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COVID-19 and Domestic PPE Production and Distribution: Issues and Policy Options

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SUMMARY

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COVID-19 and Domestic PPE Production and Distribution: Issues and Policy Options

The novel Coronavirus Disease 2019 (COVID-19) and its rapid emergence as a pandemic have highlighted issues relating to the production and distribution of personal protective equipment (PPE). PPE refers to worn articles or equipment that help minimize exposure to various hazards, including infectious pathogens. Given the role that PPE plays in mitigating the spread and reducing the impacts of COVID-19, PPE demand has spiked both globally and domestically while supply has been undercut by both rapid consumption as well as supply chain disruptions. According to multiple federal agencies, including the Government Accountability Office, the Food and Drug Administration, and various independent organizations, PPE continues to be in short supply, which has led to broad congressional and public interest in PPE production and distribution issues. The availability of effective PPE is critical to the ongoing pandemic response, but also has broader public health, emergency preparedness, and national security implications.

This report considers aspects of domestic production and distribution of PPE in the context of the COVID-19 pandemic. Specifically, the report considers (1) the availability of PPE supplies, including an assessment of PPE demand related to the COVID-19 pandemic; (2) federal actions and activities undertaken to increase PPE supplies in response to the pandemic, organized by executive agency and program; and (3) other policy options under consideration concerning PPE production and distribution, also organized by executive agency and program.

Overall, this report notes that data limitations and conflicting accounts impede the complete assessment of PPE supply chains, and this may undermine federal (as well as nonfederal) efforts to respond effectively to the COVID-19 pandemic. To the extent that data is available, current PPE production and distribution channels appear to continue to be insufficient compared to reported need. Various mechanisms that may be utilized to increase PPE supply or productive capacity, such as the provisions in the Defense Production Act of 1950 (DPA), appear to be applied selectively, and implemented unevenly, potentially based on narrow experience and limited administrative infrastructure within the federal government to oversee and manage its use in a national emergency context.

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Introduction

Personal protective equipment (PPE) shortages continue to be a factor in the ongoing federal, and nationwide, response to the COVID-19 pandemic. According to a September 2020 Government Accountability Office (GAO) report, PPE shortages "remain due to a limited supply chain with limited domestic production and high global demand."[1] The Food and Drug Administration (FDA) has listed multiple categories of PPE on its medical device shortage list.[2] In addition, recent independent surveys show that acute PPE shortages continue to be an issue in nursing home environments,[3] as well as generally among the domestic nurse population.[4] In response, Congress has issued letters,[5] introduced legislation,[6] and opened investigations[7] as a means of studying and potentially addressing the extended PPE shortage issue.

This report supports demonstrated congressional interest in this topic, given the continued relevance of PPE shortages amid the pandemic. This report considers aspects of domestic production and distribution of PPE in the context of the COVID-19 pandemic, including

1. information, context, and analysis regarding domestic production and distribution of PPE;
2. demand for PPE over the course of the pandemic and its effect on supply;
3. how the federal government has addressed shortages with existing and emergency authorities; and
4. federal policy options currently under consideration to increase domestic PPE production and supply to meet current and anticipated demand for PPE.

This report is focused specifically on PPE, and does not explicitly consider or address Trump Administration actions related to the production and distribution of other health and medical

[1] Government Accountability Office (GAO), *COVID-19: Federal Efforts Could be Strengthened by Timely and Concerted Actions*, GAO-20-701, September 2020, p. 111 (hereinafter GAO, *COVID-19: Federal Efforts*), at https://www.gao.gov/assets/710/709492.pdf.

[2] Food and Drug Administration (FDA), *Medical Device Shortages During the COVID-19 Public Health Emergency*, September 24, at https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency.

[3] Brian E. McGarry, David C. Grabowski, and Michael L. Barnett, "Severe Staffing And Personal Protective Equipment Shortages Faced By Nursing Homes During The COVID-19 Pandemic," *Health Affairs*, vol. 39, no. 10 (August 10, 2020), accessed at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.01269.

[4] American Nurses Association, *New Survey Findings from 21K US Nurses: PPE Shortages Persist, Re-Use Practices on the Rise Amid COVID-19 Pandemic*, September 1, 2020, at https://www.nursingworld.org/news/news-releases/2020/new-survey-findings-from-21k-us-nurses—ppe-shortages-persist-re-use-practices-on-the-rise-amid-covid-19-pandemic/.

[5] Letter from Hon. Richard E. Neal, Chairman, House Committee on Ways & Means, to Hon. Michael Pence, Vice President, April 1, 2020, at https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/2020.4.1%20WM%20PPE%20Ltr%20to%20Task%20Force.pdf.

[6] Office of Senator Chris Murphy, "Murphy, Blumenthal, Baldwin Introduce NDAA Amendment To Increase National Production Of Testing Supplies And PPE As Covid-19 Cases Rise," press release, June 1, 2020, at https://www.murphy.senate.gov/newsroom/press-releases/murphy-blumenthal-baldwin-introduce-ndaa-amendment-to-increase-national-production-of-testing-supplies-and-ppe-as-covid-19-cases-rise-.

[7] Letter from Hon. James E. Clyburn, Chairman, House Select Subcommittee on the Coronavirus Crisis, Hon. Maxine Waters, Chairwoman, House Committee on Financial Services, Hon. Carolyn B. Maloney, Chairwoman, House Committee on Oversight and Reform, and Hon. Stephen F. Lynch, Chairman, House Subcommittee on National Security, to Hon. Mark T. Esper, Secretary of Defense, October 2, 2020, at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-10-02.Clyburn%20Waters%20CBM%20SFL%20%20to%20Esper-%20DOD%20re%20CARES%20Act.pdf.

resources, such as vaccines or pharmaceutical ingredients. However, some of the information contained herein may be relevant to the broader production of health and medical resources, including vaccine development.

What's in a Name? PPE and Descriptive Conventions

Personal protective equipment, or PPE, refers to worn articles or equipment that help minimize exposure to various hazards, including infectious pathogens like the novel coronavirus that causes COVID-19. Examples include surgical masks, N95 respirators, sterile gloves, surgical gowns, face shields, and the like. However, because this report considers not only the finished PPE articles themselves, but the broader production and distribution of those supplies (i.e., the domestic supply chains), descriptions and analysis in this report include inputs and other production elements that may not alone be considered PPE, such as synthetic textiles or pharmaceutical agents, but are important parts of the production process. In addition, although this report focuses on PPE (and their relevant constituent production inputs), it also is potentially broadly applicable to other non-PPE medical articles or devices. This includes medical articles or devices that may be directly noted, or implied, during discussions around "PPE," as that term may be sometimes used as a metonym for a variety of articles for controlling the COVID-19 pandemic, such as testing supplies, hand sanitizer, prophylaxes, and vaccines to a certain extent—as well as their respective material or chemical components.

The data in this report are subject to regular update, correction, and reinterpretation by the agencies that release them, as well as by CRS analysts. As such, this report will be updated regularly as necessary, particularly during the duration of the COVID-19 pandemic. This report was centrally coordinated but collaboratively written between all the authors, with extensive peer review as part of the normal CRS editorial process. Individual authors' specific section contributions generally hew to their areas of expertise as tabulated in **Appendix B**.

PPE Production and Distribution: Status in Context

The COVID-19 pandemic has demonstrated ways in which the United States relies heavily on global supply chains (see text box) for many essential goods and materials related to PPE. Domestic shortages of critical supplies and medical products have prompted congressional interest in a better understanding of import trends as well as of domestic production capacity in essential industries. The pandemic also demonstrated the potential limitations of globalized supply chains, as public health countermeasures created difficulties maintaining production, while high global demand interrupted distribution.

Congress and the Trump Administration have sought ways to increase the U.S. supply of personal protective equipment (PPE), pharmaceuticals, and other medical products by providing economic incentives to firms. They have also strengthened government procurement requirements to better prioritize domestically-produced goods.[8] One policy response by the Administration, similar to what occurred in many other countries, was to impose export bans on PPE as a means of

[8] White House, "Executive Order on Maximizing Use of American-Made Goods, Products, and Materials," July 15, 2020, at https://www.whitehouse.gov/presidential-actions/executive-order-maximizing-use-american-made-goods-products-materials/, and "Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States," August 6, 2020, at https://www.whitehouse.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/. See also Andrea Shalal and Susan Heavy, "Trump Order to Buy U.S.-Made Medical Supplies Coming Soon: Navarro," *Reuters*, May 4, 2020; Kayla Tausche, Ryan Bhattacharjee, and Lauren Hirsch, "White House Preparing Executive Order Requiring Certain Essential Drugs Be Made in U.S., Sources Say," *CNBC*, May 15, 2020; and *The Hill*, "Trump to Sign Order Seeking to Boost Domestic Drug Manufacturing," August 6, 2020.

preserving domestic stocks.[9] However, some experts questioned this strategy, noting that domestic bans constrained trade flows and, in aggregate, could exacerbate supply shortages.[10]

China's Role in Domestic PPE Supply Chains

China is a major U.S. and global supplier of medical PPE, medical consumables, and active pharmaceutical ingredients. According to U.S. trade data, in 2019 China supplied over 70% of U.S. imports of textile face masks, 55% of U.S. imports of protective eyewear, and 55% of U.S. imports of protective garments for surgical and medical use.[11] The spike in demand for PPE and pharmaceuticals due to the COVID-19 pandemic has highlighted the potential risks of these dependencies on China. In January and February 2020, at the height of the COVID-19 outbreak in China, and prior to the emergence of major clusters in the United States, the Chinese government organized a large-scale purchase of PPE for China on the global market, depleting existing supplies in the United States and other countries such as Australia and Canada.

In early February 2020, the Chinese government nationalized control of the production and distribution of medical supplies in China, including PPE.[12] China's nationalization efforts, while understandable as part of its response to address its COVID-19 outbreak (which preceded similar policies by other pandemic-affected countries, including the United States), may have denied the United States and other countries timely access to critical medical supplies. Although China imposed no formal export restrictions on the export of PPE, multinational manufacturers of PPE, including Minnesota-based 3M and Canadian firm Medicom, informed the media that all masks produced in their facilities in China were procured to meet domestic demand, while China allowed only smaller manufacturers to export PPE, some of which recipient countries, including the United States, found to be unusable.[13] China did not provide notice of its *de facto* export constraints to the World Trade Organization (WTO), as other countries did.[14] Subsequently, China's imposition of new export quality checks for PPE, particularly masks, implemented by China's National Medical Products Administration (NMPA) in April 2020, further slowed exports. Some U.S. legal experts observed that China may have been using informal measures, such as administrative guidance, to prioritize exports to certain countries ahead of the United States, potentially for political reasons,[15] as the Chinese government orchestrated highly-publicized PPE deliveries to countries in Europe.

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[9] Pamela Boykoff, Clare Sebastian, and Valentina Di Donato, "In the Race to Secure Medical Supplies, Countries Ban or Restrict Exports," *CNN.com*, March 27, 2020, at https://www.cnn.com/2020/03/27/business/medical-supplies-export-ban/index.html.

[10] Stormy-Annika Mildner et al., *Export Controls and Export Bans over the Course of the Covid-19 Pandemic*, World Trade Organization, April 29, 2020, at https://www.wto.org/english/tratop_e/covid19_e/bdi_covid19_e.pdf.

[11] It is not always possible to estimate the share that imports from China—or any other trading partner—make up in total U.S. supply. Harmonized Tariff Schedule of the United States (HTSUS) codes used to record U.S. exports and imports and North American Industry Classification System (NAICS) categories used to record domestic production cannot be matched directly due to differences in how the two systems classify products. As Pierce and Schott (2009) note, HTSUS codes are based solely on product characteristics, while NAICS codes may also take into account production methods. As a result, it may not be possible to match a given HTSUS category to a single NAICS category. In addition, U.S. exports and imports cannot be broken out by the full set of NAICS categories. For more details on these limitations, see Justin R. Pierce and Peter K. Schott, "A Concordance Between Ten-Digit U.S. Harmonized System Codes and SIC/NAICS Product Classes and Industries," NBER Working Paper No. w15548, 2009. Also see CRS In Focus IF11648, *Medical Supply Chains and Policy Options: The Data Challenge*, by Andres B. Schwarzenberg and Karen M. Sutter.

[12] Zhang Pinghui and Zhou Xin, "Coronavirus: China Shifts Responsibility over Medical Supplies amid Mask Shortage, Rising Death Toll," *South China Morning Post*, February 3, 2020, updated on February 14, 2020.

[13] Keith Bradsher and Liz Alderman, "The World Needs Masks. China Makes Them—But Has Been Hoarding Them," *New York Times*, March 16, 2020; John Miller, "Swiss Warn over Faulty Protective Masks Bought During COVID-19 Rush," *Reuters*, July 17, 2020; Alexandra Stevenson and Tiffany May, "China Pushes to Churn Out Coronavirus Gear, Yet Struggles to Police It," *New York Times*, March 27, 2020; and "Coronavirus: Countries Reject Chinese-Made Equipment," *BBC*, March 30, 2020.

[14] World Trade Organization (WTO), "Standards, Regulations and COVID-19—What Actions Taken by WTO Members?" information note, May 20, 2020, at https://www.wto.org/english/tratop_e/covid19_e/standards_report_e.pdf.

[15] Steve Dickinson, "Buying Face Masks and Other PPE from China Just Got a LOT Tougher," *Harris Bricken China Law Blog*, April 2, 2020, at https://www.chinalawblog.com/2020/04/buying-face-masks-and-other-ppe-from-china-

This realization of the potential risks of concentrated dependence on China for critical products and inputs has led the U.S. government and some in U.S. industry to consider mitigating supply chain risk by diversifying sources of supply. These efforts include re-shoring some domestic production of PPE and exploration of potential sourcing arrangements with other countries and trading partners, such as Vietnam and Mexico—countries which also benefit from low labor and input costs coupled with an increasingly skilled workforce.[16] Despite relying on China for certain PPE and active pharmaceutical ingredients (API), the United States together with Europe is a global leader in high-end medical devices and novel pharmaceutical drug innovation, sectors in which China is seeking to gain an advantage through its industrial policies such as *Made in China 2025*. U.S. efforts to re-shore or diversify supply chains are primarily responding to an immediate crisis. Although they respond to current short-term shortages, these efforts may not be attuned to material requirements that will be needed at later stages in the pandemic, such as for vaccine development and deployment. These efforts may also require more strategic considerations such as how to sustain U.S. competitiveness in advanced manufacturing and medical sectors in response to China's state-led policies that may aim to dilute these advantages.

Within this context, some Members have inquired about rates of domestic PPE consumption (i.e., demand for PPE) to better understand how it may relate to domestic production, versus those imported.[17] Other Members have sought information about the potential for "reshoring," or relocating domestically, some global supply chains from abroad (particularly, but not only, China), and domestic producers' capacity to meet future U.S. demand.[18] However, definitional differences in categorizing domestic and imported products make it difficult to assess overall levels of U.S. import dependencies for PPE and other various medical goods. Relatedly, a dearth of validated and verifiable data and information limits the assessment of both the size and composition of the U.S. PPE market, as well as the overall capability of U.S.-based producers to satisfy essential national needs for PPE, in addition to pharmaceuticals and other medical supplies.

Domestic Supply: U.S. vs. Foreign Made

Because of limited data availability, establishing a baseline for domestic- and foreign-produced PPE is challenging, but necessary in order to develop policy options to address potential PPE supply chain vulnerabilities. In general, the U.S. government does not record domestic production of specific items (e.g., surgical masks or latex gloves) by quantity or value, nor does it track how much of this production is ultimately destined for the U.S. market.[19] However, the U.S.

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just-got-a-lot-tougher.html; Kate O'Keefe, Liza Lin, and Eva Xiao, "China's Export Restrictions Strand Medical Goods U.S. Needs to Fight Coronavirus, State Department Says," *Wall Street Journal*, April 16, 2020; and Dan Harris, "Webinar: Navigating PPE Purchases from China," remarks during webinar, April 23, 2020, at https://www.chinalawblog.com/2020/04/webinar-today-navigating-ppe-purchases-from-china.html.

[16] "China Is Using Uighur Labor to Produce Face Masks," *New York Times*, July 19, 2020; Kevin Sieff, "Mexican Factories Boost Production of Medical Supplies for U.S. Hospitals While Country Struggles with Its Own Coronavirus Outbreak," *Washington Post*, April 3, 2020; Bruce Delteil, Matthieu Francois, and Nga Nguyen, "Emerging from the Pandemic, Vietnam Must Position Itself for Recovery," *McKinsey & Company*, July 1, 2020; and U.S. Agency for International Development, "USAID Identifies Vietnamese Suppliers of Personal Protective Equipment (PPE) and Other Medical Supplies Needed for the U.S. Domestic COVID-19 Response," press release, April 10, 2020.

[17] See, for example, Office of Senator Lindsay Graham, "Graham: We Must No Longer Be Reliant on China for PPE," July 16, 2020, at https://www.lgraham.senate.gov/public/index.cfm/2020/7/graham-we-must-no-longer-be-reliant-on-china-for-ppe.

[18] See, for example, CRS Report R46304, *COVID-19: China Medical Supply Chains and Broader Trade Issues*, coordinated by Karen M. Sutter.

[19] Some agencies, including the U.S. Food and Drug Administration (FDA) and the U.S. Department of Commerce, collect more information than they make publicly available, which is due in part to confidentiality requirements (e.g., 13 U.S.C. §9 and 15 C.F.R. §801.5). However, none collects detailed quantity and value information of total U.S. production at the item level.

government does track categories of domestic exports to foreign markets, including for certain categories of PPE. It also collects statistics for broad industry sectors, such as gross output, value added—also known as gross domestic product (GDP)—by industry, and constituent inputs within production supply chains.[20]

Questions such as "how much PPE does the United States currently produce relative to what it imports?" or "by how much has domestic production of pharmaceuticals increased since the COVID-19 outbreak?" are not easy to answer. A complicating factor in the analysis of U.S. production and reliance on imports of PPE and medical products is that there are no domestic or internationally agreed guidelines, standards, or definitions of what specific products make up these categories. For example, KN95 respirator masks—China-made analogues to domestically regulated N95 respirators—are generally not authorized as medical PPE in the United States, though they are in many countries abroad, and have received temporary (and limited) Emergency Use Authorization from the FDA.[21] However, a rough estimate of the share that imported PPE and medical products make up in total U.S. supply can be gleaned from an annual government survey of U.S. manufacturers. This information, analyzed in conjunction with official U.S. trade statistics, provide partial insight into some domestic production activities. This estimate is discussed in the subsequent section.

Annual Survey of Manufactures and Trade Statistics

The U.S. Census Bureau's Annual Survey of Manufactures (ASM) measures current U.S. manufacturing activity, such as industry outputs, inputs, and operating status.[22] It provides sample estimates of statistics for manufacturing establishments in the United States based on the North American Industry Classification System (NAICS).[23] ASM statistics include the value added by manufacturing, total value of shipments for close to 1,400 classes of manufactured products, costs of materials, and inventories. However, NAICS categories may not capture all establishments producing PPE, pharmaceuticals, and medical products. Some goods may be dual- or multi-use for medical as well as other industries, for example, and may not be captured. Another challenge is a time lag with the data, which prevents the U.S. government from developing an understanding of current industry capacity or trends. As of October 2020, 2018 is the most recent year for which data are presently available.[24]

The U.S. Bureau of Economic Analysis (BEA) and Census Bureau collect data on U.S. exports and imports on a monthly, quarterly, and yearly basis.[25] To estimate the domestic supply of PPE and other medical articles, CRS cross-referenced BEA's dataset with the ASM to obtain a rough

[20] For more detail, see U.S. Bureau of Economic Analysis, "Industry Economic Accounts," at https://www.bea.gov/data/economic-accounts/industry. However, quantity and value information of total U.S. production is not available at the item level.

[21] FDA, Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection—Letter to Health Care Providers, October 15, 2020, at https://www.fda.gov/medical-devices/letters-health-care-providers/certain-filtering-facepiece-respirators-china-may-not-provide-adequate-respiratory-protection-letter.

[22] U.S. Census Bureau, "Annual Survey of Manufactures (ASM)," at https://www.census.gov/econ/overview/ma0300.html.

[23] For more detail on NAICS, see U.S. Census Bureau, "North American Industry Classification System: Introduction to NAICS," at https://www.census.gov/eos/www/naics/.

[24] U.S. Census Bureau, "Annual Survey of Manufactures: Summary Statistics for Industry Groups and Industries in the U.S.: 2018."

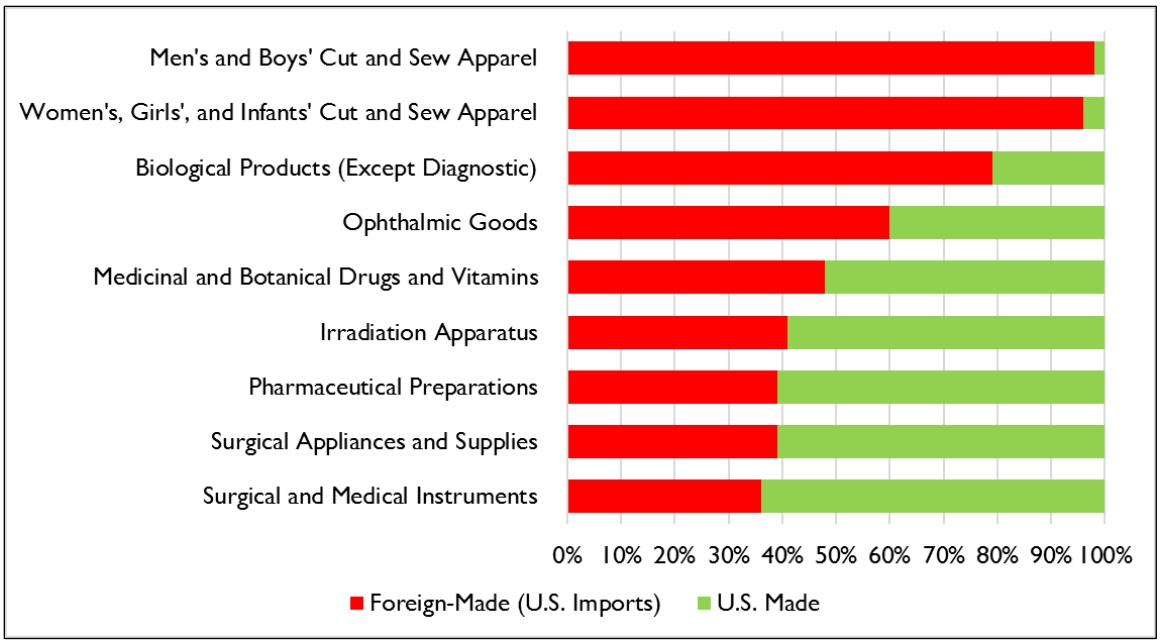
[25] U.S. Bureau of Economic Analysis ("International Transactions" and "International Trade in Goods and Services") and U.S. Census Bureau ("Foreign Trade").

estimate of the imported share of U.S. supply for some NAICS categories considered to include PPE, as well as pharmaceuticals and other medical-related products in 2018. CRS was then able to infer, by subtraction, the estimated domestic share of U.S. supply of PPE and medical goods NAICS categories. The figures were disaggregated and calculated at the NAICS six-digit subheading level—the most specific level for which NAICS data are available. However, because these are broad product categories, the data likely underestimate or overestimate actual domestic production and imports.[26]

CRS compiled and analyzed this data to develop estimates of PPE imports, which suggest that the United States' dependence on foreign imports varies from industry-to-industry, with a heavy dependence on foreign imports in several industries (for more than 90% of domestic medical-related supply in some cases) (see **Figure 1**). In 2018, the United States imported many low-supply chain and labor-intensive manufactured products from China (e.g., apparel made from fabric, such as hospital gowns). Notably, some of the higher value-added and skill-intensive imported products came mainly from Europe (e.g., irradiation machines and biological products, such as vaccines) or were produced domestically (e.g., MRI equipment). The estimates likely understate the extent to which the United States relies on China for certain products, as some U.S. imports may contain a high share of Chinese content but may not always be classified as Chinese in origin when imported into the United States, due to prevailing labeling regulations.

Figure 1. Estimate of the Domestic and Imported Shares of U.S. Supply: Selected Medical-Related NAICS Categories

share of U.S. Domestic Supply (%) in 2018



Source: CRS analysis with data from the U.S. Census Bureau, the U.S. Bureau of Economic Analysis, and the U.S. International Trade Commission.

[26] For more on data limitations, see **Appendix D**. U.S. import statistics include imports of goods from U.S.-owned affiliates abroad. (1) Rough estimates are calculated at the NAICS six-digit subheading level, which may cover products that are not for medical use; (2) 2018 is the most recent year for which annual data from the Annual Survey of Manufactures are available.

Notes: For more detail, see **Appendix D**.

This picture may have changed between 2018 and 2020, especially if the U.S. began importing more sophisticated medical and pharmaceutical goods from China. Recently, the Chinese government has invested in ambitious, state-led programs such as Made in China 2025 (MIC2025).[27] One of MIC2025's goals is to modernize the Chinese economy and turn China into a global leader in the manufacturing of biopharmaceuticals and high-performance medical devices.[28] Lack of data and other constraints limit the ability to assess in real time the progress of these efforts and their impact on the U.S. economy and industrial base.

Other Sources of Data and Information

Data limitations relate to both the availability of data, as well as gaps in U.S. government reporting, which complicates assessments of U.S. reliance on foreign goods.[29] The U.S. General Services Administration (GSA)'s federal contracting database, the Federal Procurement Data System-Next Generation (FPDS-NG), reports federal procurement contracts whose estimated value is $10,000 or more.[30] The FPDS-NG data, however, are not fully reliable. Documented quality issues relating to the accuracy, completeness, and timeliness of this data are among the limitations.[31] These concerns have prompted many analysts to primarily rely on FPDS-NG data to identify broad trends and produce rough estimates, or to gather information about specific contracts. Despite these limitations, the data may provide general information regarding the value, quantity, and types of domestic and foreign-made goods that U.S. government agencies procure. For more information about federal procurement practices, see **Appendix A**.

Other information on domestic capacity, including changes during the COVID-19 pandemic, generally comes from private research firms, news outlets, and trade associations. Many of the estimates cited are based on surveys, private entities' press releases, or industry forecasts, which may differ significantly from actual production.

COVID-19: Assessing PPE Demand

The federal government's access to valid, reliable, and timely data concerning domestic supply chains for goods, including PPE, has been a complicating factor in its response to the COVID-19 pandemic. Planning for health emergencies has been a shared responsibility between the federal and State, Local, Tribal, and Territorial (SLTT) governments. States and other subnational jurisdictions have had much of the responsibility for developing contingency planning for health emergencies, with the federal government in a support posture.[32] However, the COVID-19

[27] For more detail on MIC2025, see CRS In Focus IF10964, *"Made in China 2025" Industrial Policies: Issues for Congress*, by Karen M. Sutter.

[28] CRS In Focus IF10964, *"Made in China 2025" Industrial Policies: Issues for Congress*, by Karen M. Sutter.

[29] For more detail on the role of international trade in U.S. government procurement, see CRS In Focus IF11580, *U.S. Government Procurement and International Trade*, by Andres B. Schwarzenberg.

[30] The primary federal procurement reporting tool is scheduled to move from FPDS-NG to the System for Award Management (SAM) in October 2020.

[31] For more information on FPDS-NG data quality issues, see "Appendix A. FPDS Background, Accuracy Issues, and Future Plans" in CRS Report R44010, *Defense Acquisitions: How and Where DOD Spends Its Contracting Dollars*, by John F. Sargent Jr. and Christopher T. Mann.

[32] Office of the Assistant Secretary for Preparedness and Response (ASPR), "2017-2022 Health Care Preparedness and Response Capabilities," at https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/2017-2022-healthcare-pr-capablities.pdf.

pandemic has strained both domestic and international medical supply chains as demand for PPE escalated.

In the initial stages of the domestic COVID-19 pandemic, the Department of Health and Human Services (HHS) led the federal response, in accordance with the authorities invoked under the Public Health Emergency declared on January 31, 2020, under the Public Health Service Act.[33] In late February 2020, HHS Secretary Alex Azar testified to Congress that federal stockpiles required 300 million N95 respirator masks to adequately respond to the outbreak (as assessed in February 2020), and that federal stockpiles faced acute shortages of N95 respirators and other PPE.[34] The HHS Assistant Secretary for Preparedness and Response (ASPR) also reported that he was working with industry to anticipate and address any potential supply shortages.[35] Per Public Health Service Act Section 2811, the ASPR is "the principal advisor to the [HHS] Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies."[36] The Food and Drug Administration (FDA) within HHS also reported proactively reaching out to manufacturers to identify potential disruptions or shortages.[37] FDA's role in assessing and addressing PPE demand is discussed in further detail later in this section.

According to HHS documents released by Congress, the federal government established early in the pandemic that existing stockpiles and public health mechanisms were insufficient to meet the demands of the pandemic.[38] Media reports proliferated about inadequate PPE and other medical supplies for health care workers,[39] "essential" workers,[40] and more generally.[41] In response, reuse of PPE was reportedly widespread, and standardized practices were prescribed by major industry organizations such as the American College of Surgeons.[42]

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[33] U.S. Department of Health and Human Services (HHS), "Secretary Azar Declares Public Health Emergency for United States for Coronavirus Disease 2019," press release, January 31, 2020, at https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html. For more information, see CRS Report R46219, *Overview of U.S. Domestic Response to Coronavirus Disease 2019 (COVID-19)*, coordinated by Sarah A. Lister and Kavya Sekar.

[34] U.S. Congress, Senate Committee on Appropriations, Subcommittee on Departments of Labor, Health and Human Services, and Education, and Related Agencies, *Review of the FY2021 Budget Request for HHS*, Hearing to review the Fiscal Year 2021 funding request and budget justification for the U.S. Department of Health and Human Services, 116th Cong., February 25, 2020. See also Ted Hesson and Alexandra Alper, "Exclusive: U.S. Mulls Using Sweeping Powers to Ramp Up Production of Coronavirus Protective Gear," Reuters.com, February 27, 2020, at https://www.reuters.com/article/us-china-health-usa-production-exclusive/exclusive-u-s-mulls-using-sweeping-powers-to-ramp-up-production-of-coronavirus-protective-gear-idUSKCN20L2S0.

[35] Section on "Health System Preparedness" in CRS Report R46219, *Overview of U.S. Domestic Response to Coronavirus Disease 2019 (COVID-19)*, coordinated by Sarah A. Lister and Kavya Sekar.

[36] 42 U.S.C. §300hh–10.

[37] FDA, "FDA's Actions in Response to 2019 Novel Coronavirus at Home and Abroad," February 14, 2020, at https://www.fda.gov/news-events/press-announcements/fdas-actions-response-2019-novel-coronavirus-home-and-abroad.

[38] House Committee on Oversight and Reform, "New Document Shows Inadequate Distribution of Personal Protective Equipment and Critical Medical Supplies to States," press release, April 8, 2020, at https://oversight.house.gov/news/press-releases/new-document-shows-inadequate-distribution-of-personal-protective-equipment-and.

[39] Mariel Padilla, "'It Feels Like a War Zone': Doctors and Nurses Plead for Masks on Social Media," *New York Times*, March 19, 2020, at https://www.nytimes.com/2020/03/19/us/hospitals-coronavirus-ppe-shortage.html.

[40] Catherine Thorbecke, "'I'm Not Ready to Die': New 'Essential Workers' Call for Protections, Hazard Pay in Coronavirus Crisis," ABC News, April 17, 2020, at https://abcnews.go.com/Business/im-ready-die-essential-workers-call-protections-hazard/story?id=70142602.

[41] Zoë Schlanger, "Begging for Thermometers, Body Bags, and Gowns: U.S. Health Care Workers Are Dangerously Ill-Equipped to Fight COVID-19," *TIME*, April 20, 2020, at https://time.com/5823983/coronavirus-ppe-shortage/.

[42] American College of Surgeons, *Other PPE Recommendations*, April 8, 2020, at https://www.facs.org/covid-19/ppe/

In late March 2020, following declarations of Emergency and Major Disaster for COVID-19 under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act, as amended; P.L. 93-288), the Federal Emergency Management Agency (FEMA) took over the role as the lead federal agency coordinating the entire federal response to the pandemic.[43] Federal authorities established prior to the pandemic were utilized to procure and distribute PPE, including ASPR's Strategic National Stockpile (SNS).[44] However, FEMA and HHS determined that "the SNS alone could not fulfill all of our Nation's requirements," according to FEMA Administrator Peter Gaynor and Rear Admiral John Polowczyk, and developed new procedures during the COVID-19 pandemic response.[45]

According to FEMA officials, FEMA began working with HHS and the Department of Defense (DOD) in March to assess and stabilize the PPE supply chain after forming the Supply Chain Task Force.[46] Rear Admiral John Polowczyk helped to lead the Task Force, which was staffed by members of FEMA, HHS, DOD, and several additional federal agencies.[47] The Supply Chain Task Force focused on a four-part effort to improve the PPE supply: preservation of PPE when possible, acceleration of PPE delivery, expansion of existing PPE production, and distribution of PPE to critical areas. Project Airbridge (see **"Project Airbridge"**), a federal effort to expedite private-sector delivery of PPE from manufacturers abroad to meet domestic needs, was part of this four-part strategy.[48]

According to FEMA and DOD officials, the Supply Chain Task Force used multiple sources of data to gain visibility into the PPE supply chain, including

- **Requests for PPE** submitted by state, tribal, and territorial emergency managers receiving assistance to FEMA's National Response Coordinating Center (NRCC) and through FEMA's Public Assistance (PA) Program.[49]
- **State, local, tribal, territorial, and medical provider data** consolidated by HHS and FEMA, through the FEMA National Response Coordination Center and the HHS Protect System, respectively.[50]

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additional.

[43] This transition was initiated as a result of the President's major disaster declaration for COVID-19. Submitted Testimony of FEMA Administrator Peter Gaynor and Rear Admiral John Polowczyk, in U.S. Congress, Senate Homeland Security and Governmental Affairs Committee, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic*, hearings, 116th Cong., 2nd sess., June 6, 2020, p. 3, at https://www.hsgac.senate.gov/imo/media/doc/Testimony-Gaynor%20&%20Polowczyk-2020-06-09.pdf (hereinafter, Gaynor and Polowczyk, HSGAC hearing).

[44] For more information, see CRS In Focus IF11574, *National Stockpiles: Background and Issues for Congress*, by G. James Herrera and Frank Gottron.

[45] Gaynor and Polowczyk, HSGAC hearing, p. 4.

[46] Gaynor and Polowczyk, HSGAC hearing, p. 5.

[47] Gaynor and Polowczyk, HSGAC hearing, p. 5.

[48] FEMA has used two spellings of this program: Project Airbridge and Project Air Bridge. This report refers to the program as "Project Airbridge," reflecting FEMA's most recent and consistent spelling of the program. However, citations that use other spellings (e.g., "Project Air Bridge) are reflected verbatim.

[49] Gaynor and Polowczyk, HSGAC hearing, p. 4.

[50] Gaynor and Polowczyk, HSGAC hearing, 11-12. See also HHS, "COVID-19 Guidance for Hospital Reporting and FAQs for Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting Updated July 29, 2020," at https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf%3C; multiple FEMA, "FEMA Daily Ops Briefings, April, 2020"; and HHS, "HHS Protect: Frequently Asked Questions," July 20, 2020, at https://www.hhs.gov/about/news/2020/07/20/hhs-protect-frequently-asked-questions.html.

- **Project Airbridge** data supplied by six major U.S. medical suppliers. Project Airbridge participants Cardinal Health, Concordance, Owens and Minor, McKesson, Medline, and Henry Schein agreed to furnish FEMA with each suppliers' data on inventory imported and distributed across the United States, not limited to Project Airbridge shipments.[51]
- Additional sources referenced in Supply Chain Task Force documents, including past manufacturing data, industry estimates, and demand data.[52]

On the basis of these sources, the Supply Chain Task Force presented the charts summarized in **Table 1** to Senator Margaret Hassan, ranking member on the Senate Homeland Security and Governmental Affairs Committee's Subcommittee on Federal Spending Oversight and Emergency Management, in advance of a June 2020 hearing on federal COVID-19 response efforts. These charts documented the reported and forecasted shortfalls of supplies of N95 masks, medical gowns, surgical masks, nitrile gloves, and face shields during the pandemic through October 2020. The charts showed, broadly, that demand for these PPE materials were being met through a combination of domestic production (particularly for N95 respirators), overseas imports, and non-traditional suppliers.

Table 1 summarizes FEMA's assessment of PPE demands through October 2020 as presented to Congress in June 2020.

Table 1. Summary of FEMA PPE Demand Assessments

as presented by the Supply Chain Task Force in June 2020

PPE Type	Demand Met by End of Forecast Period? (Y/N)	Estimated Domestic Production
N95 Respirator Masks	Yes	High
Medical Gowns	No	Low
Surgical Masks	Yes	Low
Nitrile Gloves	Yes	Low / None
Face Shields	Yes	Low

Source: Tabulated by CRS from Supply Chain Task Force representative Rear Admiral John P. Polowczyk "White House COVID-19 Supply Chain Task Force," submitted to Senator Margaret Hassan in advance of hearing by U.S. Senate, Committee on Homeland Security and Governmental Affairs, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic,* June 9, 2020, at https://www.hassan.senate.gov/imo/media/doc/SCTF%20Demand%20PPE%20Chart.pdf.

Notes: The Supply Chain Task Force charts were current as of June 2020, according to FEMA. These data and graphics are produced by the COVID-19 Supply Chain Task Force. CRS cannot verify the accuracy of the data or explicate the methodology presented in these documents. According to the Supply Chain Task Force, the data

[51] Gaynor and Polowczyk, HSGAC hearing, pp. 5-6; Submitted Testimony of Supply Chain Task Force representative Rear Admiral John Polowczyk, for U.S. Congress, House Select Subcommittee on the Coronavirus Crisis, *Federal Government's Efforts for Procurement and Distribution of Critical Medical Equipment and Supplies in Response to the COVID-19 Pandemic*, hearings, 116th Cong., 2nd sess., July 2, 2020, pp. 4-5, available at https://docs.house.gov/meetings/VC/VC00/20200702/110851/HHRG-116-VC00-Wstate-PolowczykR-20200702.pdf.

[52] Supply Chain Task Force representative Rear Admiral John Polowczyk, "White House COVID-19 Supply Chain Task Force," submitted to Sen. Maggie Hassan in advance of hearing by U.S. Congress, Senate Committee on Homeland Security and Governmental Affairs, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic,* hearings, 116th Cong., 2nd sess., June 9, 2020, at https://www.hassan.senate.gov/imo/media/doc/SCTF%20Demand%20PPE%20Chart.pdf.

> does not include "procurement by states, commercial donations, distribution data of other medical-surgical distributors, direct shipments from manufacturers."

Although FEMA's assessments have conveyed confidence in U.S. capacity to meet PPE demands, independent reports document widespread and persistent PPE shortages.[53] These reports are supported by the listing of surgical gowns, gloves, and surgical respirators on the FDA's device shortages list. Pursuant to authorities established by the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136), FDA must maintain a public, up-to-date list of those devices that the agency has determined are or will be in shortage during a public health emergency declared by the HHS Secretary pursuant to Public Health Service Act Section 319.[54] PPE that meets the statutory definition of a medical device or "device" in the Federal Food, Drug and Cosmetic Act (FFDCA)—that is, PPE intended for a medical purpose—would be included on this list.[55] FDA, for the first time, published the device shortages list specific to COVID-19 on August 14, 2020. The list displays the FDA-specific product code and PPE type (e.g., surgical gown, examination gown) that is in shortage, as well as the reason for and estimated duration of the shortage, among other information.[56]

To assist FDA with maintaining this list, manufacturers of devices critical to public health must—during or in advance of a public health emergency—notify FDA of any permanent discontinuance in the manufacture of the device or of any interruption in manufacturing that is likely to lead to a meaningful disruption in its U.S. supply.[57] Manufacturers can, but are not required to, notify FDA if they are experiencing an increase in demand that may result in a shortage. Based on these notifications and other relevant information, FDA is statutorily required to take certain actions to prevent or mitigate device shortages, including prioritizing and expediting review of regulatory submissions for marketing authorization and facility inspections.[58] Additional information about FDA regulation of PPE is provided in the section "FDA-Specific Actions."[59]

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[53] See Shira Stein, Margaret Newkirk, and David R Baker, "Nurses' Pleas Spur U.S. Pledge to Tap 44 Million-Mask Stockpile," *Bloomberg*, July 31, 2020, at https://www.bloomberg.com/news/articles/2020-07-31/nurses-pleas-spur-u-s-pledge-to-tap-44-million-mask-stockpile; Andrew Jacobs, "Grave Shortages of Protective Gear Flare Again as Covid Cases Surge," *New York Times*, July 8, 2020, at https://www.nytimes.com/2020/07/08/health/coronavirus-masks-ppe-doc.html; William Wan, "America Is Running Short on Masks, Gowns and Gloves. Again." *Washington Post*, July 8, 2020, at https://www.washingtonpost.com/health/2020/07/08/ppe-shortage-masks-gloves-gowns/; Jessica Glenza," PPE Shortage Could Last Years Without Strategic Plan, Experts Warn," *Kaiser Health News*, August 17, 2020, at https://khn.org/news/ppe-shortage-could-last-years-without-strategic-plan-experts-warn/; and National Nurses United, "National Nurse Survey Reveals Devastating Impact of Reopening Too Soon," press release, July 28, 2020, at https://www.nationalnursesunited.org/press/national-nurse-survey-reveals-devastating-impact-reopening-too-soon.

[54] 21 U.S.C. §356J(g), as added by §3121 of the CARES Act, referring to a public health emergency declared by the HHS Secretary pursuant to 42 U.S.C. §247d.

[55] PPE intended for non-medical (e.g., industrial) use does not meet the FFDCA definition of a device, and is not subject to FDA regulation or inclusion on the device shortages list.

[56] FDA, "Medical Device Shortages During the COVID-19 Public Health Emergency," at https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency#shortage.

[57] 21 U.S.C. §356J(a), as added by §3121 of the CARES Act.

[58] 21 U.S.C. §356J(f), as added by §3121 of the CARES Act.

[59] Beyond these steps, non-governmental organizations have attempted to quantify PPE needs in the United States. For example, in April 2020, the Center for Health Security at the Johns Hopkins Bloomberg School of Public Health published a resource providing an initial estimate of the need for medical PPE above normal baseline utilization for a single 100-day COVID-19 wave. See E. Toner, "Interim Estimate of US PPE Needs for COVID-19," Center for Health Security at the Johns Hopkins Bloomberg School of Public Health, April 18, 2020, at https://www.centerforhealthsecurity.org/resources/COVID-19/PPE/PPE-estimate.pdf.

As required by executive order, FDA also has taken steps to identify PPE need for potential future public health emergencies.[60] Specifically, on October 30, 2020, FDA published a list of essential medicines, medical countermeasures (including PPE), and critical inputs "that are medically necessary to have available at all times in an amount adequate to serve patient needs."[61] As further directed by the executive order, FDA is coordinating with other federal agencies on strategies for acquiring the products on the list, accelerating domestic manufacturing, and identifying and addressing supply chain vulnerabilities.

Federal Actions to Increase PPE Supply

As part of the federal government's response to the COVID-19 pandemic, the Trump Administration has sought to increase PPE production and distribution through a variety of agency actions as well as through utilization of the Defense Production Act.

FEMA Actions

Production

FEMA has publicly discussed two types of actions taken to increase domestic PPE production: (1) actions pursuant to the Defense Production Act (see below), and (2) actions taken to partner with private companies interested in committing resources to PPE manufacturing on a voluntary basis.[62] Publicly available information on these partnerships remains limited.[63]

Distribution

FEMA, HHS, and DOD have worked together to distribute PPE to states, tribes, and territories in several phases since FEMA assumed the position of lead federal agency for the federal COVID-19 response in March 2020.[64]

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[60] Executive Order 13944, Combating Public Health Emergencies and Strengthening National Security by Ensuring, Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States, August 6, 2020.

[61] FDA, "FDA Publishes List of Essential Medicines, Medical Countermeasures, Critical Inputs Required by Executive Order," October 30, 2020, at https://www.fda.gov/news-events/press-announcements/fda-publishes-list-essential-medicines-medical-countermeasures-critical-inputs-required-executive.

[62] Submitted Testimony of FEMA Administrator Peter Gaynor, U.S. Congress, House Committee on Oversight and Reform, *FEMA's Natural Disaster Preparedness and Response Efforts During the Coronavirus Pandemic*, hearings, 116th Cong., 2nd sess., July 24, 2020, pp. 5-7 (hereinafter Gaynor Testimony, House Oversight, *FEMA's Efforts During Pandemic*). See also FEMA, "COVID-19 Offer of Supplies or Equipment," at https://www.fema.gov/disasters/coronavirus/offers; FEMA, "Use of Defense Production Act Authorities to Support the Pandemic Response," March 19, 2020, at https://www.fema.gov/fact-sheet/use-defense-production-act-authorities-support-pandemic-response; and FEMA, "Applying the Defense Production Act," news release, April 13, 2020, at https://www.fema.gov/news-release/20200726/applying-defense-production-act.

[63] Most recently, FEMA representatives reported that the "Stabilization Task Force is working through over 350 leads" on possible matches. Gaynor Testimony, House Oversight, *FEMA's Efforts During Pandemic* pp. 5-6. Similar information is available at FEMA, "FEMA Supply Chain Task Force Leads Four-Pronged Approach to Securing Needed Supplies and Equipment in COVID-19 Fight," July 26, 2020, at https://www.fema.gov/news-release/20200726/fema-supply-chain-task-force-leads-four-pronged-approach-securing-needed.

[64] FEMA assumed the position of the lead federal agency for the entire COVID-19 federal response efforts during the final weeks of March 2020. In congressional testimony, FEMA Administrator Peter Gaynor explained: "On March 19th, FEMA's role in the pandemic response changed. Under the direction of the White House Coronavirus Task Force, FEMA moved from playing a supporting role in assisting [HHS], which was designated as the initial lead federal

According to FEMA, in the final weeks of March 2020, FEMA's National Response Coordination Center (NRCC) and HHS distributed the remaining PPE held in the HHS Strategic National Stockpile (SNS) to states, territories, and a few large cities in several allocations (see also "Stockpile Policy Options").[65] These allocations were initially made proportional to a jurisdiction's population, although FEMA reported that the final allocation was weighted by COVID-19 infection rates derived from Center for Disease Control (CDC) models.[66] Once the SNS PPE supply was exhausted, FEMA reported that the NRCC distributed PPE held by DOD for a limited period of time.[67]

As both the SNS and DOD PPE supplies were exhausted, the newly formed Supply Chain Stabilization Task Force began acquiring new PPE and making distributions according to newly established procedures. According to FEMA, the agency exercised its authority to provide assistance directly (referred to as Direct Federal Assistance) to overwhelmed states, tribes, territories, local governments, and eligible private nonprofit organizations authorized to receive Public Assistance pursuant to declarations of Emergency and Major Disaster for COVID-19 under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act, as amended; P.L. 93-288).[68] In response to the COVID-19 pandemic, President Trump declared major disasters for all 50 states, five territories, one tribe, and the District of Columbia. This was the first instance in which major disasters were declared across the entire United States.[69]

When Direct Federal Assistance is authorized, FEMA may task its own personnel or other federal agencies, such as HHS and the CDC, to perform work eligible for Public Assistance on behalf of the requesting applicants (referred to as "mission assignments").[70] According to FEMA, the agency exercised this authority in order to procure and distribute PPE directly to nonfederal entities.[71]

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agency for the COVID-19 pandemic response, to coordinating the Whole-of-Government response to the COVID-19 pandemic," submitted testimony, U.S. Congress, House Committee on Homeland Security, *Examining the National Response to the Worsening Coronavirus Pandemic Part II*, hearings, 116th Cong., 2nd sess., July 22nd, p. 3, available at https://homeland.house.gov/imo/media/doc/Testimony%20-%20Gaynor.pdf (hereinafter Gaynor testimony, House Homeland, *Examining National Response*).

[65] The SNS is a federal cache of drugs, vaccines, and medical supplies purchased by the federal government to assist in civilian disaster response. It is managed by the HHS Assistant Secretary for Preparedness and Response, after previously being managed by CDC. See HHS, "Strategic National Stockpile," at https://www.phe.gov/about/sns/Pages/default.aspx; FEMA, phone briefing with House Committee on Homeland Security, House Committee on Oversight and Reform, and CRS, June 18, 2020; and U.S. Government Accountability Office (GAO), *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, GAO-20-625, June 25, 2020, pp. 20-23, available at https://www.gao.gov/reports/GAO-20-625 / (hereinafter GAO, *COVID-19: Opportunities)*.

[66] GAO, *COVID-19: Opportunities*, pp. 108-100; FEMA, phone briefing with House Committee on Homeland Security, House Committee on Oversight and Reform, and CRS, June 18, 2020.

[67] FEMA, "FEMA Coronavirus (COVID-19) Pandemic Response," March 22, 2020, p. 1, provided to CRS by FEMA Office of Congressional and Legislative Affairs; FEMA, "National Resource Prioritization Cell," phone briefing with House Committee on Homeland Security, House Committee on Oversight and Reform, and CRS, June 18, 2020.

[68] 42 U.S.C. §§5121 et seq. "Public Assistance—Direct Federal Assistance" is authorized in Stafford Act Sections 402 and 502; 42 U.S.C. §§5170a and 5192. See also 44 C.F.R. §206.208. For a list of the Stafford Act declarations authorizing public assistance for COVID-19, see FEMA, "COVID-19 Disaster Declarations," at https://www.fema.gov/disasters/coronavirus/disaster-declarations.

[69] For a list of the Stafford Act declarations authorizing public assistance for COVID-19, see FEMA, "COVID-19 Disaster Declarations," at https://www.fema.gov/disasters/coronavirus/disaster-declarations.

[70] See FEMA, "Mission Assignments," at https://www.fema.gov/federal-agencies/mission-assignments.

[71] Email from FEMA Congressional and Legislative Affairs to CRS, June 19, 2020.

FEMA entered into a memorandum of understanding (MOU) with the HHS Assistant Secretary for Preparedness Response (ASPR) in April 2020 that enabled FEMA to acquire and distribute critical medical supplies, including PPE, through the SNS.[72] The MOU called for the ASPR to reimburse FEMA for the cost of acquired materials, as specified in subsequent interagency agreements through June 13, 2020.[73] According to FEMA, this MOU and subsequent interagency agreements enabled FEMA to procure and distribute PPE directly to states, tribes, territories, local governments, and nonprofits without a nonfederal cost share. PPE supplies purchased after June 13, 2020, and fulfilled with FEMA support may be subject to the 25% nonfederal cost share for Public Assistance as authorized under the Stafford Act declarations for COVID-19.[74] FEMA indicated that procurement activities were transitioned to the Defense Logistics Agency (DLA) on May 29, 2020.[75] In a separate effort in April 2020, FEMA provided a two-week supply of PPE to 15,400 Medicare and Medicaid-certified nursing homes.[76]

PPE allocation was the responsibility of the National Resource Prioritization Cell, a decisionmaking entity established within the COVID-19 Supply Chain Task Force.[77] The Prioritization Cell utilized demographic data, federal supply data, private sector supply chain data, and medical data supplied by states and health care providers to determine PPE distribution priority areas over a 96-hour period.[78] According to the Trump Administration, these data sources fed into the HHS-based data systems which was shared with FEMA, HHS, the White House Coronavirus Task Force, and ASPR for response efforts that included resource allocation.[79] According to FEMA, medical data was analyzed every seven days, and included "confirmed cases, increases in confirmed cases, total mortality, and increases in mortality over seven days."[80]

Despite the federal efforts, PPE shortages continued to be reported into the summer and fall of 2020.[81] In September, the GAO reported that the federal government delivered more than 428

[72] FEMA and HHS, "Memorandum of Understanding Between the Federal Emergency Management Agency and the Department of Health and Human Services, Office of Assistant Secretary for Preparedness Response," executed April 5, 2020, provided to CRS by FEMA Office of Congressional and Legislative Affairs. Available to Congressional members and staff upon request.

[73] Ibid; FEMA, "Coronavirus Pandemic Response: Summary of Cost Share by Shared Resources," September 17, 2020, available at https://www2.illinois.gov/iema/LocalEMA/Documents/PAforms/COVID-19-CostShare.pdf.

[74] Ibid.

[75] Gaynor Testimony, House Oversight, *FEMA's Efforts During Pandemic,* p. 6.

[76] FEMA, "Personal Protective Equipment for Medicare and Medicaid Nursing Homes," April 30, 2020, at https://www.fema.gov/news-release/20200727/personal-protective-equipment-medicare-and-medicaid-nursing-homes.

[77] FEMA, "Coronavirus (COVID-19) Pandemic: National Resource Prioritization Cell," updated May 17, 2020, at https://www.fema.gov/fact-sheet/coronavirus-covid-19-pandemic-national-resource-prioritization-cell (hereinafter FEMA, "National Resource Prioritization Cell").

[78] Oral Testimony, Rear Admiral John Polowczyk, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic,* hearing, 116th Cong., 2nd sess., June 9, 2020; FEMA, "National Resource Prioritization Cell."

[79] Gaynor and Polowczyk, HSGAC hearing, pp. 11-12. See also HHS, "COVID-19 Guidance for Hospital Reporting and FAQs for Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting," updated July 10, 2020, at https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf; and CDC, "National Healthcare Safety Network (NHSN), at https://www.cdc.gov/nhsn/covid19/index.html; new guidance appears at HHS, "COVID-19 Guidance for Hospital Reporting and FAQs for Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting," updated July 29, 2020, at https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf%3C. See also CRS Report R46588, *Tracking COVID-19: U.S. Public Health Surveillance and Data*, by Kavya Sekar and Angela Napili.

[80] FEMA, "National Resource Prioritization Cell."

[81] See Andrew Jacobs, "Grave Shortages of Protective Gear Flare Again as Covid Cases Surge," *New York Times*, July 8, 2020, at https://www.nytimes.com/2020/07/08/health/coronavirus-masks-ppe-doc.html; Jessica Contrera, "The N95

million units of PPE through September 1 (see **Table 2**). However, continued PPE shortages suggest that federal deliveries have not been able to meet total demand posed by the pandemic.

Table 2. PPE Units Distributed by U.S. Government

Through September 1, 2020 (in millions)

	N95 Respirators	Face Masks	Gloves*	Nonsurgical Gowns
Units Distributed	92.4	228.4 million	79.7	28.1

Source: GAO, *COVID-19: Federal Efforts Could be Strengthened by Timely and Concerted Actions,* GAO-20-701, September 2020, p. 136.

Congressional Concerns with Federal PPE Distribution Efforts

Some Members of Congress have raised concerns about the federal government's PPE procurement and distribution procedures as well as persistent PPE supply shortages.[82] News sources have also documented many cases in which federally procured and distributed PPE was found to be expired, damaged, or otherwise faulty.[83]

Additionally, early in the pandemic response, state and territorial representatives criticized federal PPE supply chain management, stating that PPE procurement efforts "pitted states against one another and other purchasers—including the federal government…."[84] In September 2020, the GAO found that seven of eight states interviewed about PPE supplies found that this situation had improved since the onset of the pandemic.[85]

Congress has also questioned the lack of transparency surrounding federal PPE distribution efforts. Congressional concerns include, but are not limited to, the following questions:

- Which authorities, offices, and/or personnel made decisions about changes in management of the SNS during the pandemic? When were these decisions made, and what methodology is employed?[86]

Shortage America Can't Seem to Fix," *Washington Post*, September 21, 2020, at https://www.washingtonpost.com/graphics/2020/local/news/n-95-shortage-covid/; and Helena Oliviero, "Months into Pandemic, PPE Shortage Persists," *Atlanta Journal-Constitution*, October 7, 2020, at https://www.ajc.com/news/coronavirus/months-into-pandemic-ppe-shortage-persists/6OMYNYLDV5GJ5EBEMOSPWEC6MA/.

[82] See, for example, Sens. Warren, Blumenthal, and Schumer, Letter to Pandemic Response Accountability Committee Chair Michael Horowitz, June 8, 2020, at https://www.warren.senate.gov/imo/media/doc/Letter%20to%20PRAC%20re%20project%20airbridge%202020.06.pdf; and Sen. Lankford and Sen. Johnson, public statements in U.S. Senate, Committee on Homeland Security and Governmental Affairs, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic*, hearing, 116th Cong., 2nd sess., June 9, 2020.

[83] See, for example, Andrew Jacobs, "FEMA Sends Faulty Protective Gear to Nursing Homes Battling Virus," *New York Times*, July 24, 2020, at https://www.nytimes.com/2020/07/24/health/coronavirus-nursing-homes-PPE.html.

[84] National Governor's Association, Memorandum, Governor Actions to Address PPE and Ventilator Shortages," April 13, 2020, p. 1, at https://www.nga.org/wp-content/uploads/2020/04/NGA-Medical-Equipment-Memo.pdf.

[85] GAO, *COVID-19: Federal Efforts*, p. 13. The GAO conducted interviews in July and August 2020 with California, Colorado, Idaho, Massachusetts, Nebraska, New Jersey, New Mexico, and South Carolina. GAO, *COVID-19: Federal Efforts*, p. 141.

[86] Oral Testimony, Chairman of the Senate Homeland Security and Governmental Affairs Committee Ron Johnson, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19*

- What methodology informs federal PPE allocation and distribution priorities,[87] including data analysis and model design? Publicly available information on this methodology remains limited.
- What specific data elements and data sources were utilized by the National Resource Prioritization Cell to inform federal PPE allocation and distribution priorities?[88]
- What assumptions and risk assessments were used in the models to determine PPE allocations, and how were the models validated?[89]
- How did the National Resource Prioritization Cell define "hot spots" whose PPE demands were prioritized in Project Airbridge and federal PPE distribution efforts?[90]
- Which specific offices and/or personnel make up the Supply Chain Task Force, and the National Resource Prioritization Cell, and determine allocation methodology, data model design, and resource allocations?[91]
- How were state, territorial, and tribal requests for PPE assessed, and why were many recipients not aware of how and when requests for PPE from the federal government would be fulfilled?[92]
- When is PPE distributed by the federal government subject to a nonfederal cost share, given the varying sources and authorities through which federal PPE supplies are distributed?[93]

The domestic supply and distribution of PPE remain a source of ongoing congressional interest, despite reported improvements.

Pandemic, hearing, 116th Cong., 2nd sess., June 9, 2020.

[87] See, for example, Chairman of House Committee on Homeland Security Bennie Thompson, letter to DHS Acting Secretary Chad Wolf and HHS Secretary Alex Azar, March 23, 2020, p. 4, at https://homeland.house.gov/imo/media/doc/DHS%20HHS%20PPE%20Letter.pdf, and Senator Tammy Baldwin, Letter to President Trump, April 13, 2020, at https://www.baldwin.senate.gov/imo/media/doc/2020%2004%2013%20STB%20letter%20to%20POTUS%20on%20failing%20to%20act_final%20FINAL.pdf.

[88] See, for example, Rep. Sean Casten to FEMA Regional Administrator James Joseph, April 7, 2020, at https://casten.house.gov/sites/casten.house.gov/files/2020-04-07%20Casten%20FEMA%20Questions%20FINAL.pdf.

[89] Rep. Sean Casten to FEMA Regional Administrator James Joseph, April 7, 2020, at https://casten.house.gov/sites/casten.house.gov/files/2020-04-07%20Casten%20FEMA%20Questions%20FINAL.pdf.

[90] Senator Tammy Baldwin, Letter to President Donald J. Trump, April 13, 2020, at https://www.baldwin.senate.gov/imo/media/doc/2020%2004%2013%20STB%20letter%20to%20POTUS%20on%20failing%20to%20act_final%20FINAL.pdf.

[91] Chairman of House Committee on Homeland Security Bennie Thompson and Chairwoman of House Committee on Oversight Carolyn Maloney, Letter to FEMA Administrator Peter Gaynor, April 7, 2020, at https://homeland.house.gov/imo/media/doc/040720%20Joint%20FEMA%20letter%20re%20PPE.pdf.

[92] GAO, *COVID-19: Federal Efforts*, pp. 20-21.

[93] Ibid.

FEMA, ASPR, and other members of the Supply Chain Advisory Group (the successor of the Supply Chain Task Force)[94] have also reported improvements in the national PPE supply.[95] Additionally, GAO found that eight states interviewed regarding PPE supplies in July and August 2020 were rebuilding 30-day PPE stockpiles in preparation for future surges of COVID-19.[96] However, industry reports indicate that these replenished state stockpiles are expensive, challenging to maintain, and difficult to build during the ongoing real-time demand for PPE within their jurisdiction.[97] Additionally, states continue to express a need for access to SNS supplies during the pandemic, and are unsure whether federally supplied PPE may be available during future COVID case surges (for more information on nonfederal PPE stockpiles, see "Stockpile Policy Options").[98] Finally, the GAO reported in September 2020 that PPE shortages persist nationwide.[99] FEMA Administrator Peter Gaynor acknowledged the ongoing shortages in July 2020, saying "we have a ways to go in making sure we have enough PPE."[100]

Project Airbridge

As noted above, one prong of the four-pronged effort by the Supply Chain Task Force was the acceleration of PPE delivery in the United States. FEMA reported that, at the onset of the pandemic, PPE purchased on the private market was generally delivered after 30-40 days via marine transport.[101] In late March, the Supply Chain Task Force launched Project Airbridge in order to accelerate the transport of commercially-owned PPE from overseas manufacturing facilities to the United States and thereby increase available domestic supply. FEMA reported that the air bridge reduced transport time from 37 days to 24 hours.[102]

Under Project Airbridge, FEMA entered into agreements with the six leading medical suppliers in the United States: Cardinal Health, Concordance, Owens & Minor, McKesson, Medline, and

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[94] As of June 15, 2020, the Supply Chain Task Force became known as the Advisory Group, and is part of a reorganization off the original eight task forces in the Unified Coordination Group. FEMA and HHS lead the Unified Coordination Group, which was established to coordinate the federal response to COVID-19. The GAO explains: "[t]he two groups [the Supply Chain Task Force and the Advisory Group] generally have similar roles and are led by the same official, Rear Admiral John Polowcyzk, an expert in logistics planning and execution on detail from DOD's Joint Chiefs of Staff, and include officials from FEMA and HHS. According to DOD, the Supply Chain Task Force was the primary federal body coordinating and managing supply chain responsibilities. In contrast, the Advisory Group has an advisory and assistance role, focused on transitioning responsibilities to other federal stakeholders." GAO, *COVID-19: Federal Efforts*, p. 11.

[95] GAO, *COVID-19: Federal Efforts*, p. 13.

[96] GAO, *COVID-19: Federal Efforts*, p. 13. GAO conducted interviews in July and August 2020 with California, Colorado, Idaho, Massachusetts, Nebraska, New Jersey, New Mexico, and South Carolina. Ibid., p. 141.

[97] Jay Greene, "Hospitals Say They're Better Prepared with PPE Than Spring, but Supply Chain Uncertain," *Modern Healthcare*, October 25, 2020, at https://www.modernhealthcare.com/supply-chain/hospitals-say-theyre-better-prepared-ppe-spring-supply-chain-uncertain and GAO, *COVID-19: Federal Efforts*, pp. 138-140.

[98] Ibid.

[99] GAO, *COVID-19: Federal Efforts*, p. 10.

[100] Oral Testimony, FEMA Administrator Peter Gaynor, U.S. Congress, House Committee on Homeland Security, *Examining the National Response to the Worsening Coronavirus Pandemic Part II*, hearings, 116th Cong., 2nd sess., July 22, 2020.

[101] FEMA, "Phasing Out Project Airbridge," news release, June 17, 2020, at https://www.fema.gov/news-release/20200726/fema-phasing-out-project-airbridge; Submitted Testimony, FEMA Administrator Peter Gaynor, U.S. Congress, House Committee on Homeland Security, *Examining the National Response to the Worsening Coronavirus Pandemic Part II*, hearings, 116th Cong., 2nd sess., July 22, 2020, p. 7.

[102] Gaynor Testimony, House Oversight, *FEMA's Efforts During Pandemic*, p. 5.

Henry Schein.[103] Under these agreements, the federal government assumed responsibility for transporting PPE cargo owned or ordered by the six suppliers from specified locations abroad to the United States.[104] Project Airbridge memoranda of agreement between FEMA and Cardinal, McKesson, and Medline are publicly available.[105] According to these agreements, participating suppliers agreed to deliver 50% of the PPE units transported via the air bridge to customers within COVID-19 priority counties ("hot spots"[106]), as determined by the National Resource Prioritization Cell.[107] The remaining 50% of transported cargo feeds into distributors' normal supply chain to customers across the country.[108] As noted earlier in this report, publicly available information on the methodology to determine priority counties is limited.[109] When the program was suspended on June 30, 2020, FEMA reported that 249 Project Airbridge flights had transported the volume of PPE documented below in **Table 3**.[110]

Congress has raised questions regarding the operation and success of Project Airbridge. FEMA reported that the air bridge was suspended at the end of June 2020 because private manufacturers and distributors have increased domestic production and international manufacturing capacity,

[103] FEMA, "FEMA COVID-19 Supply Chain Task Force: Supply Chain Stabilization," April 7, 2020, at https://www.fema.gov/news-release/20200725/fema-covid-19-supply-chain-task-force-supply-chain-stabilization; participants are listed in Sens. Warren, Blumenthal, and Schumer, Letter to Pandemic Response Accountability Committee Chair Michael Horowitz, June 8, 2020, p.1, at https://www.warren.senate.gov/imo/media/doc/Letter%20to%20PRAC%20re%20project%20airbridge%202020.06.pdf. See also Department of Justice, "Department of Justice Issues Business Review Letter to Medical Supplies Distributors Supporting Project Airbridge Under Expedited Procedure for COVID-19 Pandemic Response," April 4, 2020, at https://www.justice.gov/opa/pr/department-justice-issues-business-review-letter-medical-supplies-distributors-supporting.

[104] See, for example, Memorandum of Agreement (MOA) between the Department of Homeland Security Federal Emergency Management Agency (DHS/FEMA) and Cardinal Health 200, LLC. Found on p. 6 of "Cardinal Response," hosted on Senator Elizabeth Warren, "Warren, Schumer, Blumenthal Release New Findings and Documents from Investigation of Trump-Kushner 'Project Air Bridge' Coronavirus Response," at https://www.warren.senate.gov/download/cardinal-response-051320.

[105] Memoranda of Agreement between FEMA and Cardinal, FEMA and McKesson, and FEMA and Medline are available at Sen. Warren, "Warren, Schumer, Blumenthal Release New Findings and Documents from Investigation of Trump-Kushner 'Project Air Bridge' Coronavirus Response," at https://www.warren.senate.gov/imo/media/doc/Cardinal%20response%2005.13.20.pdf; at https://www.warren.senate.gov/imo/media/doc/McKesson%20response%2005.13.20.pdf; at https://www.warren.senate.gov/imo/media/doc/Medline%20response%2005.13.20.pdf.

[106] FEMA, "FEMA COVID-19 Supply Chain Task Force: Supply Chain Stabilization," April 7, 2020, at https://www.fema.gov/news-release/20200725/fema-covid-19-supply-chain-task-force-supply-chain-stabilization.

[107] Ibid., p. 6-7; See also FEMA, "Coronavirus (COVID-19) Pandemic: National Resource Prioritization Cell," updated May 17, 2020, at https://www.fema.gov/fact-sheet/coronavirus-covid-19-pandemic-national-resource-prioritization-cell; FEMA, phone briefing with House Committee on Homeland Security, House Committee on Oversight and Reform, and CRS, June 18, 2020.

[108] FEMA, "FEMA COVID-19 Supply Chain Task Force: Supply Chain Stabilization," April 7, 2020, at https://www.fema.gov/news-release/20200725/fema-covid-19-supply-chain-task-force-supply-chain-stabilization.

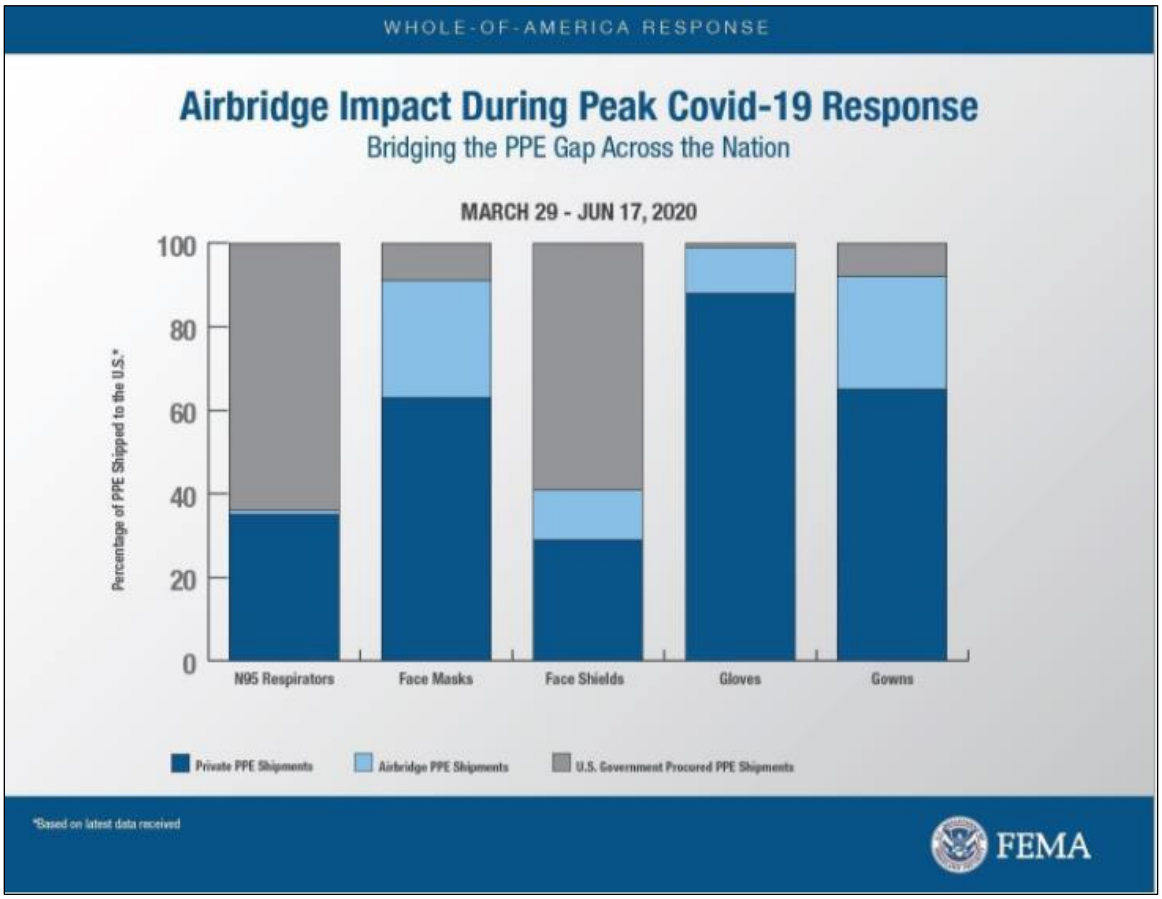
[109] The most detailed publicly available explanation is available at Rear Admiral Polowczyk, oral testimony, U.S. Congress, House Select Subcommittee on the Coronavirus Crisis, *The Administration's Efforts to Procure, Stockpile, and Distribute Critical Supplies*, 116th Cong., 2nd sess., July 2, 2020, at https://coronavirus.house.gov/subcommittee-activity/hearings, and FEMA, "National Resource Prioritization Cell."

[110] Per one Project Air Bridge MOA (publicly available on Senator Warren's website), "Company agrees to take possession of the Transported PPE shipped at Government's expense at the point of arrival (i.e., the airport)." See, for example, MOA between the Department of Homeland Security Federal Emergency Management Agency (DHS/FEMA) and Cardinal Health 200, LLC. Quote at p. 7 of "Cardinal Response," hosted by Senator Elizabeth Warren, "Warren, Schumer, Blumenthal Release New Findings and Documents from Investigation of Trump-Kushner 'Project Air Bridge' Coronavirus Response," at https://www.warren.senate.gov/download/cardinal-response-051320.

and are using more maritime resources to bring in supplies.[111] However, the GAO found that as of September 2020, states remained unable to fulfill local requests for certain types of PPE,[112] and FEMA's news releases on Project Airbridge indicated that the program facilitated transport only of a fraction of PPE shipments to the United States (see **Figure 2**). Additionally, some members of Congress have raised concerns with the program, including but not limited to: the delivery of too few supplies (particularly N95 respirators), the reported involvement of volunteer, private-sector employees in operating the federal initiative, federal pressure for Project Airbridge participants to procure PPE from a particular manufacturer, high prices of transported PPE, and the ability of private-sector partners to determine the recipient of transported PPE.[113]

Figure 2. PPE Shipment During Project Airbridge

According to FEMA, March 29-June 17, 2020



Source: FEMA, "FEMA Phasing Out Project Airbridge," June 17, 2020.

[111] GAO, *COVID-19: Federal Efforts,* p. 11, n. 16.

[112] Ibid., 15.

[113] Senator Elizabeth Warren, Charles Schumer, and Richard Blumenthal, Letter to Pandemic Response Accountability Committee, June 8, 2020, at https://www.warren.senate.gov/imo/media/doc/Letter%20to%20PRAC%20re%20project%20airbridge%202020.06.pdf; Chairwoman of House Committee on Oversight and Reform Carolyn B. Maloney, Memorandum on "Information Provided by Medical Distribution Companies on Challenges with White House Supply Chain Task Force and Project Airbridge," July 2, 2020, at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Project%20Airbridge%20Memo%2007-02-20.pdf.

Table 3. PPE Units Transported Through Project Airbridge

as reported by FEMA, March-June 30, 2020 (in millions)

	N95 Respirators	Surgical Masks	Gloves	Surgical Gowns	Face Shields
Units Delivered	Nearly 1.5	125.4	937.0	66.8	2.7

Source: FEMA, "Weekly Update: Coronavirus Pandemic Whole-of-America Response," Tuesday, July 7, 2020, at https://www.usetinc.org/wp-content/uploads/2020/07/ESF-15_WeeklyByTheNumbers_20200707-FINAL.pdf; and FEMA, "Phasing Out Project Airbridge, news release, June 17, 2020.

Notes: CRS cannot verify their accuracy as FEMA is the sole source of the information. Project Airbridge also transported other cargo, including stethoscopes, coveralls, and thermometers. Domestic distribution for products transported through Project Airbridge is the responsibility of the medical suppliers. Numbers of N-95 respirators delivered through Project Airbridge may vary across sources. Numbers of N-95 respirators reported here reflect data in FEMA, "Phasing Out Project Airbridge," which FEMA indicated should be cited in an email to CRS, September 16, 2020.

HHS and FDA Actions

Despite increased demand earlier this year, some mask manufacturers—as the largest domestic PPE producers—signaled reluctance to increase domestic manufacturing capacity, citing the risk of creating excess supply in the face of falling demand following a successful pandemic response.[114] To address such concerns, HHS awarded guaranteed contracts to five companies to incrementally purchase approximately 600 million N95 respirators to be delivered to the Strategic National Stockpile (SNS) over 18 months.[115]

According to HHS, this type of contract "supports long-term production while encouraging manufacturers to increase production of N95 respirators now—with the guarantee that they will not be left with excess supplies if private sector orders are cancelled once the COVID-19 response subsides."[116] Importantly, these contracts allow the manufacturers to fill private sector orders before the SNS order.

In addition, Congress authorized the HHS Secretary to waive most liability and to compensate eligible individuals who suffer injuries from administration or use of these products, whether used for the COVID-19 response or any other public health emergency.[117]

[114] Mike Bowen C.E.O. of Prestige Ameritech, quoted in Siddhartha Mukherjee, "What the Coronavirus Crisis Reveals About American Medicine," *The New Yorker*, April 27, 2020, at https://www.newyorker.com/magazine/2020/05/04/what-the-coronavirus-crisis-reveals-about-american-medicine.

[115] HHS, "HHS to Procure N95 Respirators to Support Healthcare Workers in COVID-19 Outbreaks," press release, March 4, 2020, at https://www.hhs.gov/about/news/2020/03/04/hhs-to-procure-n95-respirators-to-support-healthcare-workers-in-covid-19-outbreaks.html.

[116] HHS, "Procurement of N95 Respirators," at https://www.phe.gov/emergency/events/COVID19/SNS/Pages/procurement.aspx, accessed August 4, 2020.

[117] See §3103 of the CARES Act. For more information, see also CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)*, coordinated by Elayne J. Heisler.

FDA-Specific Actions

FDA regulates PPE intended for medical use (e.g., surgical masks, N95 respirators, medical gowns and gloves) as a medical device.[118] PPE intended for nonmedical (e.g., industrial) use is not considered a medical device and is therefore not subject to FDA regulatory requirements.[119]

Under most circumstances, a producer interested in manufacturing a medical device for the U.S. market would need FDA permission, which is often obtained through premarket notification (i.e., 510(k) clearance). To receive clearance, the manufacturer must submit to FDA—at least 90 days prior to marketing—a 510(k) submission demonstrating that the proposed device is substantially equivalent to (i.e., as safe and effective as) a device already on the market.[120] In addition, there are certain circumstances under which a change to an already cleared device would require a new 510(k) submission. According to FDA guidance, such changes include those involving labeling, technology, and/or materials used.[121]

Specific premarket and other regulatory requirements vary depending on the type of PPE. For example, medical gloves must receive 510(k) FDA clearance prior to marketing. Conversely, many respirators intended for use in the health care setting, such as surgical N95s, are subject to certification and approval by the National Institute for Occupational Safety and Health (NIOSH), an institute of the CDC.[122] While NIOSH, rather than FDA, generally reviews and approves surgical N95s in the premarket phase,[123] these products are still subject to other FDA regulatory requirements once on the market (e.g., current good manufacturing practices (CGMPs)).[124] Respirators intended for non-medical use (e.g., N95s for industrial uses) are subject to NIOSH requirements, but not FDA oversight.

During the COVID-19 pandemic, FDA has taken steps to address concerns about the availability of respirators and other critical PPE. While FDA cannot compel firms to make specific medical products, the agency has enabled access to non-FDA-cleared devices by granting emergency use

[118] Under the Federal Food, Drug and Cosmetic Act (FFDCA) §201(h) (21 U.S.C. §321(h)), these products are devices when intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.

[119] FDA, "Face Masks and Surgical Masks for COVID-19: Manufacturing, Purchasing, Importing, and Donating Masks During the Public Health Emergency," updated May 11, 2020, at https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/face-masks-and-surgical-masks-covid-19-manufacturing-purchasing-importing-and-donating-masks-during.

[120] FFDCA §510(k) (21 U.S.C. §360(k)). FDA, Premarket Notification 510(k), at https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

[121] FDA, "Deciding When to Submit a 510(k) for a Change to an Existing Device," Guidance for Industry and Food and Drug Administration Staff, October 2017, at https://www.fda.gov/media/99812/download.

[122] FDA, "N95 Respirators, Surgical Masks, and Face Masks," at https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks. See also Memorandum of Understanding (MOU) 225-18-006, *MOU Between the Food & Drug Administration/Center for Devices & Radiological Health and the Centers For Disease Control & Prevention/National Institute for Occupational Safety & Health/National Personal Protective Technology Laboratory*, November 2017, at https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006.

[123] Devices that exceed threshold evaluation criteria (e.g., specific disease and/or infection prevention) would also be subject to 510(k) requirements. For more information, see MOU 225-18-006, *Memorandum of Understanding Between the Food & Drug Administration/Center for Devices & Radiological Health and the Centers for Disease Control & Prevention/National Institute for Occupational Safety & Health/National Personal Protective Technology Laboratory*, November 2017, at https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006.

[124] FDA has promulgated CGMP regulations for devices through the quality system (QS) regulation (21 C.F.R. Part 820).

authorizations (EUA). FDA may grant an EUA for use of an unapproved medical product or the unapproved use of an approved product under certain circumstances.[125] FDA has issued several EUAs allowing the distribution and official medical use (not limited to treating COVID-19 patients) of certain NIOSH-approved respirators typically not used for medical purposes (e.g., preventing transmission of infection). EUAs were also issued for certain imported respirators that are not FDA-cleared or NIOSH-approved and systems for decontaminating respirators intended for single use.[126] PPE that is authorized under an EUA must comply with the conditions of authorization, including labeling and adverse event reporting, but is generally exempt from 510(k) clearance, registration requirements, and in some cases, certain CGMPs. Under normal circumstances, distributing these devices without complying with these requirements would be a violation of the FFDCA and FDA regulations, and subject to enforcement action.

To further expand availability of PPE during the COVID-19 pandemic, FDA has issued enforcement policies further describing the conditions under which producers may manufacture and distribute PPE without clearance or registration[127] for the duration of the declared public health emergency.[128] These enforcement policies have often been issued in tandem with EUAs, but FDA has noted that certain products can be authorized for marketing under the conditions laid out in the enforcement policies rather than an EUA.[129] However, PPE marketed under an existing enforcement policy rather than an EUA may not receive legal liability protections under the Public Readiness and Emergency Preparedness (PREP) Act.[130] For example, certain surgical gowns authorized under FDA's enforcement policy are not covered under the EUA for surgical gowns and other apparel.[131]

While FDA's actions have allowed additional companies to produce PPE for the U.S. market, it is not clear whether these efforts have increased domestic PPE production. In addition, waiving or modifying regulatory requirements is not without risk and may affect the safety, effectiveness, and quality of PPE. For example, on April 3, 2020, FDA issued an EUA allowing certain non-NIOSH-approved and non-FDA-cleared respirators to be imported from China in order to address

[125] FFDCA §564 (21 U.S.C. §360bbb–3). See also CRS In Focus IF10745, *Emergency Use Authorization and FDA's Related Authorities*, by Agata Bodie.

[126] FDA, "Personal Protective Equipment EUAs," updated July 31, 2020, at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas.

[127] FDA, "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)," Guidance for Industry and Food and Drug Administration Staff, updated May 2020, at https://www.fda.gov/media/136449/download. FDA, "Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency," Guidance for Industry and Food and Drug Administration Staff, March 2020, at https://www.fda.gov/media/136540/download.

[128] This refers to the public health emergency declared by the HHS Secretary for the COVID-19 pandemic on January 31, 2020, pursuant to Section 319 of the Public Health Service Act (42 U.S.C. §247d), and any renewals of such declaration. See HHS, "Public Health Emergency Declarations," at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

[129] FDA Webinar Series, "FDA's Surgical Masks EUA Umbrella," August 18, 2020, at https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-series-cdcnioshs-surgical-n95-respirator-guidance-09012020-09012020.

[130] For more information, see CRS Legal Sidebar LSB10443, *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures*, by Kevin J. Hickey.

[131] FDA, "Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency," Guidance for Industry and Food and Drug Administration Staff, March 2020, at https://www.fda.gov/media/136540/download. EUA Letter to Manufacturers of Gowns and Other Apparel; Healthcare Personnel; Hospital Purchasing Departments and Distributors; and Any Other Stakeholders, May 22, 2020, at https://www.fda.gov/media/138326/download.

reported shortages. However, FDA subsequently amended the EUA to exclude certain previously authorized respirators because they failed to demonstrate adequate filtration performance in testing conducted by NIOSH.[132] FDA has since reissued the EUA, amending the eligibility criteria for respirators imported from China.

DOD Actions: Joint Acquisition Task Force

The Department of Defense (DOD) has taken a number of actions to assist interagency efforts in increasing domestic production and distribution of PPE.[133] These actions include activities carried out by the DOD-led Joint Acquisition Task Force, by the Defense Logistics Agency, and to varying degrees under the Defense Production Act (DPA); assistance with interagency contract actions to expand PPE production capacities within the health industrial base[134] and replenish federally owned stockpiles; and PPE acquisition and distribution through the Defense Logistics Agency (DLA).[135]

JATF-Supported Coordination and Procurement

On March 25, 2020, DOD announced that it had established a new Joint Acquisition Task Force (JATF) to provide a centralized coordinating mechanism to address interagency requests for acquisition support associated with the COVID-19 pandemic response.[136] The JATF is comprised of members of the DOD acquisition workforce from the Office of the Secretary of Defense and other DOD components. The task force has been employed to support pandemic countermeasures by DOD as well as other agencies. DOD describes the JATF as "leverage[ing] DOD [acquisition] authorities, tools, and skillsets to assist in meeting the Nation's demand signal [for medical supplies and equipment such as [PPE] as defined by DOD and the interagency."[137] DOD has

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[132] FDA, "Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection—Letter to Health Care Providers," June 7, 2020, at https://www.fda.gov/medical-devices/letters-health-care-providers/certain-filtering-facepiece-respirators-china-may-not-provide-adequate-respiratory-protection-letter.

[133] See for example press briefing provided by Ellen M. Lord, Undersecretary of Defense for Acquisition and Sustainment, August 20, 2020, available at https://www.defense.gov/Newsroom/Transcripts/Transcript/Article/2319990/ellen-m-lord-undersecretary-of-defense-for-acquisition-and-sustainment-briefs-m/. See also Terri Moon Cronk, "DOD Establishes Task Force to Meet U.S. Medical Equipment Needs," *DOD News*, March 25, 2020, available at https://www.defense.gov/Explore/News/Article/Article/2124528/dod-establishes-task-force-to-meet-us-medical-equipment-needs/.

[134] The term "heath industrial base" is used to describe the domestic industrial capabilities and attendant supply chains that support the production of health and medical-related articles for the United States. It is used as a health-related analogue of the defense industrial base.

[135] Testimony of Ellen M. Lord, Undersecretary of Defense for Acquisition and Sustainment, U.S. Congress, House Committee on Armed Services, *Department of Defense COVID-19 Response to Defense Industrial Base Challenges*, 116th Cong., 2nd sess., June 10, 2020. See also CRS In Focus IF11574, *National Stockpiles: Background and Issues for Congress*, by G. James Herrera and Frank Gottron.

[136] Joint Acquisition Task Force (JATF) Fact Sheet, available at https://www.acq.osd.mil/fo/acq/docs/28AUG2020-COVID-19-Joint-Acquisition-Task-Force-Fact-Sheet.pdf. A *joint task force* is a military organizational construct that brings together personnel from at least two DOD military departments or components, generally in order to respond to a specific military operation or crisis; such a task force is typically disbanded when it has completed its mission. While the JATF does not appear to be operating as a specifically *military* (i.e., led by a military commander) joint task force, as established by DOD doctrine, statements made by DOD officials indicate that the JATF has broadly adopted and modeled itself after the temporary organizational characteristics of such a task force. See broadly Joint Publication 3-33, "Joint Task Force Headquarters," January 31, 2018, available at https://www.jcs.mil/Portals/36/Documents/Doctrine/pubs/jp3_33.pdf.

[137] JATF Fact Sheet, available at https://www.acq.osd.mil/fo/acq/docs/28AUG2020-COVID-19-Joint-Acquisition-Task-Force-Fact-Sheet.pdf; see also Office of the Under Secretary of Defense for Acquisition and Sustainment,

indicated that it may use many of the unique acquisition authorities granted to it by Congress—such as its authority to conduct *other transactions* (OT) and the Commercial Solutions Opening pilot program established by the FY2017 National Defense Authorization Act—as it provides this assistance.[138]

In response to the pandemic, the JATF's work has focused on providing *assisted acquisitions*—a type of interagency acquisition where an agency performs acquisition activities on a requesting agency's behalf, such as awarding and administering a contract, task order, or delivery order—to HHS and FEMA.[139] This assistance is intended to support HHS in expanding the domestic health industrial base, including the manufacturing throughput of health and medical resources, such as PPE (see **Table 5**). Much of the investment and industrial capacity expansion activities facilitated by the JATF use appropriations and authorities provided to HHS by the CARES Act (P.L. 116-136.)[140]

DOD officials have testified that the JATF's activities have allowed DOD to provide emergency acquisition support to procurement officers at HHS and FEMA in reaction to the urgency and volume of federal acquisitions associated with the COVID-19 pandemic response.[141] In testimony before the House Armed Services Committee in June 2020, DOD officials indicated that investments facilitated by the JATF will result in a cumulative annual increase in domestic manufacturing capacity for N-95 respirators "in excess of a billion per year" beginning in 2021.[142] **Table 4** shows selected JATF domestic PPE contracts awarded in response to the pandemic.

"COVID-19 Joint Acquisition Task Force," available at https://www.acq.osd.mil/jatf.html.

[138] See generally CRS Report R45521, *Department of Defense Use of Other Transaction Authority: Background, Analysis, and Issues for Congress*, by Heidi M. Peters and AFWERX, "COVID-19 National Response Team," available at https://www.afwerx.af.mil/coronavirus.html.

[139] See Federal Acquisition Regulation (FAR) Subsection 2.101, "Definitions;" see also FAR Subpart 17.5, "Interagency Acquisitions." See also testimony of Ellen M. Lord, Undersecretary of Defense for Acquisition and Sustainment, U.S. Congress, House Committee on Armed Services, *Department of Defense COVID-19 Response to Defense Industrial Base Challenges*, 116th Cong., 2nd sess., June 10, 2020.

[140] In part, the CARES Act provided $27.0 billion to the HHS Secretary to "prevent, prepare for, and respond to coronavirus, domestically or internationally, including the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, as well as medical surge capacity, addressing blood supply chain, workforce modernization, telehealth access and infrastructure, initial advanced manufacturing, novel dispensing, enhancements to the U.S. Commissioned Corps, and other preparedness and response activities," with provisos that in part direct these appropriated funds may be "used to develop and demonstrate innovations and enhancements to manufacturing platforms to support such capabilities"; may be used for "grants for the construction, alteration, or renovation of non-federally owned facilities to improve preparedness and response capability at the State and local level"; and may be used for the "construction, alteration, or renovation of non-federally owned facilities for the production of vaccines, therapeutics, and diagnostics where the Secretary determines that such a contract is necessary to secure sufficient amounts of such supplies." P.L. 116-136, 134 Stat. 560.

[141] Both FEMA and HHS traditionally handle relatively smaller annual budgets and associated procurements. Testimony of Ellen M. Lord, Undersecretary of Defense for Acquisition and Sustainment, U.S. Congress, House Committee on Armed Services, *Department of Defense COVID-19 Response to Defense Industrial Base Challenges*, 116th Cong., 2nd sess., June 10, 2020.

[142] Testimony of Stacy Cummings, JATF Director, U.S. Congress, House Committee on Armed Services, *Department of Defense COVID-19 Response to Defense Industrial Base Challenges*, 116th Cong., 2nd sess., June 10, 2020; see also C. Todd Lopez, "Domestic N95 Mask Production Expected to Exceed 1 Billion in 2021," *DOD News*, June 10, 2020, available at https://www.defense.gov/Explore/News/Article/Article/2215532/domestic-n95-mask-production-expected-to-exceed-1-billion-in-2021/.

Table 4. Selected JATF Domestic PPE Industrial Base-Related Contracts Awarded in Coordination with HHS to Respond to the COVID-19 Pandemic

organized by date of action in 2020

Action Date	Primary Agency	Secondary Agency	Action Award	Description
May 6	DOD	HHS	$126 million	Increase production of 26 million N95 medical-grade respirators per month, starting in October 2020
June 19	DOD	HHS	$13.5 million	Increase production capacity of meltblown filtration media
July 17	DOD	HHS	$3.5 million	Increase production of surgical masks
July 23	DOD	HHS	$22.4 million	Increase production capacity for nitrile butadiene rubber (NBR) gloves
July 25	DOD	HHS	$2.75 million	Increase production of meltblown fiber

Source: CRS review of DOD press releases and contract announcements.

Notes: In coordination with HHS and FEMA, JATF and other DOD components have undertaken additional actions in response to the COVID-19 pandemic. This table presents selected examples of JATF-facilitated contract actions to expand PPE production capacities within the domestic health industrial base.

Defense Logistics Agency

DOD's Defense Logistics Agency (DLA) has been active in the federal COVID-19 response, owing in part to its global presence and extensive experience with facilitating large and complex logistics assignments on behalf of the DOD and, at times, the federal government more broadly.

DLA is a *combat support agency* (with distinct requirements under Title 10 U.S.C.) within DOD that is responsible for providing supplies and services common to all military departments.[143] DLA's primary purpose is to meet the logistics requirements of the armed forces for food, clothing, fuel, parts, and other items including medical material. Its major responsibilities are to "(1) buy or contract, (2) warehouse when needed, and (3) distribute about 5 million distinct consumable, expendable and reparable items" to its customers.[144] The agency typically contracts for high-volume, commercially-available items based on customer requirements. It then distributes these items directly to the requesting customer (e.g., a military unit or defense facility like a shipyard), or stores the items for later delivery.[145] DLA is headquartered in Fort Belvoir, VA, but operates in most U.S. states and territories, and in 28 foreign countries, using a large distribution network consisting of both military and commercial support providers. DLA also works closely with the United States Transportation Command (USTRANSCOM) to ensure purchased or contracted supplies can be transported anywhere in the world.[146] DLA's broad logistical footprint, and demonstrated capability for administering the distribution of supplies

[143] See 10 U.S.C. §191 and 10 U.S.C. §193(f).

[144] Defense Logistics Agency (DLA), *Defense Logistics Agency Fact Sheet*, DOD, May 2020, at https://www.dla.mil/Portals/104/Documents/Headquarters/DLA%20At%20A%20Glance/DLAFactSheetMay2020.pdf.

[145] CRS In Focus IF11543, *Defense Primer: The Defense Logistics Agency*, by G. James Herrera and Hibbah Kaileh.

[146] CRS In Focus IF11479, *Defense Primer: United States Transportation Command*, by G. James Herrera and Hibbah Kaileh.

worldwide during contingency operations, has contributed to calls from some Members of Congress and elsewhere for an enhanced DLA role in response to the pandemic.[147]

DLA Support for the Domestic COVID-19 Response

DLA typically contracts for and distributes nearly all types of medical supplies to military units, DOD agencies, and other federal partners and allies as directed by the Secretary of Defense. In some cases, small stocks of certain types of medical equipment or supplies may be stored by DLA or a military service in a DOD warehouse, and, when needed, can be directly transported to DOD customers. For instance, in the early days of the COVID-19 domestic response, DOD provided approximately 5 million N-95 respirator masks and 2,000 deployable ventilators to HHS.[148] However, DOD generally employs a "just-in-time" logistics strategy for manufactured products, such as PPE, which reduces the amount of government purchased material (GPM) stockpiled in DOD warehouses in favor of commercial-reliant solutions, such as direct vendor delivery, prime vendor contracting, and contingency contracts (also called "readiness contracts").[149] Consequently, medical materials and supplies are typically stored at vendor facilities and shipped directly to customers.[150]

Following the surge in demand for certain types of medical equipment and PPE, across the country, DLA also saw a surge in demand for these same items from its customers (both within DOD and from non-DOD federal agencies). As an example of an early response measure, DLA initiated weekly conference calls at the start of the pandemic with major commercial suppliers to share information and discuss financial and logistics issues created by the pandemic.[151] DLA then established additional contracts with manufacturers to produce larger quantities of high-demand medical materials that could supplement the whole of government COVID-19 response.

Table 5 provides DLA-reported figures (from August 2020) of certain medical materials *contracted for*, and *shipped/delivered* to both DOD and non-DOD federal customers (the latter directed by HHS/FEMA, who are the lead agencies of the COVID-19 Supply Chain Task Force).[152]

Table 5. Selected Medical Materials Contracted for and Shipped/Delivered by DLA

for August 26, 2020 (in millions)

	N95 Respirator Masks	Non-Medical and Surgical Masks	Exam Gloves	Hand Sanitizers	Testing Components	Ventilators	Isolation and Surgical Gowns
Provided to DOD/Military							
Contracted	5.635	67.873	167.764	1.271	0.241	0.003	3.092

[147] See, for example, H.R. 8562.

[148] Ellen Mitchell, "Pentagon to Give 5M Respirator Masks, 2,000 Ventilators to HHS in Response to Coronavirus Outbreak," *The Hill*, March 17, 2020, at https://thehill.com/policy/defense/488085-pentagon-to-give-5m-Ven-2000-ventilators-to-hhs.

[149] CRS In Focus IF11574, *National Stockpiles: Background and Issues for Congress*, by G. James Herrera and Frank Gottron.

[150] From correspondence with DLA.

[151] Ibid.

[152] Lindsay Maizland, "U.S. Coronavirus Response: Who's In Charge of What?" Council on Foreign Relations, April 7, 2020, at https://www.cfr.org/article/us-trump-coronavirus-response-covid19-agencies-in-charge.

Shipped/ Delivered	4.279	58.331	144.468	1.087	0.103	0.002	1.650
Provided to Non-DOD Federal Agencies							
Contracted	0.060	2.883	5.692	0.027	6.394	0.004	0.056
Shipped/ Delivered	0.026	2.655	5.176	0.023	0.001	0.004	0.025

Source: Tabulated by CRS from data provided by DLA.

Note: DLA combines "shipped" and "delivered" in its accounting because Class VIII supply is normally shipped directly to customers from vendors and guaranteed delivery is part of the DOD contract. Contracted amounts are not a cumulative total of all medical materials contracted for since the start of the COVID-19 pandemic.

The figures provided in this table are for a specific date (August 26, 2020) and are not cumulative from the start of the pandemic. There can be differences in published totals attributed to fluctuations in orders. Orders fluctuate daily from new contracts, order cancellations, and quantity adjustments.[153]

As of August 31, 2020, DLA had executed over 18,000 contract actions, obligating over $1.5 billion to provide medical supplies—including test kits, ventilators, pharmaceutical drugs, and both medical and non-medical PPE—to meet customer demands and support the SNS.

According to DLA:

> DLA's existing relationships and standing agreements with FEMA and HHS were vital to the success of initial operations, enabling a rapid transition to full integration with FEMA, HHS and the White House Supply Chain Task Force. DLA provided 20 DLA personnel beginning March 22, 2020 to FEMA, HHS, the [White House Supply Chain] Task Force, the Joint Acquisition Task Force, and Operation Warp Speed [[154]]. Additionally, 18 DLA personnel supported U.S. Northern Command and DOD operations from April 5, 2020 to May 31, 2020.[155]

DLA Medical Material Support

DLA has provided PPE and other essential medical materials to both DOD and its federal government partners. Not all of these medical materials were delivered through commercial producers from direct procurements (i.e., contracting for commercial products). The following selected examples of DLA support during the COVID-19 pandemic in **Table 6** show a range of different approaches taken to provide needed medical materials to DLA customers.

[153] CRS cannot independently verify the data provided by DLA, nor necessarily match the relationship of that data to end users or health providers in response to the COVID-19 pandemic.

[154] DLA reports that as of August 31, 2020, the agency is providing eight of its personnel to FEMA, HHS, and the two task forces, including supporting Operation Warp Speed.

[155] From correspondence with DLA.

Table 6. Selected Examples of DLA Medical Material Support

selected for illustrative purposes

Example Area	Description
Support to U.S. Navy Hospitals Ships	From March to May 2020, DLA provided over $13 million in support to the USNS Comfort and USNS Mercy in preparation for their deployments to the East and West Coasts of the United States. This support included $2 million in food products, $2.8 million in fuel, and $8.5 million in medical supplies. DLA states they "ensured these critical floating hospitals were stocked with essential pharmaceuticals, PPE, subsistence items, and [N-95] respirators **redistributed from excess property**" (emphasis added by CRS).[156]
Reutilization of Excess Personal Property	Beginning in March 2020, U.S. states were requesting excess military medical supplies and equipment from DOD.[157] States made requests for several items, including vital signs monitors, anesthesia machines, gloves, gowns, and surgical drapes. In its role as the Department-wide agency responsible for excess personal property reutilization, transfer, and donation (R/T/D) for property received from the Military Services, DLA reutilized $23.6 million (approximately 4,500 requisitions) worth of excess personal property to support the U.S. COVID-19 response.[158] DLA, through its Disposition Services major subordinate command—which manages DOD's personal property disposal process—delivered the repurposed medical items to DOD and its federal partners.[159]
Rapid Prototyping to Support Manufacturing	In April 2020, DLA procured more than 11,000 face shields for first responders in New York City using a rapid prototype project, and executed this contract award and delivery in less than two weeks.[160]
Decontamination as a Means of Recycling PPE	In April 2020, DLA awarded a contract to Battelle Memorial Institute for 60 Critical Care Decontamination Systems (CCDS) and six months of service at $413 million, in support of HHS.[161] Each unit is capable of sterilizing up to 80,000 N-95 respirators per day and extend the life of a single mask by 20 uses.[162]
Targeted Procurement Contracting	Beginning in May 2020, DLA and HHS worked together to identify those domestic nursing home facilities with the highest risk of contracting COVID-19. DLA then ordered $134 million in PPE for these nursing homes. Over 30,000 deliveries consisting of masks, eye protection, gloves, gowns, and face shields were completed on August 11, 2020. Additionally, HHS requested that DLA assist with the distribution of approximately 1.5 million N-95 respirators to over 3,000 U.S. nursing homes.[163]

Source: Tabulated from DLA information and correspondence.

Notes: These examples are illustrative and do not represent an exhaustive accounting of DLA actions or activities in support of COVID-19 PPE and medical material countermeasures.

[156] From correspondence with DLA.

[157] For more information on excess personal property, see U.S. General Services Administration (GSA), "Personal Property for Reuse and Sale," accessed August 31, 2020, at https://www.gsa.gov/buying-selling/government-property-for-sale-or-disposal/personal-property-for-reuse-and-sale.

[158] See DLA Disposition Services, "Reutilization, Transfer and Donation (R/T/D)," at https://www.dla.mil/DispositionServices/Offers/Reutilization.aspx.

[159] See DLA Disposition Services, "Mission," at https://www.dla.mil/DispositionServices/About/Mission/.

[160] From correspondence with DLA.

[161] By June 2020, all 60 CCDS were delivered. From correspondence with DLA.

[162] From correspondence with DLA.

[163] Ibid.

How DLA Utilized Existing U.S. Government Platforms to Provide PPE

In addition to those medical materials that were contracted and delivered by DLA (i.e., shipped by its vendors directly to federal agencies), or repurposed through DOD's personal property disposal process, DLA also launched a facilitation program called the "FedMall Small Business E-Commerce Corridor" on June 15, 2020. The program provides a secure website that grants access to a restricted "storefront," which allows small business contractors to purchase PPE for their employees to safely perform contracts for the government. The program makes use of the U.S. government's existing e-commerce online purchasing platform known as "FedMall."

In mid-July 2020, DLA initiated a similar program known as the "State and Local Government FedMall Purchasing Program" to support state and local government purchasing of *non-medical PPE* (e.g., non-medical face masks, disinfecting wipes, hand sanitizer). This program employs the same FedMall online purchasing platform. However, under this program, state and local governments can purchase non-medical PPE at or below the micro-purchase contract threshold of $10,000 for use while performing first responder missions in support of counter drug, homeland security, or emergency response.

DLA states, the "benefit of FedMall's online shopping tool is it provides dynamic pricing and a safe shopping experience with pre-qualified suppliers."

Defense Production Act

The Defense Production Act (DPA) has been employed by the Trump Administration in response to the COVID-19 pandemic, with the apparent rate and volume of actions increasing over time (as tabulated on **Table 7**, **Table 8**, **Table 9**, and **Table 10**). However, the Administration's implementation pattern has been relatively narrow in application, and appears to have prioritized defense industrial base investments over PPE or health industrial base actions.[164]

Background on the DPA

The DPA confers broad presidential authorities to mobilize domestic industry in service of the *national defense*, defined in statute as various military activities and "homeland security, stockpiling, space, and any directly related activity,"[165] including emergency preparedness activities under the Stafford Act. Many of these authorities were delegated to executive agencies under Executive Order 13603, issued by President Barack Obama in 2012.[166]

DPA authorities relevant to the COVID-19 response include,[167] but are not limited to:

- **Title I: Priorities and Allocations**, which allows the President to require persons (including businesses and corporations) to (1) prioritize and accept government contracts for materials and services; and (2) allocate or control the general distribution of materials, services, and facilities as necessary to promote the national defense. Title I also includes provisions to prevent price gouging and the hoarding of scarce materials.

[164] For more information on the defense industrial base, see CRS In Focus IF10548, *Defense Primer: U.S. Defense Industrial Base*, by Heidi M. Peters.

[165] 50 U.S.C. §4552.

[166] Executive Order 13603, "National Defense Resources Preparedness," 77 *Federal Register* 16651-16660, March 22, 2012, at https://www.federalregister.gov/documents/2012/03/22/2012-7019/national-defense-resources-preparedness.

[167] For an in-depth discussion of the DPA's history and authorities, see CRS Report R43767, *The Defense Production Act of 1950: History, Authorities, and Considerations for Congress*, by Michael H. Cecire and Heidi M. Peters.

- **Title III: Expansion of Productive Capacity and Supply**, which allows the President to provide economic incentives to secure domestic industrial capabilities essential to meet national defense requirements. DPA Title III is specifically intended to "create, maintain, protect, expand, or restore domestic industrial base capabilities."[168] Authorized incentives include loans, loan guarantees, direct purchases and purchase commitments, and the authority to procure and install equipment in private industrial facilities.
- **Title VII: General Provisions,** which include key definitions and other distinct authorities. These provisions grant the President the authority to establish voluntary agreements with private industry; collect proprietary information; block proposed or pending foreign corporate mergers, acquisitions, or takeovers that threaten national security;[169] employ persons of outstanding experience and ability; and establish a volunteer pool of industry executives who could be called to government service.

DPA and COVID-19 Response

Since the COVID-19 pandemic emerged, the Trump Administration's implementation of DPA has appeared to be relatively narrow in scope.[170] Although the observed volume of DPA actions has increased over time (as tabulated on **Table 7**, **Table 8**, **Table 9**, and **Table 10**), publicized individual DPA Title I prioritization actions have been relatively few. With the exception of one priority-rated order on July 8, 2020, no new DPA Title I prioritization orders for health articles have occurred since April 21 (see **Table 8**). In addition, a majority of DPA Title III funding has been awarded to support the non-medical defense industrial base (**Table 10**) rather than to support and/or expand the health industrial base in response to COVID-19.[171]

In response to the COVID-19 pandemic, the Administration has issued 10 presidential directives related to the DPA (**Table 7**). Six of these actions are executive orders, and four are presidential memoranda.

The Administration has employed the DPA selectively, focusing on individual companies (e.g., General Motors, 3M) or industry sub-sectors (e.g., meat processing). Sporadic DPA efforts have been employed in response to complaints from Congress and some governors regarding ongoing shortages of PPE,[172] testing supplies,[173] and other such resources.

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[168] 50 U.S.C. §4533.

[169] 50 U.S.C. §4565(k). This provision authorizes the Committee on Foreign Investment in the United States (CFIUS). For more information, see CRS Report RL33388, *The Committee on Foreign Investment in the United States (CFIUS)*, by James K. Jackson.

[170] For further CRS accounting of DPA implementation in response to COVID-19, see CRS Insight IN11470, *Defense Production Act (DPA): Recent Developments in Response to COVID-19*, by Michael H. Cecire and Heidi M. Peters; CRS Insight IN11387, COVID-19: Defense Production Act (DPA) Developments and Issues for Congress, by Michael H. Cecire and Heidi M. Peters; and CRS Insight IN11337, The Defense Production Act (DPA) and the COVID-19 Pandemic: Recent Developments and Policy Considerations, by Michael H. Cecire and Heidi M. Peters.

[171] See CRS Insight IN11288, COVID-19 and the Defense Industrial Base: DOD Response and Legislative Considerations, by Heidi M. Peters.

[172] Centers for Disease Control and Prevention, "Operational Considerations for Personal Protective Equipment in the Context of Global Supply Shortages for Coronavirus Disease 2019 (COVID-19) Pandemic: Non-US Healthcare Settings," May 5, 2020, at https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/emergency-considerations-ppe.html.

[173] Burgess Everett and Marianne Levine, "Capitol Physician Says Senate Lacks Capacity to Test All Senators,"

The Administration's announced actions have primarily framed the DPA as a coercive instrument (e.g., the President called the DPA a "tremendous hammer"[174]) with relatively narrow application. In an interview with the media, White House trade advisor Peter Navarro reiterated prior assertions that the Administration wielded DPA authorities to influence voluntary action without the need to actually implement them.[175]

Table 7. DPA Presidential Directives

by date of directive

Date	Type	Title
March 18, 2020	Executive Order (13909)	Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID–19
March 23, 2020	Executive Order (13910)	Preventing Hoarding of Health and Medical Resources to Respond to the Spread of COVID-19
March 27, 2020	Executive Order (13911)	Delegating Additional Authority Under the Defense Production Act With Respect to Health and Medical Resources to Respond to the Spread of COVID-19
March 27, 2020	Memorandum	Memorandum on Order Under the Defense Production Act Regarding General Motors Company
April 2, 2020	Memorandum	Memorandum on Order Under the Defense Production Act Regarding the Purchase of Ventilators
April 2, 2020	Memorandum	Memorandum on Order Under the Defense Production Act Regarding 3M Company
April 3, 2020	Memorandum	Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use
April 28, 2020	Executive Order (13917)	Delegating Authority Under the Defense Production Act with Respect to Food Supply Chain Resources During the National Emergency Caused by the Outbreak of COVID-19
May 14, 2020	Executive Order (13922)	Delegating Authority Under the Defense Production Act to the Chief Executive Officer of the United States International Development Finance Corporation to Respond to the COVID-19 Outbreak
August 6, 2020	Executive Order (13944)	Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States

Source: Tabulated by CRS from the *Federal Register* and White House website.

Notes: Only the executive orders were entered into the *Federal Register*. Although presidential memoranda may be entered into the *Federal Register* at the President's discretion, that option did not appear to be exercised in these cases.

The Administration has not consistently employed DPA authorities to expedite PPE contracts, and certain Members of Congress have raised concerns over PPE availability and urged use of DPA

Politico, April 30, 2020, at https://www.politico.com/news/2020/04/30/capitol-physician-senators-coronavirus-testing-226980.

[174] Alice Miranda Ollstein, "Trump Invokes DPA for Testing Swabs, Weeks After Reported Shortages," *Politico*, April 19, 2020, at https://www.politico.com/news/2020/04/19/trump-dpa-testing-swabs-reported-shortages-195721.

[175] Priscilla Alvarez, Curt Devine, Drew Griffin, and Kristen Holmes, "Trump Administration's Delayed Use of 1950s Law Leads to Critical Supplies Shortages," *CNN.com*, July 14, 2020, at https://www.cnn.com/2020/07/13/politics/delayed-use-defense-production-act-ppe-shortages/index.html.

authorities to address those concerns.[176] On July 19, 2020, DOD and HHS announced a $3.5 million award for surgical mask production (with full delivery not expected until May 2021);[177] however, this did not appear to be accomplished under DPA authorities.

Although the DPA statute does not require the President to use directives to invoke DPA authorities, the President may issue executive orders, memoranda, or other directives as a means of framing the intent and implementation of those DPA authorities. This appears to have been the Trump Administration's practice in response to the pandemic, but this has not always been a standard practice. For example, during "peacetime," DOD (the highest volume user of DPA authorities) typically utilizes DPA Title I authorities without accompanying, specific presidential directives.[178] Additionally, the DPA statute does not provide for any requirement that DPA actions be made public. Although individual DPA actions may be made public through executive agency press releases, in FPDS reporting,[179] or in some other capacity, there is no standing requirement for publishing DPA actions, and no centralized repository where they are collected.

In August 2020, the White House Office of Trade and Manufacturing Policy released a report describing and defending the Administration's employment of DPA authorities.[180] The report includes significant details on DPA actions taken during the pandemic. However, given that DPA activities are not fully transparent and not all of the information can be independently verified, it remains unclear if the report is exhaustive. For example, with regard to the use of the allocations authorities, the report does not provide details of all occurrences.[181]

Title I Prioritization Activities

According to the White House report, the Administration has employed DPA Title I authorities 19 times in response to the COVID-19 pandemic, though only three instances related to PPE among the 19 cited by the Administration.

DPA Title I activities are shown in **Table 8**.

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[176] U.S. Congress, House, Letter to President Trump, prepared by Rep. Pramila Jayapal and Rep. Jaime Herrera Beutler, 116th Cong., June 23, 2020, at https://jayapal.house.gov/wp-content/uploads/2020/06/6.23.20_Jayapal-Herrera-Beutler-DPA-PPE-.pdf.

[177] Department of Defense, *DOD Awards $3.5 Million Contract to Crosstex International, Inc. to Increase Domestic Production of Surgical Masks*, July 19, 2020, at https://www.defense.gov/Newsroom/Releases/Release/Article/2279253/dod-awards-35-million-contract-to-crosstex-international-inc-to-increase-domest/.

[178] For example, the Department of Defense (DOD) makes frequent use of the DPA, and in particular uses Title I authorities on a routine basis. According to the Defense Production Act Committee (DPAC) report for CY2016, it notes that "virtually all DOD contracts for resources covered under DPAS (including Foreign Military Sales contracts) include a [Defense Priorities and Allocations System] priority rating [i.e., are DPA Title I actions]." U.S. Department of Homeland Security, *The Defense Production Act Committee Report to Congress, for Calendar Year 2016*, September 18, 2017, p. 5.

[179] FPDS does not have a dedicated designator for DPA actions. However, it does contain a free text field within which an agency may record a contract as a DPA action, which can provide evidence for otherwise unpublicized DPA activity. Because this practice is not always observed, it is not necessarily a reliable means of exhaustively capturing or measuring DPA activity.

[180] The White House Office of Trade and Manufacturing Policy, *How President Trump Uses the Defense Production Act to Protect America from the China Virus*, July 2020, at https://www.whitehouse.gov/wp-content/uploads/2020/08/OTMP-DPA-Report-FINAL-8.13.20.pdf.

[181] Ibid.

Table 8. DPA Title I Actions: Reported by the Administration

by announcement date

Date	Agency	Funding	Vendor	Description
March 28, 2020	FEMA	—	Puritan Medical	Upstream machine shop services.
March 28, 2020	FEMA	—	N/A	Blanket request required to invoke DPA.
March 30, 2020	HHS	$552 million	Hamilton	Contract action for 25,574 ventilators.
March 30, 2020	HHS	$350 million	Zoll	Contract action for 18,900 ventilators.
April 5, 2020	FEMA	—	N/A	Memo expediting N95 respirators to New Jersey.
April 8, 2020	HHS	$489 million	GM	Contract action for 30,000 ventilators.
April 8, 2020	HHS	$647 million	Philips	Contract action for 43,000 ventilators.
April 10, 2020	FEMA	—	Zoll	Applied rating to Zoll ventilator contract.
April 10, 2020	FEMA	—	N/A	Memo compelling sale of filtering face pieces and respirators in shipment.[a]
April 13, 2020	FEMA	—	N/A	Authorized construction of alternate care facilities.
April 13, 2020	HHS	$64 million	General Electric	Contract action for 2,410 ventilators.
April 13, 2020	HHS	$20 million	Hill-Rom	Contract action for 3,400 ventilators.
April 13, 2020	HHS	$9 million	Medtronic	Contract action for 1,056 ventilators.
April 13, 2020	HHS	$32 million	ResMed	Contract action for 2,550 ventilators.
April 13, 2020	HHS	$408 million	Vyaire	Contract action for 22,000 ventilators.
April 13, 2020	HHS	—	Combat Medical[b]	Contract action for 12,000 ventilators.
April 16, 2020	FEMA	—	N/A	Priority ratings for PPE/Equipment for DoD Medical Treatment Facilities
April 21, 2020	HHS	—	Biomedical Devices[b]	Contract action for 12,000 Powered Air Purifying Respirators.
July 8, 2020	HHS	$70 million	Becton Dickinson	50M needles and syringes to support vaccination.
August 20, 2020	HHS	—	Becton Dickinson, Quidel	Large volume purchase of diagnostic systems and assays for COVID-19 testing for nursing homes

Source: White House report on the DPA. Where possible, information listed is crossed reference against information tabulated from Administration press releases and FPDS. The August 20, 2020 entry was not included in the report, and was tabulated separately: https://www.hhs.gov/about/news/2020/08/20/trump-administration-uses-defense-production-act-to-aid-our-most-vulnerable.html.

Notes:

a. A FEMA DPA Title I priority-rated order with the 3M Company was announced on April 16, but was not tabulated as such in the White House report, though it is cited in the narrative; the April 10 table entry may refer to the 3M contract actions. The 3M contract actions were entered separately into FPDS by shipment. As of August 5, 2020, five such shipments have been identified in FPDS.

b. Funding amounts were not included in the report, and are tabulated here from publicly available executive agency press releases as available. In at least two cases—contract actions with companies Combat Medical and Biomedical Devices—those funding amounts were not publicly released. However, according to FPDS, major contract actions were made with these companies for $62 million and $110 million, respectively. These contract actions appear to comport with the Title I actions in this table, but cannot be independently verified and thus are not listed in the table.

The table above reflects data provided in the White House report, which disaggregates each Title I event by company where available, and does not include funding amounts. Additionally, the White House report also includes selected non-contract Title I actions, such as the assignment of priority ratings (which normally would occur as part of a contract action), in the table as discrete events.

Title I Allocations and Anti-Hoarding/Price Gouging Actions

The Title I actions listed above do not appear to be reflective of all Title I activities, as they do not account for some allocation actions that are known to have occurred, particularly allocations of scarce medical supplies and anti-hoarding/price gouging actions (**Table 9**). Unlike actions taken under the Title I prioritization authority, allocation actions do not yield DPA-rated contract orders, and are less frequently publicized, making them more difficult to track. Given the breadth of the Title I allocations authority and lack of a publication requirement, the usage rate or volume of allocations is not publicly known.

On April 10, 2020, FEMA, in coordination with Customs and Border Protection (CBP), released guidance on the use of DPA to allocate specific scarce medical supplies, per Executive Order (E.O.) 13090 and the President's April 3 memorandum.[182] This allocations action was justified in the final rule as a measure to preserve domestic stocks of scarce medical supplies, including PPE, because the "domestic need for them exceeds the supply." The rule allocated these supplies exclusively for domestic use, effectively prohibiting export without FEMA's authorization.[183] Although the Administration described these measures as necessary to "restrict the export of such threatened PPE," it has not released data on the policy's potential efficacy on domestic PPE supply.

Similarly, under E.O. 13090, the Administration utilized another Title I authority to police price gouging and the hoarding of scarce materials or resources, including PPE, to facilitate domestic supply. The Department of Justice (DOJ), in coordination with FEMA and other Department of Homeland Security (DHS) component agencies, established and leads a COVID-19 Hoarding and Price Gouging Task Force,[184] which has engaged in various enforcement and redistribution actions since its formation in March 2020. **Table 9** includes a selection of those actions.

[182] FEMA, "Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use," 85 *Federal Register* 20195, April 10, 2020, at https://www.federalregister.gov/documents/2020/04/10/2020-07659/prioritization-and-allocation-of-certain-scarce-or-threatened-health-and-medical-resources-for.

[183] See Ana Swanson, Zolan Kanno-Youngs, and Maggie Haberman, "Trump Seeks to Block 3M Mask Exports and Grab Masks from Its Overseas Customers," *New York Times*, April 3, 2020, at https://www.nytimes.com/2020/04/03/us/politics/coronavirus-trump-3m-masks.html.

[184] Department of Justice (DOJ), *Combatting Price Gouging and Hoarding*, accessed September 10, 2020, at https://www.justice.gov/coronavirus/combattingpricegouginghoarding/.

Table 9. DPA Anti-Hoarding and -Price Gouging Actions

by date of action

Date	Location	Description
March 30, 2020	New Jersey	Alleged hoarding and price gouging of PPE and other medical supplies.
April 2, 2020	New Jersey, New York	Medical supplies seized under the March 30 action were redistributed.
April 24, 2020	New York	Alleged hoarding and price gouging of PPE.
April 28, 2020	New York	Alleged conspiracy to price gouge.
May 26, 2020	New York	Alleged hoarding and price gouging of PPE.
May 26, 2020	New Jersey	Alleged conspiracy to price gouge.
July 8, 2020	New York	Alleged price gouging of PPE.
August 6, 2020	Georgia	Alleged hoarding and price gouging of PPE.
October 8, 2020	Illinois	Alleged price gouging of PPE.
October 13, 2020	California	Alleged hoarding and price gouging of PPE.
October 21, 2020	South Carolina	Alleged conspiracy to steal PPE.
November 24, 2020	Texas	Alleged conspiracy to price gouge.

Source: Tabulated by CRS from DOJ press releases.

Notes: These actions were identified on the DOJ website, but do not represent an exhaustive accounting of all DOJ anti-hoarding and -price gouging actions. Current as of December 3, 2020.

The actions presented above were drawn from DOJ public announcements and are not exhaustive of all such actions undertaken by the DOJ or other agencies with respect to DPA anti-hoarding and -price gouging provisions.[185] According to an October 20, 2020, press release, the DOJ has filed criminal charges in 33 COVID-19-related fraud cases "involving scam vaccines, treatments, or testing or price gouging in the sale of scarce medical supplies," and has initiated civil actions in an additional 11 cases involving "fraudulent coronavirus schemes targeting consumers."[186]

Although individual enforcement actions were publicized by the Administration, it has not released more comprehensive data on the scale of anti-hoarding/price gouging enforcement or their overall effect on the domestic PPE supply. As such, it is not clear to what degree these provisions have increased domestic availability. It is also possible that these policies could have unintentionally contributed to the diversion or delay of legitimate shipments.[187]

[185] See Geneva Sands and Priscilla Alvarez, "Feds Target Price Gouging as States and Hospitals Swarm Private Market for Supplies," *CNN.com*, April 25, 2020, at https://www.cnn.com/2020/04/25/politics/fema-doj-price-gouging-supplies/index.html.

[186] DOJ, Department of Justice is Combatting COVID-19 Fraud but Reminds the Public to Remain Vigilant, October 20, 2020, at https://www.justice.gov/usao-wdla/pr/department-justice-combatting-covid-19-fraud-reminds-public-remain-vigilant.

[187] Eleanor Tyler, "Analysis: Feds Seize PPE Using Unlitigated Hoarding Statute," *Bloomberg Law*, April 22, 2020, at https://news.bloomberglaw.com/bloomberg-law-analysis/analysis-feds-seize-ppe-using-unlitigated-hoarding-statute.

Title III Activities

CRS was able to identify six DPA Title III funding announcements through DOD's DPA Title III office.[188] **Table 10** lists DPA Title III funding actions made in response to COVID-19 by the Trump Administration through August 12, 2020.[189]

Table 10. DPA Title III Actions in Response to the Pandemic

as reported by the Trump Administration

Action Date	Action Description	Contract Amount ($ millions)	Vendor
Title III Actions in Support of the Health Industrial Base			
4/15/2020	12.5M per month capacity increase of N-95 respirators beginning in September	29.3	Owen & Minors Halyard
4/15/2020	12M per month capacity increase of N95 respirators beginning October	27.3	Honeywell
4/17/2020	13M per month capacity increase of N95 respirators beginning June	76	3M
4/27/2020	20M increase in foam swab capacity	75.5	Puritan
5/1/2020	3.1M per month capacity increase of N95 respirators beginning October	1.9	Hollingsworth and Vose
8/10/2020	110K test kits per month	3.1	BioFire Defense
Title III Actions in Support of the Defense Industrial Base			
5/19/2020	Space Solar Cell	6	*Not Reported*
5/19/2020	Space Solar Cell Substrates	9.3	*Not Reported*
5/28/2020	Shipbuilding Welding	0.5	*Not Reported*
5/28/2020	Body Armor Production	15	*Not Reported*
6/2/2020	Steel Manufacturing for Shipbuilding	19.5	*Not Reported*
6/5/2020	Aerospace Supplier Sustainment	80	*Not Reported*
6/6/2020	Aircraft Propulsion Industry Sustainment	20	*Not Reported*
6/16/2020	Die Forging Support for Aircraft	25	*Not Reported*
6/16/2020	Aircraft Fuel System Sustainment	14.9	*Not Reported*
6/16/2020	Soldier Uniform Fabrics and Textiles	2	*Not Reported*
6/16/2020	Shipbuilding Supply Chain Development	55	*Not Reported*
6/17/2020	Aircraft Propulsion Industry Sustainment	55	*Not Reported*
6/18/2020	Shipyard Improvement Program	50	*Not Reported*
6/19/2020	Domestic small Unmanned Aircraft System (sUAS) Traffic Management Tool Sustainment	3.3	*Not Reported*
6/22/2020	Space Industry Radar Sensing Ground Station Sustainment	15	*Not Reported*

[188] As of October 9, 2020.

[189] Although every effort was made to provide a complete accounting, these may not be exhaustive of all recent DPA activities, as there is no standing requirement for publishing DPA actions, and no centralized repository where they are collected.

Action Date	Action Description	Contract Amount ($ millions)	Vendor
7/1/2020	Domestic Small Unmanned Aerial System (sUAS) Component Production	1.5	*Not Reported*
7/1/2020	Domestic sUAS IR Sensor Production	1.6	*Not Reported*
7/1/2020	Domestic sUAS Component Production	4	*Not Reported*
7/1/2020	Domestic sUAS Flight Controller Production	3	*Not Reported*
7/6/2020	Navy Alloy Plate Capacity for Shipbuilding	56	*Not Reported*
7/8/2020	Aircraft Fuel Bladder Sustainment	14.9	*Not Reported*
7/10/2020	Large Fixed Pitch Propellers for Naval Ships	22	*Not Reported*
7/21/2020	Domestic Rare Earth Permanent Magnet Production	28.8	*Not Reported*
7/21/2020	Electronic Microdisplays OLED Production	33.6	*Not Reported*
7/24/2020	Shipbuilding Supply Chain Development	31	*Not Reported*
7/28/2020	Aircraft Propulsion Industry Sustainment	62.9	*Not Reported*
7/31/2020	Mobile Communications Receiver Sustainment	3.6	*Not Reported*
7/31/2020	Aircraft Propulsion Industry Sustainment	0.5	*Not Reported*
8/12/2020	Microelectronics Supply Chain Sustainment	7	*Not Reported*

Source: White House report on the DPA. Where possible, information listed is cross-referenced against information tabulated from Trump Administration press releases and FPDS. Some entries could not be verified by CRS, and were cited in the White House report as described in internal DOD documentation, and thus presumably not available in the open source domain.

The above table does not include a $765 million loan announced on July 28, 2020, co-facilitated by the International Development Finance Corporation (DFC) and DOD, to Eastman Kodak. That action was subsequently put on hold pending federal investigations into insider trading and other circumstances surrounding the loan. Including the DFC loan, the Trump Administration is supporting approximately $978 million in health related DPA Title III funding actions as of November 16, 2020. Although the DFC loan has not yet been formally canceled, its implementation may depend on the outcome of those investigations.

Discounting the DFC loan, approximately $213 million has been directed using Title III authorities to support the health industrial base.

According to the White House's August report on the use of the DPA, as tabulated above, approximately $641 million was awarded to support elements of the defense industrial base mostly unrelated to PPE, medical equipment, or pharmaceuticals. After August 2020, DOD does not appear to have used DPA Title III authorities in support of the health industrial base, and has continued to prioritize funding for the defense industrial base.[190] Instead, DOD's approach has shifted to utilizing its procurement corps to support HHS-funded actions using non-DPA funding from the CARES Act (see "DOD Actions: Joint Acquisition Task Force").[191] However, DOD and

[190] See, for example, DOD, "DOD announces $2.9 Million in Defense Production Act Title III COVID-19 Actions," press release, September 10, 2020, at https://www.defense.gov/Newsroom/Releases/Release/Article/2344437/dod-announces-29-million-in-defense-production-act-title-iii-covid-19-actions/.

[191] See, for example, DOD, "DOD Awards $6.98 Million Firm-Fixed Price Contract Action to Teel Plastics, LLC to Increase Domestic Production Capacity of Swabsticks for COVID-19 Testing Swabs," press release, October 16, 2020,

HHS cooperation on production expansion can closely resemble DPA Title III actions, and have similar aims.[192]

Voluntary Agreement Under Title VII

The Trump Administration has also engaged in other activities with potential relevance to domestic PPE production and distribution. On May 12, 2020, FEMA and the DOJ announced that they had drafted a "voluntary agreement" pursuant to Title VII of the DPA to coordinate industry cooperation.[193]

According to the draft voluntary agreement, selected participating companies (as determined by the Administration) would join a federally-led "Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic," chaired by the FEMA Administrator. Committee members would cooperate in the industrial development of critical health resources, including PPE as well as pharmaceuticals, respiratory devices, vaccines, raw materials, supplies, and medical devices.[194] Pursuant to the DPA Title VII provisions, the voluntary agreement would allow private companies to cooperate collectively and with the government, in promotion of the national defense, immune from federal antitrust action. The comment period for the draft voluntary agreement expired on June 5, 2020. The agreement expires after five years, and is meant to also provide additional capacity to prepare for future public health contingencies.

On August 17, 2020, the final text of the voluntary agreement, having taken 34 comments into account, was published in the *Federal Register*.[195] As required under Section 708(c)(2) of the DPA, the voluntary agreement was certified by the Attorney General (in consultation with the Chairperson of the Federal Trade Commission) that the purpose of the voluntary agreement could not be accomplished without antitrust exceptions, or without any voluntary agreement. The FEMA Administrator also certified that the voluntary agreement is necessary to help provide for the national defense. Although FEMA is currently accepting private sector interest for participating in the committee,[196] its specific membership, activities, and outcomes have not been made public, and are not necessarily required to be disclosed in the DPA statute.

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at https://www.defense.gov/Newsroom/Releases/Release/Article/2385096/dod-awards-698-million-firm-fixed-price-contract-action-to-teel-plastics-llc-to/; and DOD, "DOD Awards $6.18 Million Contract to Medline Industries, Inc. to Increase Domestic Production Capacity of Surgical Masks," press release, November 16, 2020, at https://www.defense.gov/Newsroom/Releases/Release/Article/2415847/dod-awards-618-million-contract-to-medline-industries-inc-to-increase-domestic/.

[192] A November 2020 GAO report on the federal government's use of DPA authorities in response to the COVID-19 pandemic includes, among other findings and analysis, an accounting of DPA Title III and "similar actions." The GAO report's inclusion of "similar actions" refer to collaborative DOD-HHS actions made under the JATF using, HHS-designated CARES Act appropriations (as opposed to DPA Title III actions drawing from the DPA Fund). U.S. Government Accountability Office, *Defense Production Act: Opportunities Exist to Increase Transparency and Identify Future Actions to Mitigate Medical Supply Chain Issues*, GAO-21-108, November 19, 2020, at https://www.gao.gov/assets/720/710806.pdf; and Correspondence with GAO, November 20, 2020.

[193] Federal Emergency Management Agency, "Meeting to Develop Pandemic Response; Voluntary Agreement," 85 *Federal Register* 28031, May 12, 2020, at https://www.federalregister.gov/documents/2020/05/12/2020-10221/meeting-to-develop-pandemic-response-voluntary-agreement.

[194] Regulations.gov, *Meeting to Develop Pandemic Response; Voluntary Agreement*, May 2020, at https://www.regulations.gov/docket?D=FEMA-2020-0016.

[195] FEMA, "Voluntary Agreement Under Section 708 of the Defense Production Act; Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic," 85 *Federal Register* 50035-50040, August 17, 2020, at https://www.federalregister.gov/documents/2020/08/17/2020-18005/voluntary-agreement-under-section-708-of-the-defense-production-act-manufacture-and-distribution-of.

[196] FEMA, "Voluntary Agreement With Private Industry To Respond To Pandemics," press release, July 17, 2020, at

Policy Options to Ensure Sufficient Emergency PPE Supply

Issues with domestic PPE production and distribution continue to be a challenge, and materially impact the federal government's and broader domestic capacity to respond to the ongoing COVID-19 pandemic. In response, Congress may consider various policy options to address both the informational aspects of PPE supply chain uncertainties, as well as the means to expand domestic supply and distribution. These policy options may address immediate aspects of the ongoing pandemic, and longer-term structural elements in anticipation of future public health crises or supply chain contingencies.

Federal Supply Chain Data Collection: Policy Options

The COVID-19 pandemic has highlighted limitations in the U.S. medical product supply chain, including concerns about U.S. reliance on foreign manufacturers (see **textbox**).[197] Absent clearer visibility into the makeup of the existing domestic supply chain, policymakers will have an incomplete or inaccurate view of existing and potential future supply chain vulnerabilities, and the means by which to remedy them.

U.S. International Trade Commission's Investigations Related to COVID-19: Market, Trade, and Supply Chain Challenges

On April 6, 2020, the Chairs of the House Committee on Ways and Means and the Senate Committee on Finance requested that the U.S. International Trade Commission (USITC) identify imported goods related to the response to the COVID-19 pandemic, their source countries, tariff classifications, and applicable rates of duty. To assist the committees and the U.S. Trade Representative (USTR) in proposing or taking appropriate and responsive actions, the Chairs asked that the USITC issue a report by April 30, 2020. The USITC released its report, "COVID-19 Related Goods, US. Imports and Tariffs," to the public on May 4, 2020, and updated it on June 30, 2020, which provided trade-related information for the products identified, and tabulated import data from 2017, 2018, and 2019. Subsequently, on August 13, 2020, the committees requested a follow-on investigation. The USITC was also asked to publish a report that builds on the earlier investigation and provide more detailed information on COVID-related industry sectors and particular products identified in the commission's previous report. The new report, "COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges," is expected to be released on December 15, 2020.

The report will aim to provide an overview of key U.S. industry sectors producing pandemic-related goods, including, but not limited to, medical devices, PPE, and pharmaceuticals. The sector overviews are expected to include information on U.S. production, employment, and trade. Members asked the USITC to carry out case studies that focus on products for which there were reported shortages in the first half of 2020, including those affected by supply chain fragility, blockages, or barriers (e.g., N-95 respirators, ventilators, vaccines, and COVID-19 test kits). Some of the supply chain challenges and constraints likely to be addressed in the report include factors affecting domestic production and foreign trade barriers and restrictions.[198] Although a partial response to broader data concerns, the report is inherently constrained in its scope on imported COVID-19-related materials, and does not address domestic production or supply chain visibility.

Vulnerabilities regarding raw materials and inputs, such as synthetic textiles and active pharmaceutical ingredients (APIs) for PPE and other related critical medical applications, are not

https://www.fema.gov/fact-sheet/voluntary-agreement-private-industry-respond-pandemics.

[197] See U.S. Congress, Senate Committee on Homeland Security and Governmental Affairs, "Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic, Hearing, June 9, 2020.

[198] Note: For more detail, see U.S. International Trade Commission, "Lawmakers Ask USITC to Identify Imported

well recorded in official trade and domestic industry data. They might be particularly difficult to track if they originate in one country but are subsequently processed in another. While facilities that manufacture drugs and medical devices for the U.S. market generally are required to register with the FDA, the agency has historically had limited data regarding the quantity produced at a specific facility, particularly with respect to raw materials or APIs.[199] In addition, the United States has relaxed definitions of what qualifies as a U.S. product with imported content, which may mask the extent to which domestically-produced products rely on foreign inputs.[200]

Domestic production data that more readily correlate with trade data—particularly in its timeliness and definitions—is essential to understanding the position of the U.S. economy and its industrial base in critical global supply chains. Integrated data could highlight emerging industry and supply chain shifts in specific areas that may be occurring, at least partially, in response to China's policy incentives and pressures. Moreover, it could help support or restore a strategic approach to U.S. supply chains that considers prospects and options to sustain U.S. leadership in critical sectors, such as advanced medical equipment and pharmaceutical innovation, but also essential goods such as PPE. Finally, it could enable U.S. policymakers to better understand the interplay of domestic and global developments and respond to them in timeframes closer to real time, assess the overall production capabilities of U.S.-based producers in sectors of concern, and better prepare for and respond to future crises.

In response to these and other concerns, Congress has introduced legislation to help regulators, stakeholders, and the public better understand the medical product supply chain. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136), for example, requires HHS to contract with the National Academies of Science, Engineering, and Medicine (NASEM) to examine and report on the security of the U.S. medical product supply chain, including U.S. dependence on foreign countries for critical drugs and devices (e.g., medical PPE).[201] In addition, the CARES Act also included a provision that aims to address some of these gaps by requiring registered drug and API producers to annually report to the FDA the amount of drugs manufactured for domestic distribution. Legislation has been introduced that would expand this requirement to medical devices (including various PPE) and make the reporting quarterly.[202]

The CARES Act also provided the FDA explicit authority to require certain device manufacturers to report interruptions or discontinuances in manufacturing during or prior to a public health emergency, to take certain actions to mitigate shortages, and to make public a list of devices that are in shortage.[203] Congress may consider requiring manufacturers of all medical devices to report actual or forecasted increases in demand to FDA that may lead to a shortage, or to report actions

Products Needed for COVID-19 Response and Related Tariff and Trade Information," News Release 20-031, Investigation 332-576, April 13, 2020, and "USITC to Investigate Industry and Supply Chain Conditions Affecting COVID-19 Industry Sectors and Products," News Release 20-097, Investigation 332-580, August 21, 2020.

[199] FDA, Testimony of Dr. Janet Woodcock, Director the Center for Drug Evaluation and Research, "Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program," December 10, 2019.

[200] The lack of statutory definitions of various terms (e.g., "manufactured" in the United States) may yield different determinations for the same product. Moreover, the "substantial transformation" test used by U.S. Customs and Border Protection (CBP) to determine a product's country of origin for trade purposes is complex, fact-specific, and thus inherently subjective in nature.

[201] P.L. 116-136, §3101, 134 Stat. 360.

[202] See, for example, S. 3781 (116th Congress).

[203] Section 506J of the Federal Food, Drug, and Cosmetic Act (FFDCA), as established by P.L. 116-136, §3121, 134 Stat. 363.

taken by other regulatory authorities that could affect U.S. supply (e.g., export restrictions). This may help FDA better anticipate and take steps to prevent shortages.

While medical product manufacturers are required to report various supply chain information to the FDA, this information is not required to be shared with other agencies and departments. As such, legislation has also been introduced in the 116th Congress that would require the FDA to share certain supply chain information with the HHS Assistant Secretary for Preparedness and Response (ASPR) and the DOD Assistant Secretary for Health Affairs.[204] In another risk mitigation approach, legislation also has been introduced to require the Secretaries of HHS, Homeland Security, and DOD to individually conduct annual risk assessments of the medical product supply chain and submit those assessments to Congress.[205] This information could be used to guide federal policy affecting the production of PPE and medical products, as well as federal acquisition efforts.

Although there may not be a single legislative solution to measure and manage supply chain dependencies and risks, Congress could consider authorizing federal agencies to collect more data on firm's activities in the United States and abroad. In the past, it has done so to monitor U.S. investment abroad as well as foreign investment in the United States.[206] Agencies could obtain, analyze, and report specific supply chain information about the status of U.S. production and distribution without disclosing business confidential information that could prejudice firms' interests. Alternatively, Congress could also direct some agencies to collect data on federally-owned public and defense stockpiles of specified items. While this would be a more targeted effort, it might be easier to manage and provide comprehensive data more quickly and at less expense to the government.

HHS: Policy Options

The lack of transparency in the medical product supply chain and perceived reliance on foreign-made medical products has been framed as a national security issue. To this end, legislation has been introduced to increase domestic production or reserves of critical medical products. As mentioned, some bills would impose additional reporting requirements on medical product manufacturers, while others would direct HHS to conduct studies or risk assessments of the medical product supply chain.

Some bills would direct HHS or its offices to develop a list of critical medical products and incentivize domestic manufacturing of those products. For example, S. 3780, the Help Onshore Manufacturing Efficiencies for Drugs and Devices Act (HOME Act), would create within HHS a Center for Domestic Advanced Manufacturing of Critical Drugs and Devices to support, through grants and loans, domestic manufacturing of critical drugs and devices using advanced technologies. While FDA has identified and published a list of essential medical supplies and critical inputs, the agency cannot compel firms to make the products on this list. However, Congress may consider legislation to require or incentivize their domestic production.[207]

Given that the PPE issue is largely a question of supply and distribution, Congress may consider expanding HHS' role to strengthen and reform the SNS, and to support national stockpiling more

[204] See, for example, S. 3781 (116th Congress).

[205] See, for example, S. 3780 (116th Congress).

[206] See, for example, 22 U.S.C. §§3101-3108.

[207] See, for example, S. 3827, the Medical Supplies for Pandemics Act of 2020, which would direct HHS to create incentives for manufacturers to diversify geographic production of medical products for the SNS.

broadly. Though it is not its primary or traditional domain, Congress also may consider directing HHS to play a supporting role for national production alongside or, in lieu of, DPA authorities.

Stockpile Policy Options

The COVID-19 pandemic response quickly depleted both federal and nonfederal stockpiles of PPE. Congress might consider policies to bolster stockpiling efforts to ensure adequate PPE emergency supplies.

Federal Strategic National Stockpile

The precise role the Strategic National Stockpile is to play in responding to public health emergencies is not defined in statute and remains subject to administrative interpretation. Since its inception in 1999, the mission of the stockpile has expanded from providing unique federal assets to respond to biological or chemical attacks, and has developed to now include marshaling material responses to natural disasters and emerging infectious diseases. The current authorizing language states the HHS Secretary

> … shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies) … in such numbers, types, and amounts as are determined … by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for and optimize the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.…[208]

The Administration has embarked on restructuring the SNS ("SNS 2.0") to focus on five priority areas:

- Replenish the SNS to include a 90-day supply of PPE,
- Refine strategy and structure to reevaluate types and quantities of supplies stockpiled,
- Establish a distribution model to improve transportation processes and geographic need determination,
- Expand the supply chain control and transparency, and
- Expand domestic manufacturing.[209]

FEMA and HHS have incorporated the need for PPE demand and supply chain visibility into proposals to enhance the SNS with titles like "Strategic National Stockpile (SNS) 2.0" or "the Next Generation SNS."[210] In support, DLA reports that it "is now focused on reconstituting supplies, preparing for potential future requirements, and increasing the United States' ability to test" for COVID-19.[211] DLA plans to procure $1.2 billion worth of PPE on behalf of HHS to replenish the SNS.[212]

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[208] 42 U.S.C. §247d-6b(a).

[209] HHS, *SNS 2.0: The Next Generation*, at https://www.phe.gov/about/sns/Pages/sns-next-generation.aspx; and GAO, *COVID-19: Federal Efforts* p.193.

[210] HHS, ASPR, "SNS 2.0: The Next Generation," at https://www.phe.gov/about/sns/Pages/sns-next-generation.aspx; Gaynor testimony, House Homeland, *Examining National Response*, p. 11.

[211] Ibid.

[212] Ibid.

Congress might consider whether the Administration's plan will sufficiently address stockpile issues. Congress could choose to wait and evaluate the sufficiency of Administration's efforts. Alternatively, Congress could limit agency discretion by codifying the Administration's plan, more precisely defining the SNS mission, or mandating other specific actions.

The 116th Congress has already amended the SNS authorizing statute to explicitly include PPE and to require annual threat-based inventory review and congressional reporting through the CARES Act (P.L. 116-136) and the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22). Congress could further define the purpose of the stockpile to specify the appropriate relative focus on particular threats such as naturally occurring events and diseases or on chemical and biological attacks. Additionally, Congress could define the scope of the stockpile, such as whether it is to be able to entirely support domestic health care needs in the face of global supply chain collapse and how it should coordinate with nonfederal stockpiles.

Publication of PPE Procurement and Allocation Authorities and Procedures

Prior to the COVID-19 pandemic, ASPR (the HHS agency that administers the SNS) distributed SNS resources to nonfederal jurisdictions on the basis of population.[213] After the SNS's PPE stores were effectively exhausted in March 2020, FEMA and HHS jointly established the National Resource Prioritization Cell (NRPC), which determined allocations of newly acquired medical supplies based on algorithms using data from private sector partners and the CDC, including data on PPE supply, COVID case numbers, mortality, and hospital capacity, and demographic information.[214]

Some Members of Congress and state, local, territorial, and tribal officials have criticized the opacity of recent federal procurement, distribution, and allocation efforts. Common concerns include leadership roles, the sources of data used in allocation, and a lack of transparency into procedures to assess demand and allocate supplies (for a non-exhaustive list of Congressional concerns concerning PPE distribution, see "FEMA Actions—Distribution," above).[215]

Congress may consider options to clarify authorities for federal activities related to provision of critical medical supplies. In the case of COVID-19, the HHS Secretary declared a Public Health Emergency under the Public Health Service Act, which authorizes the Secretary to lead the federal public health and medical response to the declared incident.[216] The President subsequently issued declarations under both the National Emergencies Act and the Stafford Act.[217] Following

[213] This population-based SNS distribution method utilized 2010 census data. See also U.S. Centers for Disease Control and Prevention (CDC), "Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness," Version 11, Mar. 28, 2014, available at https://stacks.cdc.gov/view/cdc/77036. In 2019, ASPR determined that this existing allocation procedure would be insufficient in the face of a pandemic given the scarcity of the domestic PPE supply. Among other remedies, ASPR recommended the development of a prioritization strategy. GAO, *COVID-19: Opportunities*, pp. 106-107.

[214] Gaynor and Polowczyk, HSGAC hearing, pp. 5-6; Oral Testimony, Rear Admiral John Polowczyk, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic*, hearing, 116th Cong., 2nd sess., June 9, 2020; and FEMA, "Coronavirus (COVID-19) Pandemic: National Resource Prioritization Cell," April 17, 2020, at https://www.fema.gov/fact-sheet/coronavirus-covid-19-pandemic-national-resource-prioritization-cell.

[215] Michael Bender and Rebecca Ballhouse, "How Trump Sowed COVID Supply Chaos. 'Try Getting It Yourselves,'" *Wall Street Journal*, August 31, 2020, at https://www.wsj.com/articles/how-trump-sowed-covid-supply-chaos-try-getting-it-yourselves-11598893051.

[216] The Public Health Service Act, P.L. 78-409, codified as amended at 42 U.S.C. §§201-300mm–61; Section 2801, at 42 U.S.C. §300hh(a).

[217] See CRS Report R46326, *Stafford Act Declarations for COVID-19 FAQ*, by Elizabeth M. Webster, Erica A. Lee,

the Stafford Act declarations, FEMA assumed responsibility for coordinating the federal COVID-19 response.[218] Given the simultaneous invocation of discrete emergency authorities, Congress may consider options to require the clear identification of lead federal officials responsible for aspects of PPE deployment, including acquisition, allocation, and distribution.[219]

Congress could also require responsible federal officials to regularly review, revise, and publish a clear federal allocation methodology within a specific time period, particularly in cases of competing domestic demand and scarcity.[220] Finally, Congress could require agencies to disclose data sources used to guide allocation decisions to Congress, nonfederal partners, and/or the public within a specific time period. These options could increase transparency and potentially improve coordination between federal and nonfederal partners.

Legislation has been introduced in recent months to increase the transparency of federal PPE distribution efforts. For example, the "Emergency Medical Supplies Procurement Act" (S. 3921 or H.R. 6791) would require executive agencies to publish data on distributions of federally-acquired PPE to states, tribes, and territories, as well as shortfalls and delays in response to requests. The "COVID-19 Emergency Medical Supplies Enhancement Act of 2020" (H.R. 6858) would require executive agencies to report on data models used to determine allocation of medical supplies to states during the pandemic.

Support for Nonfederal PPE Stockpiles

In addition to federal sources, the COVID-19 pandemic revealed and exacerbated PPE supply shortages among state, tribal, territorial, and local entities as well as medical providers, such as hospitals.[221] To address these nonfederal shortages, Congress may consider proposals to support and monitor PPE stockpiling among nonfederal partners through federal assistance programs, as well as other means.

There are several federal grant programs that nonfederal entities may use to purchase PPE supplies, prepare for medical emergencies, and build PPE stockpiles. The CDC Public Health Emergency Preparedness cooperative agreement (a form of grant) and the ASPR's Hospital Preparedness Program (HPP)[222] support state, local, and territorial public health departments and

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and William L. Painter, and CRS Insight IN11264, *Presidential Declarations of Emergency for COVID-19: NEA and Stafford Act*, by L. Elaine Halchin and Elizabeth M. Webster.

[218] Gaynor and Polowczyk, HSGAC hearing, p. 3. For a description of the structures to lead and coordinate the federal pandemic response, see GAO, *COVID-19: Opportunities*, pp. 87-94.

[219] GAO, *COVID-19: Opportunities*, p. 65.

[220] For more on stockpile and distribution transparency, see Preeti Mehrotra, Preeti Malani, and Prashant Yadav, "Personal Protective Equipment Shortages During COVID-19—Supply Chain-Related Causes and Mitigation Strategies," *JAMA Health Forum*, May 12, 2020, at https://jamanetwork.com/channels/health-forum/fullarticle/2766118; and Anita Patel et al., "Personal Protective Equipment Supply Chain: Lessons Learned from Recent Public Health Emergency Responses," *Health Security*, vol. 15, no. 2 (June 2017), pp. 244-252.

[221] For a survey of national stockpiles that may procure PPE, see CRS In Focus IF11574, *National Stockpiles: Background and Issues for Congress*, by G. James Herrera and Frank Gottron.

[222] See CDC, "CDC's Public Health Emergency Response Program: Every Response Is Local," at https://www.cdc.gov/cpr/whatwedo/phep.htm; and HHS, ASPR, *2017-2022 Health Care Preparedness and Response Capabilities*, November 2016, at https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/2017-2022-healthcare-pr-capablities.pdf (hereinafter HHS, *Health Care Preparedness and Response Capabilities*). For funding history and background on the Public Health Emergency Preparedness and Hospital Preparedness Program cooperative agreements, see CRS Congressional Distribution Memorandum, "Funding History for Public Health and Hospital Preparedness Cooperative Agreements to States," by Sarah Lister, Kavya Sekar, and Emma C. Nyhof, June 3, 2020 (available upon request from authors).

health system preparedness activities, and may support PPE procurement for stockpiling. All grantees participating in HPP are required to plan for "medical surge," including addressing any supply chain needs and vulnerabilities. Strategies may include maintaining an independent stockpile, accessing a vendor-owned stockpile, or establishing secondary vendors for medical supplies.[223]

Additionally, state, local, tribal, and territorial emergency management and homeland security agencies may receive financial assistance for the purchase of PPE through several of FEMA's preparedness grants, including Emergency Management Performance Grants, the State Homeland Security Program, the Urban Area Security Initiative, and Operation Stonegarden.[224] Finally, Public Assistance funds awarded for COVID-19 may support eligible purchases of PPE supplies of up to 60 days.[225]

Congress may wish to consider whether to encourage the establishment of nonfederal PPE stockpiles, and whether to continue or expand federal funding for this purpose. Some scholars find that state-based stockpiles may reduce state reliance on national stockpiles in the case of a pandemic, enable states to avoid price increases associated with periods of shortages, and reduce risk to essential workers during an infectious disease event.[226] However, nonfederal PPE stockpiles require substantial investment and present significant challenges. Some research has identified that local, state, and regional stockpiles require substantial investment and careful management to prevent waste of expired supplies.[227] Further, nonfederal stockpiles may not be easily distributed to areas of need, given their reduced geographic scope; presumably, state or local stockpiles would be controlled by the respective governments, and sharing would likely be largely voluntary. Additionally, in conceptualizing how these stockpiles may develop, consistent standards for stockpiles may encourage nationwide uniformity, but may also hinder jurisdictions' abilities to formulate supply systems and plans based on their local capacities and needs.

Should Congress wish to support nonfederal PPE stockpiles, it may consider providing additional funds to current health and emergency preparedness grant programs to account for the substantial costs involved and reduce competition for funds with other important preparedness efforts. Additionally, Congress may consider options to incentivize coordination and collaboration among states and health systems to collect, report, and share PPE inventory in order to reduce competition during periods of scarcity.[228]

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[223] HHS, *Health Care Preparedness and Response Capabilities,* pp. 33-36.

[224] FEMA, "FEMA Preparedness Grants Manual," February 2020, pp. D-6, G-5, H-15, at https://www.fema.gov/media-library-data/1581623378002-f8280c8c1ab2e38f650fe67289764826/ FEMA_PreparednessGrantsManual_21320_1605_508c.pdf; and DHS, "Notice of Funding Opportunity (NOFO) Fiscal Year (FY) 2020 Homeland Security Grant Program (HSGP)," p. 32, at https://www.fema.gov/sites/default/files/2020-07/fy_2020_hsgp_nofo.pdf.

[225] FEMA, "Coronavirus Pandemic Response: FEMA Releases New Policy for Declarations," Sept 1, 2020, at https://www.fema.gov/press-release/20200901/coronavirus-pandemic-response-fema-releases-new-policy-declarations; for additional information on Stafford Act declarations for COVID-19 see CRS Report R46326, *Stafford Act Declarations for COVID-19 FAQ,* by Elizabeth M. Webster, Erica A. Lee, and William L. Painter.

[226] William H. Dow, Kevin Lee, Laurel Lucia, "Economic and Health Benefits of a PPE Stockpile," *UC Berkeley Labor Center and UC Berkeley School of Public Health,* August 12, 2020, at https://laborcenter.berkeley.edu/ economic-and-health-benefits-of-a-ppe-stockpile/#_ftn1.

[227] Terri Rebmann et al., "Best Practices for Healthcare Facility and Regional Stockpile Maintenance and Sustainment: A Literature Review," *Health Security,* vol. 15, no. 4 (2017), pp. 409-417.

[228] Ibid. and Elodie Adida, Po-Ching C. Delaurentis, and Mark Alana Lawley, "Hospital Stockpiling for Disaster Planning," *IEE Transactions,* vol. 43, no. 5 (2011), pp. 348-362. For an example of intra-state partnerships, see Lisette Voytko, "NY Will Team Up with 6 States to Buy Medical Supplies, Cuomo Says," *Forbes,* May 3, 2020, at

Monitoring of Nonfederal PPE Supplies

Congress may consider proposals to establish greater federal visibility into PPE supply across the United States. Congress has long recognized the need for "public health and medical situational awareness" capabilities, including an ability to monitor health care supplies prior to and during an emergency. As a part of reauthorization in 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA; P.L. 113-5) required HHS to submit a detailed strategy and implementation plan to Congress for a "situational awareness" data and information sharing network for public health emergencies. HHS plans for this system-defined situational awareness to include an ability to monitor "health system resources," and "health-related response assets."[229] GAO reported that as of June 2020, HHS had made limited progress in implementing this plan.[230] Specific funding to support the plan and system had not been appropriated in the years following PAHPRA; therefore, a relevant system did not exist in time for the pandemic.[231] As a result, federal agencies such as HHS and FEMA had to create new systems for monitoring health care supply data. For instance, as of September 2020, GAO is evaluating HHS Protect, HHS's new data platform to collect, share, and analyze near real-time COVID-19 data, to assess its contribution to the agency's situational awareness.[232]

Emergency medical supplies such as PPE can be stored in a variety of locations, including stockpiles maintained by health agencies or medical supply caches held by hospitals or other health care organizations. In addition, the supplies may be used in a variety of contexts—by health care workers, responders, or citizens. As a part of HPP, ASPR requires grantees to track supply inventories and document strategies for maintaining stockpiles and medical supply caches, but does not require reporting of stockpile contents to ASPR.[233] Congress may consider how to facilitate improved automated reporting on nonfederal PPE supplies, including nonfederal stockpiles and medical caches, to include information such as PPE expiration and usage rates. Frequently updated data could enable HHS, FEMA, and/or DOD to establish ongoing visibility across federal, state, tribal, and territorial, and health care provider PPE supplies.[234]

Federal monitoring of PPE supply across the country may enable HHS, FEMA, and/or DOD authorities to (1) monitor and analyze nationwide PPE levels, expiration, and usage rates; (2) identify and help to remedy PPE supply vulnerabilities at the nonfederal level prior to supply

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https://www.forbes.com/sites/lisettevoytko/2020/05/03/ny-will-team-up-with-6-states-to-buy-medical-supplies-cuomo-says/#5a155260554a.

[229] HHS Assistant Secretary for Preparedness and Response (ASPR), "The National Public Health and Medical Situational Awareness Strategy Implementation Plan (2015-2018)," 2015, at https://www.phe.gov/about/OPP/Documents/phm-sa-ip-sept2015.pdf.

[230] GAO, *Public Health Information Technology: HHS Has Made Little Progress Toward Implementing Enhanced Situational Awareness Network Capabilities*, GAO-17-377, September 2017, p. 24, at https://www.gao.gov/assets/690/686971.pdf.

[231] Melanie Evans and Alexandra Berzon, "Why Hospitals Can't Handle Covid Surges: They're Flying Blind," *The Wall Street Journal*, September 30, 2020; and CRS analysis of Public Health and Social Services Emergency Fund (PHSSEF: account that funds ASPR) available internally at the Library of Congress.

[232] GAO, *COVID-19: Federal Efforts*, pp. 97-100.

[233] Correspondence with ASPR, August 12, 2020.

[234] Anita Patel et al., "Personal Protective Equipment Supply Chain: Lessons Learned from Recent Public Health Emergency Responses," *Health Security*, vol. 15, no. 2 (June 2017), pp. 244-252. FEMA recently exercised Defense Production Act authorities to establish a voluntary agreement through which PPE suppliers would provide supply data and increase supply chain visibility. FEMA, Homeland Security (DHS), "Voluntary Agreement Under Section 708 of the Defense Production Act; Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic," 85 *Federal Register* 50035, August 17, 2020.

shocks; (3) strategically acquire PPE as a redundancy measure if supply chains are overwhelmed; and (4) strategically deploy federal PPE assets during periods of competing demand.

However, health-related data collection presents a distinctive challenge for supply chain visibility. Generally, implementing any data collection system for health-related data has historically been challenging—health care organizations and health departments have different IT, data collection, and record management systems. These system-level issues have affected efforts to improve federal health data collection efforts, such as the prior HHS situational awareness efforts.[235] During the COVID-19 pandemic, HHS established a new data collection system through a vendor, TeleTracking, to help monitor daily medical supply utilization at hospitals.[236] Some observers have criticized this system, particularly about the reporting burden on hospitals,[237] abrupt data collection requests, and inadequate consultation from hospitals and health experts during system design.[238] Additionally, some Members of Congress have requested that GAO review the new reporting requirements.[239] Congress may also consider how to ensure that such a system is useful to all interested parties, including state and local jurisdictions.

Congress may also consider integrating PPE stockpiling into existing risk and resiliency assessments. For example, Section 322 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act requires states, tribes, and territories to submit disaster mitigation plans to FEMA that includes identifying risks and countermeasures. Congress may also consider requiring states, tribes, and territories to incorporate PPE stock and use strategies in these plans as a means to address potential PPE supply issues.[240]

DOD: Policy Options

As mentioned, the Trump Administration used the DOD acquisition system to provide surge support to the HHS and FEMA acquisition corps. DOD officials have highlighted the benefits offered by such support—both in avoidance of duplication of "capabilities at scale around the government" as well as in "sharing" the expertise of the DOD acquisition workforce to assist with the interagency response to a domestic emergency.

However, employing the DOD's acquisition workforce and authorities to respond to a domestic emergency requires DOD to balance equities related to near- and far-term defense needs, including defense and national security goals, with broader national and public policy goals

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[235] GAO, *Public Health Information Technology: HHS Has Made Little Progress Toward Implementing Enhanced Situational Awareness Network Capabilities*, GAO-17-377, September 2017, p. 24, at https://www.gao.gov/assets/690/686971.pdf.

[236] HHS, "Prepared Remarks from HHS Media Call with CDC Director Redfield and CIO Arrieta on COVID-19 Data Collection," July 15, 2020, at https://www.hhs.gov/about/news/2020/07/15/prepared-remarks-from-hhs-media-call-cdc-director-redfield-cio-arrieta-covid-19-data-collection.html.

[237] Amy Goldstein and Lena H. Sun, "Hospital Officials, Experts Say New Federal Rules for Covid-19 Reporting Will Add Burdens During Pandemic," *Washington Post*, July 15, 2020.

[238] Robbie Whelan, "Covid-19 Data Reporting System Gets Off to Rocky Start," *Wall Street Journal*, August 11, 2020; and Nicholas Florko and Eric Boodman, "How HHS's New Hospital Data Reporting System Will Actually Affect the U.S. Covid-19 Response," *STAT*, July 16, 2020.

[239] Courtney Bublé, "Lawmakers Ask Watchdog to Review New Coronavirus Data Reporting System Housed Within HHS," *Government Executive*, August 20, 2020.

[240] 42 U.S.C. §5165. See FEMA, "Hazard Mitigation Planning," at https://www.fema.gov/emergency-managers/risk/hazard-mitigation-planning; FEMA, "2019 National Threat and Hazard Identification and Risk Assessment (THIRA) Overview and Methodology," July 25, 2019, at https://www.fema.gov/sites/default/files/2020-06/fema_national-thira-overview-methodology_2019_0.pdf.

associated with responding to homeland considerations. Sub-optimal tradeoffs between those competing missions could result in DOD pursuing practices that increase costs, slow the acquisition process, and produce suboptimal capabilities for its primary customers in DOD's operational forces.

Congress could consider the potential for unintended consequences associated with using DOD's unique acquisition authorities to provide surge support to the HHS and FEMA acquisition corps.[241] For example, 10 U.S.C. §2371b, which establishes DOD's *other transaction authority* (OTA) for prototype projects, states that the authority is to provide a means of "enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense."[242] The statutory language establishing this authority does not address its use—either by DOD or by other federal agencies—to respond to national health emergencies or other domestic crises. The use of this and similar authorities to provide assisted acquisitions may contribute to DOD's emergence as an emergency acquisitions auxiliary for the federal government as a whole, which may conflict with long-standing norms and practices to segregate warfighting and civil defense functions in government, and potentially interfere with DOD's conventional focus on foreign external threats.

DOD officials have also discussed a potential disbandment of the previously mentioned Joint Acquisition Task Force (JATF) before the end of 2020, potentially as a means of withdrawing from unfamiliar domains. DOD has highlighted its work to "transition current JATF operations into an enduring policy and oversight office" within the Office of the Undersecretary of Defense for Acquisition and Sustainment "that will facilitate current and future DOD acquisition support to interagency partners." However, Congress may wish to evaluate the extent to which the JATF has successfully assisted FEMA and HHS in meeting the current and projected national "demand signal" for medical resources to respond to the COVID-19 pandemic.[243]

Defense Production Act: Policy Options

Under the DPA, the President potentially has access to a breadth of authorities that could facilitate industrial mobilization and increased domestic production and distribution of PPE, both directly and indirectly. Actual implementation of DPA authorities are at the President's sole discretion, with relatively minimal statutory roles for congressional involvement. As such, Congress's ability to encourage or compel the Administration to make more or less use of these powers is inherently limited. The following sections discuss various options available to Congress to affect the President's use of the DPA.

Encouraging DPA's Use

If Congress determined that the exercise of DPA authorities has been suboptimal, it could augment those authorities with greater administrative definition within the federal government to enumerate how DPA authorities may be exercised under this and future emergency situations, and to ensure that DPA implementation is matched to the scope of the contingency.

[241] Testimony of Ellen M. Lord, Undersecretary of Defense for Acquisition and Sustainment, U.S. Congress, House Committee on Armed Services, *Department of Defense COVID-19 Response to Defense Industrial Base Challenges*, 116th Cong., 2nd sess., June 10, 2020.

[242] 10 U.S.C. §2371(b)(1).

[243] Remarks by Ellen M. Lord, Undersecretary of Defense for Acquisition and Sustainment, press briefing, August 20, 2020, available at https://www.defense.gov/Newsroom/Transcripts/Transcript/Article/2319990/ellen-m-lord-undersecretary-of-defense-for-acquisition-and-sustainment-briefs-m/.

For example, Congress could enumerate how DPA authorities may be exercised as a means to encourage the President to make greater use of DPA Title I prioritization and allocations authorities and Title III financial incentive authorities. For example, Title III incentives could be used to fund redundant production lines for PPE, develop surge capacity among existing producers, and provide purchase guarantees to supply the SNS and other stockpiles to capacity.

The DPA also confers on the President a suite of powers that may provide more indirect means of facilitating domestic PPE production and distribution. Section 705 of Title VII also provides the President with the power to compel private companies to make their records and proprietary information available to the federal government in promotion of the national defense. Under this authority, the Executive Branch could potentially collect industry information to "map" the domestic supply chain, perform an analysis of shortfalls and/or vulnerabilities, and direct the use of Title I and Title III authorities to perform corrective measures.

Title VII of the DPA also includes an authority that allows the President to establish an executive reserve comprised of industry representatives who would be available to take positions in government during emergency situations. This power could be potentially utilized to recruit industry personnel to serve in government, temporarily and as-needed, to fill capability gaps and enable industrial mobilization, including in expanding domestic PPE production and distribution.

Establishing Executive Infrastructure for DPA Implementation

When the DPA was enacted in 1950, it was administered by multiple executive agencies established during the Second World War dedicated to mobilizing national industry. As a result, the DPA's policy intent, as well as the governmental norms surrounding its use, were already in practice to varying degrees, while a variety of executive agencies and offices existed solely to enable industrial mobilization.

Primary responsibility for implementing DPA's use fell to the Office of Defense Mobilization,[244] and its two major sub-components: (1) the Defense Production Administration, which established production goals and supervised production operations; and (2) the Economic Stabilization Agency, which coordinated and supervised wage and price controls. A number of additional sub-agencies and offices fell under these two organizations' purview.[245] However, after the end of the Korean War, institutional responsibility for industrial mobilization using DPA powers decreased in the executive branch.

Currently, responsibility for DPA authorities are disaggregated among numerous executive agencies with individual, narrow remit. In response to the COVID-19 pandemic and in anticipation of future health, defense, and other major emergencies, Congress could consider reconstituting permanent executive capabilities with centralized coordination, contingency planning, and implementation responsibilities over the DPA, and any other related authorities deemed necessary. For example, although the DOD has the most extensive experience in making use of DPA authorities, its pre-pandemic DPA posture has been largely focused on the maintenance and durability of the defense industrial base. Under E.O. 13603, issued in 2012,[246]

[244] Executive Order 10193, "Providing for the Conduct of the Mobilization Effort of the Government," 3 C.F.R. §§1949-1953.

[245] National Archives, *Records of the Office of Civil and Defense Mobilization [OCDM]*, accessed July 30, 2020, at https://www.archives.gov/research/guide-fed-records/groups/304.html.

[246] Executive Order 13603, "National Defense Resources Preparedness," 77 *Federal Register* 16651-16660, March 22, 2012, at https://www.federalregister.gov/documents/2012/03/22/2012-7019/national-defense-resources-preparedness.

responsibilities for various DPA authorities are provided, but this directive has been partially (if temporarily) superseded by subsequent presidential directives.[247]

Certain DPA coordination mechanisms do exist that may be strengthened. In the 2009 DPA reauthorization, the Defense Production Act Committee (DPAC) was created, which is a multi-agency platform developed to study and advise the President on the use of DPA authorities.[248] Under the original amending language, the DPAC would be managed by an executive director, reporting to the DPAC chairperson, appointed by the President at the rank of Deputy Assistant Secretary. However, CRS could not identify any records of any such person having been appointed. In the 2014 DPA reauthorization, this requirement was struck from the DPA statute, and replaced by a lower-ranked "coordinator," appointed by the DPAC chairperson. The DPAC's remit was also reduced to evaluating and advising on DPA Title I authorities. DPAC has not been publicly active during the pandemic, and does not appear to be playing any particular coordinating role in the federal response.

Congress could consider restoring aspects of the 2009 DPA reauthorization language to empower the DPAC. For example, the executive director position could be restored at a similar rank, or Congress could choose to allow that position to be appointed by the Cabinet secretary rather than the President. In addition, that office could be provided with separately authorized appropriations for a standing staff, and its responsibilities broadened to encompass government-wide coordination, planning, and implementation of DPA authorities.

Alternatively, Congress could create such an office separately from the DPAC, such as within an existing agency or in a new independent office or agency. For example, the recently-introduced Public Health Emergency Production Act of 2020 (PHEPA; S. 4050) would create an office in HHS ASPR with responsibility for a variety of DPA responsibilities, including a freestanding DPA Title III office, which would be led by an official at the rank of Deputy Assistant Secretary.

Ensuring Execution of Congressional Intent

Congress could pursue oversight or legislative remedies to clarify or otherwise enforce its legislative intent with respect to the implementation of DPA authorities. For example, most of DOD's use of the $1 billion in CARES Act appropriations to the DPA Fund has been related to supporting the defense industrial base (see "Title III Activities," and **Table 10**), and not in support of the health industrial base.

Section 304 of the DPA statute provides for a DPA Fund manager, and Section 309 of E.O. 13603 designates the Secretary of Defense as the DPA Fund Manager. Although the DPA Fund Manager is a custodian of the DPA Fund, the official does not have statutory discretion over the Fund's availability to support DPA Title III projects across government.

In its role, DOD has overseen the distribution of DPA funds and, to date, has been the only executive agency with a freestanding DPA Title III facility. As such, DOD was not required to coordinate the allocation of appropriations made to the DPA Fund with other executive agencies prior to the COVID-19 pandemic. Following the CARES Act's enactment, DOD announced that it would allocate approximately 75% of $1 billion in DPA Fund appropriations for health and

[247] In responding to the COVID-19 pandemic, this Administration's DPA-related presidential directives have routinely included language "notwithstanding" E.O. 13603, which effectively invokes the Administration discretion to override the national resources preparedness rubric as defined in the 2012 executive order.

[248] P.L. 111-67, 123 Stat. 2019-2020. The DPAC is now authorized in Section 722 of the DPA, 50 U.S.C. §4567.

medical resources in response to the pandemic.[249] However, in May 2020, DOD reversed its position and announced that it would allocate $688 million of the $1 billion in DPA Fund appropriations in support of the defense industrial base.[250]

On July 14, 2020, the House Committees on Financial Services, Homeland Security, Armed Services, Foreign Affairs, and Energy and Commerce released a letter addressed to the HHS and DOD secretaries.[251] The letter outlined concerns over the Trump Administration's COVID-19 response, including DOD's use of DPA Title III CARES Act appropriations, noting that congressional intent was for those funds to be reserved for health and medical countermeasures, and not support of the defense industrial base.

Following media scrutiny over its use of CARES Act DPA funding,[252] DOD released a statement in September 2020 justifying its prioritization of the defense industrial base in its Title III projects.[253] In the statement, DOD noted that its actions were consistent with CARES Act statutory requirements, its understanding of congressional intent, and that its intentions were briefed regularly to Congress. However, DOD's statement notwithstanding, there continues to be a dispute over the circumstances surrounding the use of CARES Act funds for DPA Title III. Senate minority report summaries of the CARES Act,[254] to which the House majority refers as its official summary,[255] state explicitly that DPA Fund appropriations are meant for health countermeasures to the COVID-19 pandemic.[256] By contrast, the Senate majority CARES Act summary uses broader language ("to increase access to materials necessary for national security and pandemic recovery") more consistent with DOD's position.[257]

At the same time, as previously noted, DOD's stated plans for Title III appropriations changed over time, at first favoring health industrial base investments before later revising its posture to

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[249] Department of Defense (DOD), *Undersecretary of Defense (A&S) Provides Update on DOD COVID-19 Response Efforts*, April 20, 2020, at https://www.defense.gov/Newsroom/Transcripts/Transcript/Article/2157331/undersecretary-of-defense-as-provides-update-on-DOD-covid-19-response-efforts/.

[250] See U.S. Congress, House Committee on Armed Services, *Statement by Ellen M. Lord Under Secretary of Defense for Acquisition & Sustainment*, Witness Statement, 116th Cong., June 10, 2020, at https://www.congress.gov/116/meeting/house/110794/witnesses/HHRG-116-AS00-Wstate-LordE-20200610.pdf. See also Tony Bertuca, "DOD Details Spending Plan for $10.5B in COVID-19 Relief Funds," *Inside Defense*, May 30, 2020, at https://insidedefense.com/daily-news/DOD-details-spending-plan-105b-covid-19-relief-funds.

[251] U.S. Congress, House Financial Services, Letter to DOD and HHS, July 14, 2020, at https://financialservices.house.gov/uploadedfiles/ltr_to_hhs_and_fema_7142020.pdf.

[252] Aaron Gregg and Yeganeh Torbati, "Pentagon Used Taxpayer Money Meant for Masks and Swabs to Make Jet Engine Parts and Body Armor," *Washington Post*, September 22, 2020, accessed at https://www.washingtonpost.com/business/2020/09/22/covid-funds-pentagon.

[253] DOD, "Statement on the Department's Use of Defense Production Act Title III," press release, September 23, 2020, at https://www.defense.gov/Newsroom/Releases/Release/Article/2358713/statement-on-the-departments-use-of-defense-production-act-title-iii/.

[254] U.S. Congress, Senate, *Fighting the COVID-19 Public Health Crisis*, prepared by Senate Democrats, 116th Cong., March 2020, p. 4, accessed at https://www.markey.senate.gov/imo/media/doc/C-3_summary_V1.2-updated.pdf.

[255] U.S. Congress, House Committee on Appropriations, *COVID-19 Response*, 116th Cong., accessed November 03, 2020, at https://appropriations.house.gov/news/covid-19-response.

[256] U.S. Congress, Senate Committee on Appropriations, H.R. 748 The Coronavirus Aid, Relief, and Economic Security Act: Title-By-Title Summary Prepared by the Office of Vice Chairman Leahy (D-Vt.), 116th Cong., March 25, 2020, p. 4, at https://www.appropriations.senate.gov/imo/media/doc/032520%20Title-By-Title%20Summary%20FINAL.pdf.

[257] U.S. Congress, Senate Committee on Appropriations, *$340 Billion Surge in Emergency Funding to Combat Coronavirus Outbreak*, 116th Cong., March 2020, p. 6, accessed at https://www.appropriations.senate.gov/imo/media/doc/Coronavirus%20Supplemental%20Appropriations%20Summary_FINAL.pdf.

prioritize the defense industrial base, which appears to be the event that triggered the July 2020 letters by House committee leadership over congressional intent. More recently, leadership of multiple House committees (Select Subcommittee on the Coronavirus Crisis, the Committee on Financial Services, the Committee on Oversight and Reform, and the Subcommittee on National Security) sent a letter to then-Defense Secretary Mark Esper contesting DOD's September 2020 statement, and announcing its own investigations.[258]

Congress may consider legislative remedies to further prescribe the duties and responsibilities of the DPA Fund manager and to clarify its intent over the use of DPA Title III appropriations. Alternatively, Congress could establish separate accounts for DPA Title III funds not intended for the defense industrial base.

Alternative Authorities Modeled After DPA

Because DPA implementation is closely bound to matters of presidential discretion, Congress could consider providing appropriations or, as necessary, separate authorizing legislation to ensure that various agencies have access to funding and are provided certain powers that may be modeled after the DPA. For example, funding could be provided to HHS specifically to procure PPE and/or fund the expansion of productive capacity. Similarly, separate legislation could provide DPA Title I-type authorities to other agencies as deemed necessary. Although a new program within an executive agency would still be subject to presidential direction, it could be authorized as a standing agency function, allowing it to operate independently of contingency-based presidential invocation.

[258] Letter from Hon. James E. Clyburn, Chairman, House Select Subcommittee on the Coronavirus Crisis; Hon. Maxine Waters, Chairwoman, House Committee on Financial Services; Hon. Carolyn B. Maloney, Chairwoman, House Committee on Oversight and Reform; and Hon. Stephen F. Lynch, Chairman, House Subcommittee on National Security, to Hon. Mark T. Esper, Secretary of Defense, October 2, 2020, at https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-10-02.Clyburn%20Waters%20CBM%20SFL%20%20to%20Esper-%20DOD%20re%20CARES%20Act.pdf.

Appendix A. Context: Federal Procurement Process

The overarching purpose of the federal acquisition system is to provide the means for federal agencies to buy the goods (e.g., equipment and supplies) and services they need to accomplish their missions. As described in the *Federal Acquisition Regulation* (FAR),[259] the federal acquisition system will

> (1) Satisfy the customer in terms of cost, quality, and timeliness of the delivered product or service by, for example- (i) Maximizing the use of commercial products and services; (ii) Using contractors who have a track record of successful past performance or who demonstrate a current superior ability to perform; and (iii) Promoting competition; (2) Minimize administrative operating costs; (3) Conduct business with integrity, fairness, and openness; and (4) Fulfill public policy objectives.[260]

Although the federal acquisition system was not designed to maintain or encourage domestic production of supplies or equipment, misconceptions involving certain elements of the acquisition system might lead some to view it as a possible mechanism for that purpose.[261] Beginning with its title, the Buy American Act might be viewed as a means for encouraging domestic production or sourcing for goods and construction materials.[262] The statute was developed to "restrict the purchase of supplies that are not domestic end products."[263] However, the two-part test used to determine whether an item is a domestic end product allows the item to partially contain non-domestic components. That is, an "article must be manufactured in the United States and … [t]he cost of domestic components must exceed 50 percent of all the components" for the item to be considered a domestic end product.[264] Other factors that could mitigate the cumulative effect of this statute on domestic production include its applicability (it applies only to federal agencies' purchases above certain monetary thresholds), exceptions which permit agencies "to acquire … foreign end product[s] without regard to the restrictions of the Buy American statute," and the authority exercised pursuant to the Trade Agreements Act.[265]

Another illustrative example involves subpart 6.3 of the FAR, which permits an agency to use noncompetitive procedures under seven specified circumstances. For example, noncompetitive procedures may be used when "it is necessary to award the contract to a particular source or sources in order … [t]o maintain a facility, producer, manufacturer, or other supplier available for furnishing supplies or services in case of a national emergency or to achieve industrial mobilization."[266] Application of this authority may be appropriate in several situations, including the following: "Keep vital facilities or supplies in business or make them available in the event of a national emergency," or "Train a selected supplier in the furnishing of critical supplies or services, prevent the loss of a supplier's ability and employees' skills, or maintain active engineering, research, or development work."[267] Although it is possible to obtain procurement

[259] The FAR consists of Parts 1-53 of the Title 48 of the *Code of Federal Regulations*.

[260] FAR 1.102(b). It is common practice to not include "section" or the symbol for "section" when citing the FAR in this manner.

[261] The FAR does not contain a definition of *domestic production* or *domestic goods*. As discussed below, the FAR does include a description of *domestic end product*, which is specific to the Buy American Act.

[262] The statute is codified at 41 U.S.C. §§8301-8305.

[263] FAR 25.101(a).

[264] Ibid.

[265] FAR 25.103 and 25.402.

[266] FAR 6.302-3(a)(2)(i).

[267] FAR 6.302-3(b)(1)(i) and (ii).

data from the FPDS-NG that shows which agencies, if any, have used this exception and for how many procurements, the database does not contain information that would indicate whether the desired outcome was achieved (e.g., a domestic facility was maintained) and for how long. That is, did the facility or manufacturer maintain, increase, cease, or decrease operations after the federal government contract(s) expired? Depending on the market for a particular company's products, its financial health, the pool of incumbent and potential employees, and other factors, the awarding of a federal contract (or even multiple contracts) may not be sufficient to sustain a company.

Federal Procurement Flexibilities

When dealing with an emergency or disaster, agencies may use a variety of procurement flexibilities to facilitate and expedite the procurement process. To assist agencies in identifying or finding these flexibilities, the FAR was revised in 2007 to create "a single reference to acquisition flexibilities [already available in the FAR] that may be used to facilitate and expedite acquisitions of supplies and services during emergency situations."[268] This revision of Part 18 of the FAR created two subparts: Subpart 18.1 "identifies flexibilities that may be used anytime and do not require an emergency declaration," and Subpart 18.2 "identifies the flexibilities that may be used only after an emergency declaration or designation has been made by the appropriate official."[269]

The 26 acquisition flexibilities identified in Subpart 18.1 include the following:

- FAR 6.302-2 identifies a circumstance of "unusual and compelling urgency" as a procurement flexibility for emergency situations.[270] Generally, it is the policy of the federal government to engage in full and open competition,[271] but agencies may use other than full and open competition (also known as "noncompetitive procedures") under seven circumstances, one of which is unusual and compelling urgency. FAR 6.302-2 is cross-referenced in FAR 18.104.
- FAR 4.1102(a) identifies the relevant circumstances under which a contractor is not required to be registered in the federal government's System for Award Management (SAM) at the time the contractor submits an offer or a quotation to an agency. The list of circumstances includes contracts awarded using noncompetitive procedures due to unusual and compelling urgency and contracts awarded in "the conduct of emergency operations."[272] Usually, contractors are

[268] U.S. Department of Defense, U.S. General Services Administration, and National Aeronautics and Space Administration, "Federal Acquisition Regulation; FAR Case 2005-038, Emergency Acquisitions," 72 *Federal Register* 46342, August 17, 2007.

[269] U.S. Department of Defense, U.S. General Services Administration, and National Aeronautics and Space Administration, "Federal Acquisition Regulation; FAR Case 2005-038, Emergency Acquisitions," 71 *Federal Register* 38248, July 5, 2006.

[270] Agencies also may use any of the other circumstances for procurements during emergency situations, as appropriate. They are as follows: (1) only one responsible source and no other supplies or services will satisfy agency requirements; (2) industrial mobilization; engineering, developmental, or research capability; or expert services; (3) international agreement; (4) authorized or required by statute; (5) national security; and (6) public interest. (FAR 6.302-1, 6.302-3, 6.302-4, 6.302-5, 6.302-6, and 6.302-7.)

[271] 10 U.S.C. §2304 and 41 U.S.C. §3301 require, "with certain limited exceptions (see subpart 6.2 and 6.3 [of the FAR]), that contracting officers shall promote and provide for full and open competition in soliciting offers and awarding Government contracts." (FAR 6.101(a).)

[272] FAR 4.1102(a)(3)(iii) and (5).

required to be registered in SAM at the time they submit an offer or a quotation. FAR 4.1102 is cross-referenced in FAR 18.102.

- FAR 15.203(f) states that oral requests for proposals (RFPs) may be authorized when certain conditions are met. FAR 15.203(f) allows the use of oral proposals "when processing a written solicitation would delay the acquisition of supplies or services to the detriment of the Government and a notice is not required under [FAR] 5.202 (e.g., perishable items and support of contingency or other emergency situations)." Usually, an agency is required to issue an RFP and post it on Beta.SAM.gov, a federal government website.[273] FAR 15.203(f) is cross-referenced in FAR 18.111.

Unlike Subpart 18.1, Subpart 18.2 contains acquisition flexibilities that may be used only when the appropriate official has made an emergency declaration or designation. Perhaps one of the best known acquisition flexibilities referenced in Subpart 18.2 is the local contracting preference, which is found in the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act)[274] and is cross referenced in FAR 18.203. Codified at 42 U.S.C. §5150, this provision states that, when awarding contracts for disaster or emergency assistance activities, agencies are to give preference, "to the extent feasible and practicable," to local firms.[275] The implementing regulation states that preference "may be given through a local area set-aside or an evaluation preference."[276]

The Office of Management and Budget (OMB) has explained that the preference for local firms is not applicable to the COVID-19 pandemic, noting the language of the emergency declaration under the Stafford Act that "an emergency exists nationwide."[277] OMB's guidance noted that, because "there is no locally affected area," the federal government's acquisition workforce is not required to create preferences for local firms.[278]

Federal Government Procurement Data

Information regarding pandemic-related federal government procurements may be found on the Beta.SAM.gov website, which is administered by the General Services Administration (GSA). The website contains, among other information, contract opportunities (i.e., solicitations, such as RFPs, invitations for bids (IFBs), and requests for quotations (RFQs) and information about contract awards). For example, OMB encourages agencies to use "COVID-19" or "Coronavirus" in their solicitations and related documentation to aid in identifying procurements related to the pandemic.[279]

[273] FAR 5.201.

[274] 42 U.S.C. §§5121 et seq.

[275] 42 U.S.C. §5150(a)(1).

[276] FAR 26.202(a).

[277] President Donald J. Trump, letter to Chad F. Wolf, Secretary of Homeland Security; Steven T. Mnuchin, Secretary of the Treasury; Alex M. Azar, II, Secretary of Health and Human Services; and Pete T. Gaynor, Administrator, Federal Emergency Management Agency, March 13, 2020, p. 2, at https://www.whitehouse.gov/wp-content/uploads/2020/03/LetterFromThePresident.pdf.

[278] Margaret M. Weichert, Deputy Director for Management, U.S. Office of Management and Budget, "Managing Federal Contract Performance Issues Associated with the Novel Coronavirus (COVID-19)," M-20-18, March 20, 2020, pp. 6-7, at https://www.whitehouse.gov/wp-content/uploads/2020/03/M-20-18.pdf.

[279] Ibid., p. 7.

Information about contract actions,[280] including those related to the pandemic, resides in the Federal Procurement Data System-Next Generation (FPDS-NG or FPDS) database, which may be accessed using Beta.SAM.gov.[281] Agencies are required to submit data regarding unclassified contract actions whose value exceeds the micropurchase threshold to FPDS.[282]

In March 2020, GSA created a National Interest Action (NIA) name and code for pandemic-related contract awards: COVID-19 2020 and P20C, respectively. Initially, agencies were to assign the COVID-19 2020 code to contract actions related to the pandemic and that involved "the exercise of emergency authorities identified in" Subpart 18.2 of the FAR.[283] Subsequently, the Office of Federal Procurement Policy updated this guidance, stating that agencies are to assign the code to "all procurement actions reported into FPDS that are issued in response to the pandemic."[284] In this context, "all procurement actions" includes new contract awards and any modifications issued to address COVID-19, "irrespective of whether the contract being modified was originally awarded to address the pandemic."[285] Initially, the end date for applying the NIA code for COVID-19 was July 1, 2020.[286] Subsequently, in an undated announcement posted on the FPDS website, GSA stated the end date had been changed to March 31, 2021.[287]

The COVID-19 Report, a periodically updated spreadsheet that contains all contract actions assigned the NIA code for the pandemic, is available from the main page of the FPDS website and the Contract Data Reports-Static web page of Beta.SAM.gov.

[280] The term *contract action* means "any oral or written action that results in the purchase, rent, or lease of supplies or equipment, services, or construction using appropriated dollars over the micro-purchase threshold, or modifications to these actions regardless of dollar value. Contract action does not include grants, cooperative agreements, other transactions, real property leases, requisitions from Federal stock, training authorizations, or other non-FAR based transactions." (FAR 4.601.)

[281] FPDS is available at https://www.fpds.gov/fpdsng_cms/index.php/en/; Beta.SAM.gov is available at https://beta.sam.gov/.

[282] FAR 4. 606(a). Generally, the micropurchase threshold is $10,000.

[283] Weichert, "Managing Federal Contract Performance Issues Associated with the Novel Coronavirus (COVID-19)," p. 7.

[284] Message sent on behalf of Michael E. Wooten, Administrator for Federal Procurement Policy, "Update to Guidance on Application of National Interest Action (NIA) Code to Increase Transparency," April 6, 2020, at https://www.acquisition.gov/sites/default/files/page_file_uploads/Update-to-Guidance-on-Application-of-NIA-Code-to-Increase-Transparency-April-6-2020.pdf. (Underlining in original.)

[285] Ibid.

[286] Weichert, "Managing Federal Contract Performance Issues Associated with the Novel Coronavirus (COVID-19)," p. 7.

[287] U.S. General Services Administration, Federal Procurement Data System-Next Generation, "NIA Extension for COVID-19," at https://www.fpds.gov/fpdsng_cms/index.php/en/newsroom.html.

Appendix B. Experts List

Table B-1. CRS Authors and Relevant Reporting

by issue area

Issue Area	Relevant CRS Products	CRS Analyst(s)
DOD Acquisition	• CRS Insight IN11288, *COVID-19 and the Defense Industrial Base: DOD Response and Legislative Considerations*, by Heidi M. Peters	• **Heidi M. Peters,** Analyst in U.S. Defense Acquisition Policy
Defense Logistics Agency	• CRS In Focus IF11543, *Defense Primer: The Defense Logistics Agency*, by G. James Herrera and Hibbah Kaileh • CRS In Focus IF11574, *National Stockpiles: Background and Issues for Congress*, by G. James Herrera and Frank Gottron	• **G. James Herrera,** Analyst in U.S. Defense Readiness and Infrastructure • **Tyler F. Hacker,** Analyst in Defense Logistics (non-author)
Defense Production Act	• CRS Insight IN11470, *Defense Production Act (DPA): Recent Developments in Response to COVID-19*, by Michael H. Cecire and Heidi M. Peters • CRS Insight IN11387, *COVID-19: Defense Production Act (DPA) Developments and Issues for Congress*, by Michael H. Cecire and Heidi M. Peters • CRS Insight IN11337, *The Defense Production Act (DPA) and the COVID-19 Pandemic: Recent Developments and Policy Considerations*, by Michael H. Cecire and Heidi M. Peters • CRS Insight IN11280, *COVID-19: Industrial Mobilization and Defense Production Act (DPA) Implementation*, by Michael H. Cecire and Heidi M. Peters • CRS Insight IN11231, *The Defense Production Act (DPA) and COVID-19: Key Authorities and Policy Considerations*, by Michael H. Cecire and Heidi M. Peters • CRS Report R43767, *The Defense Production Act of 1950: History, Authorities, and Considerations for Congress*, by Michael H. Cecire and Heidi M. Peters	• **Michael H. Cecire,** Analyst in Intergovernmental Relations and Economic Development Policy • **Heidi M. Peters,** Analyst in U.S. Defense Acquisition Policy
Federal Procurement	• CRS Report 98-505, *National Emergency Powers*, by L. Elaine Halchin • CRS Insight IN11264, *Presidential Declarations of Emergency for COVID-19: NEA and Stafford Act*, by L. Elaine Halchin and Elizabeth M. Webster • CRS Report RS22536, *Overview of the Federal Procurement Process and Resources*, by L. Elaine Halchin	• **L. Elaine Halchin**, Specialist in American National Government
FDA Regulation of PPE and Related Activities	• CRS In Focus IF11488, *Personal Protective Equipment (PPE) and COVID-19: FDA Regulation and Related Activities*, by Agata Bodie and Victoria R. Green • CRS Report R46507, *FDA's Role in the Medical Product Supply Chain and Considerations During COVID-19*, by Victoria R. Green, Agata Bodie, and Kate M. Costin • CRS In Focus IF10745, *Emergency Use Authorization and FDA's Related Authorities*, by Agata Bodie	• **Agata Bodie**, Analyst in Health Policy • **Victoria R. Green**, Analyst in Health Policy

Issue Area	Relevant CRS Products	CRS Analyst(s)
International Trade and Finance	• CRS Report R46304, *COVID-19: China Medical Supply Chains and Broader Trade Issues*, coordinated by Karen M. Sutter • CRS In Focus IF11648, *Medical Supply Chains and Policy Options: The Data Challenge*, by Andres B. Schwarzenberg and Karen M. Sutter • CRS In Focus IF10964, *"Made in China 2025" Industrial Policies: Issues for Congress*, by Karen M. Sutter • CRS In Focus IF11580, *U.S. Government Procurement and International Trade*, by Andres B. Schwarzenberg • CRS In Focus IF11551, *Export Restrictions in Response to the COVID-19 Pandemic*, by Christopher A. Casey and Cathleen D. Cimino-Isaacs	• **Andres B. Schwarzenberg,** Analyst in International Trade and Finance • **Michael D. Sutherland**, Analyst in International Trade and Finance • **Karen M. Sutter**, Specialist in Asian Trade and Finance
Public Health Surveillance and Data	• CRS Report R46588, *Tracking COVID-19: U.S. Public Health Surveillance and Data*, by Kavya Sekar and Angela Napili	• **Kavya Sekar**, Analyst in Health Policy
Strategic National Stockpile	• CRS In Focus IF11574, *National Stockpiles: Background and Issues for Congress*, by G. James Herrera and Frank Gottron	• **Frank Gottron,** Specialist in Science and Technology Policy

Source: Tabulated by CRS.

Notes: This experts list is not necessarily exhaustive and may not cover all aspects of a particular request, which may require additional expertise not listed here.

Appendix C. COVID-19 Supply Chain Task Force Data on PPE Supply and Demand

The COVID-19 Supply Chain Task Force presented the following charts to Senator Margaret Hassan, ranking member on the Senate Homeland Security and Governmental Affairs Committee's Subcommittee on Federal Spending Oversight and Emergency Management, in advance of a June 9, 2020, hearing held by the committee on federal COVID-19 response efforts. The Senator made these documents public.

The introduction to the documents explained that "The demand estimates are at the high end of expectations to ensure medical workers, first responders, etc. do not go without necessary PPE during a future pandemic or natural disasters."

Note: These data and graphics are produced by the COVID-19 Supply Chain Task Force. CRS cannot verify the accuracy of the data or explicate the methodology presented in these documents. CRS has requested updated information and data from FEMA, but had received no response as of November 2020.

Supply Chain Task Force Definitions

According to the Supply Chain Task Force, the definitions included in the charts are as follows:

- "Our high end demand estimates" are informed by: Interagency analyses; Industry estimates; Historical demand data from industry and best available data from six major U.S. medical-surgical distributors; Historical manufacturing data; [is] Exclusive of SNS needs; Steadily declining COVID hospitalization rates should reduce daily hospital PPE usage, but demand through summer may remain constant as hospitals and states replenish stockpiles, and to meet reopening requirements.
- "Estimated monthly production" is informed by: For N95 respirators: actual figures from 3M, Owens and Minor, Honeywell, Moldex, and Prestige Ameritech; For surgical masks, gloves, face shields, gowns: estimates calculated from the actuals and reported production percentages; Estimated overseas production are produced overseas and distributed domestically to satisfy requirement; Non-traditional suppliers *(sic)* estimated impact on production; Battelle decontamination methods can lengthen the useful life of a N95mask; Historical manufacturing data.
- "Delivered—provided by Big 6" is informed by: Best available distribution data of six major U.S. medical-surgical distributors. Big 6 Distributors make up 90% of the U.S. medical-surgical distributors; "Delivered—provided by Big 6" includes Airbridge, other FEMA procurements, and the recent nursing home deliveries. Also accounted for in addition to deliveries: Non-traditional suppliers for face shields; Boeing, Ford, Universities, etc.; Reusable gowns estimated shipments *(sic)*.

The following graphics, which are now publicly available, originated from Supply Chain Task Force representative Rear Admiral John P. Polowczyk, "White House COVID-19 Supply Chain Task Force," submitted to Senator Margaret Hassan in advance of a June 2020 hearing.[288] These data and graphics are produced by the COVID-19 Supply Chain Task Force. As such, CRS cannot verify the accuracy of the data or explain the methodology presented in these documents. According to the Supply Chain Task Force, the data does not include "procurement by states, commercial donations, distribution data of other medical-surgical distributors, direct shipments from manufacturers."

[288] U.S. Senate, Committee on Homeland Security and Governmental Affairs, Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic, June 9, 2020, at https://www.hassan.senate.gov/imo/media/doc/SCTF%20Demand%20PPE%20Chart.pdf.

Figure C-1. COVID-19 Supply Chain Task Force Data on N95 Respirator Supply and Demand

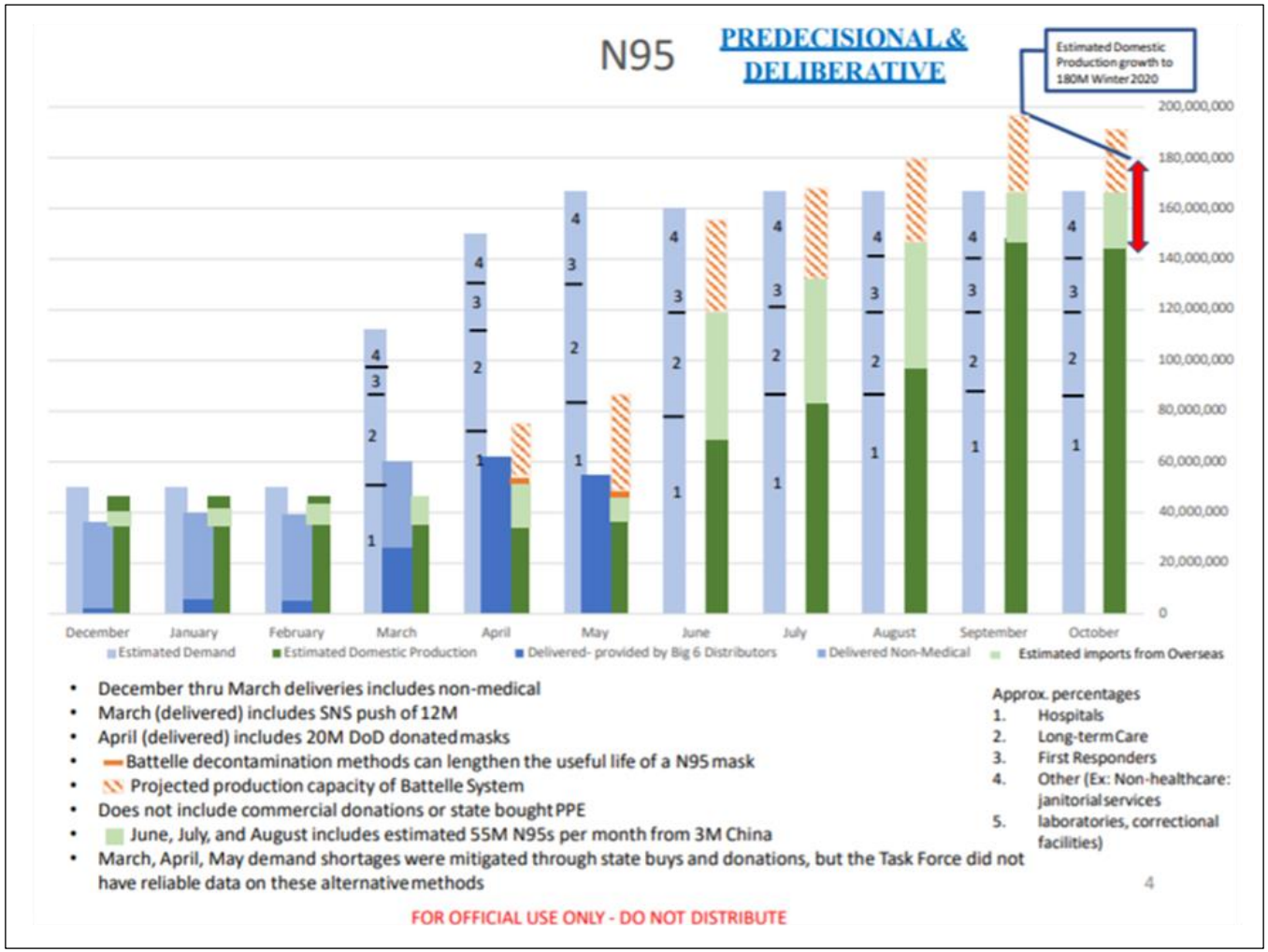


Figure C-2. Supply Chain Task Force Data on Gown Supply and Demand

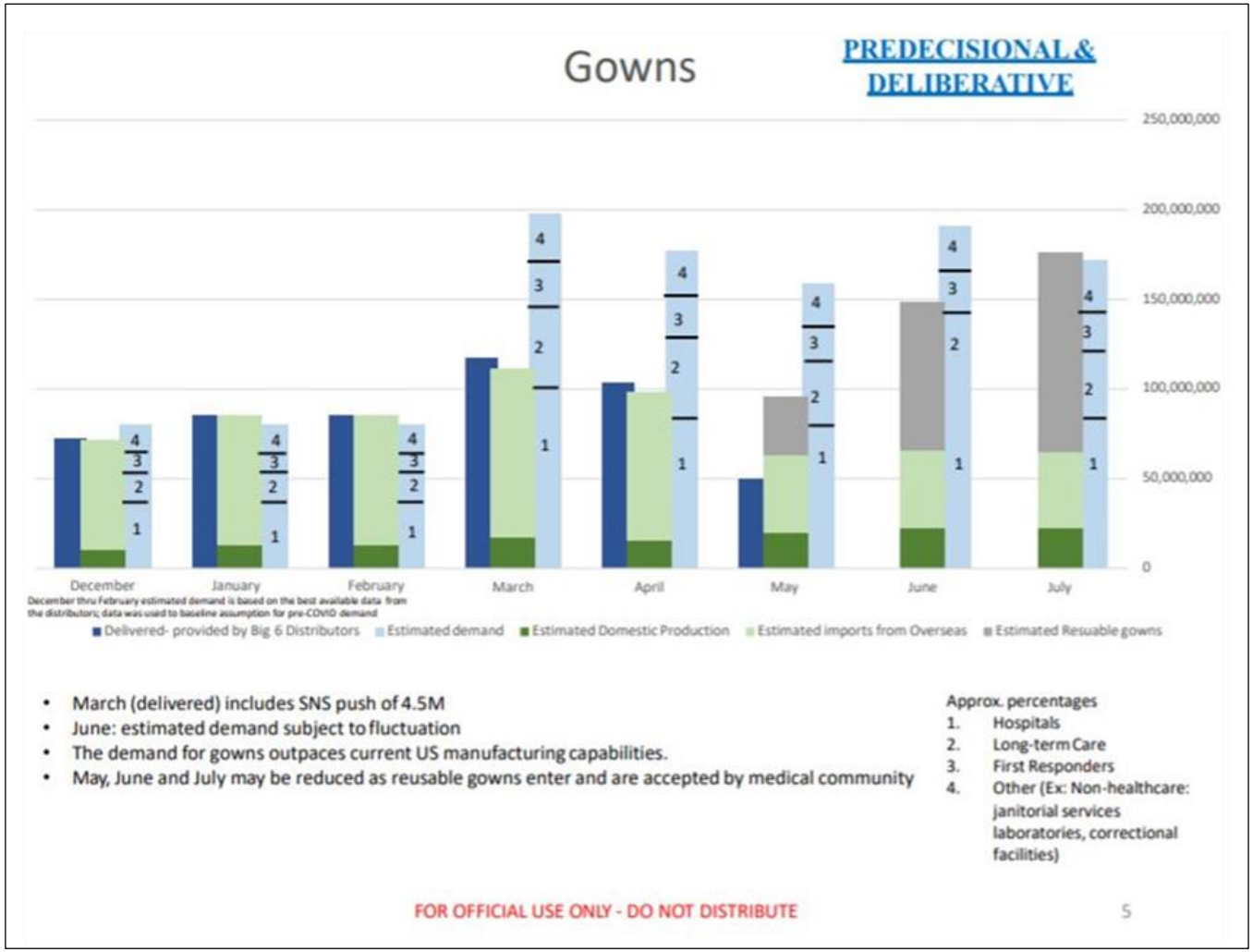


Figure C-3. Supply Chain Task Force Data on Surgical Mask Supply and Demand

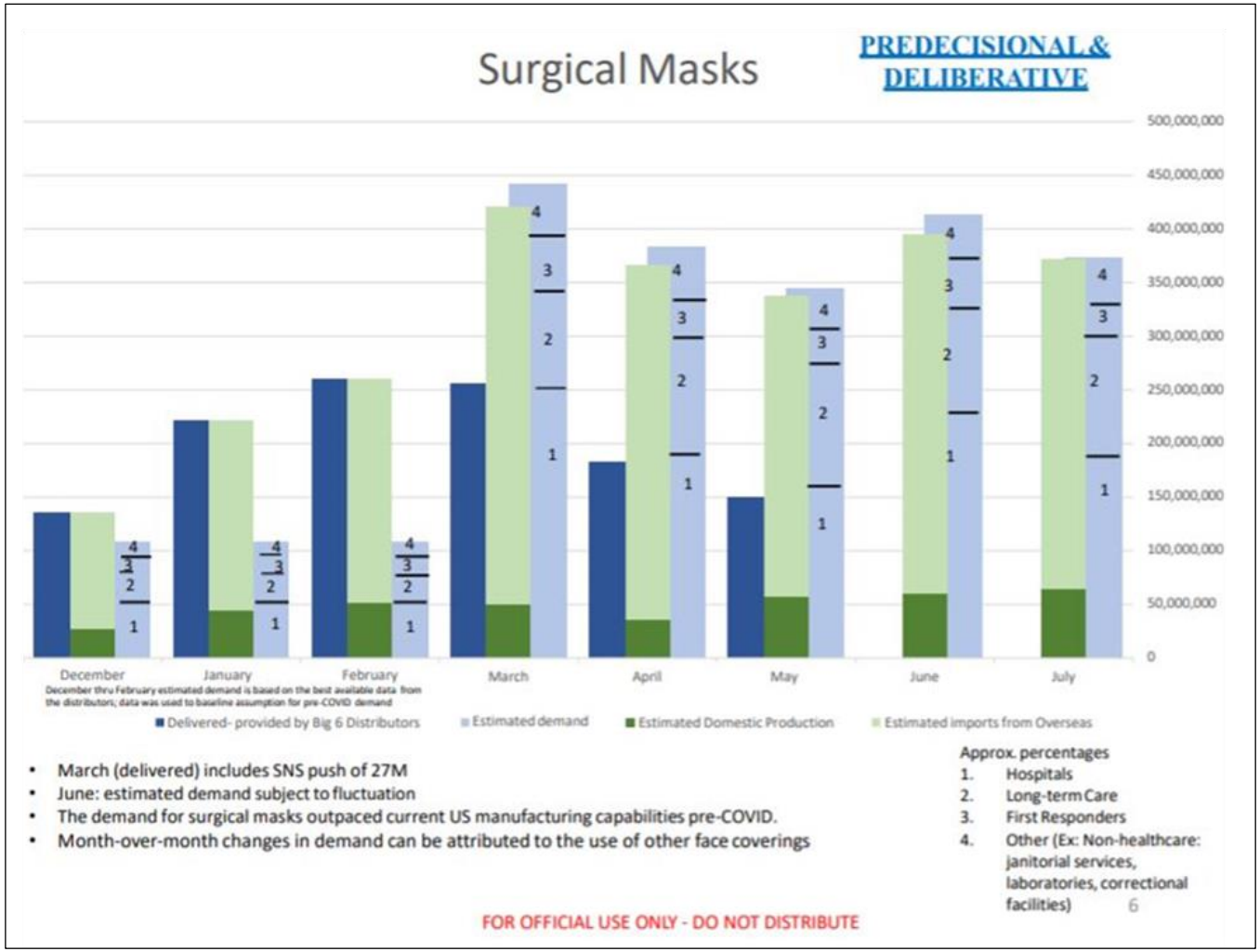


Figure C-4. Supply Chain Task Force Data on Nitrile Gloves Supply and Demand

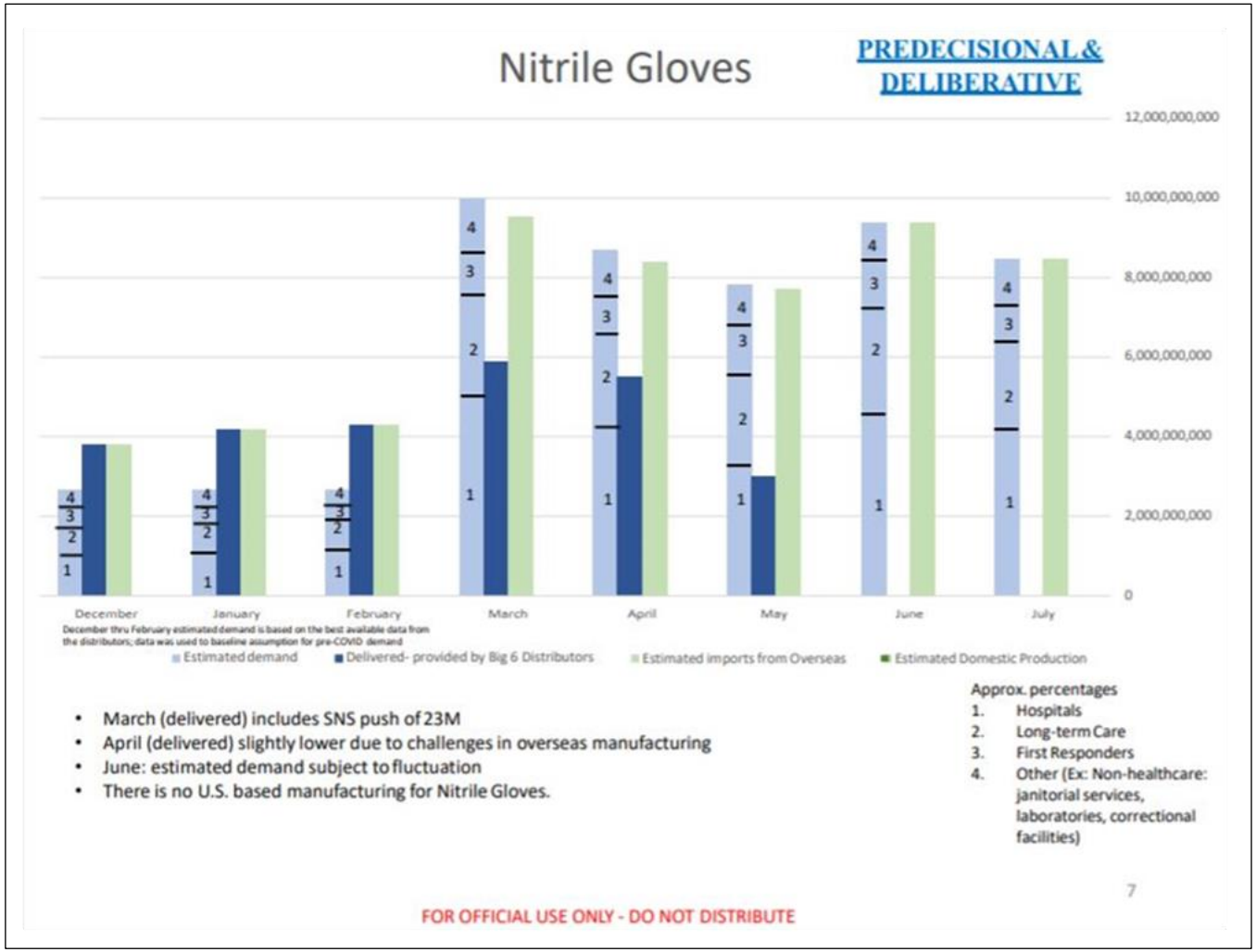
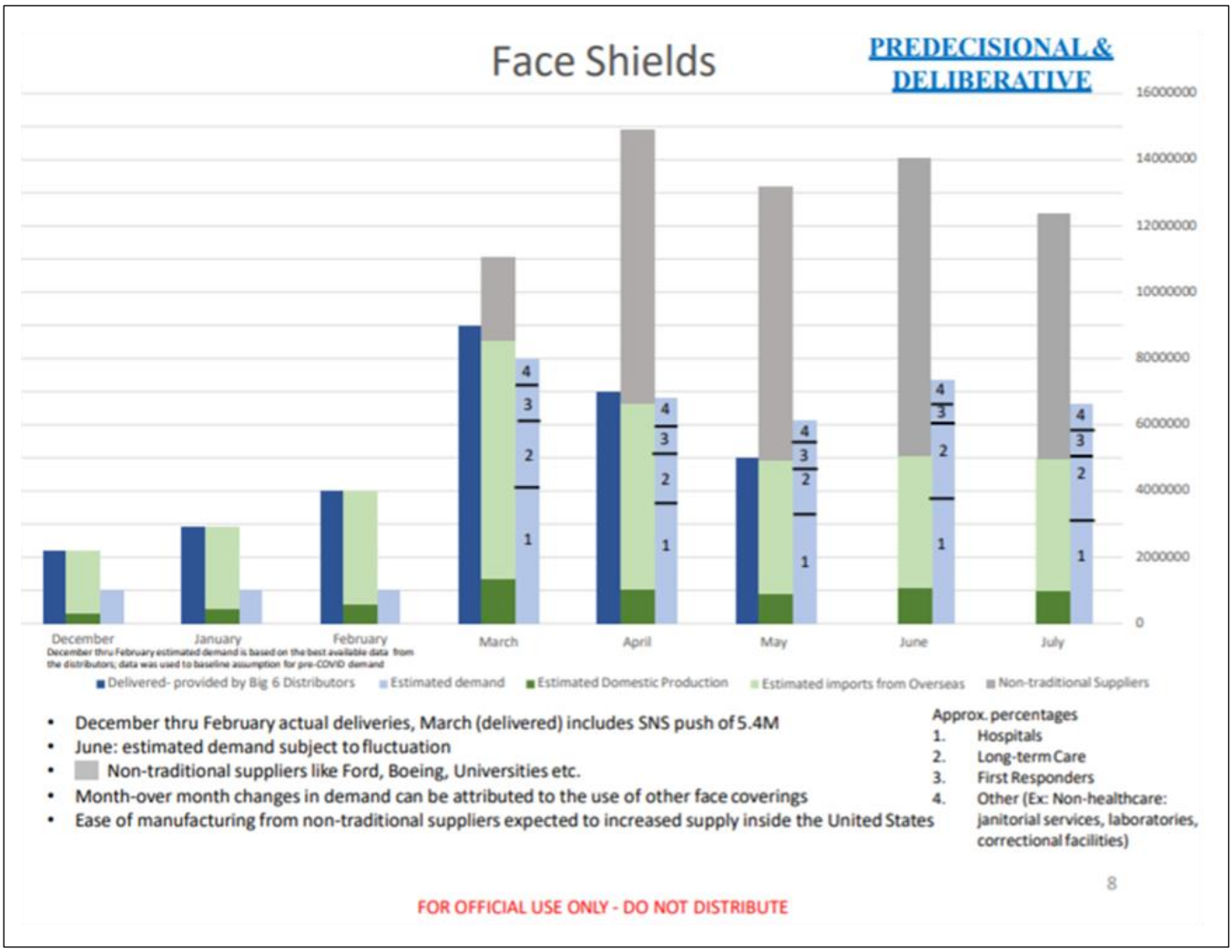


Figure C-5. Supply Chain Task Force Data on Face Shields Supply and Demand



Appendix D. PPE Imports Tabulations

Table D-1. Estimate of the Imported Share of U.S. Domestic Supply: Selected PPE and Medical-Related Categories

Share of Domestic Supply (%) in 2018

NAICS Code	Description	Total Imports, Share of U.S. Supply	Imports from the EU28, Share of U.S. Supply	Imports from China. Share of U.S. Supply
315220	**Men's and Boys' Cut and Sew Apparel** **[apparel from fabric, including hospital/medical/laboratory service apparel]**	**98**	**3**	**20**
315240	**Women's, Girls', and Infants' Cut and Sew Apparel** **[apparel from fabric, including hospital/medical/laboratory service apparel]**	**96**	**3**	**36**
333314	Optical Instruments and Lenses [microscopes, telescopes, prisms, and lenses; coating or polishing lenses; and mounting lenses]	94	14	23
325414	Biological Products (Except Diagnostic) [vaccines, toxoids, blood fractions, and culture media of plant or animal origin, except diagnostic]	79	59	*
339115	**Ophthalmic Goods** **[prescription eyeglasses, contact lenses, sunglasses, eyeglass frames, reading glasses made to standard powers, and protective eyewear]**	**60**	**22**	**20**
313210	**Broadwoven Fabrics** **[fabrics and felts, including surgical gauzes]**	**55**	**10**	**17**
325411	Medicinal and Botanical Drugs and Vitamins [uncompounded medicinal chemicals and their derivatives and botanicals]	48	34	8
325413	In-Vitro Diagnostic Substances [chemical, biological, or radioactive diagnostic substances]	48	27	3
325199	All Other Basic Organic Chemicals [isopropyl alcohol and glycerin]	42	14	9
334517	Irradiation Apparatus [beta-rays, gamma-rays, X-rays, or other ionizing radiation apparatus]	41	25	4
339113	**Surgical Appliances and Supplies** **[orthopedic devices, prosthetic appliances, surgical dressings, crutches, surgical sutures, personal industrial safety devices]**	**39**	**15**	**6**
325412	Pharmaceutical Preparations [in-vivo diagnostic substances and pharmaceutical preparations]	39	23	*

NAICS Code	Description	Total Imports, Share of U.S. Supply	Imports from the EU28, Share of U.S. Supply	Imports from China. Share of U.S. Supply
339112	Surgical and Medical Instruments [syringes, needles, anesthesia apparatus, blood transfusion equipment, catheters, surgical clamps, and medical thermometers]	36	10	2

Source: CRS analysis with data from the U.S. Census Bureau, the U.S. Bureau of Economic Analysis, and the U.S. International Trade Commission.

Notes: (1) Rough estimates calculated at the NAICS six-digit subheading level, which may cover products that are not for medical use; (2) * = Share of domestic supply is less than 0.05%; (3) descriptions in brackets are only selected examples of products covered by the NAICS subheading; (4) data likely understate the extent to which the United States relies on China for certain products. NAICS categories in **bold** likely include articles that could be considered PPE.

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