to more than \$150 million in June 2020.<sup>875</sup> From March to June 2020, some hand sanitizer production was primarily directed toward healthcare providers and first responders, in line with the direction from government officials; as supply caught up, companies started to provide product to general consumers.<sup>876</sup>

<sup>873</sup> The total U.S. market size, including hand wipes, was \$515 million in 2017, according to an estimate by Grand View Research. Research and Markets, "United States Hand Sanitizer Industry to 2025," April 24, 2020; Vogt, "These Unknown Brands Took Over," August 5, 2020; Grand View Research, "Hand Sanitizer Market Size," April 2020.

<sup>874</sup> Private-label brands sell custom-branded hand sanitizers, made according to FDA standards, with the client's preferred logo. Henneberry, "Top Suppliers of Hand Sanitizer" (accessed November 9, 2020); Statista, "Leading Hand Sanitizer Brands in the United States," September 7, 2020.

<sup>875</sup> Chaudhuri, "Unilever Capitalizes," July 23, 2020; Ochwat, "Nielsen's New May Data," May 29, 2020; Pisani, "Looking for Hand Sanitizer," March 4, 2020; Chain Drug Review, "Nielsen: Coronavirus Having Huge Impact on Hand Sanitizer Sales," February 28, 2020.

<sup>876</sup> Gojo Industries, "Front Lines Prioritized by Purell Brand," April 13, 2020.



## U.S. Manufacturing Industry

The United States has a substantial domestic hand sanitizer manufacturing industry. Producers of leading brands—such as Gojo Industries (maker of Purell, produced in Cuyahoga Falls and Wooster, both in Ohio) and Vi-Jon (Germ-X, produced in Smyrna, Tennessee, and St. Louis, Missouri)—operate multiple plants in the United States and supplied 35.5 percent of total 2019 sales.<sup>877</sup> There is also extensive manufacturing by firms that produce less commonly known brands and/or private-label brands for retailers, such as Best Sanitizers (Walton, Kentucky), Nutrix (Salt Lake City, Utah), HealthSpecialty (Santa Fe Springs, California), Cosmetic Solutions (Boca Raton, Florida), and Carroll Company (Garland, Texas).<sup>878</sup>

Established U.S. hand sanitizer producers rapidly increased production well before the pandemic was declared. Gojo Industries immediately increased production in December 2019 upon the news of a developing outbreak in China; Gojo’s manufacturing facilities were working around the clock at the same time that the company was investing in a new facility (in Navarre, Ohio) for storage and distribution.<sup>879</sup> Vi-Jon, producer of the second-best-selling U.S. hand sanitizer, announced in October 2020 that it would invest \$70 million in its facilities (in Smyrna and St. Louis) with the expectation of adding about 400 jobs.<sup>880</sup>

While production expanded for established manufacturers, several new firms entered the market when supplies were tight. Among those were chemical, cosmetic, alcoholic beverage, and medical supply producers. In March 2020, for example, medical supply firm Medline Industries (Hartland, Wisconsin, and Meriden, Connecticut), brought new production capacity on line in just three weeks.<sup>881</sup> Similarly, in April 2020, cleaning product producer SC Johnson partnered with chemical firm, Dow, to convert a line reserved for product testing at Dow’s largest global manufacturing plant (in Mount Pleasant, Wisconsin) to hand sanitizer production.<sup>882</sup> Further, over 800 distilleries began to produce hand sanitizers to assist in getting supply to consumers.<sup>883</sup> Distillers were uniquely positioned to pivot toward hand sanitizer production because they had the primary ingredient—ethanol—to produce hand sanitizers, and already had the distilled spirits permits required to handle ethanol of the type used both for liquor and as a hand sanitizer ingredient.<sup>884</sup> The fact that many distilleries had temporarily shut down, coupled with the

<sup>877</sup> Henneberry, “Top Suppliers of Hand Sanitizer” (accessed November 9, 2020); Statista, “Leading Hand Sanitizer Brands in the United States,” September 7, 2020; Leggate, “Where to find hand sanitizers,” March 6, 2020.

<sup>878</sup> Best Sanitizers, “Our Manufacturing Facility” (accessed September 13, 2020); Nutrix, “Hand Sanitizer, Private Label Manufacturer” (accessed September 13, 2020); HealthSpecialty, “Contract Manufacturing, Made in USA” (accessed September 13, 2020); Cosmetic Solutions, “The Process: Skin Care Contract Manufacturing” (accessed November 9, 2020); Carroll Company, “Contract Manufacturing” (accessed September 13, 2020).

<sup>879</sup> The company expects that expansion will employ 100 workers. Gojo, “GOJO Continues to Add Production Capacity,” May 5, 2020; Gojo, “Gojo Takes Significant Steps to Expand Its Capacity,” June 9, 2020. Gojo Corporate Statement, “GOJO Manufacturing Operations Running 24/7,” March 13, 2020.

<sup>880</sup> Cotton, “New Jobs Heading,” October 7, 2020; Kirn, “Manufacturer adding Middle Tennessee,” October 7, 2020.

<sup>881</sup> Once production started, 120 employees produced 200,000 bottles within three weeks. Medline, “200,000 Bottles,” April 20, 2020.

<sup>882</sup> SC Johnson, “SC Johnson Converts Line,” April 22, 2020.

<sup>883</sup> Browning, “Distilleries Raced,” August 4, 2020

<sup>884</sup> Buchanan, “A Look Inside How Distilleries” (accessed November 9, 2020).

updated FDA compounding guidelines<sup>885</sup> and later guidance, meant that distillers could enter production rapidly to bridge the gap between supply and demand. Although demand is still high, it has dropped considerably in recent months. Given this shift and the fact that more hand sanitizer capacity came online at larger companies during the summer, many distillers have returned to alcohol production.<sup>886</sup>

## U.S. Imports

The United States also imports hand sanitizers from various countries.<sup>887</sup> From January 2019 to March 2020, monthly imports of hand sanitizer via ocean freight were relatively low, typically not exceeding 1,000 metric tons per month (figure 6.8).<sup>888</sup> U.S. imports began to increase in April 2020, peaking in July at more than 90,000 metric tons before falling in August. China was the leading source of imports via ocean freight, followed by South Korea.<sup>889</sup> The United States also imports hand sanitizer from Mexico. These imports are primarily transported by land and are generally not captured in the data presented below.<sup>890</sup>

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<sup>885</sup> FDA prepared guidance describing its policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in state or territory-licensed pharmacies, federal facilities, and registered outsourcing facilities. New entrants, such as distilleries, also had to adhere to these guidelines, which included policies on denaturing their alcohol. FDA, “Temporary Policy Compounding,” 6, August 7, 2020; Brandt, “TTB Announces Exemption,” March 18, 2020; Curpen et al., “New Exemptions and Specific Requirements,” April 15, 2020.

<sup>886</sup> Browning, “Distilleries Raced,” August 4, 2020; Pomranz, “Distilleries Are Stuck,” August 4, 2020; Janzen, “How Distilleries Are Navigating,” April 6, 2020; Zhang, “Having Pivoted at the Start,” August 4, 2020.

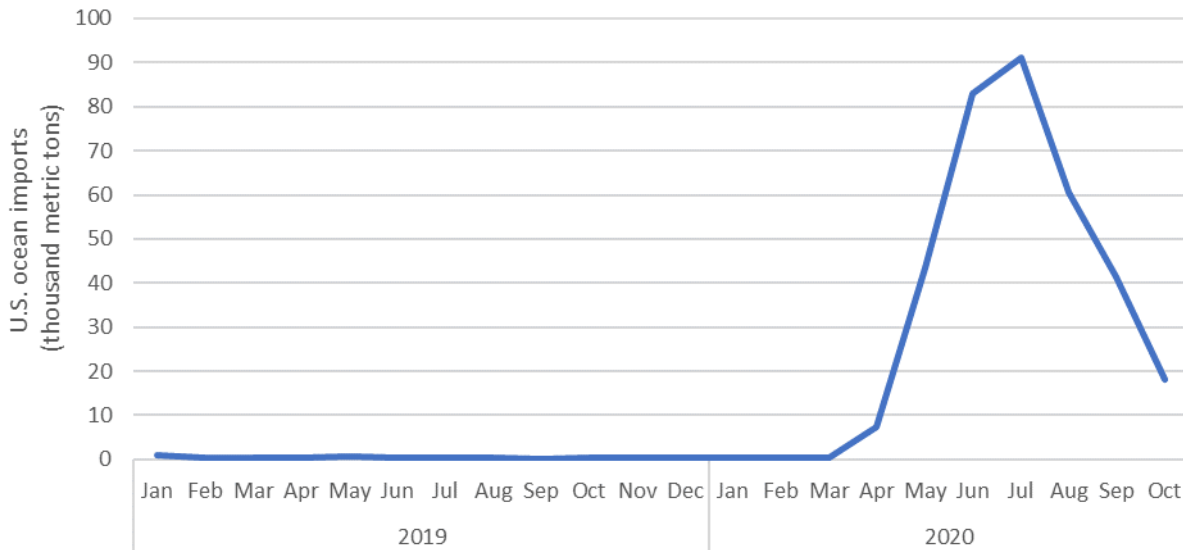
<sup>887</sup> Imports of hand sanitizer are classified in the Harmonized Tariff Schedule of the United States (HTS) under 10-digit statistical reporting number 3824.99.9297, which is a basket category. Such goods are excluded from section 301 duties. HTS chapter 99 subchapter 3 note 20.

<sup>888</sup> Trade Data Information Services, Import Genius database (accessed September 1, 2020).

<sup>889</sup> Examples of leading suppliers in China included Fujian Haojin Toiletries Co. Ltd., Guangzhou Xuelei Cosmetic Co. Ltd., and Nanjing Aogrand International Trade. Trade Data Information Services, Import Genius database (accessed September 1, 2020); Touchland, “Safety Manufacturing Update” (accessed October 19, 2020).

<sup>890</sup> Trade Data Information Services, Import Genius database (accessed September 1, 2020).

**Figure 6.8** U.S. imports of hand sanitizer by ocean freight, by volume, January 2019–October 2020 (in thousands metric tons)



Source: Trade Data Information Services, Import Genius database (accessed November 8, 2020).

Note: Data only include those goods in shipping manifest records that could specifically be identified as hand sanitizer. Further, records that included both hand sanitizer and other items were excluded. The excluded shipments represented less than 5 percent of hand sanitizer imports during January to October 2020.

## Supply Chain Challenges and Constraints

During the March–April timeframe, the supply of hand sanitizer was extremely constricted, with demand outstripping supply. Production rapidly increased, but as it did so domestic producers, both existing producers and new entrants, faced challenges sourcing inputs. Some new producers also struggled to meet the regulatory requirements specific to hand sanitizer. Imports also rapidly increased, but some of these products contained harmful substances.

### Factors Affecting U.S. Production

The just-in-time supply chain approach used by hand sanitizer producers before the onset of the pandemic created several supply chain challenges that affected domestic production and distribution.<sup>891</sup> The rapid increase in production resulted in shortages and price increases for a number of inputs—including bottles, caps, alcohol, seals, and thickener—for the final product.<sup>892</sup>

Initially, the primary supply chain constraint for producers was the alcohol used in making hand sanitizers. Before the pandemic, producers only stored enough alcohol to supply projected near-term production because of its inherent chemical properties, including its liquid state and limited shelf life.<sup>893</sup>

<sup>891</sup> Ogbe, “Shortage in Supply Can Halt Hand Sanitizer Production,” April 5, 2020; Holde, “Shortages Delay Production of Hand Sanitizers,” April 3, 2020.

<sup>892</sup> Vogt, “These Unknown Brands Took Over,” August 5, 2020; Lodging Kit Company, “Private Label Hand Sanitizer, Gel, 75% Alcohol” (accessed September 13, 2020); Holde, “Shortages Delay Production of Hand Sanitizers,” April 3, 2020; Terlep, “One Company’s Hands-On Effort to Ramp Up Sanitizer Production,” March 16, 2020.

<sup>893</sup> Hoke, “Shortage of Ingredients Delays Production of Sanitizers,” April 1, 2020.

Hence, the spike in demand caused the price per pound of ethyl alcohol to jump to six to eight times its normal level, while isopropyl prices more than tripled compared to pre-COVID-19 pricing.<sup>894</sup>

Both new and established producers struggled with later shortages that developed for additional inputs, such as bottles, caps, and seals.<sup>895</sup> As the latter are essential inputs for the whole soap and cleaning product industry, hand sanitizer producers had to compete with other manufacturers to source these packaging items.<sup>896</sup> While firms such as AptarGroup, a U.S. dispenser manufacturer, increased investment to produce dispenser pumps at a faster rate, firms continued to face challenges in meeting product demand.<sup>897</sup> However, some companies, such as Gojo Industries and Medline, were already producing these inputs in-house, which helped lessen supply constraints for production.<sup>898</sup>

Nontraditional entrants to the market faced challenges in adapting to meet the regulatory requirements specific to hand sanitizer. Some new producers of hand sanitizer, particularly distillers of libations, had to evolve their operations to meet regulatory standards for the product. The FDA required distillers to turn spirits into denatured alcohol to discourage people from drinking the hand sanitizer.<sup>899</sup> This required expensive ingredients that became an obstacle to acquire and can irreparably contaminate the distillers' equipment for the future production of spirits.<sup>900</sup> To ease some of the burden wrought by other regulations, the FDA waived the requirements to obtain additional permits to manufacture hand sanitizers or to supply ethanol for use in the production of hand sanitizers. Another agency, the U.S. Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB), exempted producers from paying the federal excise tax on alcohol in the case of sanitizer made with denatured ethanol.<sup>901</sup> Once the hand sanitizer market recovered, the distilleries that had initially stepped in to produce in March and April began to curtail hand sanitizer production by the fall of 2020.<sup>902</sup>

## Factors Affecting U.S. Imports

Quality assurance of imported product was a serious challenge encountered by importers. After March 20, 2020, when the regulatory requirements were relaxed, there was a sudden influx of new brands into the market. Some of these proved to be contaminated, including product that was sold to

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<sup>894</sup> According to S&P Global Platts, isopropyl alcohol prices in the United States have more than tripled since March 10, 2020. They reached \$3,160 per metric ton on March 31, 2020, the highest price on record (dating back to 1986). Wallace, "Coronavirus Pandemic Sparks," April 3, 2020; Kaplan, "Stocked Out," August 20, 2020.

<sup>895</sup> Chaudhuri, "Soap Makers Are Cleaning Up," July 10, 2020.

<sup>896</sup> Mak, "The Real Reason," September 10, 2020; Johnson, "Manufacturers of Liquid Soap," July 17, 2020.

<sup>897</sup> Johnson, "Manufacturers of Liquid Soap," July 17, 2020.

<sup>898</sup> Byard, "GOJO to Expand," May 29, 2015; Medline, "Bottle Pumps" (accessed October 1, 2020).

<sup>899</sup> Denatured alcohol, or denatured rectified spirit, is ethanol that has additives to make it poisonous, bad-tasting, foul-smelling, or nauseating in order to discourage recreational consumption. Kunkel, "Why Aren't Distilleries," June 4, 2020; Browning, "Distilleries Raced," August 6, 2020; USITC, hearing transcript, September 24, 2020, 450 (testimony of Robert M. Tobiassen, National Association of Beverage Importers); FDA Website, "Temporary Policy Compounding," August 7, 2020, 6; McGuireWoods, "Got Hand Sanitizer?," March 24, 2020; Brandt, "TTB Announces Exemption," March 18, 2020; FDA, "Temporary Policy Compounding," August 7, 2020.

<sup>900</sup> Browning, "Distilleries Raced," August 6, 2020; USITC, hearing transcript, September 24, 2020 (testimony of Robert M. Tobiassen, National Association of Beverage Importers); FDA, "Temporary Policy Compounding," August 7, 2020.

<sup>901</sup> McGuireWoods, "Got Hand Sanitizer?," March 24, 2020; Brandt, "TTB Announces Exemption," March 18, 2020.

<sup>902</sup> Kunkel, "Why Aren't Distilleries," June 04, 2020; Zhang, "Having Pivoted," August 4, 2020.

consumers (the primary contaminant, methanol, can be toxic when absorbed through the skin).<sup>903</sup> By mid-June, the FDA identified over 135 products containing toxic chemicals in the market; FDA warned consumers not to use these products and issued a voluntary recall.<sup>904</sup> These products were produced by various companies, but primarily originated in Mexico.<sup>905</sup> As of September 30, 2020, U.S. government officials reported seizures of more than 300,000 counterfeit and illicit hand sanitizers at the border.<sup>906</sup>

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<sup>903</sup> Shaban, “FDA Says to Avoid,” August 8, 2020; FDA, “Coronavirus (COVID-19) Update,” July 27, 2020; FDA, “Q&A for Consumers,” September 17, 2020.

<sup>904</sup> Shaban, “FDA Says to Avoid,” August 8, 2020; FDA, “Coronavirus (COVID-19) Update,” July 27, 2020.

<sup>905</sup> Several U.S.-made hand sanitizers have also been recalled. FDA, “FDA Updates on Hand Sanitizers” (accessed September 14, 2020); Shaban, “FDA Says to Avoid,” August 8, 2020.

<sup>906</sup> U.S. government official, email message to USITC staff, October 22, 2020.



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# **Appendix A Request Letter**



DOCKET NUMBER  
3485  
OFFICE OF THE  
SECRETARY  
INT'L TRADE  
COMMISSION

**Congress of the United States**  
Washington, DC 20515

RECEIVED 5:00 P.M.  
August 13, 2020  
OFFICE OF THE  
SECRETARY  
U.S. INT'L TRADE  
COMMISSION

August 13, 2020

The Honorable Jason E. Kearns  
Chairman  
U.S. International Trade Commission  
500 E Street, SW  
Washington, DC 20436

Dear Chairman Kearns:

In response to a request made by the House Committee on Ways and Means and Senate Committee on Finance on April 6, 2020, the U.S. International Trade Commission (Commission) conducted an expedited investigation, No. 332-576, *COVID-19 Related Goods, U.S. Imports and Tariffs*, and produced a report that identified goods related to treating and otherwise responding to the COVID-19 pandemic. The report also identified the goods' source countries, tariff classifications, and applicable duty rates. The Commission's timely release of that report on May 4, 2020, as well as the follow-up report that it released on June 30, 2020, provided the Committees and USTR with an objective assessment of facts to inform critical policymaking decisions.

In light of the Commission's recent investigation and report, the ongoing pandemic, and the persistent challenges in meeting supply for these critical products, we are writing today to request that the Commission conduct a follow-on investigation and prepare a report under section 332(g) of the Tariff Act of 1930. The report should build on the earlier investigation and report by providing more detailed information on COVID-related industry sectors and particular products identified in the Commission's previous report.

Specifically, we seek information on the following:

- A brief overview of key U.S. industry sectors producing COVID-related goods, including, but not limited to, medical devices; personal protective equipment; and medicines (pharmaceuticals). These overviews should include, to the extent practicable, information on U.S. production, employment, and trade.
- More detailed case studies on key products within each relevant industry sector, such as N95 respirators, ventilators, vaccines, and COVID-19 test kits. We are particularly interested in case studies on products for which there were reported shortages in the first half of 2020, including those affected by supply chain fragility, blockages, or barriers. The case studies should draw upon all available information including the relevant literature, and to the extent practicable, should include information on:

- The U.S. industry, market, and trade, including, to the extent available:
  - An overview of the product, including key components and the production process;
  - Information on the size and characteristics of the U.S. market;
  - An overview of the U.S. manufacturing industry, including key producers of finished goods and intermediate inputs, the extent of U.S. production, and employment;
  - Information on U.S. imports of finished goods and inputs, including leading source countries and supplying firms (to the extent available) ; and
  
- Information on supply chain challenges and constraints, including, but not limited to:
  - Information on factors affecting domestic production, including, to the extent practicable, regulatory requirements that may impact entry into the market.
  - Information on foreign trade barriers and restrictions and other factors that may affect U.S. imports of finished goods or inputs needed for domestic production.

We request that the Commission deliver its report no later than December 15, 2020. As we intend to make the report available to the public, the report should not include confidential business information. Your assistance in this matter is greatly appreciated.

Sincerely,



Richard E. Neal  
Chairman  
Committee on Ways and Means



Charles E. Grassley  
Chairman  
Committee on Finance



Kevin Brady  
Ranking Member  
Committee on Ways and Means

# **Appendix B**

# **Federal Register Notice**







public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the OSMRE; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the OSMRE enhance the quality, utility, and clarity of the information to be collected; and (5) how might the OSMRE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**Abstract:** 30 CFR 872 establishes a procedure whereby States and Indian tribes submit written statements announcing the State/Tribe's decision not to submit reclamation plans, and therefore, will not be granted AML funds.

**Title of Collection:** Abandoned Mine Reclamation Funds.

**OMB Control Number:** 1029-0054.

**Form Number:** None.

**Type of Review:** Extension of a currently approved collection.

**Respondents/Affected Public:** State and Tribal abandoned mine land reclamation agencies.

**Total Estimated Number of Annual Respondents:** 6.

**Total Estimated Number of Annual Responses:** 100.

**Estimated Completion Time per Response:** 150 hours.

**Total Estimated Number of Annual Burden Hours:** 15,000.

**Respondent's Obligation:** Required to Obtain or Retain a Benefit.

**Frequency of Collection:** One time.

**Total Estimated Annual Nonhour Burden Cost:** None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

**Mark J. Gehlhar,**

*Information Collection Clearance Officer,  
Division of Regulatory Support.*

[FR Doc. 2020-18738 Filed 8-25-20; 8:45 am]

**BILLING CODE 4310-05-P**

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-580]

### COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges; Notice of Institution of Investigation and Scheduling of a Public Hearing

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice of institution of investigation and scheduling of a public hearing.

**SUMMARY:** Following receipt on August 13, 2020, of a joint request from the House Committee on Ways and Means and the Senate Committee on Finance (the Committees), under section 332(g) of the Tariff Act of 1930, the U.S. International Trade Commission (Commission) instituted Investigation No. 332-580, *COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges*, for the purpose of providing a report that provides detailed information on COVID-related industry sectors and particular products identified in Commission inv. No. 332-576, *COVID-19 Related Goods, U.S. Imports and Tariffs*.

**DATES:**

*September 11, 2020:* Deadline for filing requests to appear at the public hearing.

*September 14, 2020:* Deadline for filing prehearing briefs and statements.

*September 21, 2020:* Deadline for filing copies of oral testimony to be presented at the hearing.

*September 23, 2020:* Public hearing.

*September 30, 2020:* Deadline for filing post-hearing briefs and statements.

*October 2, 2020:* Deadline for filing all other written submissions.

*December 15, 2020:* Transmittal of Commission report to the Committees.

**ADDRESSES:** All Commission offices are located in the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. All written submissions should be submitted electronically and addressed to the

Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

**FOR FURTHER INFORMATION CONTACT:** Co-Project Leader Samantha DeCarlo (202-205-3165 or [samantha.decarlo@usitc.gov](mailto:samantha.decarlo@usitc.gov)) or Co-Project Leader Andrew David (202-205-3368 or [andrew.david@usitc.gov](mailto:andrew.david@usitc.gov)) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202-205-3091 or [william.gearhart@usitc.gov](mailto:william.gearhart@usitc.gov)). The media should contact Margaret O'Laughlin, Office of External Relations (202-205-1819 or [margaret.olaughlin@usitc.gov](mailto:margaret.olaughlin@usitc.gov)). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202-205-1810. General information concerning the Commission may also be obtained by accessing its website (<https://www.usitc.gov>). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

**Background:** As requested by the Committees, the Commission will conduct an investigation and prepare a report that provides, to the extent practical, the following information:

- A brief overview of key U.S. industry sectors producing COVID-related goods, including, but not limited to, medical devices; personal protective equipment; and medicines (pharmaceuticals). These overviews should include, to the extent practicable, information on U.S. production, employment, and trade.

- More detailed case studies on key products within each relevant industry sector, such as N95 respirators, ventilators, vaccines, and COVID-19 test kits. The Committees stated that they are particularly interested in case studies on products for which there were reported shortages in the first half of 2020, including those affected by supply chain fragility, blockages, or barriers. The Committees stated that the case studies should draw upon all available information including the relevant literature, and to the extent practicable, should include information on:
  - The U.S. industry, market, and trade, including, to the extent available:
    - An overview of the product, including key components and the production process;
    - Information on the size and characteristics of the U.S. market;

- An overview of the U.S. manufacturing industry, including key producers of finished goods and intermediate inputs, the extent of U.S. production, and employment;
- Information on U.S. imports of finished goods and inputs, including leading source countries and supplying firms (to the extent available); and
  - Information on supply chain challenges and constraints, including, but not limited to:
    - Information on factors affecting domestic production, including, to the extent practicable, regulatory requirements that may impact entry into the market; and
    - Information on foreign trade barriers and restrictions and other factors that may affect U.S. imports of finished goods or inputs needed for domestic production.

The Committees asked that the Commission deliver the report no later than December 15, 2020. The Committees stated that they intend to make the Commission's report available to the public and asked that the report not include any confidential business information.

**Public Hearing:** A public hearing in connection with this investigation will be held beginning at 9:30 a.m. on September 23, 2020, using a videoconference platform. More detailed information about the hearing, including how to participate, will be posted on the Commission's website at ([https://usitc.gov/research\\_and\\_analysis/what\\_we\\_are\\_working\\_on.htm](https://usitc.gov/research_and_analysis/what_we_are_working_on.htm)). Once on that web page, scroll down to the entry for Investigation No. 332–580, *COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges*, and click on the link to "Hearing Information." Interested parties should check the Commission's website periodically for updates.

Requests to appear at the public hearing should be filed with the Secretary no later than 5:15 p.m., September 11, 2020, in accordance with the requirements in the "Written Submissions" section below. All prehearing briefs and statements should be filed not later than 5:15 p.m., September 14, 2020, and all post-hearing briefs and statements should be filed not later than 5:15 p.m., September 30, 2020. Post-hearing briefs and statements should address matters raised at the hearing. To facilitate the hearing, including the preparation of an accurate written transcript of the hearing, oral testimony to be presented at the hearing must be submitted to the Commission electronically no later than the close of business September 21,

2020. In the event that, as of the close of business on September 11, 2020, no witnesses are scheduled to appear at the hearing, the hearing will be canceled.

**Written Submissions:** In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received not later than 5:15 p.m., October 2, 2020. All written submissions must conform to the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8), as temporarily amended by 85 FR 15798 (March 19, 2020). Under that rule waiver, the Office of the Secretary will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802), or consult the Commission's Handbook on Filing Procedures.

**Confidential Business Information:** Any submissions that contain confidential business information must also conform to the requirements of section 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "non-confidential" version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

As requested by the Committees, the Commission will not include any confidential business information in the report that it sends to the Committees. However, all information, including confidential business information, submitted in this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel (a) for cybersecurity purposes

or (b) in monitoring user activity on U.S. government classified networks. The Commission will not otherwise disclose any confidential business information in a way that would reveal the operations of the firm supplying the information.

**Summaries of Written Submissions:** Persons wishing to have a summary of their position included in the report should include a summary with their written submission and should mark the summary as having been provided for that purpose. The summary should be clearly marked as "summary for inclusion in the report" at the top of the page. The summary may not exceed 500 words, should be in MS Word format or a format that can be easily converted to MS Word, and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will list the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found.

By order of the Commission.

Issued: August 21, 2020.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2020–18796 Filed 8–25–20; 8:45 am]

BILLING CODE 7020–02–P

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–345]

### Recent Trends in U.S. Services Trade, 2021 Annual Report

**AGENCY:** United States International Trade Commission.

**ACTION:** Schedule for 2021 report and opportunity to submit information.

**SUMMARY:** The Commission has prepared and published annual reports in this series under Investigation No. 332–345, *Recent Trends in U.S. Services Trade*, since 1996. The 2021 report, which the Commission plans to publish in April 2021, will provide aggregate data on cross-border trade in services for the period ending in 2019, and transactions by affiliates based outside the country of their parent firm for the period ending in 2018. The report's analysis will focus on professional services (including management consulting services, research and development services, education services, healthcare services, architecture and engineering services,

# **Appendix C**

## **Calendar of Hearing Witnesses**



**CALENDAR OF PUBLIC HEARING**

Those listed below appeared as witnesses at the United States International Trade Commission’s hearing via videoconference:

**Subject:** COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges

**Inv. No.:** 332-580

**Dates & Time:** September 23 and 24, 2020 – 9:30 a.m.

***Wednesday, September 23, 2020***

**EMBASSY APPEARANCE:**

**Embassy of Canada  
Washington, DC**

**Nadia Bourély, Minister-Counsellor, Economic and Trade Policy**

**PANEL 1: Medical Devices and Safety Equipment**

**ORGANIZATION AND WITNESSES:**

Advanced Medical Technology Association (“AdvaMed”)  
Washington, DC

**Susan Van Meter**, Executive Director, AdvaMedDx

**Abby Pratt**, Vice President of Global Strategy and Analysis,  
Chair of AdvaMed’s COVID-19 Supply Chain Task Force

**Ralph Ives**, Executive Vice President, Head of the Department of  
Global Strategy and Analysis, AdvaMed

Sandler, Travis and Rosenberg, P.A.  
Washington, DC  
on behalf of

Armourx Inc.

**Joe Nadler**, Co-Founder, Armourx Inc.

**Nicole Bivens Collinson**, President, International Trade and  
Government Relations, Sandler Travis and Rosenberg, P.A.

**PANEL 1: Medical Devices and Safety Equipment (continued)**

**ORGANIZATION AND WITNESSES:**

CHF Solutions, Inc.  
Eden Prairie, MN

**Nestor Jaramillo, Jr.**, President and Chief Operating Officer

International Safety Equipment Association (“ISEA”)

**Daniel Glucksman**, Director of Public Affairs, ISEA

Baker & McKenzie LLP  
Washington, DC  
on behalf of

Rexnord Industries, LLC  
Zurn Industries, LLC  
World Dryer Corporation

**Wesley Cline**, Vice President, Global SCM, Zurn Industries, LLC

**Christine M. Streatfeild**) – OF COUNSEL

**PANEL 2: Medical Goods and Supply Chains**

**ORGANIZATION AND WITNESSES:**

Alliance for American Manufacturing (“AAM”)  
Washington, DC

**Scott N. Paul**, President

Carnegie Mellon University  
Pittsburgh, PA

**Professor Erica R.H. Fuchs**, Department of Engineering  
and Public Policy; and Research Associate,  
National Bureau of Economic Research

**Associate Professor Valerie J. Karplus**, Department of  
Engineering and Public Policy

**Nikhil Kalathil**, Doctoral Student, Department of Engineering  
and Public Policy

**PANEL 2: Medical Goods and Supply Chains (continued)**

Center for Global Development  
Washington, DC

**Dr. Prashant Yadav**, Senior Fellow  
Public Citizen  
Washington, DC

**Lori Wallach**, Director, Global Trade Watch Division

**Daniel Rangel**, Research Director

**PANEL 3: Chemicals and Pharmaceuticals**

**ORGANIZATION AND WITNESSES:**

America’s Blood Centers (“ABC”)  
Washington, DC

**Katherine Fry**, Chief Executive Officer

American Chemistry Council (“ACC”)  
Washington, DC

**Ed Brzytwa**, Director, International Trade

Association for Accessible Medicines (“AAM”)  
Washington, DC

**Jonathan Kimball**, Vice President, Trade and International Affairs

Kelley Drye & Warren, LLP  
Washington, DC  
on behalf of

Plasma Protein Therapeutics Association (“PPTA”)

**Amy Efantis**, President and Chief Executive Officer, PPTA

**Paul Rosenthal** ) – OF COUNSEL

***Thursday, September 24, 2020***

**PANEL 4: Distributors and Logistics**

**ORGANIZATION AND WITNESSES:**

Dealmed Medical Supplies, LLC ("Dealmed")  
New York, NY

**Michael Einhorn**, President

Health Industry Distributors Association ("HIDA")  
Alexandria, VA

**Linda Rouse O'Neill**, Vice President, Government Affairs

Techman Sales Inc.  
Plymouth, MI

**David R. Greer, Jr.**, Sales Representative and Minority Owner

Critical Infrastructure Supply Chain Council ("CISCC")  
Arlington, VA

**Bryan Zumwalt**, Executive Vice President, Consumer Brands Association

National Association of Beverage Importers, Inc. ("NABI")  
Washington, DC

**Robert M. Tobiassen**, President



**PANEL 5: Personal Protective Equipment (Textiles, Apparel, and Rubber)**

**ORGANIZATION AND WITNESSES:**

American Apparel & Footwear Association (“AAFA”)

Washington, DC

**Beth Hughes**, Vice President, Trade and Customs Policy

Sorini, Samet & Associates

Washington, DC

on behalf of

Garflex, Inc. (d/b/a Fulflex)

**Anand Kulkarni**, Vice President of Sales, Garflex, Inc.

**Patrick Curtin**, Director of Product Marketing and Technology,  
Garflex, Inc.

**Daniel Neumann**, Vice President of Government Affairs, Sorini,  
Samet & Associates

Vidalia Mills

Vidalia, LA

**Dan Feibus**, President and Chief Executive Officer

Renco Corporation

Manchester, MA

**Richard Alan Renehan**, President and Chief Executive Officer

National Council of Textile Organizations (“NCTO”)

Washington, DC

**Kimberly Glas**, President and Chief Executive Officer

**-END-**



# **Appendix D**

## **Summary of the Views of Interested Parties**



## Views of Interested Parties

Interested parties had the opportunity to file written submissions to the Commission in the course of this investigation and to provide summaries of the positions expressed in the submissions for inclusion in this report. This appendix contains these written summaries, provided that they meet certain requirements set out in the notice of investigation. The Commission has not edited these summaries. This appendix also contains the names of other interested parties who filed written submissions during this investigation but did not provide written summaries. A copy of each written submission is available in the Commission's Electronic Docket Information System (EDIS), <https://www.edis.usitc.gov>. In addition, the Commission also held a public virtual hearing in connection with this investigation on September 23–24, 2020. The full text of the transcript of the Commission's hearing is also available on EDIS.

## Written Submissions

### **Government of Canada**

Written summary attached below.

### **99 Degrees**

No written summary. Please see EDIS for full submission.

### **Advance Medical Design, Inc.**

No written summary. Please see EDIS for full submission.

### **Advanced Medical Technology Association (AdvaMed)**

No written summary. Please see EDIS for full submission.

### **American Air Filter Company, Inc.**

No written summary. Please see EDIS for full submission.

### **American Apparel and Footwear Association**

Written summary attached below.

### **American Blood Centers**

Written summary attached below.

### **American Chemistry Council**

No written summary. Please see EDIS for full submission.

### **Armourx, Inc.**

No written summary. Please see EDIS for full submission.

### **Association for Accessible Medicines**

Written summary attached below.

**ASTM International**

No written summary. Please see EDIS for full submission.

**Carnegie Mellon University**

No written summary. Please see EDIS for full submission.

**CHF Solutions**

No written summary. Please see EDIS for full submission.

**Garflex, Inc., dba Fulflex**

Written summary attached below.

**Gildan Activewear, Inc.**

No written summary. Please see EDIS for full submission.

**Health Industry Distributors Association**

No written summary. Please see EDIS for full submission.

**Healthcare Supply Chain Association**

No written summary. Please see EDIS for full submission.

**Household & Commercial Products Association**

No written summary. Please see EDIS for full submission.

**International Safety Equipment Association**

Written summary attached below.

**Life Science Manufacturing Alliance**

Written summary attached below.

**Medline Industries, Inc.**

No written summary. Please see EDIS for full submission.

**MSA Worldwide, LCC**

No written summary. Please see EDIS for full submission.

**National Association of Beverage Importers**

Written summary included below.

**National Council of Textile Organizations**

Written summary included below.

**Pharmaceutical Research and Manufacturers of America (PhRMA)**

No written summary. Please see EDIS for full submission.

**Plasma Protein Therapeutics Association**

Written summary attached below.

**Public Citizen's Global Trade Watch**

Written summary attached below.

**Rexnord Industries, LLC**

No written summary. Please see EDIS for full submission.

**Standard Textile Co., Inc.**

No written summary. Please see EDIS for full submission.

**Techman Sales, Inc.**

No written summary. Please see EDIS for full submission.

**TSG Finishing, LLC**

No written summary. Please see EDIS for full submission.

**United States Pharmacopeia**

Written summary attached below.

**Varex Imaging Corporation**

No written summary. Please see EDIS for full submission.

**Vidalia Mills**

Written summary attached below.

**Summary for Inclusion in the Report**  
**Government of Canada**  
**U.S. International Trade Commission's (ITC) Investigation on COVID-19-Related Goods and Supply Chain Challenges in the U.S.**

The United States and Canada enjoy one of the most collaborative, mutually beneficial and largest trading relationships in the world. In 2019, bilateral trade in goods and services totalled over \$725 billion or almost \$2 billion in trade daily. Trade and investment with Canada supports millions of U.S. jobs and the United States-Canada-Mexico Agreement will further strengthen supply chains and support joint economic prosperity.

The challenges brought by COVID-19 have reinforced the value of our bilateral cooperation, as exemplified by our mutual agreement to ensure the safety and security of our border and limit the spread of the virus. We have reduced the number of cross-border travelers, while maintaining the flow of essential goods and workers.

As well, the Government of Canada has taken a number of actions at home to address COVID-19 challenges, including introducing flexible regulatory measures, ensuring adequate procurement of PPE, and increasing domestic production of PPE and medical supplies. Some of these new products are now being exported to the U.S. And, in view of the even more critical importance of trade during a public health crisis, Canada took temporary measures to liberalize trade in medical products, including waiving duties and taxes on imports for emergency use. Importantly, Canada has not imposed export or trade restrictions on medical goods.

Both the U.S and Canada rely heavily on overseas suppliers, which creates shared vulnerabilities, but has also increased partnership opportunities.

Canada has played a vital role in the U.S. response to the pandemic. This was confirmed by the ITC's June 2020 Report on COVID-19 imports. According to the Report, in 2019 Canada was a top-5 supplier for 69 of the 203 imported COVID-19 related products, ranking sixth overall with imports totalling \$8.8 billion. This contribution includes both finished goods and component parts and services.

The Federal Emergency Management Agency's announcement to exempt exports to Canada from the export restrictions on certain PPE clearly recognized Canada's unique role in the national and economic security of the U.S., along with the importance of our bilateral collaboration to allow for the smooth flow of PPE across the border. A number of Canadian companies have retooled or increased production in order to support U.S. partners.

Finally, both the U.S. and Canada have rich research and development capacity, and are advancing together new therapies and vaccines to fight COVID-19, from research to product approval and commercialization.

By avoiding policies that would negatively affect our long-standing cross-border medical supply chains, we facilitate our mutual economic recovery.

In conclusion, Canada shares many common challenges and concerns with the U.S. but sees an opportunity to approach these in a North American context, building on and further strengthening



mutually beneficial ties. Canada's COVID-19 actions and work with U.S. partners will expand and strengthen the North American supply base for medical supplies, PPE, pharmaceuticals, and vaccine R&D trials.



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October 2, 2020

Secretary  
U.S. International Trade Commission  
500 E Street SW  
Washington DC 20436

**Summary for Inclusion in the Report: Inv. No. 332-580 COVID-19 Related Goods: The U.S. Industry, Market, Trade and Supply Chain Challenges**

Dear Secretary:

On behalf of the American Apparel & Footwear Association (AAFA), I am providing a summary for inclusion in the COVID-19 Related Goods report. AAFA is the trusted public policy and political voice of the apparel and footwear industry, its management and shareholders, its nearly four million U.S. workers, and its contribution of more than \$400 billion in annual U.S. retail sales.

Just like many industries, ours was hit hard by the pandemic as its impact manifested itself alternately and repeatedly as supply and demand shocks echoed throughout the globe. The apparel and footwear supply chain is diverse and integrated and our reach is global, which means we've been experiencing this on a global basis. In an effort to slow the spread of COVID-19, our members initially suspended or limited retail and production operations in line with global health guidelines to protect their workers and consumers. As conditions have warranted and local authorities approved, we have begun to open and reopen those operations in a safe and responsible manner. At the same time, our members rallied quickly to repurpose facilities, factories, and supply chains to produce and quickly distribute PPE and other urgently needed medical materials.

Below are some of the supply chain and policy challenges we encourage you to explore:

- In order to promote more U.S. production of PPE, a strong industrial base requires long term and consistent domestic demand signals from the U.S. government.
- It may also be possible to promote more domestic manufacturing by modifying our government procurement requirements while still maintaining our international trade obligations to our supply chain partners around the world who helped us meet our own PPE needs.
- Imports of life-saving PPE still face high duties despite the cost incurred on first responders, medical personnel, and the American people. We recommend the immediate suspension of all normal and punitive duties on all PPE and the inputs used to produce PPE.
- Forced labor in any form is intolerable, as is repression of ethnic minorities, wherever it takes place.

Thank you for the opportunity to provide a summary for inclusion in the report on this very important issue. Please contact me at [bhughes@aafaglobal.org](mailto:bhughes@aafaglobal.org) if you have any questions or would like additional information.

Sincerely,

A handwritten signature in black ink that reads "Beth Hughes". The signature is written in a cursive, flowing style.

Beth Hughes  
Vice President, Trade & Customs Policy  
American Apparel & Footwear Association

**America's Blood Centers Summary for Inclusion in the Report  
Investigation No. 332-580, COVID-19 Related Goods: The U.S. Industry, Market, Trade,  
and Supply Chain Challenges.**

The U.S. blood supply is supported by a network of not-for-profit organizations. Independent community-based blood centers collect nearly 60 percent of the U.S. blood supply and 80 percent of the COVID-19 convalescent plasma (CCP) used so far to treat patients with COVID-19.

Blood centers have quickly transitioned their operations to ensure a sufficient blood supply during the pandemic to account for extensive drive cancellations, social distancing, and other public health measures. Changes in blood usage early in the pandemic and increased costs to collect blood components have resulted in financially unsustainable drops in revenues, causing many centers to furlough workers while determining how to collect a sufficient blood supply and create a process for collecting CCP.

Early in the pandemic, CCP was identified as a promising therapeutic option when no other therapeutics existed. Plasma, the liquid portion of blood, from patients that have recovered from COVID-19 contains antibodies to SARS-CoV-2 (the virus that causes COVID-19), allowing patients fighting COVID-19 to potentially benefit from the immunity built up by recovered donors. CCP collections are currently outpacing distributions, allowing blood centers to build a national stockpile. The financial resources made available by the U.S. government to fully fund the activities necessary for the rapid production and distribution of CCP have been essential in identifying and recruiting potential donors and allowing blood centers to undertake necessary operational changes.

The first step in the supply chain for any blood component is recruiting a volunteer donor. Donors are screened and tested for transfusion transmitted diseases to ensure the safety of the blood supply. Additionally, CCP donors must have evidence of prior COVID-19 infection (either a positive diagnostic test or two positive antibody tests), and be symptom free for at least 14 days. Donor eligibility criteria disqualify a large percentage of potential donors; for every 10,000 potential donors, fewer than 200 CCP doses are collected. Additional donors are critical to continued CCP availability.

Recruitment efforts by blood centers, Operation Warp Speed, and others have solicited outside stakeholder involvement from national insurance plans, clinical testing laboratories, hospitals, and state and local public health agencies in identifying potential CCP donors. Blood centers must rely on third parties to conduct outreach as the potential donor information still cannot be shared directly with the blood center despite attempts to remove HIPAA regulatory barriers. A far more effective system would allow industry partners to share the patient lists directly with the blood centers who are trained and prepared to recruit potential donors in a confidential manner.

As with other areas of health care, blood centers rely on supplies from a decreasing number of suppliers. The leaning down of blood center operations in response to financial constraints before the pandemic has resulted in single supplier and just-in-time inventory models, which are not appropriate for disasters. As the pandemic continues, various supplies are impacted as utilization

increases for both blood centers and other healthcare providers. As an essential part of the health care system, blood centers must be prioritized for supply distributions.



**Association for Accessible Medicines  
Summary Statement  
U.S. International Trade Commission  
*COVID-19 Related Goods: The U.S. Industry, Market, Trade and Supply Chain  
Challenges: Investigation 332-580*  
September 30, 2020**

Generic and biosimilar medicines play an integral role in health care and enhance patient access to life-saving treatments. The expiration or invalidation of patents and the resulting introduction of multiple generic and biosimilar manufacturers competing against each other on price result in significant savings for patients and the health care system. As a result of a globally diverse and resilient supply chain, U.S. patients continue to have access to these needed and cost-saving therapies during the global COVID-19 pandemic.

In fact, according to an August 2020 McKinsey report<sup>1</sup> on global supply chains, the pharmaceutical industry's supply chain is one of the most resilient: "Despite recent headlines," the report states "we find that pharmaceuticals are relatively less exposed than most other industries."

To enhance the strength of this supply chain and to support economic growth and job creation in the United States, the Association for Accessible Medicines developed a framework that lays out concrete actions to attract additional investment in the U.S. generic sector and to ensure U.S. patients and the U.S. health care system have access to a secure and consistent supply of critical medicines.<sup>2</sup> AAM's [\*Blueprint to Enhance the Security of the U.S. Supply Chain\*](#) builds upon the existing generics manufacturing base in the U.S., which produces at least 70 billion doses annually and more than 30,000 jobs in greater than 70 manufacturing facilities across the country. Creating the conditions that support and encourage this investment are critical to ensuring the most needed medicines – those most essential to our country's health and security – are manufactured in the U.S. In order to establish this environment, AAM's *Blueprint* recommends the following:

- Identify the list of medicines most critical for U.S.-based manufacturing;
- Provide new grant and tax incentives to secure the U.S. supply chain;

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<sup>1</sup> McKinsey Global Institute, "[Risk, resilience, and rebalancing in global value chains](#)," August 6, 2020. Section 1.

<sup>2</sup> AAM, "A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain," April 30, 2020.



- Supply the Strategic National Stockpile, the U.S. Department of Veterans Affairs and the Department of Defense with essential medicines on a long-term basis with guaranteed price and volume contracts;
- Reduce regulatory inefficiencies to streamline federal approval for U.S.-based facilities to manufacture medicines; and
- Promote a global, cooperative approach to diversifying the supply chain.

The *Blueprint* includes actionable short-term steps to expedite more U.S.-based production of essential medicines, while putting in place a series of incentives to enhance the security of the U.S. pharmaceutical supply chain. Given that modern manufacturing facilities can take 5-7 years and cost up to \$1 billion to build, a long-term, consistent commitment from the federal government is critical to building an expanded generics manufacturing base in the United States.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read 'Jonathan Kimball', is written over a light blue horizontal line.

Jonathan Kimball  
Vice President, Trade and International Affairs



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Lisa R. Barton  
Secretary to the Commission  
United States International Trade Commission  
500 E Street S.W.  
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*Submitted via EDIS*

RE: Summary of Testimony, Investigation No. 332-580, *COVID-19 Related Goods: Conditions in the U.S. Industry and Key Supply Chains*

Please see below for our 500-word testimony summary for inclusion in the ITC report:

Mr. Anand Kulkarni, Vice President of Sales and Pat Curtin, Director of Product Marketing and Technology testified on behalf of Garflex, Inc and its brand, Fulflex. Fulflex is a key manufacturer for U.S.-made Personal Protective Equipment (“PPE”), including N95 masks. Fulflex believes there are serious constraints in the market that must be addressed if the current and growing demand for Berry-compliant PPE that satisfy necessary standards can be met.

Fulflex started manufacturing elastic rubber products in 1932. Located in Brattleboro, Vermont, Fulflex is the *sole* domestic manufacturer of elastic rubber tape, thread and valve products for the *mask and Personal Protective Equipment (PPE)* industry. Fulflex is a *critical component supplier of Key Starting Material (KSM)* and has been designated an essential supplier throughout the current COVID-19 pandemic. All products are produced in accordance with the requirements of the *Berry Amendment (10 U.S.C. 2533a)* and *DFAR 252.225-7012*. Furthermore, for Berry compliant products, our Vermont facility executes all manufacturing, packaging, inspection and shipping operations in-house. We supply the domestic US as well as the global market from our location in Vermont. Since the start of the Covid-19 pandemic we have supplied the domestic facemask industry with critical components to manufacture in excess of 400 million masks.

An N95 mask is only as effective as its seal on the users’ face. Fulflex uses unique and proprietary formulations and process technology to provide superior fit and comfort, essential for proper functioning of N95, surgical and industrial facemasks and other PPE such as surgical and isolation gowns, face shields and eye protection.

We agree that the domestic supply chain for facemasks and PPE faces a number of constraints. Facemask and other PPE manufacturers continue to ramp up their production. Their demand for Fulflex elastic exceeds Fulflex’s current production capacity. We are the sole domestic



manufacturer of these elastics and our lack of capacity is a constraint to ramping up the manufacture of facemasks and other PPE in the United States.

Current domestic *demand for the largest US facemask manufacturer exceeds capacity by 250,000 lbs. per month*. Based on *forecasts* we expect domestic demand to increase by an *additional 250,000 lbs. per month*, which will result in *tripling of the demand* in comparison to pre-pandemic times. Other customers are experiencing similar unprecedented increases in demand.

Fulflex believe the federal government should work to assist proven manufacturers in expanding domestic production. Our proposed expansion would require significant investment in capital equipment, including internal mixers, mixing mills, extruders, calender line, curing ovens, finishing equipment, laboratory equipment, finishing equipment and packaging and material handling equipment.

Having Federal Government support the expansion of proven vendors will help speed to market U.S.-made products that continue to meet the high-quality standards we and our U.S. customers currently meet. Failure to provide timely assistance to expand will result in delays, equipment shortfalls, and a continued reliance on foreign-made PPE.

Respectfully Submitted,



Daniel Neumann  
Vice President of Government Affairs  
Sorini, Samet & Associates

APPENDIX I:  
Examples of FulFlex Products:



AS PREPARED FOR DELIVERY

ISEA Comments; Investigation No. 332-580  
October 2, 2020  
page 8

**Summary for Inclusion in the Report:  
International Safety Equipment Association (ISEA)**

The International Safety Equipment Association (ISEA) represents U.S. companies that design, test, manufacture and supply personal protective and safety equipment. ISEA members produce and distribute personal protective equipment (PPE) used in many occupations, including healthcare. ISEA members produce and supply COVID-19-related products such as disposable respirators, reusable respirators, face shields and protective eyewear, non-medical gloves, and protective garments. Among disposable respirators, ISEA members produce the majority of N95 masks made and distributed in the United States. As the pandemic developed, Chinese domestic demand and export restrictions caused bottlenecks in imported supplies of PPE, including N95 masks.

Reusable respirators, including half-mask respirators, full-facepiece respirators and Powered Air Purifying Respirators (PAPRs), have also been crucially important during the COVID-19 response. Reusable respirators are largely made in the United States and can alleviate the demand for disposable respirators, such as N95s. They have generally experienced fewer production bottlenecks or shipment delays during the pandemic.

The safety equipment industry is global in nature. ISEA believes that better planning, not major changes to our international trading system involving PPE, would improve a pandemic response. PPE is included in the Trade Agreements Act (TAA) and some organizations have proposed restricting the trade flows that the TAA enables. If modified, key TAA-sourced components could very well become more difficult to source and prices of PPE would likely rise. Moreover, economic cooperation stemming from the TAA is well-known to have strategic benefits that advance our international policy objectives.

ISEA fully supports a plan by the current management team at the Strategic National Stockpile, or SNS, to create a data system that collects the public health community's demand for a wide array of needed items, and in turn shares that data with the supplier community. This type of system will allow suppliers and end-users alike to avoid a situation in which competing interests result in the misallocation of needed supplies.

The use of the Defense Production Act (DPA) has been effective. However, the DPA should be invoked with industry cooperation. Absent good planning, the DPA could (and has) shifted the supply of needed components from one company to another.

Finally, an area of significant concern is the rise of counterfeit products and fraudulent schemes by bad actors taking advantage of the desperate demand for PPE. Frequently, these counterfeit products do not meet industry or government standards, and they put users at risk of injury, sickness, or death. Further, the fraudulent schemes typically involve demands for upfront payment from would-be consumers and promises to deliver large quantities of PPE that the fraudsters do not actually possess. Both private and public efforts are on-going to curtail counterfeiting, fraudulent claims, and faked performance, but more needs to be done.

There are certainly lessons to be learned from the current pandemic experience. The single biggest factor affecting the market and availability for PPE products was, and continues to be, the surge in demand. Because the unprecedented demand for essentially every COVID-19-related product materialized very quickly, supply chains were overwhelmed. That situation revealed the need for better preparedness planning going forward.

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**Summary for inclusion in the report:**

The Life Science Manufacturing Alliance (“LSMA”) is a coalition of global companies that research, design, and manufacturing critical inputs used in the development of medicines, therapeutics, diagnostics, laboratory equipment, and pharmaceutical products. Our sector contributes \$1.3 trillion to the U.S. economy annually and employs approximately 800,000 U.S. workers. LSMA companies are among the leaders in the fight against the COVID-19 pandemic. Our companies provide critical raw materials for COVID-19 diagnostic tests and equipment necessary to develop COVID-19 vaccines. One of our members was the first company in the U.S. to produce and scale the products to enable COVID-19 testing.

The COVID-19 pandemic has created an urgent need for reliable and cost-efficient resources for the healthcare system. This includes the diagnostic equipment, life sciences tools, and pharmaceutical industry inputs and supplies that LSMA companies can provide. Global demand for LSMA company products has soared during the pandemic, while there is a country-to-country competition for scarce resources. We believe that improvements to the current tariff system will best position the United States for not only the current pandemic, but the possibility for a future pandemic involving an unknown novel pathogen.

Tariffs on the inputs manufactured or sourced by our companies make it harder and more expensive to obtain the supplies needed to produce diagnostic products, therapeutics, and vaccines. Trade barriers and tariffs on our inputs have a range of negative effects:

1. Tariffs overall result in a net loss of manufacturing capabilities and export volume.
2. Tariffs raise the cost for governments, hospitals, universities, and research institutions.
3. Tariffs make it more difficult for U.S. manufacturers to compete globally by raising the cost of products manufactured in the United States.
4. Tariffs will only slow the development of current and future treatments for patients.

The current system can be improved easily in two ways. First, pharmaceutical inputs should be subject to across-the-board zero tariff treatment. Second, removal of Section 301 tariffs on pharmaceutical inputs and tools would rectify an immediate problem facing LSMA companies that has been exacerbated by the COVID-19 pandemic. While some products, tools, inputs, and materials are manufactured in sufficient quantities in the United States, many are not. Section 301 tariffs have only increased costs for products needed by the U.S. healthcare system, and this problem has only been exacerbated by COVID-19.

The exclusion process implemented by the administration has failed to solve this problem. Since the introduction of Section 301 tariffs, companies reliant on our products have seen significant increases in annual duty payments. However, the exclusion process is exceptionally time-consuming for the experts who must assist with the drafting of detailed tariff exclusion requests, while the process and actions taken by the Administration have been insufficient and slow. Further, LSMA understands that the majority of exclusion requests filed by life science companies were denied in 2018 and 2019. A more efficient process is needed to guarantee the U.S. healthcare system has access to our products at the best price possible and without delay.

**Summary for Inclusion in Report (October 2, 2020)**

**Global Supply Chain and Domestic Distribution Disruptions Experience – COVID-19 Crisis (Investigation No. 332-580)**

The National Association of Beverage Importers (NABI), since 1935, is the leading advocate for importers of distilled spirits, wine, and beer. Logistics disruptions experienced by NABI Members exemplify generically the problems faced at steps in the global and domestic supply chains.

**Global Supply Chain:**

Disruptions in exporting country of origin from Government-mandated shut-downs of producers, transporters, and Ports activities. Restrictions at any one step has a domino effect on all subsequent steps.

Ports of export and imports have shortages of shipping containers resulting from “blank” sailings. Social distancing rules delay loading/unloading and extended wait times for truckers. Extra time to disinfect containers. Exhaustion of crewmembers and increase in vessel casualty rates. Disputed allocations of new costs between importers, shippers, and port authorities.

**Domestic Distribution Commercial Channels:**

Shortage of Commercial Driver License (CDL) holders leading to review of age limitations for CDLs. Drivers fearful for safety seeking authority to carry concealed weapons. Lack of personal protection equipment for drivers.

Longer wait times at truck stops to use showers, eating facilities for on-premise and off-premise food, and general store supplies in order to accommodate social distancing and additional sanitation. CDL drivers have many personal supply needs because they “live” in their trucks for long-haul distance trips. Some States shut-down rest-stops on the highways to both travelers and truckers, including not allowing truckers to stop and rest in the parking lots.

Non-uniformed “essential” employee or worker determinations at Federal, State, and local government levels. Federal Government promulgated “guidelines” through Department of Homeland Security (DHS) and its Cybersecurity and Infrastructure Security Agency (CISA) but left it up to the States and local governments to set the actual standards within their jurisdictions. Reported incidents of CDL drivers being stopped and questioned by State and local law enforcement role on essential worker status. NABI and National Custom Brokers and Forwarders Association of American (NCBFAA) designed a formal letter statement where the employer declares the employee as “essential” under the DHS Guidelines. Question remains on whether a formal or informal form credential should be established by the Federal Government level. Federal Government mandates rather than guidance would lead to uniformity among the States.

The world-wide catastrophe character of the COVID-19 crisis, unlike isolated disasters impacting a country or a region, such as a hurricane or earthquake, reveals weaknesses in the global supply chain that are exacerbated by weaknesses in the domestic supply chain distribution

channels. Inter-dependence of one on the other is revealed clearly. Solutions must address this inter-dependence for the future and rely on cooperation between countries, industries, and other stakeholders and establish multiple sources of products. Accordingly, all products will benefit and not simply COVID-19 related ones. Finally, these disruptions are only exacerbated by the “trade wars” with China and the European Union as the resulting unpredictable reduced trade levels impact the number of sailings with cargo containers and port arrival forecasts.



**Summary for Inclusion in the Report  
Kimberly Glas - National Council of Textile Organizations  
USITC Investigation No. 332-580**

This submission is made on behalf of the National Council of Textile Organizations (NCTO), which represents the full spectrum of U.S. textile manufacturing and its 585,000 workers.

In response to COVID-19, NCTO members quickly mobilized, manufacturing millions of PPE items when global competitors failed to supply our national needs. Despite these heroic efforts, onshoring a permanent PPE industry requires new government policies to incentivize long-term U.S. investment.

America's predicament is exacerbated by China's virtual monopolization of global PPE markets. With the onset of COVID-19, China's PPE production surged exponentially, aided by use of forced Uyghur labor. Despite their surge, China instituted PPE export restrictions at the pandemic's height. This triggered price gouging and hoarding as supply fell catastrophically short of surging demand. Those arguing that tariffs contributed to these shortages are naive or purposely misconstruing events. The scarcity experienced was the result of shortages in global supply, contrived in large part by certain monopolistic suppliers deliberately withholding access to lifesaving PPE.

Beyond China, additional challenges include:

**Lack of Long-term Federal Contracts** – Virtually all federal PPE contracts during the pandemic have been short-term, averaging 90-120 days. This short-term approach has chilled U.S. PPE investment. Manufacturers need 3-to-5-year contracts to justify PPE investment.

**Disjointed Contracting Process** – HHS and DLA coordination on PPE procurement needs improvement along with greater transparency and coordination with domestic industry. Examples include changes in product specifications and priorities even after a Request for Proposal (RFP) has been issued. An RFP this summer for reusable Level 1 isolation gowns was abruptly changed to request mainly disposable Level 2-4 gowns. Companies positioned to supply Level 1 product were forced to idle capacity and lay off workers.

Additionally, awards issued under the reconfigured RFP have raised concerns regarding capacity, technical proficiency, and Berry compliance of certain offerors. Federal agencies must enforce Berry compliance and verify performance capabilities of awardees.

**No Domestic Sourcing Requirements** – The lack of statutory requirements to source domestically creates uncertainty over true long-term demand for U.S.-made PPE. Made in U.S. requirements, such as the Berry Amendment, will lead to domestic PPE investments.

**Western Hemisphere** – PPE partnerships are needed within the Western Hemisphere where free trade agreements and preference programs can couple U.S. textile manufacturing expertise with cut and sew capabilities abundant in the region. This will establish a layered supply system able to meet U.S. PPE needs in any future crisis.

**Trade Policy and Enforcement** – Low U.S. duties and lack of market reciprocity for U.S.-made PPE has allowed China to dominate PPE markets. Congress must maintain PPE tariffs while rejecting tariff elimination proposals, like expanding the Generalized System of Preferences to textiles. Enforcement must also be strengthened to eradicate illegal trade and labor practices related to PPE imports.

In conclusion, investments to reconstruct a permanent U.S. PPE industry won't be made blindly. Investment risk must be justified through contracting support and consistent demand for U.S.-made PPE from the government. Without such policies, PPE markets will be monopolized by state-sponsored and exploitive offshore competitors, namely China.





**Summary for Inclusion in the Report**

Oral Testimony of Amy C. Efantis, President & CEO, Plasma Protein Therapeutics Association  
Hearing on *COVID-19 Related Goods: Conditions in the U.S. Industry and Key Supply Chains*  
U.S. International Trade Commission  
September 23, 2020

PPTA represents manufacturers of plasma protein therapies and plasma collection centers. Last year, U.S. centers collected over 50 million plasma donations, which were manufactured into therapies for thousands of Americans and others with rare, life threatening and frequently chronic conditions. This industry is unique, different from vaccines, from chemical pharmaceuticals, and even different from the blood sector. It is built on a complex, global supply chain that must be preserved to ensure access for the patients that depend on it.

Plasma is collected from donors and manufactured through a months-long process called fractionation into highly purified protein therapies to treat a range of conditions. One therapy is called immunoglobulin, or Ig, which is protective against a wide range of diseases and has shown to be an effective treatment for some complications of COVID-19, including Multisystem Inflammatory Syndrome in Children (MIS-C). Plasma collected specifically from donors who have recovered from a disease is called convalescent plasma, which companies use to manufacture hyperimmune globulins ("hyperimmunes") to target that specific disease. PPTA members are working hard to develop COVID-19 hyperimmunes.

More plasma is collected in the U.S. than can be processed here and, since most PPTA member companies have facilities both here and abroad, maintaining access to manufacturing capacity around the world is of critical importance. PPTA members have made enormous investments in manufacturing facilities in the U.S., employing tens of thousands of Americans in well-paying jobs. That capacity is growing; new facilities can cost more than \$1 billion and take more than 6 years to complete.

To be most efficient, companies must move plasma to the facility where it is most needed, a liter of plasma must be made into as many products as possible, and those products all need to find a market. In many cases, that plasma returns to the U.S. in the form of a final therapy. Cutting off access to plasma or final therapies in a particular country could cause ripple effects throughout the supply chain. Taking any of action that results in retaliatory measures could prevent the re-export of those final therapies back to the U.S. The FDA has not licensed any product made from non-U.S. plasma for use in the U.S.

For a variety of pandemic-related reasons, plasma collections plummeted in March and April and have not yet returned to levels seen in prior years. We appreciate the Administration's characterization of plasma collection as a national imperative, and the jurisdictions that have prioritized plasma donors and center employees by deeming both to be "essential." Any efforts to increase that messaging will help to ensure access to core therapies and any COVID-19 -specific therapies licensed in the future.

Plasma protein therapies, including Ig and potential COVID-19 hyperimmunes, are the products of delicate, complex, and global supply chains that will serve American patients in more ways than ever before. Any attempt to separate out any piece of this process or location in which it takes place could disrupt the process and have implications for patients far beyond COVID-19.



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October 2, 2020

**SUMMARY OF WRITTEN SUBMISSIONS FOR INCLUSION IN THE REPORT**

**U.S. INTERNATIONAL TRADE COMMISSION INVESTIGATION NO. 332–580:  
“COVID–19 RELATED GOODS: THE U.S. INDUSTRY, MARKET, TRADE, AND  
SUPPLY”**

Decades of hyperglobalization have undermined our resilience against COVID-19. With our economies organized to serve a production model focused almost exclusively on “efficiency” and reliant on long, brittle global supply chains and production of many goods in too few countries, even the world’s wealthiest countries can neither produce nor obtain sufficient supplies of ventilators, respirators and masks and other essential medical supplies. The public health emergency has dramatically increased U.S. public awareness and policymakers concern about the lack of U.S. capacity to produce and procure goods needed to combat this public health emergency and/or whatever next crises may emerge.

Among the key factors that have undermined our security and contributed to the hollowing out of U.S. domestic production capacity are:

- corporate-rigged trade policies that made it easier and less risky to move production overseas to pay workers less,
- a lack of disciplines against currency misalignments that undermined domestic firms trying to compete with imported products, and
- a merger mania enabled by a lack of competition policy, which resulted in the elimination of “redundant” production facilities as a few dominant firms in key sectors sought to maximize “efficiency” by relying on thin, globalized supply chains with final production concentrated in a few locations.

Recent data shows that the U.S. has grown even more dependent on imports from China and the rest of the world for key medical goods during the COVID-19 era as the U.S.-China and U.S.-world deficits in key medical goods increased through July 2020. Additionally, historical data indicate that the sources of U.S. imports of critical COVID-19 response goods have substantially shrank over the last decades. Moreover, imports of pharmaceuticals in 2019 show deep U.S. reliance on China and India for many categories of medicines.

Public Citizen also submitted data to debunk two myths propagated by those seeking to maintain the current hyperglobalization regime and/or advocating for expanding the current model. First, a timeline showing that U.S. restrictions on exports of key medical goods initiated in April 2020 did not trigger export restrictions of key medical goods in other countries. If anything, the United States was one of the last nations that undertook measures trying to guarantee domestic supply of these products. Second, data showing that U.S. Section 301 enforcement actions and tariffs on certain Chinese imports did not trigger shortages in PPE and other COVID-critical goods.

Public Citizen's analysis of this data supports the surging claims demanding that the United States both increase domestic production and diversify import sources for critical goods in order to better manage what will be an ongoing COVID-19 crisis for some time, and also be better prepared for the next crisis, health or otherwise. To accomplish these goals will require the use of all of the tools available from taxation to government procurement to trade to government investment in research, training, and incentives to develop local supply chains with sufficient numbers of entrants to ensure competition.

VIA ELECTRONIC SUBMISSION

September 29, 2020

Lisa R. Barton  
Secretary to the Commission  
U.S. International Trade Commission  
500 E Street, S.W.  
Washington, D.C. 20436

**Re: Summary for Inclusion in the Report  
Investigation No. 332-580; COVID-19 Related Goods: The U.S. Industry,  
Market, Trade, and Supply Chain Challenges**

The global pharmaceutical supply chain is currently affected by challenges and constraints, such as a general lack of resiliency and transparency. There is a lack of geographic diversity in the supply chain as a result of concentrated manufacturing and sourcing in few countries and disparate regulatory environments. A geographically concentrated pharmaceutical supply chain can result in drug shortages, especially when disruptions occur, such as natural disasters, trade wars, and pandemics. In order to minimize or prevent the occurrence of drug shortages due to disruptions, the United States Pharmacopeia (USP) encourages diversifying the supply chain and building redundancies into the system. To support supply chain resiliency, incentives for industry may be needed, such as federal government contracts or grants to encourage multiple suppliers of certain drug products in disperse locations.

The greater adoption of advanced manufacturing technologies by the pharmaceutical industry can also support resilience in the supply chain. Continuous manufacturing has the potential to foster greater quality control and increased cost-efficiency of active pharmaceutical ingredient (API) and finished product production. USP is currently engaging with a broad group of stakeholders, including academic research centers and manufacturers, to identify and articulate appropriate quality standards and practices to help make advanced manufacturing more accessible and achievable for industry uptake.

The complexity of the global medicine supply chain, which includes numerous players, such as ingredient suppliers, manufacturers, packagers, labelers, distributors, and contractors, is exacerbated by the generalized lack of transparency among these players regarding their roles. Thus, information about the origin, production volume, and distribution chain for drug products is not readily accessible to the public. The ability to identify potential safety problems with a drug product and respond quickly and efficiently may also be affected.

USP supports more transparency from the pharmaceutical industry to support a more resilient supply chain to help ensure the continued availability of safe, quality medicines. Practitioners and patients would also benefit with more publicly available supply chain information, especially in the event of a safety or quality related problem linked to a drug ingredient, such as the API.

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One King Timahoe Drive, Vidalia, LA 71373

**Summary for Inclusion in the Report  
Dan Feibus – CEO Vidalia Mills  
USITC Investigation No. 332-580**

Vidalia Mills is an integrated U.S. textile manufacturer of premium yarns, Selvedge denim and other unique fabrics. Though focused on apparel components, Vidalia recognized the desperate need for medical personal protective equipment at the onset of COVID-19. We repurposed production and retrained workers to provide emergency PPE to front-line health care workers, including materials for U.S. made masks and isolation gowns. Beyond the current crisis, Vidalia is committed to long-term PPE production. We are purchasing and installing machinery to make Vidalia the only U.S. manufacturer of three types of medical masks, including N-95 respirators.

Vidalia undertook the significant financial risk to supply PPE without government contracts or aid to help alleviate the catastrophic shortages faced by our nation. With that said, a key challenge in onshoring a viable PPE industry is the need to mitigate investment risk. It is unrealistic for textile companies facing a historic downturn in demand due to the pandemic to shoulder alone the financial risk needed to construct a PPE industry. The government must establish tax credits and funding grants to mitigate risk and incentivize PPE investment. This would be a reasonable federal expense in return for the public benefit and improved national security of a self-sufficient domestic PPE sector.

A second challenge is the absence of buy-American preferences for federal PPE procurement. The Department of Defense employs the Berry Amendment, which requires 100% U.S. content for textiles. Federal buy-American mandates like Berry should be adopted for the Strategic National Stockpile and other federal purchases of PPE to spur investment.

Another challenge is the process of gaining NIOSH and FDA certifications. Heroic efforts to rush product to market were slowed by certifications that are alien to new entrants to the medical PPE field. Federal agencies should increase resources to expedite applications that expand the U.S. production base of PPE.

Finally, there is the massive issue of price. China and other Asian suppliers have dramatic and often illegal pricing advantages allowing them to dominate global PPE markets. Once the pandemic subsides, sourcing agents will revert to price determinations that initially drove the PPE industry offshore. While a buy-American statute would cover federal purchases, the larger market rests with the private sector. The government must incentivize hospitals and others to buy U.S. made PPE. This could be aided by tax credits to the private sector for the purchase of U.S.

made PPE and a government program to certify manufacturers as “Made in the USA” to allow customers to qualify for such credits.

In conclusion, many companies like Vidalia are committed to bringing a viable PPE industry back onshore. However, without rational procurement and tax policies, we will again concede the U.S. PPE market to countries that use unfair trade practices to undercut domestic production.

Vidalia stands ready to participate in this critical policy discussion to assist in helping solve our national PPE shortage.

# **Appendix E**

## **Data Tables for Figures**





**Table E.1** Change from the same month of the prior year, U.S. airlines scheduled transport of international passengers by number and international air cargo by weight, January–September 2020

Month and year	Schedule passengers (percent)	Air cargo (percent)
Jan 2020	2	-10
Feb 2020	1	-6
Mar 2020	-53	-14
Apr 2020	-99	-16
May 2020	-98	-8
Jun 2020	-96	-1
Jul 2020	-90	5
Aug 2020	-88	2
Sep 2020	-84	11

Source: USDOT, BTS, “U.S. Airlines Carried,” November 10, 2020; USDOT, BTS, “U.S. Airlines September 2020 Passengers,” November 12, 2020.  
Note: September data are preliminary. Corresponds to [figure 2.3](#).

**Table E.2** Hong Kong to North America air freight rates, January 2019–October 2020

Month and year	Rate
Jan 2019	3.66
Feb 2019	3.54
Mar 2019	3.38
Apr 2019	3.6
May 2019	3.71
Jun 2019	3.46
Jul 2019	3.44
Aug 2019	3.29
Sep 2019	3.44
Oct 2019	3.49
Nov 2019	3.84
Dec 2019	3.62
Jan 2020	3.14
Feb 2020	3.19
Mar 2020	4.03
Apr 2020	5.69
May 2020	7.73
Jun 2020	5.86
Jul 2020	4.96
Aug 2020	5.5
Sep 2020	5.26
Oct 2020	5.66

Source: Air Cargo News, “Airfreight Rates—TAC Index” (accessed November 15, 2020).  
Note: Corresponds to [figure 2.4](#).

**Table E.3** Geographical distribution of establishments, medical device manufacturing, first quarter 2020

State	Number of establishments	State	Number of establishments
Alabama	80	Montana	28
Alaska	16	Nebraska	27
Arizona	123	Nevada	37
Arkansas	31	New Hampshire	46
California	1,157	New Jersey	243
Colorado	136	New Mexico	48
Connecticut	89	New York	299

## COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges

State	Number of establishments	State	Number of establishments
Delaware	19	North Carolina	162
District of Columbia	13	North Dakota	11
Florida	585	Ohio	188
Georgia	191	Oklahoma	47
Hawaii	3	Oregon	93
Idaho	55	Pennsylvania	206
Illinois	457	Rhode Island	51
Indiana	169	South Carolina	157
Iowa	56	South Dakota	10
Kansas	42	Tennessee	179
Kentucky	72	Texas	498
Louisiana	63	Utah	168
Maine	23	Vermont	14
Maryland	120	Virginia	171
Massachusetts	200	Washington	170
Michigan	319	West Virginia	14
Minnesota	349	Wisconsin	140
Mississippi	24	Wyoming	4
Missouri	100		

Source: Bureau of Labor Statistics (BLS), Quarterly Census of Employment and Wages, first quarter 2020, NAICS 334510, 334517, 339112, and 339113 (accessed October 2020).

Note: An establishment is “a single physical location at which business is conducted or services or industrial operations are performed.” Census Bureau, “Glossary” (accessed August 13, 2020). Corresponds to [figure 3.1](#).

**Table E.4** Medical device establishments, employment, payroll, and receipts, by enterprise size, 2017 (in percent)

	Establishments	Employment	Payroll	Receipts
SMEs	85	30	25	19
Large firms	15	70	75	81

Source: Statistics of U.S. Businesses data from the Census Bureau, NAICS 334510, 334517, 339112, and 339113 (accessed October 2020).

Note: Data for receipts are preliminary data. “Receipts (net of taxes collected from customers or clients) are defined as operating revenue for goods produced or distributed, or for services provided.” Business size is based on the size of the enterprise. “An enterprise (or ‘company’) is a business organization consisting of one or more domestic establishments that were specified under common ownership or control.” For more information, see Census Bureau, “Glossary” accessed August 13, 2020). Corresponds to [figure 3.2](#).

**Table E.5** U.S. medical device shipments and value added, 2015–18 (in billion dollars)

	Value added				Shipments			
	2015	2016	2017	2018	2015	2016	2017	2018
Electromedical	16.9	17.1	21.0	22.9	27.0	26.3	33.0	36.4
Irradiation	5.5	5.1	5.6	6.1	7.7	7.1	9.3	10.0
Instruments	27.2	27.9	26.7	28.5	40.1	41.0	39.7	41.3
Supplies	21.8	22.0	20.6	24.1	30.3	30.6	33.4	36.2
Total	71.4	72.2	73.9	81.6	105.1	105.1	115.4	123.9

Source: Annual Survey of Manufactures and Economic Census data from Census Bureau, NAICS 334510, 334517, 339112, and 339113 (accessed October 2020). Note: Corresponds to [figure 3.3](#).

**Table E.6** U.S. employment, medical device manufacturing, 2015–19 and first quarter 2020 (in thousand employees)

	Calendar year					Jan–Sep	
	2015	2016	2017	2018	2019	2019	2020p
Electromedical	59,475	63,408	67,838	68,537	71,093	71,093	73,552
Irradiation	12,729	13,161	13,422	14,093	14,627	14,627	14,423
Instruments	118,897	120,352	121,691	128,163	132,983	132,983	135,779
Supplies	100,421	99,960	100,864	102,024	104,327	104,327	104,677
Total	291,522	296,881	303,815	312,817	323,030	323,030	328,431

Source: BLS, Quarterly Census of Employment and Wages, NAICS 334510, 334517, 339112, and 339113 (accessed August 2020).

Note: p=preliminary. These NAICS codes include most PPE; however, PPE is discussed separately in chapter 4. Corresponds to [figure 3.4](#).

**Table E.7** U.S. imports, medical devices, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)

	Calendar year					Jan–Sep	
	2015	2016	2017	2018	2019	2019	2020
Electromedical	10.3	10.7	11.4	12.5	13.1	9.8	9.2
Irradiation	3.8	4.0	4.0	4.3	4.3	3.1	2.7
Instruments	12.3	13.4	14.1	15.8	17.6	13.2	13.0
Supplies	13.7	14.1	15.7	17.1	18.3	13.5	13.7

Source: USITC DataWeb/USDOC, NAICS 334510, 334517, 339112, and 339113 (accessed November 2020).

Note: These NAICS codes include most PPE; however, PPE is discussed separately in chapter 4. Corresponds to [figure 3.5](#).

**Table E.8** U.S. imports, medical devices, by country 2015–19, January–September 2019, and January–September 2020 (in billion dollars)

	Calendar year					Jan–Sep	
	2015	2016	2017	2018	2019	2019	2020
Mexico	6.7	7.4	7.7	8.3	9.3	7.0	6.8
Ireland	5.4	5.6	6.1	7.3	7.8	5.7	4.6
China	4.4	4.7	4.8	5.1	5.1	3.9	4.9
Germany	4.2	4.4	4.7	5.1	5.5	4.2	3.7
Switzerland	2.4	2.4	2.7	3.0	3.0	2.2	2.0
Other sources	17.0	17.9	19.2	20.9	22.6	16.6	16.5
Total	40.1	42.3	45.1	49.7	53.3	39.5	38.6

Source: USITC DataWeb/USDOC, NAICS 334510, 334517, 339112, and 339113 (accessed November 2020).

Note: These NAICS codes include most PPE; however, PPE is discussed separately in chapter 4. Corresponds to [figure 3.6](#).

**Table E.9** U.S. exports, medical devices, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)

	Calendar year					Jan–Sep	
	2015	2016	2017	2018	2019	2019	2020
Netherlands	4.3	4.2	4.0	4.8	4.9	3.7	3.4
Japan	3.5	3.5	3.3	3.5	3.5	2.6	2.3
China	2.7	2.9	3.0	3.2	3.4	2.5	2.5
Belgium	2.7	2.7	2.9	2.4	2.4	1.8	1.6
Germany	2.6	2.5	2.4	2.4	2.5	1.9	2.1
Other sources	17.5	17.4	17.4	18.3	18.9	14.1	12.9
Total	33.2	33.2	33.0	34.6	35.7	26.6	24.7

Source: USITC DataWeb/USDOC, NAICS 334510, 334517, 339112, and 339113 (accessed November 2020).

Note: These NAICS codes include most PPE; however, PPE is discussed separately in chapter 4. Corresponds to [figure 3.7](#).

**Table E.10** U.S. imports of ventilators and other goods in the broader HTS subheading, all transportation modes and air freight, January 2019–September 2020 (in million dollars)

Month and year	All imports	All imports via air
January 2019	195	30
February 2019	182	38
March 2019	224	45
April 2019	219	47
May 2019	244	51
June 2019	214	42
July 2019	235	45
August 2019	231	32
September 2019	239	36
October 2019	247	39
November 2019	226	34
December 2019	240	44
January 2020	227	34
February 2020	204	33
March 2020	216	47
April 2020	317	137
May 2020	299	158
June 2020	282	116
July 2020	334	116
August 2020	347	103
September 2020	310	92

Source: USITC DataWeb/USDOC, HTS 9019.20.0000 (accessed November 2020); IHS Market, Global Trade Atlas database, HTS 9019.20.0000 (accessed November 2020).

Note: Corresponds to [figure 3.9](#).

**Table E.11** U.S. producer prices for personal safety equipment and clothing, January 2015–September 2020 (Index, January 2015 = 100)

Month and year	Index
January 2015	100.0
February 2015	100.0
March 2015	100.0
April 2015	100.1
May 2015	100.0
June 2015	100.0
July 2015	101.4
August 2015	101.8
September 2015	101.8
October 2015	102.5
November 2015	102.5
December 2015	102.0
January 2016	102.0
February 2016	102.0
March 2016	103.3
April 2016	103.3
May 2016	103.3
June 2016	103.3
July 2016	103.3
August 2016	103.3
September 2016	103.3

<b>Month and year</b>	<b>Index</b>
October 2016	103.3
November 2016	103.3
December 2016	103.3
January 2017	103.3
February 2017	103.2
March 2017	103.2
April 2017	103.2
May 2017	100.0
June 2017	100.0
July 2017	100.0
August 2017	100.0
September 2017	100.0
October 2017	96.4
November 2017	96.5
December 2017	96.5
January 2018	98.6
February 2018	98.7
March 2018	98.7
April 2018	100.5
May 2018	100.9
June 2018	100.9
July 2018	100.9
August 2018	100.9
September 2018	100.9
August 2018	103.2
September 2018	102.1
October 2018	102.1
November 2018	103.0
December 2018	103.0
January 2019	103.2
February 2019	104.1
March 2019	103.4
April 2019	103.4
May 2019	103.4
June 2019	103.4
July 2019	103.4
August 2019	103.4
September 2019	103.4
October 2019	103.4
November 2019	104.3
December 2019	104.3
January 2020	104.5
February 2020	104.5
March 2020	104.5
April 2020	104.5
May 2020	104.5
June 2020	106.2
July 2020	106.2
August 2020	100.0
September 2020	100.0

Source: BLS, Producer Price Indexes, Series Id WPU1571 (accessed November 8, 2020).

Note: Data for June–September 2020 are preliminary. Corresponds to [figure 4.1](#).

**Table E.12** U.S. imports of selected personal protective equipment (PPE), by country, July–September 2020 (in billion dollars)

Country	July	August	September
China	2,756	2,386	2,033
Malaysia	168	191	269
Vietnam	259	192	130
Thailand	59	65	77
Mexico	75	68	57
Other sources	254	273	237
Total	3,570	3,175	2,803

Source: USITC DataWeb/USDOC (accessed October 2020).

 Note: See table 4.1 for HTS numbers. Corresponds to [figure 4.3](#).

**Table E.13** U.S. imports of respirators and other goods included in the broader HTS grouping, by air freight, January 2019–September 2020 (in thousand metric tons)

Month and year	Other	N95	Other Respirators	Disposable Masks	Other Masks	Other (from July 2020)
January 2019	606	0	0	0	0	0
February 2019	312	0	0	0	0	0
March 2019	510	0	0	0	0	0
April 2019	706	0	0	0	0	0
May 2019	651	0	0	0	0	0
June 2019	537	0	0	0	0	0
July 2019	679	0	0	0	0	0
August 2019	700	0	0	0	0	0
September 2019	578	0	0	0	0	0
October 2019	648	0	0	0	0	0
November 2019	564	0	0	0	0	0
December 2019	525	0	0	0	0	0
January 2020	513	0	0	0	0	0
February 2020	309	0	0	0	0	0
March 2020	1,724	0	0	0	0	0
April 2020	26,869	0	0	0	0	0
May 2020	43,173	0	0	0	0	0
June 2020	27,104	0	0	0	0	0
July 2020	0	6,311	334	6,783	7,258	3,027
August 2020	0	937	484	4,972	6,515	1,288
September 2020	0	385	162	2,019	5,563	1,074

Source: Official U.S. trade statistics from IHS Markit, Global Trade Atlas database, HTS 6307.90.9845, 6307.90.9850, 6307.90.9870, 6307.90.9875, 6307.90.9891, 6307.90.9889 (accessed September–November 2020).

 Note: Corresponds to [figure 4.6](#).

**Table E.14** U.S. imports of N95 respirators, by country, July–September 2020 (in million respirators)

Type	China	Other	Total
N95 – July 2020	597	23	620
N95 – August 2020	444	25	469
N95 – September 2020	529	26	555
Other Respirators – July 2020	80	10	89
Other Respirators – August 2020	130	8	138
Other Respirators – September 2020	68	7	75
Total – July 2020	676	33	709
Total – August 2020	574	33	607
Total – September 2020	597	33	630

Source: USITC DataWeb/USDOC, HTS 6307.90.9845 and 6307.90.9850 (accessed November 2020).

Note: Corresponds to [figure 4.7](#).

**Table E.15** U.S. imports of broader category of medical gowns from January 2019–September 2020 (in million garments and million dollars)

Month and year	Value (\$)	Number of Garments
January 2019	155	230
February 2019	140	193
March 2019	126	162
April 2019	134	177
May 2019	147	211
June 2019	129	189
July 2019	153	222
August 2019	146	196
September 2019	135	185
October 2019	147	207
November 2019	121	189
December 2019	129	207
January 2020	148	224
February 2020	130	169
March 2020	124	111
April 2020	286	379
May 2020	718	641
June 2020	1,265	792
July 2020	979	726
August 2020	799	747
September 2020	539	583

Source: USITC DataWeb/USDOC, HTS 3926.20.9050, 6113.00.1012, 6210.10.2000, 6210.10.5000, 6210.10.9040, 6210.50.5555, 6211.42.1081, and 6211.43.1091 (accessed November 12, 2020).

Note: These import numbers are likely overstated for medical gowns as they include nonmedical gown apparel as well. Corresponds to [figure 4.10](#).

**Table E.16** Imports of a broader HTS grouping containing medical gowns, by country, 2019, January–September 2019, January–September 2020 (in million dollars and million garments)

U.S. imports of gowns		China	Vietnam	Mexico	Turkey	Cambodia	Other	Total
Values	Year							
	2019	806	118	179	3	-	555	1,662.4
	2019 Jan–Sep	626.3	83	134	3	-	417	1,265.3
	2020 Jan–Sep	3,434.2	493	283	182	-	594	4,987.8
Quantities	Year							
	2019	1,949.4	82	72	0	85	178	2,368.3

<b>U.S. imports of gowns</b>								
Year	China	Vietnam	Mexico	Turkey	Cambodia	Other	Total	
2019 Jan–Sep	1,470.4	55	51	0	56	131	1,765.9	
2020 Jan–Sep	3,500.4	247	151	0	152	320	4,371.8	

Source: USITC DataWeb/USDOC, HTS 3926.20.9050, 6113.00.1012, 6210.10.2000, 6210.10.5000, 6210.10.9040, 6210.50.5555, 6211.42.1081, and 6211.43.1091 (accessed November 12, 2020).

Note: These import numbers are likely overstated for medical gowns as they include nonmedical gown apparel as well. Countries shown for value are the top four import sources by value, and countries shown by volume are the top four import sources by volume. Corresponds to [figure 4.11](#).

**Table E.17** U.S. imports of selected nonwovens of the type inputs for surgical and isolation gowns and other goods, January 2019–September 2020, by value (million dollars)

U.S. imports of gowns	Value (\$ In Millions)
January 2019	56
February 2019	42
March, 2019	48
April 2019	48
May 2019	46
June 2019	42
July 2019	45
August 2019	40
September 2019	42
October 2019	46
November 2019	40
December 2019	40
January 2020	45
February 2020	38
March 2020	49
April 2020	53
May 2020	51
June 2020	50
July 2020	59
August 2020	64
September 2020	74

Source: USITC DataWeb/USDOC, HTS 5603.11 and 5603.12 (accessed November 2020).

Note: Corresponds to [figure 4.12](#).

**Table E.18** U.S imports of medical and surgical gloves, January 2019–September 2020 (in billion gloves and million dollars)

U.S. imports of gloves	Value (\$ in Millions)	Gloves (in Billions)
January 2019	185	6.8
February 2019	160	5.7
March 2019	181	6.7
April 2019	165	6.0
May 2019	185	6.8
June 2019	163	6.0
July 2019	169	6.3
August 2019	172	6.4
September 2019	173	6.4
October 2019	189	7.1
November 2019	178	6.7



U.S. imports of gloves	Value (\$ in Millions)	Gloves (in Billions)
December 2019	179	7.1
January 2020	196	7.4
February 2020	174	6.4
March 2020	198	7.4
April 2020	203	7.7
May 2020	202	6.7
June 2020	243	7.7
July 2020	265	7.7
August 2020	287	7.5
September 2020	348	8.3

Source: USITC DataWeb/USDOC, HTS 3926.20.1010, 4015.11.0110, 4015.11.0150, 4015.19.0510, 4015.19.0550 (accessed November 2020).

Note: Corresponds to [figure 4.14](#).

**Table E.19** Unit values of U.S. medical and surgical glove imports, January 2019–September 2020 (Index, January 2019 = 100)

Gloves unit value	Medical			Surgical	
	Medical/surgical vinyl	Medical latex	Medical nitrile/other synthetic rubber	Surgical latex	Surgical nitrile/other synthetic rubber
January 2019	100	100	100	100	100
February 2019	101.1	107	98.9	96.9	103.9
March 2019	95.5	113.5	95.8	79.8	73.6
April 2019	95.5	116.0	96.0	79.3	80.8
May 2019	99.2	116.7	97.5	97.7	94.3
June 2019	95.4	110.5	93.4	95.5	86.0
July 2019	94.8	113.3	93.6	76.8	89.5
August 2019	98.4	115.4	95.8	71.5	95.6
September 2019	95.6	129.5	98.7	81.1	93.4
October 2019	95.4	110.3	94.0	94.0	65.9
November 2019	99.4	114.7	91.9	89.6	81.3
December 2019	96.9	105.1	93.8	76.0	72.1
January 2020	96.0	119.1	96.0	77.3	61.8
February 2020	100.9	113.5	93.6	78.1	71.4
March 2020	103.4	119.1	91.8	59.0	77.1
April 2020	117.4	114.7	99.2	81.5	59.5
May 2020	138.6	140.9	105.5	73.1	71.6
June 2020	183.1	145.3	112.3	84.3	64.8
July 2020	225.0	149.7	123.7	86.2	65.3
August 2020	257.5	168.5	137.6	71.5	42.8

Source: USITC DataWeb/USDOC, HTS 3926.20.1010, 4015.11.0110, 4015.11.0150, 4015.19.0510, 4015.19.0550 (accessed November 2020).

Note: Corresponds to [figure 4.15](#).

**Table E.20** Geographical distribution of establishments, pharmaceutical manufacturing, first quarter 2020

State	Number of establishments	State	Number of establishments
Alabama	60	Montana	28
Alaska	4	Nebraska	27
Arizona	87	Nevada	37
Arkansas	25	New Hampshire	46
California	715	New Jersey	243
Colorado	197	New Mexico	48
Connecticut	30	New York	299

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State	Number of establishments	State	Number of establishments
Delaware	23	North Carolina	162
District of Columbia	17	North Dakota	11
Florida	379	Ohio	188
Georgia	116	Oklahoma	47
Hawaii	3	Oregon	93
Idaho	38	Pennsylvania	206
Illinois	233	Rhode Island	51
Indiana	85	South Carolina	157
Iowa	49	South Dakota	10
Kansas	40	Tennessee	179
Kentucky	52	Texas	498
Louisiana	23	Utah	168
Maine	29	Vermont	14
Maryland	130	Virginia	171
Massachusetts	97	Washington	170
Michigan	125	West Virginia	14
Minnesota	42	Wisconsin	140
Mississippi	15	Wyoming	4
Missouri	89		

Source: Bureau of Labor Statistics (BLS), Quarterly Census of Employment and Wages, January–March 2020, NAICS 3254 (accessed October 2020).

Note: An establishment is defined as a single physical location at which business is conducted or services or industrial operations are performed. For more information, see Census Bureau, “Glossary” (accessed August 13, 2020). Corresponds to [figure 5.1](#).

**Table E.21** Pharmaceutical establishments, employment, payroll, and receipts, by enterprise size, 2017, percent

	Establishments	Employment	Payroll	Receipts
SMEs	75	23	17	10
Large firms	25	77	83	90

Source: Statistics of U.S. Businesses data from the Census Bureau, <https://data.census.gov/cedsci/> (accessed August 2020).

Note: Data for receipts are preliminary data. “Receipts (net of taxes collected from customers or clients) are defined as operating revenue for goods produced or distributed, or for services provided.” Business size is based on the size of the enterprise. “An enterprise (or ‘company’) is a business organization consisting of one or more domestic establishments that were specified under common ownership or control.” For more information, see Census, “Glossary” (accessed August 13, 2020). Corresponds to [figure 5.2](#).

**Table E.22** Pharmaceutical shipments, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)

	Calendar year					Jan-Sep	
	2015	2016	2017	2018	2019	2019	2020
U.S. pharmaceutical shipments	215.7	219.9	233.3	251.6	268.7	198.5	221.0

Source: Census, “Manufacturers’ Shipments, Inventories, and Orders,” Series U25BVS (NAICS 3254) (accessed August–October 2020).

Note: Includes all NAICS in 3254, including 325413 (In-Vitro Diagnostic Substance Manufacturing). Corresponds to [figure 5.3](#).

**Table E.23** U.S. producer price index for four pharmaceutical industry groups, January 2015–September 2020 (Index, January 2015 = 100)

<b>325411--Medicinal and botanical manufacturing</b>												
Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2015	180.7	180.8	180.9	181.0	181.0	181.0	180.6	180.3	180.2	180.3	180.3	180.3
2016	179.3	179.0	179.0	177.8	177.7	176.7	176.8	176.8	177.2	177.2	177.2	177.2
2017	176.1	176.1	176.1	176.1	176.1	176.1	176.2	176.8	176.2	176.2	176.2	176.2
2018	176.8	183.2	183.2	183.2	183.2	183.2	183.2	183.2	183.2	183.2	183.3	183.1
2019	182.6	182.6	182.6	182.6	182.6	182.6	182.6	183.2	183.2	182.0	182.0	182.0
2020	185.0	185.0	185.4	187.0	187.0	180.4	180.4	183.4	183.4			

<b>325412--Pharmaceutical preparation manufacturing</b>												
Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2015	700.3	701.3	701.4	700.7	704.6	729.0	729.4	729.4	729.9	729.8	729.6	733.4
2016	768.4	771.2	771.3	772.3	772.8	782.7	784.1	787.6	788.5	790.2	790.2	791.3
2017	821.1	821.2	821.2	821.2	824.8	832.2	833.4	833.8	827.4	843.1	842.9	843.7
2018	867.2	867.2	867.4	866.2	865.1	867.5	875.0	871.0	872.3	874.8	880.3	883.2
2019	898.5	898.5	900.4	901.4	900.5	899.6	900.0	900.2	900.2	900.5	900.4	899.3
2020	916.4	919.7	920.5	920.5	920.4	920.8	921.8	922.4	922.3			

<b>325413--In-vitro diagnostic substance manufacturing</b>												
Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2015	176.2	175.8	175.7	178.7	179.8	180.4	179.3	178.1	177.0	174.7	174.9	174.3
2016	174.4	174.8	174.8	174.9	175.3	177.4	177.2	176.9	177.0	177.3	176.9	177.3
2017	177.9	178.1	177.2	178.0	177.4	176.9	176.2	177.7	177.1	177.8	177.0	176.7
2018	176.9	177.6	178.3	178.4	178.9	177.0	178.0	178.3	178.0	178.0	178.4	177.7
2019	179.3	179.0	181.1	178.5	177.8	178.0	178.2	179.5	179.3	178.9	178.4	178.0
2020	176.7	178.2	178.3	177.4	179.9	177.0	179.7	180.4	180.0			

<b>325414--Biological product (except diagnostic) manufacturing</b>												
Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2015	197.0	197.7	198.1	201.2	201.0	201.1	201.9	201.7	204.4	202.0	202.1	202.1
2016	205.7	206.2	206.2	212.1	212.1	209.9	209.9	210.3	207.0	207.2	207.7	207.9
2017	209.6	209.9	208.7	208.7	204.7	204.7	205.1	205.1	205.1	205.1	205.1	205.1
2018	207.9	208.8	209.2	209.4	209.4	210.6	211.2	211.2	211.2	211.2	211.2	212.1
2019	217.8	220.4	220.6	222.2	221.7	221.8	222.0	223.4	223.4	223.4	223.4	223.6
2020	227.4	227.5	227.5	227.5	227.5	227.5	227.8	227.8	227.8			

Source: BLS, Producer Price Indexes, NAICS 325411, 325412, 325413, 3254214 (accessed October 21, 2020).

Note: Data are for primary products. Corresponds to [figure 5.4](#).**Table E.24** U.S. employment, pharmaceutical manufacturing, by industry, 2015–19 and first quarter 2020 (in thousand employees)

Item	Calendar year					First quarter
	2015	2016	2017	2018	2019	2020p
Medicinal and botanical	25,301	27,230	28,662	29,908	31,888	34,160
Pharmaceutical preparation	201,588	201,665	203,965	201,668	209,715	211,351
In-vitro diagnostic	23,441	25,186	26,052	26,888	28,043	27,707
Biological product	29,801	31,381	33,337	35,551	36,274	37,190
Total	280,131	285,462	292,016	294,015	305,920	310,408

Source: BLS, Quarterly Census of Employment and Wages, (accessed November 2020).

Note: p=preliminary. 2015–19 data are annual averages. Data for 2020 are from the first quarter. Corresponds to [figure 5.5](#).

**Table E.25** U.S. imports of pharmaceuticals, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)

Item	Calendar year					Jan-Sept	
	2015	2016	2017	2018	2019	2019	2020
Medicinal and botanical	13.9	10.5	8.7	9.9	9.0	7.2	7.5
Pharmaceutical preparation	75.5	78.9	74.2	84.5	94.9	70.2	75.4
In-vitro diagnostic	3.5	3.8	4.4	5.1	5.2	3.8	4.8
Biological product	16.9	20.1	26.3	36.5	41.8	31.5	37.8
Total	109.9	113.3	113.6	136.1	150.9	112.7	125.5

Source: USITC DataWeb/USDOC, NAICS 325411, 325412, 325413, 325414 (accessed November 2020).

 Notes: Corresponds to [figure 5.6](#).

**Table E.26** U.S. imports, pharmaceuticals, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars and million kilograms)

Calendar year	Ireland	Germany	Switzerland	United Kingdom					Canada	Other sources	Total
				India	China	Mexico	Other sources	Total			
Value (billion dollars)											
2015	24.3	15.1	10.4	10.3	6.5	NA	NA	NA	43.3	109.9	
2016	26.4	14.0	10.8	7.9	8.0	NA	NA	NA	46.2	113.3	
2017	31.8	12.7	12.3	5.8	6.6	NA	NA	NA	44.3	113.6	
2018	35.9	16.1	14.7	7.1	6.8	NA	NA	NA	55.4	136.1	
2019	37.7	18.1	16.5	7.1	8.1	NA	NA	NA	63.5	150.9	
Jan–Sep 2019	27.6	14.0	12.4	5.5	6.2	NA	NA	NA	47.0	112.7	
2020	30.2	16.1	14.6	6.3	6.6	NA	NA	NA	51.7	125.5	
Volume (million kg)											
2015	NA	36.0	NA	NA	69.5	137.3	50.9	57.4	183.0	534.1	
2016	NA	38.9	NA	NA	73.3	133.5	64.8	53.6	184.5	548.5	
2017	NA	53.0	NA	NA	77.1	133.7	102.3	57.5	202.4	626.0	
2018	NA	65.9	NA	NA	91.9	147.9	125.4	65.2	224.4	720.7	
2019	NA	43.8	NA	NA	104.2	164.6	79.7	63.0	224.5	679.8	
Jan–Sep 2019	NA	32.9	NA	NA	78.1	121.9	61.7	47.8	169.0	511.4	
2020	NA	36.7	NA	NA	83.6	178.4	97.9	52.5	179.3	628.3	

Source: USITC DataWeb/USDOC (accessed November 2020).

 Note The countries presented are in the top five in value during January 2015–September 2020 and top five by total volume during January 2015–September 2020. Note: Corresponds to [figure 5.7](#).

**Table E.27** U.S. exports, pharmaceuticals, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)

Country	2015	2016	2017	2018	2019	2019	2020
Belgium	7.3	5.6	3.9	4.5	4.3	3.4	2.5
Netherlands	4.2	4.3	3.9	5.0	5.1	3.9	3.9
Germany	3.4	3.5	3.9	4.9	5.9	4.3	4.6
Italy	2.8	4.1	3.8	4.4	5.1	4.1	2.8
Japan	3.5	3.7	3.7	4.0	4.1	3.1	3.2
Other sources	32.8	30.9	32.0	32.0	35.2	26.8	26.6
Total	53.9	52.1	51.1	54.7	59.8	45.5	43.5

Source: USITC DataWeb/USDOC, NAICS 3254 (accessed November 2020).

 Note: The countries presented are in the top five in total value during January 2015–September 2020. Corresponds to [figure 5.8](#).

**Table E.28** U.S. imports of reagents for PCR-type molecular tests, July–September 2020 (in million dollars and metric tons)

<b>Value of reagent imports for U.S.</b>					
<b>(\$ millions)</b>	<b>China</b>	<b>Netherlands</b>	<b>Canada</b>	<b>Sweden</b>	<b>Other</b>
July 2019	7	5	13	4	4
August 2019	11	8	5	5	4
September 2019	8	11	7	6	7
<b>Volume of reagent imports for U.S. (metric tons)</b>					
	<b>Netherlands</b>	<b>Sweden</b>	<b>Canada</b>	<b>South Africa</b>	<b>Other</b>
July 2020	37,933	36,794	26,441	13,756	14,733
August 2020	86,145	49,598	15,352	1,020	10,536
September 2020	145,053	48,043	23,610	891	16,843

Source: USITC DataWeb/USDOC, HTS 3822.00.5050 (accessed November 2020).

Note: Corresponds to [figure 5.13](#).**Table E.29** U.S. imports of plastic laboratory ware, by country, January 2019–September 2020 (in million dollars)

<b>Month and year</b>	<b>Other</b>	<b>China</b>	<b>Austria</b>	<b>Canada</b>	<b>Total</b>
January 2019	25	9	.6	2	37
February 2019	26	6	.6	2	35
March 2019	28	5	.6	3	36
April 2019	26	7	.5	4	38
May 2019	29	7.8	.4	5.6	43
June 2019	27	6	.5	5	39
July 2019	31	8	.6	3	44
August 2019	28	8	1	3	42
September 2019	26	6	1	8	42
October 2019	27	7	1	5	41
November 2019	26	7	1	7	42
December 2019	26	8	1	6	41
January 2020	24	8	.7	2	37
February 2020	23	5	1	6	36
March 2020	28	3	1	4	38
April 2020	27	8	2	3	42
May 2020	31	14	4	6	55
June 2020	29	17	5	5	57
July 2020	30	22	11	8	71
August 2020	28	19	18	9	75
September 2020	32	20	14	11	77

Source: USITC DataWeb/USDOC, HTS 3926.90.9910 (accessed November 2020).

Note: Corresponds to [figure 5.14](#).

**Table E.30** U.S. imports of other articles of wadding of man-made fibers (including swabs), January 2019–September 2020 (in million dollars)

Month and year	China	Italy	South Korea	Other
January 2019	110	353	32	715
February 2019	172	359	34	151
March 2019	63	416	62	175
April 2019	102	346	95	262
May 2019	101	259	136	618
June 2019	132	191	61	235
July 2019	326	312	39	339
August 2019	346	304	69	257
September 2019	214	170	45	230
October 2019	114	272	71	213
November 2019	92	491	79	362
December 2019	59	277	49	279
January 2020	87	289	121	431
February 2020	76	341	37	299
March 2020	45	275	107	338
April 2020	290	1,434	122	445
May 2020	2,380	1,547	323	502
June 2020	3,667	1,230	146	373
July 2020	2,157	1,405	884	250
August 2020	2,380	887	2,732	646
September 2020	3,028	1,643	1,274	194

Source: USITC DataWeb/USDOC for HTS statistical reporting number 5601.22.0090 (accessed November 2020).

Note: Corresponds to [figure 5.15](#).

**Table E.31** U.S. imports of viral transport medium, July–September 2020 (in million dollars and metric tons)

Country	July	August	September
	<b>Value</b>		
China	28	13	7
South Korea	6	12	6
Italy	4	4	4
Other	1	2	0.5
Total	39	31	18
	<b>Volume</b>		
	<b>July</b>	<b>August</b>	<b>September</b>
China	215	120	98
Italy	150	107	97
South Korea	36	86	34
Other	34	67	8
Total	436	380	237

Source: USITC DataWeb/USDOC, HTS 3821.00.0010 (accessed November 2020).

Note: Corresponds to [figure 5.16](#).

**Table E.32** U.S. imports of vaccines for human use, by country, 2015–19, January–September 2019, and January–September 2020 (in metric tons)

Country	Calendar Year					Jan–Sep	
	2015	2016	2017	2018	2019	2019	2020
Belgium	363	370	338	496	780	620	581
Ireland	456	330	324	328	245	196	7
Germany	232	310	229	287	254	246	228
Canada	147	160	205	213	202	161	192
United Kingdom	224	167	90	25	68	63	49
Other	136	136	212	212	306	233	227

Source: USITC DataWeb/USDOC, HTS 3002.20.0000 (accessed November 8, 2020).

Note: Top five countries in 2015–September 2019 imports. Corresponds to [figure 5.20](#).

**Table E.33** U.S. imports of serum bottles, vials, and other pharmaceutical containers of glass, of a capacity not exceeding 0.15 liter, by country, 2015–19, January–September 2019, and January–September 2020 (in million containers)

Country	Calendar Year					Jan–Sep	
	2015	2016	2017	2018	2019	2019	2020
France	116	144	376	186	186	147	145
Mexico	114	125	133	138	224	158	206
China	68	111	83	108	168	119	118
Germany	122	125	101	119	95	79	43
Italy	66	95	109	98	58	43	32
Other	75	65	99	65	96	69	110
Total	561	665	902	713	827	614	652

Source: USITC DataWeb/USDOC, HTS 7010.90.0540 (accessed November 2020).

Note: Top five countries in 2015–September 2019 imports. Corresponds to [figure 5.21](#).

**Table E.34** U.S. imports of hypodermic syringes, with or without their needles, by country, 2015–19, January–September 2019, and January–September 2020 (in million syringes)

Country	Calendar Year					Jan–Sep	
	2015	2016	2017	2018	2019	2019	2020
China	402	347	432	656	682	503	564
South Korea	346	389	349	390	279	220	169
Thailand	193	178	48	109	62	49	39
Mexico	113	40	95	117	151	138	103
Philippines	84	82	68	99	81	67	45
Other	153	113	140	158	150	118	259
Total	1,289	1,149	1,131	1,529	1,405	1,095	1,180

Source: USITC DataWeb/USDOC, HTS 9018.31.0040 (accessed November 2020).

Note: Corresponds to [figure 5.22](#).

**Table E.35** Geographical distribution of establishments, soap and cleaning compound manufacturing, first quarter 2020

State	Number of establishments	State	Number of establishments
Alabama	15	Montana	2
Alaska	2	Nebraska	5
Arizona	22	Nevada	9
Arkansas	6	New Hampshire	6
California	164	New Jersey	72
Colorado	28	New Mexico	9
Connecticut	17	New York	59
Delaware	3	North Carolina	67
District of Columbia	NA	North Dakota	1
Florida	100	Ohio	81
Georgia	99	Oklahoma	14
Hawaii	8	Oregon	24
Idaho	6	Pennsylvania	52
Illinois	109	Rhode Island	9
Indiana	42	South Carolina	44
Iowa	15	South Dakota	6
Kansas	12	Tennessee	48
Kentucky	17	Texas	118
Louisiana	20	Utah	25
Maine	8	Vermont	10
Maryland	16	Virginia	25
Massachusetts	30	Washington	34
Michigan	73	West Virginia	4
Minnesota	29	Wisconsin	53
Mississippi	18	Wyoming	
Missouri	67		

Source: Bureau of Labor Statistics (BLS), Quarterly Census of Employment and Wages, First Quarter 2020, NAICS 32561 (accessed October 2020).

Note: NA = not available. An establishment is “a single physical location at which business is conducted or services or industrial operations are performed.” For more information, see Census Bureau, “Glossary” (accessed August 13, 2020). Corresponds to [figure 6.1](#).

**Table E.36** Soap and cleaning compound establishments, employment, payroll, and receipts, by enterprise size, 2017

	Establishments	Employment	Payroll	Receipts
SME's	88%	50%	43%	23%
Large firms	12%	50%	57%	77%

Source: U.S. Census Bureau, Statistics of U.S. Businesses data, NAICS 32561 (accessed August 2020).

Note: Data for receipts are preliminary data. “Receipts (net of taxes collected from customers or clients) are defined as operating revenue for goods produced or distributed, or for services provided.” Business size is based on the size of the enterprise. “An enterprise (or ‘company’) is a business organization consisting of one or more domestic establishments that were specified under common ownership or control.” For more information, see Census, “Glossary” (accessed August 13, 2020). Corresponds to [figure 6.2](#).



**Table E.37** Soap and cleaning compound shipments and value added, 2015–18 (top, in billion dollars) and share of shipments by product type, 2016 (bottom, percent of shipments)

Year	Value added (billion dollars)				Shipments (billion dollars)			
	2015	2016	2017	2018	2015	2016	2017	2018
Soap and cleaning compound	23.2	24.9	23.4	23.4	38.8	39.4	39.1	38.5

	Share of 2016 shipments
Detergents (household)	27%
Detergents (non-household)	21%
Surface active agents	19%
Specialty cleaning and sanitation products	14%
Soaps (household)	7%
Bleach (household)	3%
Other	8%

Source: U.S. Census Bureau, Annual Survey of Manufactures and Economic Census data, NAICS 32561 (accessed August 2020).

Note: Corresponds to [figure 6.3](#).

**Table E.38** U.S. employment, soap and cleaning compound manufacturing, 2015–19 and first quarter 2020 (in thousand employees)

Description	Calendar Year				Jan-Mar	
	2015	2016	2017	2018	2019	2020
Soap and cleaning compound manufacturing	52,725	52,959	53,140	54,701	54,756	54,741

Source: BLS, “Quarterly Census of Employment and Wages,” NAICS 32561 (accessed October 2020).

Note: Corresponds to [figure 6.4](#).

**Table E.39** U.S. imports of soaps and cleaning compounds, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)

	Calendar Year					Jan-Sep	
	2015	2016	2017	2018	2019	2019	2020
Canada	0.9	0.8	0.8	0.9	0.8	0.6	0.7
Mexico	0.7	0.7	0.7	0.8	0.9	0.6	1.0
China	0.3	0.4	0.4	0.5	0.4	0.3	0.8
All other	1.7	1.7	1.9	2.1	2.0	1.5	2.2
Total	3.3	3.3	3.5	3.7	3.7	2.8	3.9

Source: USITC DataWeb/USDOC, NAICS 32561 (accessed November 2020).

Note: Corresponds to [figure 6.5](#).

**Table E.40** U.S. exports of soaps and cleaning compounds, by country, 2015–19, January–September 2019, and January–September 2020 (in billion dollars)

	Calendar Year					Jan-Sep	
	2015	2016	2017	2018	2019	2019	2020
Canada	2.4	2.4	2.5	2.5	2.5	1.9	2.2
Mexico	0.7	0.7	0.7	0.8	0.8	0.6	0.5
China	0.6	0.6	0.7	0.7	0.5	0.4	0.4
All other	3.7	3.7	3.9	3.9	3.8	2.9	2.7
Total	7.5	7.4	7.8	7.9	7.6	5.7	5.9

Source: USITC DataWeb/USDOC, NAICS 32561 (accessed November 2020).

Note: Corresponds to [figure 6.6](#).



# **Appendix F**

## **FDA Regulation of Drugs, Biologics, and Medical Devices**



# FDA Regulation of Drugs, Biologics, and Medical Devices

The Food and Drug Administration (FDA) figures prominently across numerous product areas covered in the report, owing to its power to grant emergency use authorizations, its involvement in vaccine research, and its regulation of COVID-19 related products. FDA oversees the safety and effectiveness of drugs and medical devices under the Federal Food, Drug, and Cosmetic Act and of biological products under the Public Health Services Act.<sup>907</sup> FDA’s mission continues after product approval, including through the agency’s ongoing review of reports of adverse events (such as adverse drug reactions) and its other programs for the surveillance of products after they are sold.<sup>908</sup>

Several of FDA’s centers are responsible for regulating important products related to COVID-19. For example, its Center for Biologics Evaluation and Research oversees biological products, including all vaccines. The Center for Drug Evaluation and Research oversees small-molecule drugs and certain therapeutic biologics. Another important center, the Center for Devices and Radiological Health, oversees medical devices and radiologic products.<sup>909</sup>

## Drugs and Biologics: Review Processes

FDA generally requires the sponsor (usually the manufacturer) of a new drug or biologic to submit data from clinical trials to provide evidence of the drug’s safety and effectiveness, or in the case of biologics, the product’s safety, purity, and potency.<sup>910</sup> Before beginning clinical testing, the sponsor must file an investigational new drug (IND) application—a request for permission to administer an investigational drug or biologic to humans before it is approved or licensed.<sup>911</sup> In completing the IND application, the sponsor includes information about the drug or biologic and its chemistry, manufacturing, and controls; the proposed clinical study design; completed animal test data; and an assurance that an institutional review board will oversee the clinical studies, among other things.<sup>912</sup>

The clinical trials needed to support an application are typically conducted in three phases. Phase 1 clinical trials assess safety, and both safety and immunogenicity for biologics, in a small number of volunteers. Phase 2 trials assess dosing and side effects, and they may enroll hundreds of volunteers. Phase 3 trials assess effectiveness and continue to monitor safety; they typically include hundreds to

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<sup>907</sup> A biological product is “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.” PHSa § 351(i), 42 U.S.C. § 262(i). *See also* FFDCa §§ 201(g) and 201(h), 21 U.S.C. §§ 321(g) and 321(h).

<sup>908</sup> FDA, “Surveillance: Post Drug-Approval Activities,” February 5, 2018.

<sup>909</sup> CRS, “Medical Product Regulation: Drugs, Biologics, and Devices,” January 28, 2019, 1.

<sup>910</sup> FFDCa § 505(a), 21 U.S.C. § 355(a); PHSa § 351(a), 42 U.S.C. § 262(a); CRS, “Development and Regulation of Medical Countermeasures,” June 25, 2020, 15.

<sup>911</sup> FFDCa § 505(i), 21 U.S.C. § 355(i); PHSa § 351(a)(3), 42 U.S.C. § 262(a)(3); CRS, “Development and Regulation of Medical Countermeasures,” June 25, 2020, 15.

<sup>912</sup> CRS, “Development and Regulation of Medical Countermeasures,” June 25, 2020, 15-16.

thousands of volunteers.<sup>913</sup> Once a sponsor completes clinical trials, the sponsor submits the results of those investigations, along with other information, to FDA in a new drug application (NDA) or a biologics license application (BLA). The requirements and review pathways for NDAs and BLAs are generally similar.<sup>914</sup> On average, FDA took 10 months to approve standard NDAs and BLAs and 8 months to approve priority applications in 2018.<sup>915</sup>

## Medical Devices: Review Processes

Medical devices range from simple products, like medical gloves and tongue depressors, to complex programmable ventilators and in vitro diagnostic products, such as reagents and test kits.<sup>916</sup> The pathway to FDA approval of a medical device depends on its risk classification as Class I (low risk), Class II (moderate risk), or Class III (high risk). As the level of risk increases, regulatory review and controls also increase (table F.1).

**Table F.1** Medical device review and examples

Class	Review requirement	COVID-19 related product examples
I	General controls	Medical gloves (including patient examination and surgical gloves); nonsurgical gowns
II	Special controls and 510(k) clearance	Surgical gowns and surgical isolation gowns; surgical masks and surgical N95 filtering facepiece respirators (FFRs)
III	Premarket approval (PMA)	Certain ventilators

Sources: FDA, “Step 3: Pathway to Approval,” February 9, 2018; CRS, “Personal Protective Equipment (PPE) and COVID-19,” September 22, 2020; Van Norman, “Drugs, Devices, and the FDA: Part 2,” June 2016, 279.

Notes: Surgical N95 FFRs are also subject to approval by the National Institute for Occupational Safety and Health (NIOSH). Medical gloves also require a 510(k) clearance.

As an initial matter, all devices must meet “general controls,” which scrutinize registration, labeling, and compliance with current “good manufacturing practice” regulations, unless there has been an exemption.<sup>917</sup> Most Class II devices (and some Class I devices) also must meet “special” or device-specific controls and obtain a section 510(k) clearance. Obtaining this clearance requires the manufacturer to demonstrate that the device proposed to be marketed is substantially equivalent to a device already on the market; it does not typically require the submission of clinical data.<sup>918</sup> Generally, Class III (and some Class II) devices require premarket approval from FDA based on reasonable assurances that a device is safe and effective for its intended use. As with drugs, effectiveness generally is established through rigorous (and often lengthy) clinical trial processes.<sup>919</sup>

For most Class I devices, the option of self-registration by the manufacturer is generally available and may be completed in as little as a week (although medical gloves also are subject to 510(k) clearance).

<sup>913</sup> CRS, “Development and Regulation of Medical Countermeasures,” June 25, 2020, 16; FDA, “Vaccine Product Approval Process,” January 30, 2018.

<sup>914</sup> CRS, “Development and Regulation of Medical Countermeasures,” June 25, 2020, 16; FDCA § 505(b), 21 USC § 355(b).

<sup>915</sup> FDA, “FY 2019 Performance Report to Congress for the Prescription Drug User Fee Act,” n.d., 22.

<sup>916</sup> In vitro diagnostics may also be biological products subject to section 351 of the Public Health Service Act.

<sup>917</sup> CRS, “Personal Protective Equipment (PPE) and COVID-19,” September 22, 2020, 1.

<sup>918</sup> CRS, “Personal Protective Equipment (PPE) and COVID-19,” September 22, 2020, 1.

<sup>919</sup> FDA, “Step 3: Pathway to Approval,” February 9, 2018.

Most Class II devices require 510(k) certifications, with an average FDA clearance time of about six months. However, if the manufacturer opts to rely on third-party certification bodies, review times may be substantially shorter.<sup>920</sup> For Class III devices, once the manufacturer submits the premarket approval (PMA) application and accompanying clinical trial data, the approval time is about eight months.<sup>921</sup> The entire life cycle of the product development process—from concept to research and development and to clinical testing—may take 3 to 7 years for a medical device, and an average of 12 years for a drug.<sup>922</sup>

## Accelerated Review Processes

FDA has several mechanisms in place to speed approval processes for drugs, biologics, and medical devices related to COVID-19 (table F.2). FDA has particularly relied on one expedited approval mechanism for COVID-19 related medical products: emergency use authorizations (EUAs).<sup>923</sup> The Secretary of the U.S. Department of Health and Human Services (HHS) may issue an EUA to permit the use of an unapproved medical product, or the unapproved use of an approved product, if the Secretary makes the requisite declaration of a public health emergency.<sup>924</sup> Effective February 4, 2020, the HHS Secretary made such a determination for the virus that causes COVID-19, and declared that circumstances exist justifying the authorization of emergency use of various medical products.<sup>925</sup> Thereafter, FDA may issue EUAs for COVID-19 medical products if, after consulting with National Institutes of Health (NIH), CDC, and HHS, it concludes that (1) COVID-19 can cause a serious or life-threatening disease or condition; (2) based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in preventing or treating COVID-19; (3) the known and potential benefits of the product outweigh its known and potential risks; and (4) there is no adequate, approved, and available alternative product.<sup>926</sup> The EUAs have provided a much faster pathway than otherwise would be available for the development and approval of diagnostic tests and other medical products. They remain in effect for the duration of the emergency declaration by the HHS Secretary, unless revoked at an earlier date.<sup>927</sup>

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<sup>920</sup> Emergo, “How Long it Takes,” March 2017, 5; Fenton, “How Long Does the FDA,” December 3, 2019.

<sup>921</sup> Fenton, “How Long Does the FDA,” December 3, 2019.

<sup>922</sup> Van Norman, “Drugs, Devices, and the FDA: Part 2,” June 2016, 277.

<sup>923</sup> FDA, “Emergency Use Authorization,” November 24, 2020 (listing all current EUAs).

<sup>924</sup> The Secretary also may authorize the introduction into interstate commerce (i.e., the sale and importation) of a medical product intended for emergency use. FDCA §§ 564(a) and (b), 21 U.S.C. §§ 360bbb-3(a) and (b).

<sup>925</sup> 85 Fed. Reg. 13907, March 10, 2020 (effective February 4, 2020). *See also* 85 Fed. Reg. 17335, March 27, 2020 (effective February 4, 2020). *See also* FDA, “Emergency Use Authorization,” November 24, 2020.

<sup>926</sup> FDCA § 564(c), 21 U.S.C. § 360bbb-3(c).

<sup>927</sup> AdvaMed and AdvaMedDX, post-hearing submission to the USITC, October 2, 2020, 3; FDCA § 564(c), 21 U.S.C. § 360bbb-3(c).

**Table F.2** Mechanisms, criteria, and features of accelerated FDA review processes

<b>Mechanisms</b>	<b>Qualifying products</b>	<b>Criteria</b>	<b>Features</b>
Accelerated approval pathway	Drugs, biologics	<ul style="list-style-type: none"> <li>• Treat a serious condition;</li> <li>• Provide a meaningful advantage over available therapies; and</li> <li>• Demonstrate an effect on a clinical or surrogate endpoint (such as a laboratory test) that is reasonably likely to predict clinical benefit</li> </ul>	<ul style="list-style-type: none"> <li>• Manufacturer is required to conduct post-marketing clinical trials to verify the drug’s benefit. Approval can be revoked if trials are unsuccessful</li> </ul>
Fast-track product designation	Drugs, biologics	<ul style="list-style-type: none"> <li>• Intended to treat a serious condition; and</li> <li>• Nonclinical or clinical data demonstrate potential to address unmet medical need</li> <li>• Also, a drug (not biologic) may be eligible if designated a qualified infectious disease product</li> </ul>	<ul style="list-style-type: none"> <li>• Frequent interactions with FDA review team</li> <li>• Priority review</li> <li>• Rolling review (portions of application before completed)</li> </ul>
Breakthrough designation	Drugs, biologics	<ul style="list-style-type: none"> <li>• Intended to treat a serious condition; and</li> <li>• Preliminary clinical evidence indicates that the drug demonstrates substantial improvement on a clinically significant endpoint over available therapies</li> </ul>	<ul style="list-style-type: none"> <li>• Rolling review</li> <li>• Intensive FDA guidance on designing an efficient drug development program</li> <li>• Experienced personnel facilitate collaborative, cross-disciplinary review to expedite development and review</li> </ul>
Priority review designation	Drugs, biologics	<ul style="list-style-type: none"> <li>• Significantly improve the treatment, diagnosis, or prevention of serious conditions; and</li> <li>• Would provide a significant improvement in safety or effectiveness, if approved</li> <li>• May also qualify if submitted with a priority review voucher (for certain tropical diseases, rare pediatric diseases, and medical threats) or if the drug (not biologic) is a qualified infectious disease product</li> </ul>	<ul style="list-style-type: none"> <li>• FDA will attempt to review the application within 6 months rather than the usual 10 months</li> </ul>
Breakthrough device designation	Medical devices	<p>FDA can prioritize review of devices that:</p> <ul style="list-style-type: none"> <li>• Provide more effective diagnosis or treatment of a life-threatening or irreversibly debilitating condition; and</li> <li>• Represent breakthrough technologies for which no approved alternatives exist, that offer significant advantages over existing alternatives, or that are in the patient’s best interests</li> </ul>	<ul style="list-style-type: none"> <li>• Expedited development, assessment and review of devices in premarketing approval, 510(k) clearance, or marketing authorization</li> </ul>

Sources: FDA, “Development & Approval Process, Drugs,” October 28, 2019; CRS, “Development and Regulation of Medical Countermeasures,” June 25, 2020, 18–19.



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# **Appendix G**

## **Counterfeit and Other Illicit COVID-19 Related Products**



# Counterfeit and Other Illicit COVID-19 Related Products

Several U.S. government agencies are involved in the response to counterfeit and other illicit COVID-19 related goods. These include the U.S. Department of Health and Human Services (HHS), including the Food and Drug Administration (FDA) and the National Institute for Occupational Safety and Health (NIOSH); the U.S. Department of Homeland Security (DHS), including U.S. Customs and Border Protection (CBP) and Homeland Security Investigations (HSI), which is part of U.S. Immigration and Customs Enforcement (ICE); and the U.S. Department of Justice (DOJ). Table G.1 gives examples of U.S. government activities to thwart the distribution of counterfeit and other illicit COVID-19 related products.

To address this illicit activity, legitimate producers must divert resources from critical business operations to focus on protecting their brands and policing online platforms. Small and medium-sized companies are most likely to be harmed because they have fewer resources to invest in monitoring and enforcement and less cushion to absorb losses from illicit activity.<sup>928</sup> Notable private legal actions include 18 federal lawsuits brought by 3M accusing unauthorized vendors of price gouging and deceptive practices connected to sales of N95 respirators. Similarly, Abbott Laboratories and others have sued for trademark violations and fraud related to sales of diagnostic test kits.<sup>929</sup>

**Table G.1** Selected U.S. government actions related to illicit COVID-19 products

U.S. government agencies	U.S. government measures and activities	Examples
HSI	HSI launched Operation Stolen Promise, a public-private partnership of federal law enforcement and regulatory agencies and the private sector, in April 2020 to address COVID-19 related fraud and criminal activity.	As of November 6, 2020, the Operation reported, among other results: <ul style="list-style-type: none"> <li>• Disrupted transactions and recovered funds valued at \$18.8 million;</li> <li>• Seizures of \$12.7 million in illicit proceeds;</li> <li>• 170 criminal arrests, 148 search warrants, and 51 disruptions of illicit activities;</li> <li>• Analysis of 69,086 COVID-19 related domain names for fraud or counterfeiting; and</li> <li>• 1,621 seizures of COVID-19 related illicit products.<sup>a</sup></li> </ul>

<sup>928</sup> National Association of Manufacturers, “Countering Counterfeits,” July 2020, 4.

<sup>929</sup> Donahue, “Facing COVID-19 Scams,” October 21, 2020.

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U.S. government agencies	U.S. government measures and activities	Examples
CBP	CBP may exclude from entry, detain, and/or seize trademark- or copyright-infringing products as well as products subject to USITC exclusion orders. CBP also works with other government agencies to identify and seize unapproved or otherwise substandard products. <sup>b</sup>	As of September 30, 2020, U.S. government officials reported seizures of more than: <ul style="list-style-type: none"> <li>• 177,000 COVID-19 test kits prohibited by the FDA;</li> <li>• 12.7 million counterfeit face masks;</li> <li>• 36,000 anti-virus lanyards prohibited by the Environmental Protection Agency (EPA);</li> <li>• 5,000 tablets of antibiotics, such as azithromycin, and</li> <li>• 300,000 seizures of hand sanitizers.<sup>c</sup></li> </ul>
NIOSH	NIOSH approves respirators that are compliant with their standards and publishes notices of respirators that have been falsely labeled as approved.	In August 2020, NIOSH publicly listed more than 20 instances of respirators that had been falsely identified as NIOSH-approved. <sup>d</sup>
FDA	FDA issues warning letters to firms selling fraudulent products that purport to prevent or treat COVID-19. It also pursues seizures, injunctions, or criminal prosecutions against products and firms or individuals that violate the law.	FDA has issued more than 100 warning letters to firms selling fraudulent products with claims to prevent, treat, mitigate, diagnose, or cure COVID-19. <sup>e</sup>
DOJ	DOJ prosecutes criminal cases under mail and wire fraud statutes and other statutes. The mail and wire fraud statutes prohibit (1) any knowing participation in a scheme to defraud, together with (2) the use of the mail, or communications by interstate wires, to further the scheme—and other statutes. DOJ also prosecutes violations of prohibitions on hoarding under section 102 of the Defense Production Act and Executive Order 13910.	On March 21, 2020, DOJ obtained a restraining order in an alleged wire fraud scheme conducted by the operators of the website “coronavirusmedicalkit.com.” <sup>f</sup>  On September 29, 2020, a Thai national was indicted for defrauding a U.S. company with false representations that he was an authorized distributor of 3M N95 respirators and surgical masks. <sup>g</sup>
HHS	On March 23, 2020, the President issued Executive Order 13910, which delegated authority to the HHS Secretary to prohibit the hoarding of health and medical resources needed to respond to COVID-19. <sup>h</sup>	On March 25, 2020, the Secretary designated the following products as subject to this prohibition: PPE, respirators, ventilators, drug products with chloroquine phosphate or hydroxychloroquine as an active ingredient, sterilization services, disinfecting devices, and medical gowns or apparel. <sup>i</sup>

<sup>a</sup> DHS, HSI, “Operation Stolen Promise,” November 6, 2020.

<sup>b</sup> CBP, “What Every Member of the Trade Community Should Know,” August 2012, 6.

<sup>c</sup> U.S. government official, email message to USITC staff, October 22, 2020.

<sup>d</sup> CDC, NIOSH, NPPTL, “Counterfeit Respirators / Misrepresentation of NIOSH-Approval,” August 25, 2020.

<sup>e</sup> FDA, “Fraudulent Coronavirus Disease 2019 (COVID-19) Products,” September 21, 2020.

<sup>f</sup> DOJ, “Justice Department Files Its First Enforcement Action,” March 22, 2020.

<sup>g</sup> DOJ, USAO-NJ, “Thailand National Indicted for Defrauding New Jersey Company,” September 29, 2020.

<sup>h</sup> Executive Office of the President, Executive Order no. 13910, March 23, 2020.

<sup>i</sup> HHS, “HHS Implements President Trump’s Hoarding Prevention Executive Order,” March 25, 2020.

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