



December 2021

# COVID-19

## Agencies Are Taking Steps to Improve Future Use of Defense Production Act Authorities

Accessible Version



A Century of Non-Partisan Fact-Based Work

# GAO Highlights

Highlights of [GAO-22-105380](#), a report to congressional committees

## Why GAO Did This Study

COVID-19 put the U.S. health care system under severe strain, affecting federal agencies' ability to buy and maintain critical medical supplies to help treat patients and protect health care workers. The federal government's COVID-19 response included a significant use of DPA authorities, as well as other actions focused on expanding domestic production of medical supplies to help stabilize the medical supply chain. The CARES Act and other supplemental appropriations provided at least \$11 billion for DPA purchases and other actions related to COVID-19 or other public health emergencies through September 2025.

The CARES Act includes a provision for GAO to monitor funds provided for the COVID-19 pandemic. This report summarizes federal agencies' use of the DPA to respond to COVID-19 and industry perspectives, as well as implementation challenges and steps agencies have taken to address these challenges. This report summarizes information contained in reports issued in [June](#), [September](#), and [November](#) 2020, and [January](#), [March](#), [April](#) and [July](#) 2021, and provides data updates through September 2021.

## What GAO Recommends

In November 2020, GAO recommended that HHS identify how the DPA and other actions will be used to increase production of domestic medical supplies and reduce U.S. reliance on foreign sources. HHS agreed but has not yet determined what specific actions it will take.

View [GAO-22-105380](#). For more information, contact W. William Russell at (202) 512-4841 or [RussellW@gao.gov](mailto:RussellW@gao.gov)

December 2021




## COVID-19

### Agencies Are Taking Steps to Improve Future Use of Defense Production Act Authorities

## What GAO Found

Federal agencies used the Defense Production Act (DPA) and other actions over 100 times to help address COVID-19 medical supply needs through September 2021. Agencies used DPA authorities to 1) prioritize contracts so those orders can get preference over others, (2) fund projects to expand domestic production of supplies, and (3) enter into partnerships with private companies (see figure).

#### Defense Production Act and Other Actions, March 2020-September 2021

Defense Production Act Authorities	 Priority-rated contracts	 Domestic production expansion	 Public-private partnerships
<b>Number of actions</b>	73 contracts and orders	60 projects and other actions <sup>a</sup>	1 overarching agreement
<b>Examples of output</b>	<ul style="list-style-type: none"><li>Supported manufacturing of COVID-19 vaccines</li><li>Prioritized delivery of over 800 million N95 respirators</li></ul>	<ul style="list-style-type: none"><li>Increased production capacity of N95 respirators by over 50 million per month</li></ul>	<ul style="list-style-type: none"><li>Developed plan that helps coordinate distribution of personal protective equipment.</li></ul>

Source: GAO analysis of federal agency information. | GAO-22-105380

#### Text of Defense Production Act and Other Actions, March 2020-September 2021

Defense Production Act Authorities	Priority related contracts	Domestic production expansion	Public-private partnerships
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Examples of output	<ul style="list-style-type: none"><li>Supported manufacturing of COVID-19 vaccines</li><li>Prioritized delivery of over 800 million N95 respirators</li></ul>	<ul style="list-style-type: none"><li>Increased production capacity of N95 respirators by over 50 million per month</li></ul>	<ul style="list-style-type: none"><li>Developed plan that helps coordinate distribution of personal protective equipment.</li></ul>

<sup>a</sup>Other actions refer to production expansion projects not executed under DPA Title III authority.

Source: GAO analysis of federal agency information. | GAO-22-105380

Representatives from companies that received DPA awards generally stated that the use of the DPA gave them timely access to raw materials and supplies and helped them expand production faster than they could have on their own.

GAO previously reported that federal agencies faced challenges using DPA authorities. Agencies have taken some steps to address these obstacles as well as one of two recommendations GAO made.

- The Department of Health and Human Services (HHS), which had limited DPA experience prior to COVID-19, reported establishing offices to review DPA priority rating requests and to manage industrial base expansion efforts. However, it has not developed a plan for using DPA and other actions to address future medical supply needs as GAO recommended.
- The Department of Defense, which has been providing significant contracting support to HHS, documented procedures to facilitate the timely transfer of funds between the two agencies and established a permanent office in October 2020 to support interagency needs.
- The Office of Management and Budget established a web page to collect and publish data on DPA priority ratings, which addressed a prior GAO recommendation concerning transparent reporting of these DPA actions.

Additional DPA and other actions are expected through 2025 as agencies use \$10 billion appropriated in the American Rescue Plan Act for medical supply investments and implement a September 2021 national strategy to strengthen the domestic medical industrial base. GAO plans to monitor agencies' efforts.

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#### **Abbreviations**

COVID-19	Coronavirus Disease 2019
DOD	Department of Defense
DPA	Defense Production Act
FEMA	Federal Emergency Management Agency
HHS	Department of Health and Human Services
PPE	personal protective equipment
Stafford Act	Robert T. Stafford Disaster Relief and Emergency Assistance Act

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December 16, 2021

## Congressional Committees

The emergence of the Coronavirus Disease 2019 (COVID-19) pandemic put the U.S. health care system under severe strain. The federal government struggled to meet medical supply needs, in part, because the U.S. is dependent on foreign sources for some medical supplies, such as surgical gowns and nitrile gloves, and global demand for these items surged during the pandemic. In March 2020, within one month of the start of the pandemic, the Department of Health and Human Services (HHS) had distributed most of the personal protective equipment (PPE) supplies in the Strategic National Stockpile to states and other entities.<sup>1</sup>

Additionally, 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.

As early as March 2020, federal agencies began using authorities delegated under the Defense Production Act (DPA) of 1950 to address medical supply chain needs. According to federal agencies, the extent of use of the DPA in a medical context was unprecedented. Among other things, the authorities allow federal agencies to:

- place priority ratings on medical supply contracts so that agencies' orders can get preference over others, including those by private industry organizations;
- provide incentives or investments to private industry to expand domestic production of medical supplies and reduce foreign dependence; and
- enter into public-private agreements with industry to coordinate emergency responses.<sup>2</sup>

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<sup>1</sup>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.

<sup>2</sup>Pub. L. No. 81-774 (1950), codified at 50 U.S.C. App. §§ 4501 et seq., as amended.

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As of September 2021, Congress provided agencies at least \$11 billion in funding—through the July 2020 CARES Act and other supplemental legislation—for DPA purchases and other actions related to COVID-19 or future pandemics through fiscal year 2025.<sup>3</sup> For purposes of this report, other actions refers to industrial base expansion projects for medical supplies that have similar goals but were not executed under the DPA Title III authority.

The CARES Act includes a provision for GAO to conduct monitoring and oversight of the use of funds made available to prepare for, to respond to, and to recover from the COVID-19 pandemic.<sup>4</sup> We have issued nine products relating to COVID-19 oversight, listed in the Related GAO Products section, which include products with information on agencies' use of the DPA since March 2020. This report summarizes our key observations from those reports and provides updated data we collected since July 2021 related to (1) federal agencies' use of the DPA and other actions to respond to COVID-19 and industry perspectives and (2) steps agencies have taken to address DPA implementation challenges.

To describe federal agencies' use of the DPA and other actions to respond to COVID-19, we updated analyses from our prior work on DPA priority ratings, domestic production projects, and public-private agreements with industry to cover the time period from March 2020 through September 2021. We also summarized contractor perspectives that we previously collected through written responses from six vaccine manufacturers, and semi-structured interviews with representatives from six companies that were executing DPA Title I priority-rated contracts, a domestic production expansion project, or both. The companies we

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<sup>3</sup>The CARES Act provided the Department of Defense (DOD) \$1 billion specifically for DPA purchases to prevent, to prepare for, and to respond to COVID-19 domestically or internationally. Pub. L. No. 116-136, title III, division B (2020). DOD used approximately \$200 million for medical supplies, \$100 million for a loan program managed by the U.S. Development Finance Corporation, and the remainder to offset financial distress in the defense industrial base. The American Rescue Plan Act of 2021 appropriated \$10 billion to support the use of the DPA for medical supplies. Pub. L. No. 117-2, title III, § 3101 (2021). As of September 30, 2021, HHS also used approximately \$2.9 billion in funding from the following legislation for domestic production investments: Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123 (2020), and Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139 (2020).

<sup>4</sup>Pub. L. No. 116-136, § 19010 (2020).

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selected for this nongeneralizable sample varied in size, federal contracting experience, and the types of products they produced.

To determine steps agencies have taken to address DPA implementation challenges, we summarized information from our previous reports, interviewed agency officials and collected documentation related to efforts to address the challenges. We also assessed the status of two previous recommendations we made to agencies regarding the use of DPA authorities. More detailed information on our objectives, scope, and methodology for the nine products can be found in each of the reports cited in the Related GAO Products section.

We conducted the work on which this product is based 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.

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## Background

During the Korean War, Congress enacted the Defense Production Act of 1950 to ensure the availability of industrial resources to meet the Department of Defense's (DOD) needs. 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 human-caused events not amounting to an armed attack on the U.S. The definition of national defense in the DPA 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

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protection and restoration.<sup>5</sup> In 2018, Congress reauthorized the DPA through September 30, 2025.<sup>6</sup>

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

- **Title I: Priorities and Allocation Authority.** Title I 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. The President has delegated Title I authority to various agency heads, including at the Departments of 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.

In 2008, we found that some agencies did not have a system or regulations in place for the priorities and allocations authority.<sup>7</sup> We recommended that several civilian agencies develop and implement a system for using the priorities and allocations authority for each agency's respective area of expertise. Since then, each of these agencies 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

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<sup>5</sup>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. 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.

<sup>6</sup>Pub. L. No. 115-232, §1791 (2018).

<sup>7</sup>GAO, *Defense Production Act: Agencies Lack Policies and Guidance for Use of Key Authorities*, [GAO-08-854](#) (Washington, D.C.: June 26, 2008).

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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.** Title III authorizes the President to provide a variety of financial incentives—loans, loan guarantees, direct purchases, and purchase commitments—to companies 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 domestic suppliers associated with the capitalization and investments required to establish, expand, or preserve production capabilities.

Executive Order 13603, signed in 2012, delegated the authority to implement Title III actions to the Secretary of Defense and the head of each agency engaged in procurement for the national defense. It also designated the Secretary of Defense as the DPA Fund Manager for the government.<sup>8</sup> 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.

- **Title VII: General Provisions.** Title VII 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. Title VII also provides for investigative authority to collect information on the U.S. industrial base. For purposes of this report, we focused on the Title VII authority to enter into voluntary agreements for preparedness programs with industry representatives.

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<sup>8</sup>Exec. Order No. 13603, 77 Fed. Reg. 16651 (March 22, 2012).

Since March 2020, eight executive orders related to the DPA and COVID-19 medical supply chain issues have been issued, as shown in table 1.

**Table 1: Executive Orders Related to the Defense Production Act and Medical Supplies, March 2020-September 2021**

Executive order number	Date <sup>a</sup>	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 Coronavirus Disease 2019 (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 I and VII authorities are also provided. <sup>b</sup>
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
13987	January 2021	Establishes the position of COVID-19 Response Coordinator as a direct report to the President and establishes the position of deputy response coordinator
14001	January 2021	Requires immediate assessments of selected medical supplies and the ability of the domestic industrial base to produce these supplies; requires development of a strategy to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and biological threats by July 2021
14017	March 2021	Requires 100-day supply chain risk assessments for the public health and defense sectors, among others

Source: GAO analysis of presidential executive orders | GAO-22-105380

<sup>a</sup>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); Exec. Order No. 13944, 85 Fed. Reg. 49929 (Aug. 14, 2020); Exec. Order No. 13987, 86 Fed. Reg. 7019 (Jan. 25, 2021); Exec. Order 14001, 86 Fed. Reg. 7219 (Jan. 26, 2021); and Exec. Order 14017, 86 Fed. Reg. 11849 (Mar. 1, 2021).

<sup>b</sup>Title VII 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, among other things.

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## Federal Agencies Used DPA and Other Actions to Help Address COVID-19 Medical Supply and Vaccine Needs

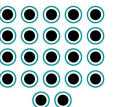















Federal agencies used DPA and other actions over 100 times to respond to COVID-19 and stabilize the medical supply chain through September 2021. Agencies used DPA Title I priority ratings to expedite the delivery of supplies to help replenish the U.S. Strategic National Stockpile and support vaccine development. Agencies also made investments with commercial companies using DPA Title III authority and through other actions to expand domestic production capacity for a range of medical supplies. Further, FEMA established a voluntary agreement using DPA Title VII authority to help the federal government coordinate with industry partners for the COVID-19 response and for potential future pandemics.

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### Types of Medical Supplies with Priority-Rated Contracts Shifted throughout the Pandemic

Federal agencies used priority ratings for medical supplies like N95 respirators and ventilators early in the pandemic response, then shifted to focus on COVID-19 vaccines, therapeutics, and diagnostics. As shown in figure 1, agencies placed 73 priority ratings on contracts and orders during the pandemic, as of September 2021. Most of these ratings were placed in 2020 when medical supply manufacturers were addressing PPE shortages, and other manufacturers were beginning to develop COVID-19 vaccines, therapeutics, and diagnostic supplies.

Figure 1: Defense Production Act Priority-Rating Actions by Supply Type, March 2020 – September 2021

Supply type	2020			2021			Total by Supply types
	Mar. - June	July - Sept.	Oct. - Dec.	Jan. - Mar.	Apr. - June	July - Sept.	
Medical supplies <sup>a</sup>			—	—	—	—	25
Vaccine supplies <sup>b</sup>						—	20
Vaccines and therapeutics <sup>c</sup>	—						17
Diagnostics <sup>d</sup>	—			—			11
Total by time period	25	18	15	5	6	4	73

● Number of priority-rated contracts

Source: GAO analysis of federal agency data. | GAO-22-105380

Data table for Figure 1: Defense Production Act Priority-Rating Actions by Supply Type, March 2020 – September 2021

Supply type	2020 Mar. – June	2020 July – Sept.	2020 Oct. – Dec.	2021 Jan. – Mar.	2021 Apr. – June	2021 July – Sept.	Total by supply types
Medical Supplies /a/	22	3	--	--	--	--	25
Vaccines Supplies /b/	3	6	3	4	4	--	20
Vaccines and therapeutics /c/	--	6	8	1	1	1	17
Diagnostics	--	3	4	--	1	3	11
Total by time period	25	18	15	5	6	4	73

Source: GAO analysis of federal agency data. | GAO-22-105380

<sup>a</sup>Medical supplies include N95 respirators, ventilators, air purifying respirators, and goggles.<sup>b</sup>Vaccine supplies include syringes, vials, manufacturing equipment, and other items necessary to support the production and delivery of Coronavirus Disease 2019 (COVID-19) vaccines.<sup>c</sup>Therapeutics being purchased include monoclonal antibodies, which are laboratory-made antibodies that may potentially be used to prevent or treat COVID-19 infection.<sup>d</sup>Diagnostics include COVID-19 diagnostics and expansion products related to ancillary supplies of diagnostics.

The majority of priority-rating actions through September 2020 were for medical supplies, such as N95 respirators and ventilators. For example, HHS and FEMA placed priority ratings on orders for over 800 million N95 respirators to support states and medical providers. HHS also placed priority ratings on contracts for ventilators and other medical supplies to help replenish the Strategic National Stockpile, which had exhausted its inventory of certain supplies early in the pandemic.

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Subsequently, agencies placed priority ratings on contracts relating to vaccines, therapeutics, and COVID-19 diagnostics. For example, agencies placed priority ratings on six vaccine manufacturing contracts and additional ratings for monoclonal antibody therapeutics, which are laboratory-made antibodies potentially used to prevent or treat COVID-19 infection.

According to most industry representatives we spoke with, these priority ratings helped manufacturers expedite the delivery of critical supplies and raw materials and helped support development of the vaccines. For example, one company representative said that demand increased significantly for meltblown material—a raw material for N95 respirators and ventilators—in the spring of 2020. The company was able to place priority-rated orders with its meltblown material manufacturer to ensure it could meet the contractual delivery date. Additionally, vaccine manufacturers told us that these priority ratings helped them maintain a steady flow of supplies. However, one COVID-19 vaccine manufacturer representative told us that priority ratings could constrain supplies for other lifesaving medicines, such as the seasonal flu vaccine.<sup>9</sup>

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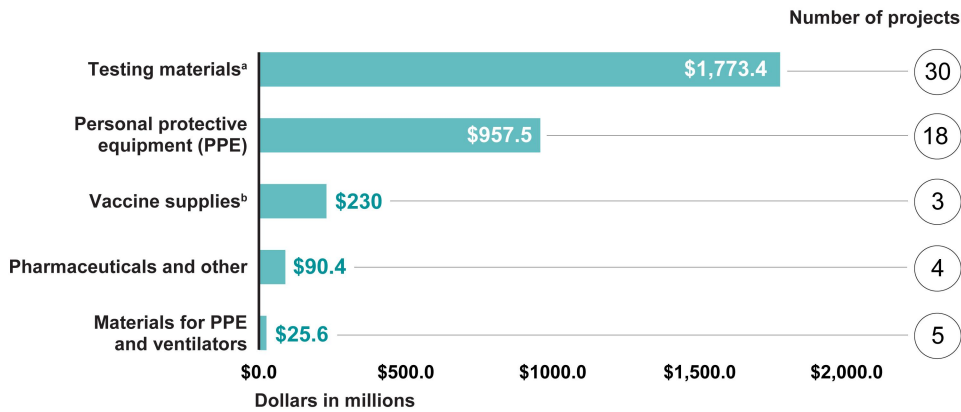
## Federal Investments Are Increasing Domestic Production of Medical Supplies

Federal agencies also invested in a range of projects to increase the domestic production of medical supplies needed to support the COVID-19 response, and, in some cases, to reduce U.S. reliance on foreign manufacturers. Specifically, between March 1, 2020, and September 30, 2021, DOD reported investing approximately \$3.1 billion in 60 domestic production expansion projects through DPA and other actions. Six of these were DPA projects with approximately \$200 million in award value. The remaining 54 projects were other actions with about \$2.9 billion in award value. The companies are using the funding, among other things, to procure additional equipment and materials as well as to optimize production at existing facilities. Figure 2 shows the number of projects by supply type and the associated dollar value.

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<sup>9</sup> GAO, *COVID-19: Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation*, [GAO-21-443](#) (Washington, D.C.: Apr. 14, 2021).

**Figure 2: Defense Production Act and Other Actions to Increase Domestic Medical Supply Production, March 2020–September 2021**



Source: GAO analysis of program information. | GAO-22-105380

**Data table for Figure 2: Defense Production Act and Other Actions to Increase Domestic Medical Supply Production, March 2020–September 2021**

Action	Amount in millions	Number of projects
Testing materials <sup>/a/</sup>	\$1,773.4	30
Personal protective equipment (PPE)	\$957.5	18
Vaccine supplies <sup>/b/</sup>	\$230	3
Pharmaceuticals and other	\$90.4	4
Materials for PPE and ventilators	\$25.6	5

Note: *Other actions* refers to industrial base expansion projects for medical supplies that have similar goals but were not executed under Defense Production Act Title III authority. Of the 60 projects listed above, six were DPA projects and the remaining 54 were other actions.

<sup>a</sup>Testing materials include Coronavirus Disease 2019 (COVID-19) tests, and ancillary materials, such as swabs or swabsticks used to perform tests.

<sup>b</sup>Vaccine supplies include syringes, vials, manufacturing equipment, and other items necessary to support the production and delivery of COVID-19 vaccines.

Source: GAO analysis of program information. | GAO-22-105380

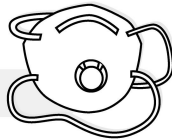
According to DOD, 19 projects have been completed as of September 2021. Projects are considered complete when the companies begin producing supplies at the agreed upon higher rate of production. Twenty-nine more projects are expected to be completed between October 2021 and September 2022, and the remaining 12 projects are expected to be completed by September 2024.

For some supplies, these projects expanded an existing domestic industrial base to meet surging demand during the pandemic. For

example, according to federal estimates prior to 2020, domestic N95 respirator manufacturers were able to meet a majority of U.S. demand, primarily from industrial sectors including construction and mining. Domestic manufacturers pivoted to producing N95 respirators for health care workers but needed additional investments through federal and private funding to further increase production. Other projects are aimed at further developing a domestic industrial base to help reduce reliance on foreign manufacturers, such as for nitrile gloves. Figure 3 describes investments made to increase the domestic production of N95 respirators and nitrile gloves.

**Figure 3: Domestic Production Expansion Projects for Selected Medical Supply Types, March 2020–September 2021**

#### N95 respirators



In March 2020 at the beginning of the pandemic, domestic manufacturers were unable to fully meet U.S. demand for N95 respirators. According to May 2021 federal agency data, four expansion projects increased production by over 50 million per month. These projects, and additional investments made by manufacturers, helped drive a six fold increase in the monthly domestic production of N95 respirators from approximately 46 million in March 2020 to 281 million. These projects generally included facility expansions or installation or upgrades to manufacturing equipment. As a result of this increase, domestic manufacturers developed enough capacity to meet and exceed the estimated U.S. demand by May 2021.

#### Nitrile gloves



The U.S. remained almost entirely reliant on foreign manufacturers for nitrile gloves. Between May and September 2021, federal agencies entered into ten projects for nitrile gloves and raw materials to help reduce this dependence and better prepare for future pandemics or other medical emergencies. These projects include construction of new production facilities and installation of additional manufacturing lines. These projects are expected to increase domestic production of nitrile gloves by approximately 1.5 billion per month by September 2024.

Source: GAO analysis of federal agency information. | GAO-22-105380

#### **Text of Figure 3: Domestic Production Expansion Projects for Selected Medical Supply Types, March 2020–September 2021**

##### **N95 respirators**

- In March 2020 at the beginning of the pandemic, domestic manufacturers were unable to fully meet U.S. demand for N95 respirators. According to May 2021 federal agency data, four expansion projects increased production by over 50 million per month. These projects, and additional investments made by manufacturers, helped drive a six fold increase in the monthly domestic production of N95 respirators from approximately 46 million in March 2020 to 281 million. These projects generally included facility expansions or installation or upgrades to manufacturing equipment. As a result of

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Source: GAO analysis of federal agency information. | GAO-22-105380

We previously reported in March 2021 that medical supply company representatives we interviewed generally stated that the DPA and other actions were useful in helping them expand domestic production. For example, representatives from five of the six companies we interviewed that received funding for domestic production expansion projects said the funding allowed their companies to expand production faster than they could have on their own. Representatives at three companies further stated that their companies would not have made the investments to expand production without receiving government funding.

Representatives from all six companies said that their companies experienced some minor issues navigating the federal government's procurement process, such as developing and submitting white papers to propose a project, negotiating the final terms and conditions of their contracts or agreements, and submitting invoices for payment. However, some representatives said that agency officials were helpful in answering questions. Agency officials also provided training and documents to help these companies through the priority rating process.

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## **FEMA Created Voluntary Communication Channels to Share Information and Coordinate Distribution of Medical Supplies with Industry**

FEMA established a voluntary agreement to enhance coordination and cooperation with private sector manufacturers, distributors, and other industry representatives using DPA Title VII authorities on August 17,

2020. According to FEMA officials, this agreement created communication channels with the private sector not present at the start of the pandemic. Officials said that FEMA now has an established list of industry contacts that the agency can communicate with to send requests for information or coordinate a pandemic response through 2025, the duration of the agreement. Additionally, agency officials said that FEMA is now familiar with how to create a Title VII agreement and could establish similar agreements more quickly in the future if needed.

FEMA established five working groups—PPE, medical devices, diagnostic test kits, drug products, and medical gases—to consider next steps for coordinating manufacturer and distributor efforts to respond to pandemics through 2025. Some of these working groups have concluded their activities.

- FEMA published a PPE plan on December 8, 2020. This plan allows federal agencies—including FEMA, HHS, and DOD—to gather data from private-sector representatives to inform the government’s demand estimates for PPE and to coordinate actions to distribute supplies, among other things. According to FEMA officials, the PPE working group then held a series of meetings through spring 2021 to develop findings and recommendations and shared these with other federal agencies.
- FEMA officials stated that the medical devices, diagnostic test kit, and drug products working groups held meetings between June and August 2021 to discuss requirements for these items. Officials said these working groups did not identify any issues requiring continued meetings at this time.
- According to FEMA officials, the medical gases working group is focusing its efforts on medical oxygen based on its preliminary discussions. Officials also stated that, as of September 2021, the group plans to hold meetings through fall 2021 and develop recommendations and an implementation plan for executing the recommendations.

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## Agencies Are Taking Some Actions to Address Challenges They Experienced When Using DPA Authorities

HHS, FEMA, and DOD identified challenges while executing DPA authorities, including gaps in DPA expertise and administrative obstacles to interagency support. Agency officials stated that they have taken some steps to address these and other challenges as well as one of two previous GAO recommendations. Agencies are also working on plans to further mitigate medical supply chain risks, such as using \$10 billion from the American Rescue Plan Act to expand and sustain the industrial base for testing and diagnostics, vaccines, and PPE.

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### HHS and FEMA Are Addressing DPA Expertise Gaps

The severity of the pandemic and the surge in demand for medical supplies surpassed HHS's capacity to respond quickly to COVID-19 in early 2020, including using DPA authorities to address medical supply needs. For example, in September and November 2020, we reported that HHS officials said the department's contracting workforce had limited experience with and training on how to use DPA authorities. Since March 2020, HHS has relied on DOD organizations for contracting support to execute DPA domestic production expansion projects for key medical supplies like N95 respirators.

According to HHS officials, the agency has taken some initial steps to address its DPA expertise and staffing challenges. For example, an HHS official told us that a DPA office was created within the Office of the Assistant Secretary for Preparedness and Response in June 2020. This office is expected to be responsible for managing and centralizing all department-related DPA activities. HHS officials also said an industrial base expansion program office was created in September 2020. This office is expected to manage requirements for medical supply domestic production expansion projects. As of September 30, 2021, HHS had not provided us with information about the staffing for these organizations.

Senior DOD and HHS officials signed a memorandum of understanding in May 2021 to establish a framework whereby the agencies will identify a path to enhance HHS's own capabilities while incrementally reducing DOD's support. This memorandum is in effect through September 2023. According to agency officials, progress on implementing this

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memorandum has been delayed due to the resurgence of COVID-19 cases, among other reasons. The two agencies were supposed to develop a 90 day transition plan by August 2021. However, as of October 2021, this plan had not been completed.

FEMA also identified gaps in its DPA expertise. In a January 2021 self-assessment of its COVID-19 response, the agency identified lack of trained, permanent personnel with expertise to address technical supply chain issues as a major operational gap.<sup>10</sup> Specifically, it noted that the FEMA DPA Program Office consisted of four full-time employees. The team was given 26 additional federal employees from DOD, HHS, and FEMA during the COVID-19 response, but only some were familiar with DPA authorities and many required DPA training. FEMA's assessment recommended taking steps to support the DPA office in times of need, such as developing a plan to recruit and train staff and formalizing an interagency process to allow staff with DPA expertise from other federal agencies to support FEMA.

As of October 2021, FEMA officials stated that 10 FEMA employees have been identified to offer surge support to the DPA office in a future emergency. FEMA has also started discussions with other federal agencies to establish memoranda of agreement for interagency staffing support.

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## DOD Improved Its Ability to Provide Interagency Support

Based upon its experience early in the pandemic, DOD took two actions to improve the manner in which it supports other federal agencies during COVID-19 and potential future crises.

- First, in June 2020, the Under Secretary of Defense for Acquisition and Sustainment testified that DOD had difficulty facilitating the timely transfer of funding from other agencies to DOD for execution.<sup>11</sup> This included the transfer of funds from HHS to DOD to award other actions for medical supply domestic production expansion projects.

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<sup>10</sup> Federal Emergency Management Agency, Pandemic Response to Coronavirus Disease 2019 (COVID-19) Initial Assessment Report (January 2021).

<sup>11</sup> House Committee on Armed Services. "Department of Defense COVID-19 Response to Industrial Base Challenges." Wednesday, June 10, 2020. This transfer of funding was generally made through orders under the Economy Act. 31 U.S.C. § 1535.

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To address this challenge, the Under Secretary of Defense for Acquisition and Sustainment stated in June 2020 that DOD and HHS had assessed the interworking of the Economy Act and how to legally assist each other in acquisition and distribution of funds. DOD formally documented the interagency process for transferring and executing funds in a handbook, which was last updated in October 2021.

- Second, as other federal agencies turned to DOD for assistance at the start of the pandemic, DOD recognized that it needed to centralize its contracting support for the COVID-19 response. DOD initially established the Joint Acquisition Task Force to be the single point of entry to the DOD acquisition enterprise, in support of FEMA's and HHS's COVID-19 response efforts.

On October 13, 2020, DOD replaced the Joint Acquisition Task Force with a permanent office, the Defense Assisted Acquisition Cell, to provide policy, guidance, and oversight for current and future DOD support to interagency partners. The office is located within the Under Secretary of Defense for Acquisition and Sustainment's Joint Rapid Acquisition Cell and will continue to serve as the single entry point for urgent interagency requests for DOD assisted acquisition.

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## Agencies Are Considering the Effects of Priority Ratings on Supply Chains

Federal agencies recognized the importance of maintaining awareness of the effect of priority ratings on suppliers and took action to enhance coordination to avoid supply chain disruptions. We previously reported one example of a potential supply chain disruption related to priority ratings. An HHS official told us that priority ratings were placed on multiple ventilator and N95 respirator contracts. Ventilators and N95 respirators share a common raw material—meltblown fabric, which was in short supply early in the pandemic—and the official said more than 10 companies with priority ratings were trying to obtain this material at the same time. To avoid material shortages, HHS officials worked with the ventilator and N95 companies to identify alternative suppliers and methods for producing meltblown fabric.

To address this problem, an HHS official stated that HHS, DOD, FEMA, the Department of Commerce, and other agencies began meeting in the spring of 2020 to discuss the potential effects of priority ratings on supply chains. HHS's DPA Program Office also developed a template to help

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employees assess the potential effect of priority rating requests, such as the impact to other contracts or suppliers.

According to HHS and FEMA officials, agencies are still meeting to discuss the potential effect of priority ratings on medical and nonmedical supply chains. For example, FEMA officials stated that agencies discussed the effect that placing priority ratings on liquid oxygen contracts for hospitals' use might have on municipality water treatment sites or military and other space launch sites that also use this product. HHS officials also said that federal agencies met several times to ensure that medical and firefighting communities had access to resin, which is used in products such as syringes and firehoses. HHS officials stated that resin production has been severely limited due to hurricanes and ice storms over the last year in Texas and Louisiana, a region where most domestic resin production occurs.

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### Agencies Are Taking Actions to Improve Reporting on Their Use of DPA Priority Ratings

In November 2020 we found that agencies did not comprehensively and consistently identify DPA priority ratings in the Federal Procurement Data System.<sup>12</sup> There was no existing data field to allow agencies to indicate priority ratings electronically within the data system. Further, federal agencies were not required to identify priority ratings. Without identifying priority ratings in a single source, agencies were missing an opportunity to promote transparency of federal actions and provide quality information to support government-wide analysis of the efficacy of use of the DPA. Therefore, we recommended that the Office of Management and Budget direct the Office of Federal Procurement Policy to issue guidance to federal agencies to identify DPA priority ratings. In response, in July 2021, the Office of Federal Procurement Policy created a page in its MAX Information System, an Office of Management and Budget government-

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<sup>12</sup>[GAO-21-108](#). The Federal Procurement Data System is a comprehensive, web-based tool for agencies to report contract actions. It is a searchable database of contract information that provides a capability to examine data across government agencies and provides managers a mechanism for determining where contract dollars are spent.

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wide collaboration site, to collect information on past and future COVID-related DPA Title I awards.<sup>13</sup>

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## Options to Further Mitigate Medical Supply Chain Risks Using DPA Authorities Are Being Considered

Moving forward, the federal government is evaluating what actions it will take with regard to domestic production of medical supplies, including the use of DPA authorities. For example, in March 2021, the American Rescue Plan Act appropriated \$10 billion to support the use of the DPA for medical supplies.<sup>14</sup>

HHS officials provided us with some details of how they plan to use over \$6 billion of this funding through fiscal year 2022:

- **Vaccine supplies and materials.** Approximately \$3.4 billion is targeted for projects to expand production of vials, syringes, and other consumables and raw materials.
- **PPE capacity and raw materials.** Nearly \$1.4 billion is targeted for projects related to expanding or sustaining production of gloves, gowns, and respiratory protection items.
- **Testing capacity and raw materials.** Over \$1 billion is targeted for projects to expand production of testing consumables, such as tips and swabs, as well as at-home test kits, and other items.
- **Platform technology and commercialization.** \$100 million is targeted for the distributed production of drug substances and drug products, biofabrication of key starting materials, and distributed production of supportive care fluids.

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<sup>13</sup>The Office of Management and Budget uses the MAX Information System to collect, validate, analyze, model, collaborate with agencies on, and publish information relating to its government-wide management and budgeting activities. For example, one of the end products of the MAX system is the Budget of the United States Government, also known as the President's Budget.

<sup>14</sup> The American Rescue Plan Act provided \$10 billion to carry out titles I, III, and VII of the DPA. These amounts must generally "be used for the purchase, production (including the construction, repair, and retrofitting of government-owned or private facilities as necessary), or distribution of medical supplies and equipment (including durable medical equipment) related to combating the COVID-19 pandemic." Pub. L. No. 117-2, tit. III, § 3101, (2021).

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- **Program management and acquisition support.** \$225 million is targeted for use by HHS to hire more personnel, enhance its technical and supply chain analysis capabilities, and reimburse other agencies for acquisition support.

Agency officials are coordinating with White House officials to define a spend plan for the remaining funding through fiscal year 2025.

Additionally, in September 2021, federal agencies published a strategy in response to Executive Order 14001, which considers how to design, build, and sustain a medical domestic production capability.<sup>15</sup> This strategy states that the domestic medical supply chain remains vulnerable to future pandemics without transformational, long-term investment, and reaffirms that a robust medical supply chain is critical to national security. The strategy includes several recommendations to build resilience into the medical supply chain so that the U.S. can be responsive to a variety of possible disruptions, including two recommendations that specifically mention DPA authorities.

- One recommendation calls for significant, sustained federal investments in domestic medical supply manufacturing over the next 10 years, beyond funding already appropriated to respond to COVID-19. As part of this recommendation, the strategy states that HHS should determine the appropriate financial incentives, including the use of DPA authorities for industrial base expansion.
- Another recommendation states that HHS's Office of the Assistant Secretary for Preparedness and Response and the Food and Drug Administration should establish regular meetings with government agencies and industry to identify problems that may delay providing support in response to future public health emergencies and should develop solutions to these problems. The recommendation further states that DPA Title VII processes should complement other coordination efforts with private industry to capture as many voluntary

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<sup>15</sup> Departments of Defense, Health and Human Services, Homeland Security, Commerce, State, and Veterans Affairs. *National Strategy for a Resilient Public Health Supply Chain* (Washington, D.C.: Sept. 3, 2021); *A Sustainable Public Health Supply Chain*, Exec. Order No. 14001, § 4, 86 Fed. Reg. 7219, 7220-21 (Jan. 21, 2021).

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private industry participants as possible and to avoid duplication in effort.<sup>16</sup>

In response to these two recommendations, HHS officials stated that they are currently working to develop a policy for DPA use that will strengthen America's supply chains and domestic manufacturing. At this time, there is no estimate or timeframe for the release of a strategy.

In November 2020, we made a similar recommendation that, as part of federal efforts to reduce U.S. dependence on foreign manufacturers of medical supplies, HHS should identify how the DPA and other actions will be used to increase domestic production of medical supplies in the future. HHS concurred with the recommendation and is working with the White House and other agencies to determine how the remaining \$4 billion in American Rescue Plan funding will be used to expand or sustain the medical industrial base. However, HHS has not yet determined how it will use DPA authorities as part of its efforts to implement our recommendation. We will continue to monitor HHS's implementation efforts.

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## Agency Comments

We provided a draft of this report to DOD, FEMA, and HHS for comment. Each agency provided technical comments that we incorporated in the report, as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services; the Secretary of Homeland Security; and the Secretary of Defense. In addition, the report is available at no charge on the GAO website at <https://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](mailto:russellw@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on

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<sup>16</sup> One such coordination effort is the Critical Infrastructure Partnership Advisory Council, which facilitates relationships between government agencies and representatives from critical infrastructure owners and operators to discuss and support critical infrastructure security and resilience efforts. There are 16 sectors covered under the council, including a Health care and Public Health sector which is managed by HHS.

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the last page of this report. GAO staff who made key contributions to this report are listed in appendix I.

A handwritten signature in black ink, reading "W. William Russell". The signature is fluid and cursive, with a stylized "W" and "R".

W. William Russell  
Director, Contracting and National Security Acquisitions

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## Appendix I: GAO Contact and Staff Acknowledgments

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### GAO Contact

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### Staff Acknowledgments

In addition to the contact named above, Cheryl Andrew, Assistant Director; Daniel Glickstein, Analyst in Charge; Matthew Crosby, Lori Fields; Kurt Gurka; Stephanie Gustafson; and Julia Kennon made key contributions to this report. Other staff who made key contributions to the products cited in this report are identified in the source products, which are listed in the Related GAO Products section.

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## Related GAO Products

*COVID-19: Additional Actions Needed to Improve Accountability and Program Effectiveness of Federal Response.* [GAO-22-105051](#). Washington, D.C.: October 27, 2021.

*COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity.* [GAO-21-551](#). Washington, D.C.: July 19, 2021.

*COVID-19: Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation.* [GAO-21-443](#). Washington, D.C.: April 14, 2021.

*COVID-19: Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year.* [GAO-21-387](#). Washington, D.C.: March 31, 2021.

*COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention.* [GAO-21-265](#). Washington, D.C.: January 28, 2021.

*COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response.* [GAO-21-191](#). Washington, D.C.: November 30, 2020.

*Defense Production Act: Opportunities Exist to Increase Transparency and Identify Future Actions to Mitigate Medical Supply Chain Issues.* [GAO-21-108](#). Washington, D.C.: November 19, 2020.

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

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

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