United States Government Accountability Office

Report to Congressional Committees

November 2020

# DEFENSE PRODUCTION ACT

# Opportunities Exist to Increase Transparency and Identify Future Actions to Mitigate Medical Supply Chain Issues

GAO-21-108

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## Opportunities Exist to Increase Transparency and Identify Future Actions to Mitigate Medical Supply Chain Issues

GAO Highlights

Highlights of GAO-21-108, a report to congressional committees

## Why GAO Did This Study

COVID-19 has put the U.S. health care system under severe strain, including affecting the federal government's ability to buy and maintain critical medical supplies to treat patients and protect health care workers.

In March 2020 agencies began using DPA authorities to rapidly obtain and expand domestic production of medical supplies for COVID-19. The CARES Act provided the Department of Defense (DOD) $1 billion for DPA purchases related to COVID-19. HHS also reported using some of the $8.4 billion it obligated to buy supplies and replenish the Strategic National Stockpile to increase domestic production of medical supplies, which GAO refers to as similar actions.

The CARES Act includes a provision for GAO to monitor funds provided for the COVID-19 pandemic. This report examines (1) federal agencies' use of these actions to address COVID-19, and (2) the federal approach for using DPA and similar actions for medical supplies, among other issues. GAO analyzed agency announcements, federal procurement data, contracts, project data, and planning documents from March 18 through September 30, 2020, and interviewed HHS, DOD, and FEMA officials.

## What GAO Recommends

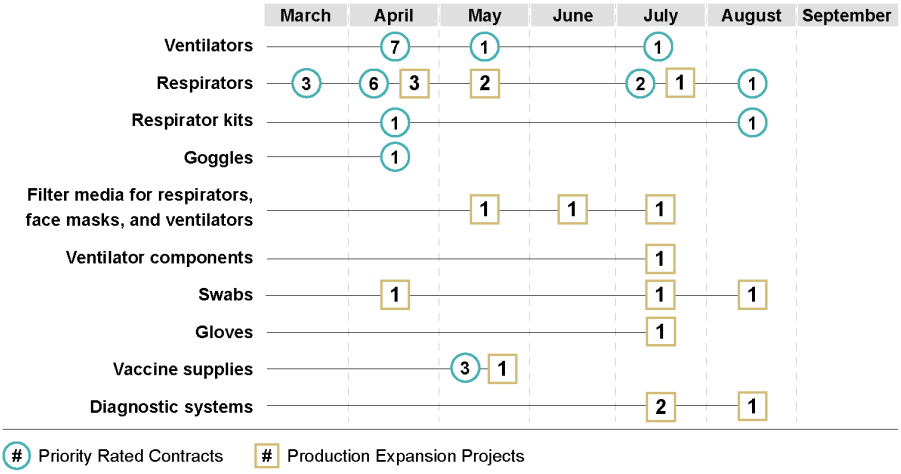
GAO is making two recommendations, including that HHS identify how DPA and similar actions will be used to increase domestic production of essential medical supplies as part of efforts to reduce reliance on foreign manufacturers. HHS concurred with the recommendation.

View GAO-21-108. For more information, contact W. William Russell at (202) 512-4841 or RussellW@gao.gov.

## What GAO Found

Federal agencies used the Defense Production Act (DPA) to help address medical supply shortages from COVID-19. The DPA gives agencies the authority to (1) prioritize contracts for medical supplies so those orders get preference over others, and (2) expand domestic production of medical supplies. GAO identified 43 contracts and agreements—initially valued at about $3.9 billion—where agencies placed priority ratings on or funded domestic production expansion projects for COVID-19 medical supplies (see figure). Department of Health and Human Services (HHS) and Federal Emergency Management Agency (FEMA) officials stated that nearly all the approximately 181,000 ventilators and 166.5 million of the respirators they placed on priority rated contracts, respectively, have been delivered as of September 2020.

**Federal Agencies' Use of Defense Production Act and Similar Actions for Medical, Testing, and Vaccine Supplies, March 2020-September 2020**




Source: GAO analysis of Departments of Defense and Health and Human Services data. | GAO-21-108

Note: One respirator contract included orders for powered air purifying respirator kits and goggles. We show these as three separate actions.

Federal agencies initially used a targeted DPA approach to address early COVID-19 medical supply issues, such as for ventilators and N95 respirators. By September 2020, agencies increased use of DPA and similar actions to a total of 10 types of medical supplies, and additional DPA actions are likely for masks, pharmaceuticals, screening and diagnostics, and personal protective equipment. In light of COVID-19 supply issues, an August 2020 executive order also directed that agencies take steps to reduce U.S. reliance on foreign manufacturers of medical supplies and other items. To support this order, HHS is leading an effort to identify and mitigate risks for increasing domestic production of medical supplies, but the agency has not yet identified its plans. As HHS completes this effort, an opportunity exists to identify how the DPA and similar actions may be needed to support the effort. Specifically, identifying further use of the DPA and similar actions to increase domestic production of key medical supplies can help alleviate national security risks from continued reliance on foreign manufacturers.

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Figures



**Abbreviations**

| | |
|---|---|
| COVID-19 | Coronavirus Disease 2019 |
| DOD | Department of Defense |
| DPA | Defense Production Act |
| FEMA | Federal Emergency Management Agency |
| FPDS-NG | Federal Procurement Data System-Next Generation |
| HHS | Department of Health and Human Services |
| OMB | Office of Management and Budget |

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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November 19, 2020

Congressional Committees

The emergence of the Coronavirus Disease 2019 (COVID-19) pandemic has put the U.S. health care system under severe strain, including affecting the federal government's ability to purchase and maintain inventories of critical medical supplies. The supplies are needed to test and treat patients, protect health care workers, and ensure that vials and syringes are available once one or multiple vaccines are approved. In March 2020, within 1 month of the start of the pandemic, the Department of Health and Human Services (HHS) had distributed most of the personal protective equipment supplies in the Strategic National Stockpile to states and other entities. Moreover, the Federal Emergency Management Agency (FEMA) received requests for millions of N95 respirators and gloves—from states, local, tribal, and territorial governments—that far exceeded domestic supply. According to a FEMA official, there was also concern that the inventory of ventilators would be exhausted. The federal government struggled to meet medical supply needs because the U.S. is dependent on foreign sources for many personal protective equipment supplies such as gowns and gloves, and is competing against countries all over the world for the same supplies during this pandemic.

As early as March 2020, federal agencies began using authority delegated under the Defense Production Act (DPA) to address medical supply chain needs. Based on this delegation, federal agencies have the authority to, among other things, place priority ratings on medical supply contracts so that agencies' orders would get preference over others, as well as provide incentives to expand domestic production of medical supplies so that the U.S. will be less dependent on foreign sources of supply.[1] The CARES Act provided the Department of Defense (DOD) $1 billion specifically for DPA purchases to prevent, prepare for, and respond to COVID-19, domestically or internationally.[2] DOD plans to use approximately $213 million of this funding for medical supplies and $687 million to offset the financial distress in the defense industrial base caused by COVID-19. DOD also plans to use $100 million to support DPA loans, in collaboration with the U.S. International Development Finance

[1]Pub. L. No. 81-774 (1950), codified at 50 U.S.C. App. §§ 4501 et seq., as amended.

[2]Pub. L. No. 116-136, (2020).

Corporation under Executive Order 13922. HHS reported that it obligated about $8.4 billion to buy supplies and replenish the Strategic National Stockpile. HHS is obligating some of these funds to expand domestic production of medical supplies.[3] Throughout the report, we refer to actions for placing priority ratings on contracts and awarding contracts or agreements for domestic production expansion projects (whether the actions were taken with funds specifically designated for DPA purchases or provided to HHS) as DPA and similar actions.

The CARES Act includes a provision for GAO to conduct monitoring and oversight of the use of funds made available to prepare for, respond to, and recover from the COVID-19 pandemic.[4] This report examines the federal government's use of DPA and similar actions to address COVID-19 medical supply chain issues, including (1) the extent that federal agencies have used DPA and similar actions; (2) the federal approach for using DPA and similar actions for medical supplies; and (3) federal agencies' efforts to identify lessons learned on the use of the actions. This is the first in a series of reports we plan to issue on the use of DPA and similar actions for COVID-19.

To determine the extent that federal agencies have used DPA and similar actions to address COVID-19 medical supply chain needs, we initially relied on HHS, FEMA, and DOD agency announcements stating the use of these authorities between March 18, 2020, and September 30, 2020. We corroborated this information with contract and other data provided to us by these agencies. We also verified whether the contracts and other procurement actions were included in the federal government's procurement database, known as the Federal Procurement Data System-Next Generation (FPDS-NG) and determined whether they were identified as DPA actions in the database. HHS, FEMA, and DOD officials were able to provide contracts or other information for 43 DPA or similar actions that were mentioned in agency announcements. There were four additional DPA or similar actions that were mentioned in agency announcements or identified by HHS related to assays, diagnostic systems, and ventilators.[5] HHS has not yet provided contract or other

[3]HHS officials identified the Public Health and Social Services Emergency Fund as an example of appropriations available to expand domestic production of medical supplies. Pub. L. No 116-136, Division B, Title VIII.

[4]Pub. L. No. 116-136, § 19010.

[5]An assay provides a sensitive, nucleic-acid-based diagnostic tool for evaluating specimens from patients in the acute phase of an infection.

information to corroborate these. Therefore, we excluded these four actions from our analysis. We plan to continue to seek this information from the agency.

We used the contract and other documents to determine the type, dollar value, and production timeframes of medical supplies where a priority rating was placed on the contract, as well as the equipment being purchased for domestic production expansion projects and the increased production capacity expected. We also reviewed relevant standards for internal control in the federal government, including those for information and communication management. HHS also has other contracts to procure medical supplies, which we did not include in this review because they did not include a priority rating or were not for domestic production expansion purposes. Lastly, our review focused on medical supplies and did not include priority ratings or production expansion efforts for pharmaceuticals, therapeutics, or vaccine research.

To determine the federal approach for using DPA and similar actions for medical supplies, we analyzed information and interviewed officials from HHS, FEMA, and DOD that serve on various task forces or are in organizations that support the review, approval, and execution of DPA authorities. This included officials from the Supply Chain Advisory Group, Joint DPA Office, DOD's Joint Acquisition Task Force, and DOD's DPA offices, which help award domestic expansion projects. We examined pertinent documents, such as Executive Orders, HHS strategic planning documents, and a leadership briefing to gain insight on how DPA authorities have been and are intended to be used to address critical supply needs. We also reviewed standards for internal control in the federal government for managing change in order to identify opportunities federal agencies may have as they respond to executive direction to reduce foreign dependence for medical supplies.

To determine federal agency efforts to identify lessons learned on the use of these actions, we analyzed available documentation from DOD, FEMA, and HHS aimed at capturing lessons learned and interviewed agency officials about ongoing efforts.

We conducted this performance audit from May 2020 to November 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that

the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Background

During the Korean War, Congress enacted the Defense Production Act of 1950 to ensure the availability of industrial resources to meet DOD's needs.[6] The DPA facilitates the supply and timely delivery of products, materials, and services to military and civilian agencies in times of peace as well as in times of war. Since it was enacted in 1950, Congress amended the DPA to broaden its definition beyond military application and expanded coverage to include crises resulting from natural disasters or "man-caused events" not amounting to an armed attack on the U.S. The definition of "national defense" in the Act has been amended to include emergency preparedness activities conducted pursuant to Title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) and critical infrastructure protection and restoration.[7] In 2018, Congress reauthorized the DPA through September 30, 2025.[8]

### Defense Production Act Provisions

There are three major authorities of the DPA that are currently in effect, DPA Titles I, III, and VII.

- **Title I: Priorities and Allocation Authority:** authorizes the President to require priority performance on contracts or orders and allocate materials, services, and facilities as necessary or appropriate to promote the national defense.[9] The President can delegate Title I authority to various agencies, including the Departments of Homeland

[6]Pub. L. No. 81-774 (1950), codified at 50 U.S.C. App. §§ 4501 et seq., as amended.

[7]A declaration under the National Emergencies Act authorizes the President to activate existing emergency authorities in other statutes, and the President must cite the authorities being exercised. 50 U.S.C. § 1621. A governor may request an emergency declaration under the Stafford Act if the situation is of such severity and magnitude that effective response is beyond the capabilities of the state and the affected local governments, and federal assistance is necessary. 42 U.S.C. § 5191. According to the Federal Emergency Management Agency, the President declared a nationwide emergency pursuant to 42 U.S.C. § 5191(b) to avoid governors needing to request individual emergency declarations. The Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, permits the President to declare a major disaster after a state's governor or chief executive of an affected Indian tribal government—a governing body of an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that is federally recognized—finds that the emergency or major disaster is of such a severity and magnitude beyond the State, Indian tribal government, and local government's capabilities. 42 U.S.C. § 5170. Governor means the chief executive of any state, which includes, among others, Puerto Rico and the U.S. Virgin Islands. 42 U.S.C. § 5122 (4)(5).

[8]Pub. L. No. 115-232, §1791 (2018).

[9]Throughout the report we use the term contracts to refer to both contracts and orders.

Security, Commerce, Defense, and HHS, among others. The authority each department holds is based upon its area of expertise in different sectors such as industrial resources, water, or health resources.

Title I authority allows priority-rated contracts or orders to take preference over any other unrated contracts or orders if a contractor cannot meet all required delivery dates. It also enables agencies to issue three types of allocation orders that require a person or corporation to (1) reserve resource capacity in anticipation of a rated order; (2) take or refrain from taking certain actions or divert use of materials, services, or facilities from one purpose to another; or (3) limit the amount of a resource to be used for a specific purpose.

In 2008, we found that some agencies did not have a system or regulations in place for the priorities and allocations authority.[10] We recommended that several civilian agencies develop and implement a system for using the priorities and allocations authority for each agency's respective resources. Since then, each agency that is designated as a resource department developed its own priorities and allocations systems. We also recommended that, to maximize effective use of the priorities and allocations authority, the Secretaries at the Departments of Agriculture, Energy, HHS, Homeland Security, and Transportation consider, in advance of an emergency, approving programs and placing priority ratings on contracts for items that are likely to be needed in an emergency. Agencies later informed GAO that processes and procedures for placing priority ratings on contracts prior to an emergency were either in place or being assessed.

- **Title III: Expansion of Productive Capacity and Supply:** authorizes the President to provide a variety of financial incentives—loans, loan guarantees, direct purchases, and purchase commitments—to firms to meet a variety of national defense goals, including maintaining, restoring, and expanding the domestic industrial base. The financial incentives may be used only when certain conditions are met. For example, purchase commitments may generally be made when, among other conditions, the President finds that the U.S. industry cannot reasonably be expected to provide the capability for the needed industrial resources, material, or critical technology in a timely manner. Title III financial incentives can help reduce the risks for

[10]GAO, Defense Production Act*: Agencies Lack Policies and Guidance for Use of Key Authorities,* GAO-08-854 (Washington, D.C.: June 26, 2008).

domestic suppliers associated with the capitalization and investments required to establish, expand, or preserve production capabilities.

Executive Order 13603, signed in 2012, designated the authority to implement Title III actions to the Secretary of Defense and the heads of other federal agencies and designated the Secretary of Defense as the DPA Fund Manager.[11] According to DOD officials, the Deputy Assistant Secretary of Defense for Industrial Policy provides management, direction, and oversight of the DPA Title III program, on behalf of the Under Secretary of Defense for Acquisition and Sustainment. The Air Force serves as the Executive Agent for DOD's Title III program and maintains a program office to execute the authority under the guidance of the Office of the Secretary of Defense. According to DOD Title III officials, DOD typically awards technology investment agreements for these projects.[12]

- **Title VII: General Provisions:** provides for a range of authorities, which include giving private firms that participate in voluntary agreements for preparedness programs limited protection from aspects of the antitrust laws and protecting contractors who honor priority-rated contracts from lawsuits brought by other customers. Title VII allows for establishing an executive reserve for employment in executive positions in the government during periods of national defense emergency. Title VII also provides for investigative authority to collect information on the U.S. industrial base. For example, the Department of Commerce completed assessments of the U.S. rocket propulsion industrial base and the U.S integrated circuit design and manufacturing industry in 2018 and 2019, respectively. It also completed an assessment of the impact of foreign sourcing on the health-related infrastructure in 2011, which Department of Commerce officials stated was its only assessment of health and medical resources as of June 2020.

[11]Exec. Order No. 13603, 77 Fed. Reg. 16651 (March 22, 2012).

[12]A technology investment agreement is an assistance instrument used to stimulate or support research. It may be either a kind of cooperative agreement or a type of assistance transaction other than a grant or cooperative agreement. The ultimate goal for using a technology investment agreement is to foster the best technologies for future defense needs. Technology investment agreements differ from and complement other assistance instruments in that they address the goal by fostering civil-military integration. 32 C.F.R. §§ 37.110 and 37.115.

## Executive Orders Allowing Use of DPA Authorities for COVID-19

On March 13, 2020, the President declared COVID-19 a national emergency under the National Emergencies Act and a nationwide emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act. The President also approved major disaster declarations under the Stafford Act for all 50 states, the District of Columbia, and five territories. The President then issued several executive orders from March 2020 through August 2020 allowing agencies to use DPA authorities to mitigate COVID-19 supply chain issues. Table 1 provides a description of the executive orders related to medical supplies.

**Table 1: Executive Orders Related to Defense Production Act for Medical Supplies, March 2020-August 2020**

| Executive Order Number | Date[a] | Description |
|---|---|---|
| 13909 | March 2020 | Provides authority to the Secretary of Health and Human Services to determine, in consultation with the Secretary of Commerce and the heads of other executive departments and agencies, proper nationwide priorities and allocations of all health and medical resources needed to respond to COVID-19 within the United States. |
| 13910 | March 2020 | Addresses prevention of hoarding and price gouging of resources such as personal protective equipment and disinfecting and sanitizing products. |
| 13911 | March 2020 | Provides the Secretary of Health and Human Services and the Secretary of Homeland Security the authority to expand production capacity of resources such as personal protective equipment and ventilators. Delegation of Defense Production Act Title VII authorities are also provided. |
| 13922 | May 2020 | Provides the Chief Executive Officer of the United States International Development Finance Corporation the authority to, among other things, make loans to create, maintain, protect, expand, and restore the domestic industrial base capabilities, including supply chains within the United States and its territories. |
| 13944 | August 2020 | Provides authority to the Secretary of Health and Human Services to determine priorities and allocations of essential medicines, medical countermeasures, and critical inputs, including active pharmaceutical ingredients. |

Source: GAO analysis of Presidential Executive Orders. | GAO-21-108

[a]Exec. Order No. 13909, 85 Fed. Reg.16227 (Mar. 23, 2020); Exec. Order No. 13910, 85 Fed. Reg. 17001 (Mar. 26, 2020); Exec. Order No. 13911, 85 Fed. Reg. 18403 (Apr. 1, 2020); Exec. Order No.13922, 85 Fed. Reg. 30583 (May 19, 2020); and Exec. Order No. 13944, 85 Fed. Reg. 49929 (Aug. 14, 2020).

## Organizations That Approve and Assist with Execution of DPA Authorities for COVID-19 Medical Supplies

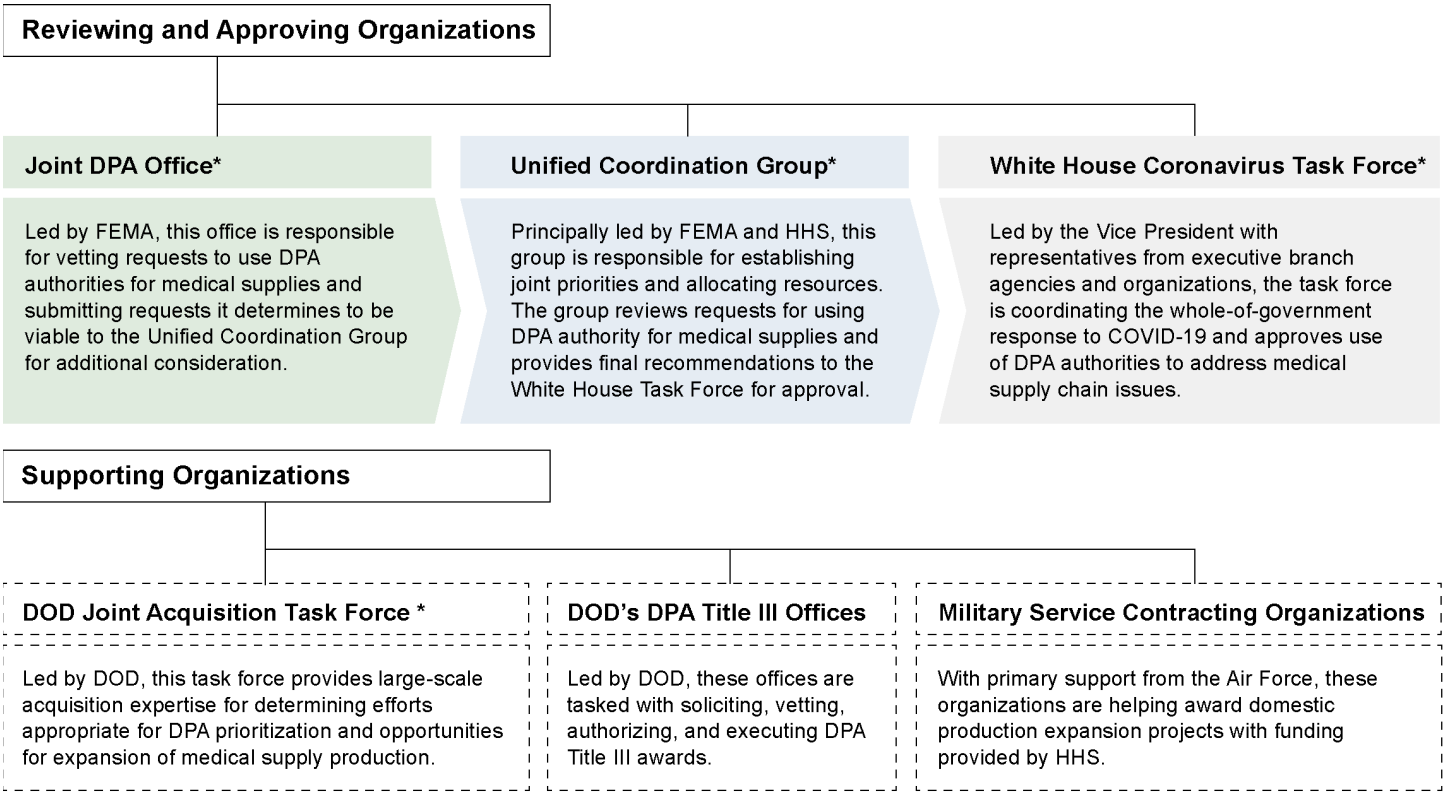
According to FEMA and DOD officials, a process has been put in place for three organizations to review and approve agency requests to use

DPA authorities in response to COVID-19.[13] These organizations include the Joint DPA Office, the Unified Coordination Group, and the White House Coronavirus Task Force.[14] Officials stated that the Joint DPA Office and the Unified Coordination Group are jointly led by FEMA and HHS officials. In addition, several DOD organizations support the execution of these authorities—the Joint Acquisition Task Force, DPA Title III Offices, and military service contracting offices. All of these organizations were established from January through April 2020 to help respond to COVID-19 with the exception of the DPA Title III offices and the military service contracting offices, which were preexisting. Figure 1 describes the DPA review and approval process.

[13]According to FEMA officials, not all DPA requests underwent the review process as some items, specifically ventilators, were approved directly through Presidential Memorandum.

[14]According to a FEMA official, as of June 15, 2020, FEMA's DPA program assumed responsibilities of the Joint DPA Office.

**Figure 1: Process for Reviewing and Approving Federal Agencies' Use of Defense Production Act (DPA) Authorities to Address COVID-19 Medical Supply Chain Issues**




Source: GAO discussions with Department of Health and Human Services (HHS), Federal Emergency Management Agency (FEMA), and Department of Defense (DOD) officials. | GAO-21-108

*Denotes organization created in response to COVID-19.

According to FEMA officials, the White House Coronavirus Task Force makes the final decision on use of DPA authorities for medical supplies. Exceptions could occur under an expedited process. In these situations, the White House Coronavirus Task Force has 1 hour to review the request; if no objection is identified in that time frame, approval is granted. In determining whether to approve use of these authorities, a FEMA official stated that the White House Coronavirus Task Force considers existing business relationships that manufacturers have with healthcare providers, the capacity of the manufacturer to meet all customer needs, and the extent to which individual states are also procuring medical resources from some of these same manufacturers to meet their own needs.

In addition to its role in the DPA review and approval process, the Unified Coordination Group has responsibility for operational command, leadership, and decision making for the COVID-19 pandemic response. Eight operational task forces were established by the Unified Coordination Group to provide operational guidance and secure resources to coordinate the whole-of-government response to COVID-19, including the Supply Chain Task Force. Initially this task force was responsible for maximizing the nationwide availability of mission-essential protective and lifesaving resources and equipment based on need. For example, the task force launched Project Air Bridge on March 29, 2020, to expedite the delivery of critical supplies from overseas manufacturers to distribute them to areas of need in the U.S., reducing shipment time from weeks to days, according to FEMA's website. The task force has since been renamed the Supply Chain Advisory Group and is responsible for advising the procurement of medical supplies to replenish the Strategic National Stockpile and assisting with the transition of procurement responsibilities to other federal stakeholders.

## Previous GAO Reports

In June 2020, we reported that HHS was using DPA authorities to address supply chain needs and to help replenish the Strategic National Stockpile for some items.[15] According to the President's budget proposal for fiscal year 2021, the Strategic National Stockpile is the largest federally owned repository of pharmaceuticals, critical medical supplies, federal medical stations, and medical equipment available for rapid delivery to support the response to a public health emergency when state and local supplies are depleted.[16] However, according to officials from HHS's Office of the Assistant Secretary for Preparedness and Response—the organization that oversees the stockpile—the Strategic National Stockpile did not have the capacity to provide states with supplies at the scale necessary to respond to a nationwide event such as the COVID-19 pandemic. For example, an HHS official stated that the stockpile did not contain the number of N95 respirators that would be needed in a severe pandemic.

The administration announced plans to restructure the Strategic National Stockpile on May 14, 2020, based on lessons learned from recent pandemics, including COVID-19. The HHS Office of the Assistant

[15]GAO, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts*, GAO-20-625 (Washington, D.C.: June 25, 2020).

[16]Department of Health and Human Services, Fiscal Year 2021 Public Health and Social Services Emergency Fund: Justification of Estimates for Appropriations Committee.

Secretary for Preparedness and Response issued a request for information to gather input from the private sector and other organizations on how to restructure the stockpile and improve supply availability, among other things. We have ongoing work examining the contents and management of the Strategic National Stockpile.

In September 2020, we reported that the federal government had taken steps to mitigate medical supply chain shortages.[17] However, we noted that there are ongoing constraints around certain types of personal protective equipment and testing supplies, such as nitrile gloves, surgical gowns, N95 respirators, swabs, reagents, tubes, pipettes, and transport media. Additionally, we noted that up to this point in the federal response, responsibility for stabilizing and expanding the medical supply chain relied on the coordination of multiple federal departments and their staff, many of whom were temporarily assigned to support COVID-19 response efforts. As the response evolves, many of these responsibilities—including monitoring supply availability, acquiring supplies, and building a resilient domestic manufacturing base—are transitioning or have recently transitioned over to HHS. For example, the Supply Chain Advisory Group is transitioning its medical supply chain management responsibilities to HHS. Responsibility for procuring and distributing testing supplies to states transitioned from FEMA to HHS in July 2020, according to HHS officials. DOD also began transitioning acquisition responsibilities back to HHS.

We made two recommendations to help facilitate future efforts to address COVID-19 supply chain issues.

- First, we recommended that HHS, in coordination with FEMA, should immediately document roles and responsibilities for supply chain management functions transitioning to HHS, including continued support from other federal partners, to ensure sufficient resources exist to sustain and make the necessary progress in stabilizing the supply chain, and address emergent supply issues for the duration of the COVID-19 pandemic.
- Second, we recommended that HHS, in coordination with FEMA, further develop and communicate to stakeholders plans outlining specific actions the federal government will take to help mitigate remaining medical supply gaps necessary to respond to the

[17]GAO, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions*, GAO-20-701 (Washington, D.C.: Sept. 21, 2020).

remainder of the pandemic, including through the use of Defense Production Act authorities.

HHS and FEMA both non-concurred with the recommendations. In general, HHS and FEMA stated that they have established adequate lines of communication and have taken significant action to meet federal, state, local, tribal, and territorial government medical supply requests. We acknowledged many of these efforts in the report, but reemphasized the need for further action.

## Agencies Have Used DPA and Similar Actions to Address COVID-19 and Increase Production of Medical Supplies, but Full Use of the Authorities Is Not Centrally Reported

Federal agencies used priority ratings on contracts early in the pandemic to get needed medical supplies to healthcare providers as quickly as possible, most notably ventilators and N95 respirators. HHS and DOD also have domestic production expansion projects underway to increase production of N95 respirators and other supplies. GAO found 43 awards where DPA and similar actions were used. These awards were initially valued at about $3.9 billion. Federal agencies do not centrally report all DPA Title I actions in FPDS-NG, which among other things, makes it difficult for federal agencies to assess the effectiveness of these authorities in addressing medical supply chain needs. Appendix I includes a list of the priority rated contracts and domestic production expansion projects that we identified.

### HHS and FEMA Placed Priority Ratings on Medical Supply Contracts to Address COVID-19

HHS and FEMA used DPA Title I authorities to place priority ratings on 25 medical supply contracts as of September 30, 2020. The contracts were initially valued at about $3.3 billion. HHS placed priority ratings on 19 and FEMA placed priority ratings on six. The majority of the contracts were awarded from March through May 2020 and most of the ratings were placed on contracts for ventilators and respirators. Table 2 provides details on federal agencies' use of DPA Title I authority to place priority ratings on medical supply contracts.

**Table 2: Defense Production Act Title I Priority Rated Contracts for Medical Supplies, March 2020-September 2020**

| Type of Medical Resource | Number of Prioritized Contracts | Total Awarded Amount (dollars in millions) | Number of Units |
|---|---|---|---|
| Ventilators | 9 | 2,340.4[a] | 180,906[a] |
| Respirators (N95, K95, KN90)[b] | 12 | 623.5 | 888,592,540 |
| Air purifying respirator kits | 2 | 136.5 | 28,950 |
| Goggles | 1 | 3.4 | Over 200,000 |
| Syringes | 3 | 154.6 | Not Provided[c] |
| **Totals** | **25[d]** | **3,258.4** | **N/A** |

Source: GAO analysis of Department of Health and Human Services (HHS) and Federal Emergency Management Agency contract offices documentation data. | GAO-21-108

[a]The contract award amount includes additional medical supplies than those indicated, such as hoods and consumables. The figure also represents the initial contract value and number of ventilators procured. According to HHS officials, it modified two contracts to procure fewer ventilators, but did not provide us with updated ventilator contract values and quantity data.

[b]The N95, KN90, and KN95 respirators model types provide a letter to indicate a resistance to oils and the nation in which the respirator's standards were approved, and a number to show the degree to which the respirator filters airborne particles.

[c]HHS provided three syringe contracts but redacted information on the number of units procured.

[d]One contract for N95 respirators also included orders for powered air purifying respirator kits and goggles. We included the contract for the kits and goggles in the individual rows, but excluded them from the total count to avoid double counting.

HHS placed priority ratings on nine contracts to initially procure over 180,000 ventilators. An HHS official stated that the agency recently modified two of the contracts, to procure fewer ventilators due to decreased demand. HHS, however, did not provide us with updated information on those contract modifications. We plan to continue to seek this information from the agency. Nearly 80,000—or about 44 percent of the initial number of ventilators acquired through priority-rated contracts—were to be produced through two contracts with traditional ventilator manufacturers and automotive manufacturers that had excess capacity at that time. Specifically, General Electric partnered with Ford Motor Company for one contract, and Ventec Life Systems partnered with General Motors for another contract. HHS did not provide detailed delivery information, but an official stated that the majority of ventilators acquired with priority rated contracts had been delivered by September 30, 2020.

HHS and FEMA placed priority ratings on 12 contracts and task orders with five contractors to procure a total of about 889 million N95 and other respirators. One of the HHS N95 respirator contracts also included powered air purifying respirator kits and goggles. HHS has not yet provided us with delivery information on the N95 respirators it ordered or

the powered air purifying respirator kits and goggles. We plan to continue to seek this information from the agency. An official from FEMA stated that 166.5 million of the respirators it ordered had been delivered as of September 10, 2020. HHS also awarded three contracts for syringes, but has not yet been able to provide detailed information on the quantities procured or delivered. We plan to continue to seek this information from the agency .

FEMA issued an Allocation Order, published as a Temporary Final Rule, to prohibit certain personal protection equipment items from being inappropriately diverted abroad, consistent with the April 3, 2020, Presidential Memorandum on "Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use". FEMA's initial Temporary Final Rule was published on April 10, 2020, a Notification of Exemptions was published on April 21, 2020, and an updated Temporary Final Rule was published on August 10, 2020, effective through December 31, 2020.[18] According to FEMA, as of September 4, 2020:

- N95 respirators for medical use are still subject to high demand within the U.S., and supply is not expected to catch up with demand until January 2021. FEMA had open requests for over 2.7 million medical grade N95 respirators from state, local, tribal, and territorial jurisdictions.
- Domestic supply of surgical masks does not meet current demands. FEMA had open requests for over 15.8 million surgical masks from state, local, tribal, and territorial jurisdictions.
- Domestic supply for latex and vinyl examination and surgical gloves has largely caught up with demand, but there is still a significant shortage of nitrile gloves.[19] FEMA had open requests for over 149.3 million nitrile gloves from state, local, tribal, and territorial jurisdictions.
- FEMA had open requests for 8.8 million gowns from state, local, tribal, and territorial jurisdictions.

[18]85 Fed. Reg. 48113 (Aug. 10, 2020).

[19]Nitrile gloves are disposable gloves made of a non-latex synthetic material used to reduce the risk of contamination between medical examiner and a patient.

## DOD and HHS Have Efforts Underway to Increase Domestic Production of Medical Supplies

DOD and HHS are also using DPA Title III or similar actions to increase domestic production of personal protective equipment, testing, and vaccine delivery supplies. For example, while priority ratings were placed on N95 respirator contracts, agencies are also pursuing projects to increase domestic production of N95 respirators. According to HHS and DOD, the country's ability to produce personal protective equipment domestically is critical not only to respond to pandemics, but also to ensure the security of the nation.

According to HHS and DOD officials, they plan to award $1.513 billion for domestic production expansion projects for medical supplies using CARES Act appropriations—$1.3 billion from funds HHS designated to buy supplies for the COVID-19 response and replenish the Strategic National Stockpile and approximately $213 million from funds provided to DOD that were specifically designated for DPA Title III investments.[20] According to the Under Secretary of Defense for Acquisition and Sustainment, DOD is using an additional $687 million in DPA Title III CARES Act funding to offset the financial distress in the defense industrial base caused by COVID-19, primarily in the aviation, space, shipbuilding, and microelectronics sectors. We plan to examine these other projects as part our future defense industrial base work.

As of September 30, 2020, DOD awarded more than $637 million on 18 medical supply domestic production expansion projects—or nearly 40 percent of the planned funding. DOD awarded some of these projects on behalf of HHS.[21] These projects help to address some of the current and projected supply chain needs for personal protective equipment, materials for N95 respirators and ventilators, testing materials, and vaccine delivery supplies.

The projects are being completed by companies that are already manufacturing these supplies in the U.S. An official from the DOD DPA Title III office stated that companies submitted domestic production

[20]DOD told us they are making the DPA Title investments under the authority of 50 U.S.C. 4533. DOD also told us that it allocated $100 million in CARES Act appropriations to support domestic loans under the authority of 50 U.S.C. 4532, in collaboration with the United States International Development Finance Cooperation, to increase the domestic production of N95 respirators, other personal protective equipment, pharmaceuticals, ventilators, airway management consumables, and testing supplies.

[21]For example, the Economy Act authorizes agencies to obtain supplies or services from another agency or from other major organizational units within an agency. 31 U.S.C. § 1535.

expansion proposals that balanced the companies' ability to meet the country's increased demand for certain supplies while also being able to maintain profitability over a longer period. The companies are using the funding to, among other things, procure additional equipment and materials, as well as to expand or build new facilities in some cases. Table 3 provides additional details of the domestic expansion efforts for medical resources.

**Table 3: DOD and HHS Use of Defense Production Act Title III and Other Contracts and Agreements for Increased Domestic Production of Medical Resources as of September 30, 2020**

| Medical Item | Number of Awards | Maximum Contract Value (dollars in millions)[a] | Projected production increase by January 2021 | Projected annual full rate production increase quantity |
|---|---|---|---|---|
| **Personal Protective Equipment** | | | | |
| N95 Respirators | 5 | 278.7 | 450 million | 822 million |
| Gloves | 1 | 22.4 | 225 million | 450 million |
| Surgical Masks | 1 | 3.5 | No production increase expected by this time | 100 million |
| **Materials needed to produce Personal Protective Equipment** | | | | |
| Ventilator Components | 1 | 4.9 | No production increase expected by this time | 7.8 million |
| Filter Media | 3 | 18.2 | | |
| N95 Respirators | | | 637 million | 1,957 million |
| Face Masks | | | 2,304 million | 6,648 million[b] |
| Ventilators | | | 330 million | 330 million |
| **Testing Materials** | | | | |
| Swabs | 3 | 136.7 | 422.4 million | 952.8 million |
| Test Kits | 3 | 35.1 | 73 million | over 120 million |
| **Vaccine Supplies** | | | | |
| Syringes | 1 | 138 | 540 million | 540 million |

Source: GAO analysis of Department of Defense (DOD) and Department of Health and Human Services (HHS) data. | GAO-21-108

Note: Filter media helps prevent virus particles from passing through N95 respirators, face masks, and ventilators.

[a]Contract values in table represent the government's portion of total award.

[b]According to the agreement language, the filter media will be used for either face masks or respirators.

Our analysis of data for the 18 projects shows that six projects, including syringes and filter media for ventilators, are scheduled to be completed by the end of 2020. The remaining 12 are scheduled to be completed between January 2021 and November 2021. DOD officials said that the

agency tracks the delivery of equipment to monitor progress of domestic production expansion projects. They also stated that DOD officials have visited some contractor facilities to assess progress. We plan to examine the status of these medical supply expansion efforts and the extent to which they help meet projected demand for the items as part of our future work assessing the use of DPA authorities in response to COVID-19.

## Use of DPA Title I Authority is Not Fully Reported in the Federal Procurement Data System

We determined that there is no data field in FPDS-NG—the federal government's central repository for procurement actions—that identifies when DPA rated contracts have been awarded in response to COVID-19. In April 2020, the Office of Management and Budget (OMB) directed federal agencies to use a special code in FPDS-NG that indicates when procurement actions were issued in response to COVID-19.[22] This included new contract awards for supplies and services as well as modifications, irrespective of whether the contract being modified was originally awarded to address COVID-19. The memorandum stated that these actions were intended to promote full, clear, and consistent transparency in the tracking of COVID-related procurement actions. OMB did not provide any additional reporting guidance for tracking the use of DPA authorities or similar actions to fund domestic production expansion projects. For example, federal agencies were not required to include additional information in the description of requirements data field when a priority rating was placed on a contract.

As of September 30, 2020, we found that over 72,000 contract actions reported in FPDS-NG were related to COVID-19, and only four of the 25 priority rated contracts actions we identified indicated in FPDS-NG that a priority rating was placed on the contract. Specifically, the FPDS-NG description field for four of six task orders FEMA placed on an indefinite delivery, indefinite quantity contract for N95 respirators indicated that they were a DPA order.[23] HHS and FEMA officials stated that they do not require their contracting officers to identify priority ratings in the description field for procurement actions because OMB guidance does not specifically direct them to identify these actions. FEMA officials stated

[22]OMB required agencies to use National Interest Action code P20C for COVID-19 actions in FPDS-NG.

[23]Indefinite delivery indefinite quantity contracts are awarded to one or more contractors when the exact quantities and timing for products or services are not known at the time of award.

that contracting officers added more detailed information in the FPDS-NG description field for the four task orders on their own volition.

By contrast, OMB provided updated guidance to federal agencies on April 17, 2020, to take additional steps to identify when agencies reimburse a contractor for the cost of paid leave incurred during COVID-19. For example, federal agencies are directed to enter "COVID-19 3610" at the beginning of the FPDS-NG description in the requirements data field on the contract action report for the modification. The guidance states that central collection of these data will support federal-wide analysis of contractor payments and implementation oversight, as well as help safeguard taxpayer dollars against duplicative and wasteful spending.

In the absence of additional clarifying direction to federal agencies to identify DPA rated contracts in FPDS-NG, OMB will miss an important opportunity to help agencies further promote full, clear, and transparent tracking of COVID-related actions, and federal agencies would not have complete information to support federal-wide analysis of the effectiveness of the DPA and similar actions to address medical supply needs. Moreover, Congress will not be able to fully track related procurement data and assess the overall effectiveness of these actions. *Standards for Internal Control in the Federal Government* states that agencies should obtain relevant data in a timely manner for management to make informed decisions and evaluate the agency's performance in achieving key objectives and addressing risks.[24]

[24]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014).

# Federal Agencies' Approach to Using DPA and Similar Actions Have Helped Address Some Medical Supply Issues, But Future Actions Have Not Been Identified

## Initial Actions to Address COVID-19 Were Focused on Ventilators and N95 Respirators, but Have Expanded to Other Types of Supplies

Federal agencies used DPA and similar actions to target limited types of medical supplies—such as ventilators and N95 respirators early in the COVID-19 response—but later took actions for other personal protective equipment and testing supplies. Part of the reason is because, according to the head of the Supply Chain Advisory Group, the pandemic caught the federal government off guard and the government has been playing catch-up ever since. In addition, HHS, FEMA, and DOD officials also stated that since COVID-19 began, the White House Coronavirus Task Force has advocated using a tailored approach when using the DPA to ensure that health institutions are sufficiently equipped while also minimizing disruptions to private industry.

Most of the DPA actions taken as of September 30, 2020, were targeted at addressing critical medical item shortages to treat patients and protect healthcare providers based on requests from state, local, tribal, and territorial governments. As previously noted, these included actions to quickly place priority ratings on contracts or to increase domestic production of ventilators and N95 respirators, and filter media projects, which are expected to take several months or more than a year to complete.

Federal agencies also used DPA Title I authorities to allocate and prevent hoarding of N95 respirators, as well as other critical medical supplies for COVID-19. The Department of Justice established a COVID-19 Hoarding and Price Gouging Task Force to develop effective enforcement measures, establish best practices, and coordinate nationwide investigations into allegations of individuals violating the allocation order. The Department of Justice made at least two announcements where it

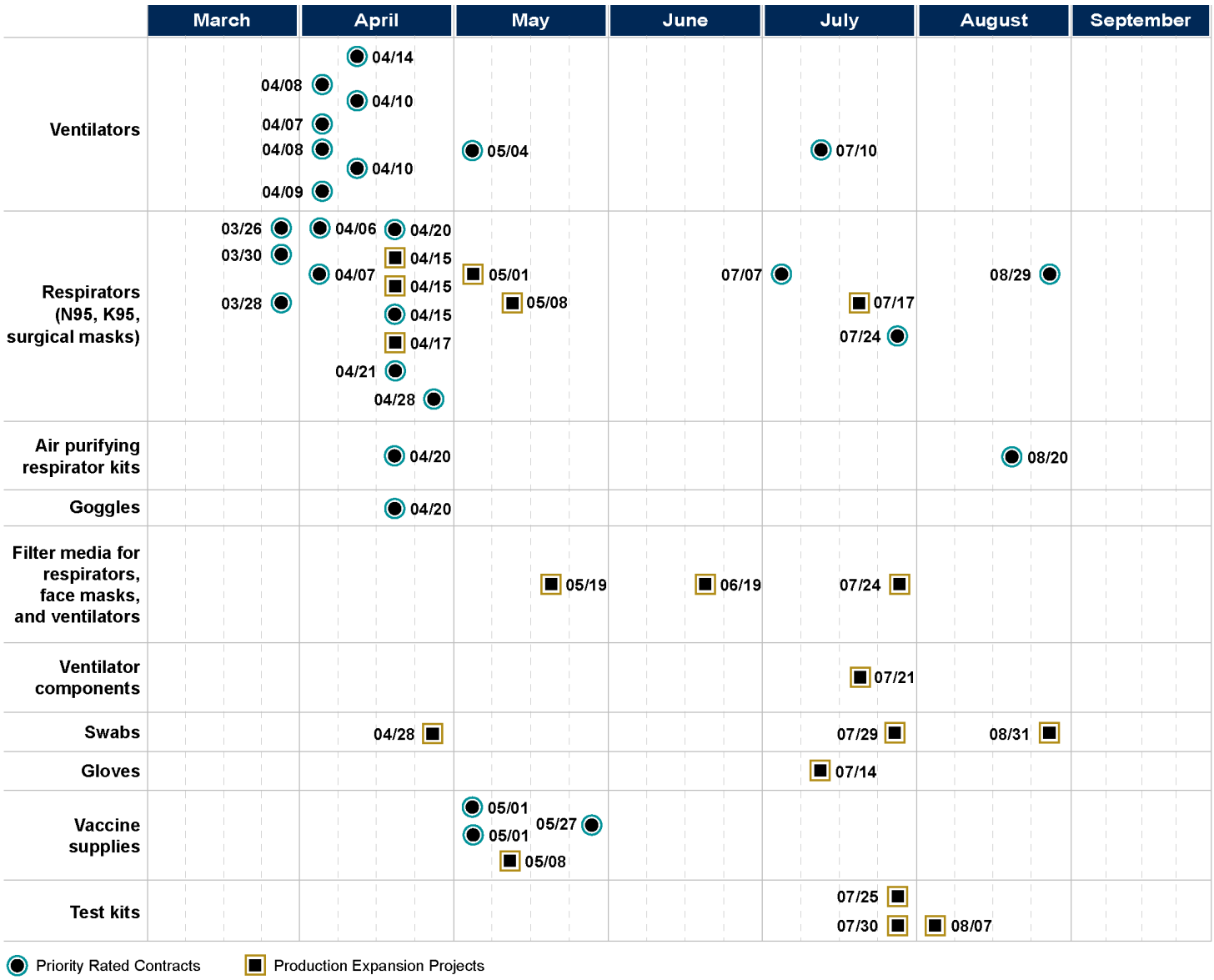
charged individuals for hoarding medical supplies and devices.[25] In one instance, it announced charges against an individual for hoarding personal protective equipment and seized more than 100,000 facemasks, 10,000 surgical gowns, nearly 2,500 full-body isolation suits, and more than 500,000 pairs of disposable gloves.

More recently, DPA and similar actions have been used to address supply shortages for other personal protective equipment and testing supplies, as well as to ensure that supplies, such as syringes, are on hand to support the delivery of a vaccine once available. We have ongoing work examining efforts to increase testing capacity and data collection, as well as vaccine development and delivery efforts that will be performed through project Operation Warp Speed.[26] Figure 2 provides an overview of federal agencies' actions to address a total of 10 types of COVID-19 medical supply needs through September 30, 2020.

[25]HHS, in accordance with Executive Order 13910, identified medical supplies and devices that were scarce and may not be accumulated (1) in excess of the reasonable demands of business, personal, or home consumption, or (2) for the purpose of resale at prices in excess of prevailing market prices. These supplies included N95 filtering facepiece respirators, powered air purifying respirators, portable ventilators, chloroquine phosphate or hydroxychloroquine, disinfecting devices and other sanitizing and disinfecting products suitable for use in a clinical setting, medical gowns or apparel (e.g., surgical gowns or isolation gowns), and personal protective equipment such as coveralls, face masks, surgical masks, and gloves or surgical gloves.

[26]On May 15, 2020, the President announced Operation Warp Speed. This is a joint HHS and DOD effort, with coordination from other agencies, to achieve the priority goal of accelerating development, production, and distribution of effective diagnostics, therapeutics, and vaccines to counter COVID-19.

**Figure 2: Use of Defense Production Act (DPA) or Similar Actions to Address Critical Medical Item Shortages, March 2020-September 2020**




Source: GAO analysis of Department of Defense and Department of Health and Human Services data. | GAO-21-108

Note: One contract for N95 respirators also included orders for powered air purifying respirator kits and goggles. We included the contract for the kits and goggles as separate actions.

Additional DPA actions are likely to be taken by agencies. The Joint Acquisition Task Force reached out to industry between July 10, 2020 and August 15, 2020, for domestic production expansion proposals for masks, pharmaceuticals, screening and diagnostics, and personal protective equipment. According to task force officials, as of August 28, 2020, teams of experts were reviewing and ranking the proposals.

The federal government recently announced that it will be using Title VII authorities—voluntary agreements with private firms—to address longer term medical supply needs. With required approval from the U.S. Attorney General, on August 17, 2020, FEMA established a voluntary agreement for enhanced coordination and cooperation with private sector manufacturers, distributors, and industry representatives to provide critical healthcare resources to respond to a pandemic, including expediting the distribution of needed medical supplies throughout the U.S. This voluntary agreement establishes the Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic, which consists of a chairperson, representatives from FEMA, HHS, Department of Justice, and other federal agencies with equities in the agreement, and participants who have substantive capabilities to carry out the purpose of the agreement.

The FEMA Administrator appoints the chairperson from FEMA senior executives. Among other things, and as directed by the chairperson, the committee members will collectively identify and resolve the allocation of scarce resources amongst all necessary public and private sector domestic needs. The chairperson makes decisions and may create and execute specific plans of action. Participants to the agreement receive limited protection from antitrust liability for specific actions taken under the agreement.

## Opportunities Exist for HHS to Identify How DPA and Similar Actions Could Further Reduce the Risk of U.S. Reliance on Foreign Manufacturers of Medical Supplies

An HHS strategic plan and a recently issued Executive Order identified reliance on foreign manufacturers as a risk to the U.S. healthcare supply chain and stated that steps should be taken to increase domestic production of medical supplies. HHS has not yet identified how DPA and similar actions could be used to address this risk.

HHS's Office of the Assistant Secretary for Preparedness and Response is the principal advisor to the Secretary of HHS on matters related to federal public health and medical preparedness and response for public health emergencies. In April 2020, the office issued its Strategic Plan for 2020-2023. The plan states that in an increasingly complex and dangerous world, being ready and able to protect the health of all

Americans is paramount to U.S. national security. The plan described the risk environment for the medical supply chain as follows:

> Supply Chain Disruption and Corruption: Highly efficient supply chains have resulted in a “just-in-time” approach regarding day-to-day healthcare capabilities throughout the U.S. and globally, as well as surge medical capacities in an emergency. This situation may leave health-related facilities and systems with limited inventories and the rapid onset of cascading impacts in the event of a supply chain disruption or corruption. Strategically, the biggest risk to healthcare sector supply chains is the U.S. dependency on foreign sources of pharmaceuticals, precursor ingredients or materials, and finished medical products or devices. When such commodities — including ordinary items such as protective masks and surgical gloves — are unavailable, or if reach-back support is significantly affected, patients will be directly impacted by accompanying disruptions and delays in the provision of key medical services. Interruption of foreign supply chains as a result of significant natural disasters, regional military or political conflicts, or trade disputes compounds the risk of disruptions that can directly impact healthcare provision in the U.S.

As shown in figure 3, the strategic plan lays out four priority goals. Priority Goal 3 provides a general approach for addressing the potential for supply chain disruptions, including the risks of foreign ownership of medical countermeasures, such as personal protective equipment.

**Figure 3: Excerpts from the Department of Health and Human Services Assistant Secretary for Preparedness and Response's Strategic Plan for 2020-2023**


Source: GAO presentation of agency data. | GAO-21-108

Note: According to the Centers for Disease Control and Prevention, medical countermeasures are life-saving medicines and medical supplies regulated by the U.S. Food and Drug Administration that can be used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear threats, emerging infectious diseases, or a natural disaster.

Efforts to increase domestic production of critical medical supplies are included in the Office of the Assistant Secretary for Preparedness and Response's planned restructuring of the Strategic National Stockpile. As stated earlier, the office issued a request for information in May 2020 to gather input from the private sector and other organizations on how to restructure the stockpile and improve supply availability. Among other things, manufacturers that responded to the request for information were asked to answer questions about strategies their company could employ to increase domestic production capability. For example, this included questions about how many shifts they could add, how long it would take to add a new production line, and if there were steps the government could take to encourage the company to transition activities domestically. Responses were due by May 29, 2020. Officials from the Office of the

Assistant Secretary for Preparedness and Response stated that they are currently evaluating the responses.

Executive Order 13944, which was issued on August 6, 2020, further emphasized the need to reduce U.S. dependence on foreign manufacturers of medical supplies, particularly with the development of needed medicines and medical countermeasures. For example, the Executive Order states, among other things, that it is the policy of the U.S. to

- accelerate the development of cost-effective and efficient domestic production of essential medicines and medical countermeasures and have adequate redundancy built into the domestic supply chain for essential medicines, medical countermeasures, and critical inputs; and
- create, maintain, and maximize domestic production capabilities for critical inputs, finished drug products, and finished devices that are essential to protect public safety and human health and to provide for the national defense.

The Executive Order requires federal agencies to take swift action in some cases to implement the policy. For example, federal agencies are required within 90 days of the date of the order to develop and implement procurement strategies to strengthen and mobilize the domestic industrial base for essential medicines, medical countermeasures, and critical inputs. In addition, the Secretary of HHS, in coordination with the Food and Drug Administration and in consultation with the Director of OMB, is required within 180 days of the date of the order to take all necessary and appropriate action to identify supply chain vulnerabilities for these items and to mitigate those vulnerabilities. The Executive Order states that this could include proposing regulations on the collection of information from manufacturers on the sources of finished products and devices and the use of any scarce inputs, as well as determining whether any Food and Drug Administration regulations may be a barrier to domestic production, among other things.

The DPA and similar actions are powerful tools that can help HHS meet the strategic plan goal of reducing reliance on foreign manufacturers and the related Executive Order policy of increasing domestic production of essential medical items. As discussed earlier in this report, HHS has been using these tools to address COVID-19 by increasing domestic production of medical supplies, such as N95 respirators, ventilator components, and the filter media needed for use in these items. While it

is likely that HHS would use them to meet the strategic plan goal and Executive Order policy, HHS has not yet specifically identified how DPA or similar actions would be used.

As the HHS Office of the Assistant Secretary for Preparedness and Response completes its 180-day effort to identify and mitigate supply chain vulnerabilities for essential medical items, an opportunity exists for the HHS to identify how DPA and similar actions may be needed to support the effort. *Standards for Internal Control in the Federal Government* states that when an agency is affected by changes in external conditions, such as the recognition that the U.S. is over reliant on foreign sources, it should identify, analyze, and respond to the changes on a timely basis, which includes identifying the necessary actions to address the changing conditions.[27] Identifying further use of the DPA and similar actions can help inform efforts to reduce reliance on foreign manufacturers and increase domestic production of essential medical items to address this national security concern.

## Agencies Have Begun Identifying Lessons Learned for Future Interagency Coordination and Use of DPA and Similar Actions

DOD, HHS, and FEMA officials stated that they are beginning to collect lessons learned about actions needed to improve future COVID-19 response efforts and national emergencies, including use of DPA. For example, while DOD officials stated the agency has not developed a complete list, on June 10, 2020, the Under Secretary of Defense for Acquisition and Sustainment testified that individual agencies are working to memorialize lessons learned over the course of the COVID-19 pandemic response to enable swift interagency action and alignment in future national emergencies.[28] The Under Secretary mentioned difficulties in facilitating the timely execution and interagency transfer of funding from HHS to DOD, which generally must be made for an order under the Economy Act.

The Under Secretary stated that DOD and HHS have since come to understand the interworking of DPA authorities and how to legally assist each other in acquisition and distribution, and ensure proper documentation is in place so coordination efforts can be activated quickly. HHS and DOD signed a memorandum of understanding on April 23, 2020, documenting the procedures that would be used to transfer funds from HHS to DOD and how DOD would assist HHS in the acquisition of

[27]GAO-14-704G.

[28]House Committee on Armed Services. “Department of Defense COVID-19 Response to Industrial Base Challenges.” Wednesday, June 10, 2020.

supplies and services in response to COVID-19. In addition, as of August 2020, DOD officials stated they were in the process of creating a new policy office that will provide policy guidance and oversight of future DOD support to interagency partners. According to DOD officials, lessons learned will also be codified into the existing Joint Rapid Acquisition Office interagency support processes as it takes over the Joint Acquisition Task Force's current role and responsibilities to establish a more permanent interagency focal point.

In addition, the HHS Office of the Assistant Secretary for Preparedness and Response indicated that it has also identified lessons learned and is considering:

- Adding a clause to contracts that indicates a priority rating is possible, which would make it more efficient to place a priority rating on a contract in the future. This is in line with a recommendation we made in a 2008 report on the use of DPA authorities.[29] HHS stated in a written response to our inquiry that it had not previously placed priority ratings on contracts in advance of an emergency because there were no limitations to accessing needed supplies in the commercial market.
- Providing both regular and just in time training on DPA Title I authority, which includes written guidance, to its contracting officers. In a written response, HHS officials noted that three of 20 contracting officers had experience using DPA Title I authorities and that there was no formal training in using this authority prior to the COVID-19 pandemic.

It should also be noted that prior to COVID-19, HHS conducted emergency exercises throughout 2019. In August 2019, these exercises culminated in what is known as the Crimson Contagion Functional Exercise, which among other things, identified lessons learned in using DPA authorities. These exercises reviewed the nation's ability to respond to a large-scale outbreak of a novel virus that quickly spreads around the world and included representatives from multiple federal agencies including HHS, FEMA, DOD, and the White House. In the exercises' after-action report, HHS indicated that participants were not clear on the applicability or use of DPA authorities to mitigate medical supply shortages. In response, HHS recommended that agencies should clarify the possible uses of the DPA by (1) examining the applicability of Title III and Title VII authorities to address supply chain and material shortages

[29]GAO-08-854.

during a pandemic response, and (2) providing an educational briefing on DPA authorities and its possible uses in different kinds of incidents. In June 2020, HHS officials told us that they had not implemented actions to address the recommendations from the Crimson Contagion exercise prior to the pandemic response.

According to FEMA officials, the agency is also developing initial observations about COVID-19 response efforts and national emergencies—to include the use of DPA—and is working with its program offices to collect additional information, augment analysis, and revise observations. They stated that the final lessons learned will be included in the after-action report, which will be published in 2021. According to officials, given the size, scale, and ongoing nature of the response, as well as the necessity of distributing accurate information, FEMA intends to share these findings once they have been fully validated.

## Conclusions

The DPA can be a powerful tool for federal agencies to mitigate medical supply chain issues and protect our national security during the time of an emergency. In the case of COVID-19, agencies have efforts underway to expedite deliveries and expand medical supply production from the U.S. industrial base through DPA and similar actions.

Much is unknown about how effective the use of DPA and similar actions will be in meeting projected COVID-19 needs because complete information on use of the authorities is not centrally reported in FPDS-NG. OMB directed federal agencies to identify COVID-related procurement actions in FPDS-NG, but did not direct agencies to further identify their use of DPA Title I in FPDS-NG. The lack of clarity could be rectified by having contracting officials more clearly identify their use of DPA Title I in FPDS-NG. This would promote full, clear, and consistent transparency in the tracking of COVID-related actions, and federal agencies would have complete information to support federal-wide analysis of the effectiveness of the DPA and similar actions.

It is also unclear how DPA and similar actions will be used to more broadly reduce the risk of U.S. dependence on foreign manufacturers of medical supplies, which the administration has determined to be a national security threat. This is because HHS has not yet identified how DPA and similar actions could be used to address this risk and meet the U.S. policy of increasing domestic production of essential medical items. This could also be rectified as HHS leads a 180-day effort to identify and

mitigate supply chain vulnerabilities for essential medical items in response to an Executive Order.

## Recommendations for Executive Action

We are making the following two recommendations to OMB and the HHS's Assistant Secretary for Preparedness Response, respectively:

OMB should direct the Office of Federal Procurement Policy to develop appropriate agency reporting guidance to provide greater transparency on the use of DPA Title I authorities for COVID purposes. The reporting guidance should enable taxpayers and other interested stakeholders to see where a priority rating was placed on the contract or contract modification for COVID-19 purposes. (Recommendation 1)

The HHS Assistant Secretary for Preparedness and Response should identify how DPA and similar actions will be used to increase domestic production of medical supplies going forward. This could be included in HHS's 180-day effort to identify and mitigate vulnerabilities for essential medicines, medical countermeasures, and critical inputs that is required to support Executive Order 13944, which is aimed at reducing reliance on foreign manufacturers of medical supplies. (Recommendation 2)

## Agency Comments

We requested comments on a draft of this product from the Office of Federal Procurement Policy within the Office of Management and Budget, HHS, FEMA, and DOD. The Office of Federal Procurement Policy and HHS provided email comments that are summarized below. FEMA and DOD provided technical comments that we incorporated in the report, as appropriate.

The Office of Federal Procurement Policy concurred with our recommendation to develop appropriate agency reporting guidance to provide greater transparency on the use of DPA Title I authorities for COVID purposes. In its response, staff from the Office of Federal Procurement Policy noted that the ability to identify contracts or actions using the DPA is a shared objective and that the office welcomes the opportunity to consider how to track such actions.

HHS concurred with our recommendation to identify how DPA and similar actions will be used to increase domestic production going forward. An official from the Assistant Secretary for Preparedness and Response office that has responsibility for the DPA stated that HHS has established a Supply Chain and Industrial Base Assurance Steering Committee to assure a viable and resilient medical countermeasure supply chain and industrial base. The official also stated that in an assessment of lessons

learned, HHS identified a need to establish a DPA program office, similar to those in DOD, the National Aeronautics and Space Administration and the Departments of Homeland Security, Commerce, and Transportation. Further, the official stated that the Office of the Assistant Secretary for Preparedness and Response has created a new branch to lead and coordinate use of DPA authorities for HHS, which will include finalizing the Health Resources Priorities and Allocations System and establishing a program office that will develop guidance and templates for use, training for contracting officers and program managers, all on a new HHS webpage.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services; the Secretary of Homeland Security; the Secretary of Defense; and the Director of the Office of Management and Budget. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-4841 or russellw@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

W. William Russell
Director, Contracting and National Security Acquisitions

*List of Committees*

The Honorable Richard C. Shelby
Chairman
The Honorable Patrick J. Leahy
Vice Chairman
Committee on Appropriations
United States Senate

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Ron Johnson
Chairman
The Honorable Gary C. Peters
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable James Lankford
Chairman
The Honorable Kyrsten Sinema
Ranking Member
Subcommittee on Regulatory Affairs and Federal Management
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Nita M. Lowey
Chairwoman
The Honorable Kay Granger
Ranking Member
Committee on Appropriations
House of Representatives

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Greg Walden
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Bennie Thompson
Chairman
The Honorable Mike D. Rogers
Ranking Member
Committee on Homeland Security
House of Representatives

The Honorable Carolyn B. Maloney
Chairwoman
The Honorable James R. Comer
Ranking Member
Committee on Oversight and Reform
House of Representatives

# Appendix I: Priority Rated Medical Contracts and Domestic Production Expansion Projects for COVID-19

**Table 4: Priority Rated Medical Contracts for COVID-19, Defense Production Act Title I**

| Medical Supply | Contractor | Award Date[a] | Contract Award Amount[b] (dollars in millions) |
|---|---|---|---|
| **Department of Health and Human Services** | | | |
| Ventilators | Philips North America LLC. | 4/7/2020 | 646.7 |
| | ResMed Corp. | 4/8/2020 | 32.0 |
| | Hill-Rom Company Inc. | 4/8/2020 | 20.1 |
| | Medtronic Public Limited Company | 4/10/2020 | 9.1 |
| | Vyaire Medical, Inc. | 4/10/2020 | 408.0 |
| | General Electric-Datex-Ohmeda | 4/14/2020 | 336.0 |
| | Zoll Medical Corp. | 4/9/2020 | 350.0 |
| | General Motors Company | 5/4/2020 | 476.1 |
| | Combat Medical Systems | 7/10/2020 | 62.5 |
| N95 Respirators | Honeywell Safety Products USA Inc. | 3/28/2020 | 168.5 |
| | Honeywell Safety Products USA Inc. | 4/20/2020 | 4.4 |
| | 3M Company | 3/26/2020 | 172.9 |
| | O&M Halyard, Inc. | 3/30/2020 | 62.3 |
| | Draeger, Inc. | 4/7/2020 | 31.2 |
| | Moldex-Metric, Inc. | 4/6/2020 | 49.9 |
| Air Purifying Respirator Kits | Honeywell Safety Products USA Inc. | 4/20/2020 | 26.5 |
| | Bio-Medical Devices International | 8/20/2020 | 110.0 |
| Goggles | Honeywell Safety Products USA Inc. | 4/20/2020 | 3.4 |
| Vaccine Supplies | Becton, Dickinson and Company | 5/27/2020 | 11.7 |
| | Marathon Medical Corp. | 5/1/2020 | 27.4 |
| | Retractable Technologies Inc. | 5/1/2020 | 83.8 |
| **Department of Homeland Security, Federal Emergency Management Agency** | | | |
| N95 Respirators | 3M Company | 4/15/2020 | 4.0 |
| | 3M Company | 4/21/2020 | 18.8 |
| | 3M Company | 4/28/2020 | 49.5 |
| | 3M Company | 7/7/2020 | 6.1 |
| | 3M Company | 7/24/2020 | 22.4 |
| | 3M Company | 8/29/2020 | 3.5 |

Source: Based on GAO analysis of agency data. | GAO-21-108

[a]Due to incomplete information, we were unable to verify all award dates.

[b]The contract award amount covers medical supplies and associated components or consumables that facilitate operation. The figure also represents the initial contract value. According to HHS officials, it modified two contracts to procure fewer ventilators, but did not provide us with updated ventilator contract value and quantity data.

**Table 5: The Departments of Defense and Health and Human Services Domestic Production Expansion Projects, Defense Production Act Title III and Similar Actions**

| Medical Supply | Contractor | Award Date[a] | Maximum Contract Value[b] (dollars in millions) | Annual Capacity Increase After Completion |
|---|---|---|---|---|
| **N95 Respirators** | | | | |
| | Moldex-Metric, Inc. | 5/8/2020 | 20.1 | 60,000,000 |
| | 3M Company | 5/1/2020 | 126.0 | 312,000,000 |
| | 3M Company | 4/17/2020 | 76.0 | 156,000,000 |
| | Honeywell Safety Products USA Inc. | 4/15/2020 | 27.3 | 144,000,000 |
| | O&M Halyard, Inc. | 4/15/2020 | 29.3 | 150,000,000 |
| **Surgical Masks** | | | | |
| | Crosstex International, Inc. | 7/17/2020 | 3.5 | 100,000,000 |
| **Filter Media for N95 Respirators and Ventilators** | | | | |
| | Lydall Performance Materials, Inc. | 6/19/2020 | 13.5 | 4,608,000,000 (Masks) or 1,200,000,000 (N95) |
| | National Packaging Services (NPS) Corp. | 7/24/2020 | 2.8 | 2,040,000,000 (Masks) or 720,000,000 (N95) |
| | Hollingsworth & Vose Company | 5/19/2020 | 1.9 | 330,000,000 (Ventilators) 38,000,000 (N95 Face Masks) |
| **Ventilator Components** | | | | |
| | Pall Biomedical Inc. | 7/21/2020 | 4.9 | 7,800,000 |
| **Gloves** | | | | |
| | Renco Corp. | 7/14/2020 | 22.4 | 500,000,000 |
| **Syringes** | | | | |
| | ApiJect Systems America, Inc. | 5/8/2020 | 138.0 | 540,000,000 |
| **Swabs** | | | | |
| | Hardwood Products Company LP and Puritan Medical Products | 7/29/2020 | 51.2 | 540,000,000 |
| | Hardwood Products Company LP and Puritan Medical Products | 4/28/2020 | 75.5 | 240,000,000 |
| | Copan Industries, Inc. | 8/31/2020 | 10.0 | 172,800,000 |
| **Test Kits** | | | | |
| | Hologic Inc. | 7/25/2020 | 7.6 | 24,000,000 |
| | Becton, Dickinson and Company | 7/30/2020 | 24.4 | 156,000,000 |
| | BioFire Defense, LLC. | 8/7/2020 | 3.1 | Information is not for public release |

Source: Based on GAO analysis of agency data. | GAO-21-108

[a]Due to incomplete information, we were unable to verify all award dates.

[b]Contract values in table represent the government's portion of total award.

# Appendix II: GAO Contact and Staff Acknowledgements

## GAO Contact

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## Staff Acknowledgements

In addition to the contact named above, Cheryl Andrew, Assistant Director; Sameena Ismailjee, Analyst-in-Charge; Christopher Allison; Philip Farah; Lori Fields; Kurt Gurka; Stephanie Gustafson; Julia Kennon; Tim Moss; and Megan Setser made key contributions to this report.

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