
July 2021

COVID-19 CONTRACTING

Actions Needed to Enhance Transparency and Oversight of Selected Awards

GAO@100 Highlights

Highlights of [GAO-21-501](#), a report to congressional committees

Why GAO Did This Study

In March 2020, Congress passed the CARES Act as part of the federal response to COVID-19. The act had certain provisions for federal contracting, including providing additional flexibilities. Contracting plays a critical role in the pandemic response as agencies obligate billions of dollars for goods and services.

The act also included a provision for GAO to review federal contracting in response to COVID-19. This report examines, among other objectives, the extent to which the Departments of Defense, Health and Human Services, and Homeland Security—the only agencies that reported using other transaction agreements in response to COVID-19 in the federal procurement database—used such agreements, including awards to consortia, and oversight of such use.

GAO analyzed federal procurement data as of March 2021; reviewed a nongeneralizable sample of 15 agreements selected based on high dollar amounts, agency, a mix of products and services, among other criteria; reviewed agency policies; and interviewed agency officials.

What GAO Recommends

GAO is making 14 recommendations to selected agencies, to improve the transparency of agreement awards in the federal procurement database and update policies to improve the oversight of agreements awarded through consortium management firms. The agencies agreed with 11 of the recommendations and did not agree with three of them. GAO continues to believe the recommendations are valid, as discussed in the report.

View [GAO-21-501](#). For more information, contact Marie A. Mak at (202) 512-4841 or makm@gao.gov.

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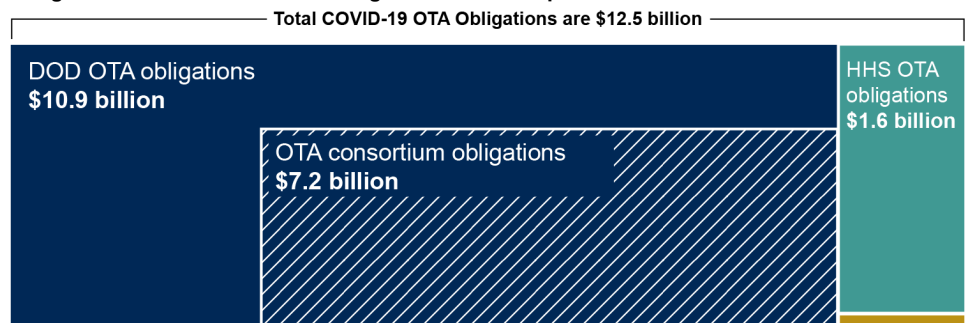
Actions Needed to Enhance Transparency and Oversight of Selected Awards

What GAO Found

In response to COVID-19, as of March 2021, the Departments of Defense, Health and Human Services, and Homeland Security obligated at least \$12.5 billion using a contracting mechanism that gave them the flexibility to quickly respond to urgent pandemic needs. This mechanism—known as an other transaction agreement—is not subject to certain federal contract laws and requirements but allowed the agencies to customize the agreements. Agencies cited the timeliness of awards as a major factor for using these agreements, including awards that accelerated COVID-19 vaccine manufacturing.

The Department of Defense used this mechanism to award \$7.2 billion to consortium members—organizations and federal contractors organized around a specific topic area—through one consortium management firm (see figure).

Obligations on Other Transaction Agreements in Response to COVID-19 as of March 2021



DHS = Department of Homeland Security
DOD = Department of Defense
FPDS-NG = Federal Procurement Data System-Next Generation
HHS = Department of Health and Human Services
OTA = Other transaction agreement

Source: GAO analysis of FPDS-NG data and information from DOD, HHS, and DHS. | GAO-21-501

GAO's analysis found two challenges with how the agencies tracked these agreements due to limitations with the federal procurement database. First, the three agencies did not properly identify at least \$1.6 billion of the \$12.5 billion as COVID-19-related agreements. Second, the Department of Defense reported that one consortium management firm received \$7.2 billion in agreements, as noted above. In actuality, the management firm distributed nearly all of the awarded dollars to five pharmaceutical companies, with each receiving \$450 million to \$2 billion. The database is the only way for Congress and the public to track these obligations, but transparency is limited without accurate reporting.

Also, two agencies' policies on other transaction agreements did not address the requirement for enhanced oversight of certain activities that consortium management firms may perform, potentially posing risks to the government. According to Office of Federal Procurement Policy guidance, these types of activities require enhanced oversight because they can closely support tasks fundamental to the public interest, such as the award of contracts. By not addressing such oversight in their policies, agencies may not fully consider the range of actions they should take to mitigate risks of inappropriate influence for government decisions.

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Abbreviations

ASPR	Office of the Assistant Secretary for Preparedness and Response
ATI	Advanced Technology International
COVID-19	Coronavirus Disease 2019
DHS	Department of Homeland Security
DOD	Department of Defense
GSA	General Services Administration
FAR	Federal Acquisition Regulation
FPDS-NG	Federal Procurement Data System-Next Generation
HHS	Department of Health and Human Services
OTA	other transaction agreement

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July 26, 2021

Congressional Committees

The Coronavirus Disease 2019 (COVID-19) pandemic has resulted in catastrophic loss of life and substantial damage to the global economy. In the U.S., there have been over 33 million reported cases and over 595,000 reported deaths due to COVID-19 as of July 2, 2021.¹ The country also continues to experience serious economic repercussions. Among other actions in response to this unprecedented global crisis, in March 2020, Congress passed, and the President signed into law, the CARES Act, which provided over \$2 trillion in emergency assistance and health care response for individuals, families, and businesses affected by COVID-19. The CARES Act also provided supplemental appropriations for federal agencies to respond to COVID-19 and included a number of provisions related to federal contracting efforts to facilitate agencies' responses to the pandemic. Federal contracting continues to play a critical role in the response to COVID-19. Agencies have obligated nearly \$69 billion as of March 2021 through a variety of contracting mechanisms to acquire vital goods and services.

One type of contracting mechanism, called other transaction agreements (OTA), has played a significant role in the response to COVID-19. Unlike procurement contracts, OTAs are not subject to federal acquisition regulations. The CARES Act removed certain requirements related to the use of OTAs for the Department of Health and Human Services (HHS) and the Department of Defense (DOD), such as requirements related to congressional reporting and who can approve certain OTAs.² The CARES Act also relaxed certain limitations on DOD's use of undefinitized contracts—a procurement contract mechanism that is subject to federal

¹Data on COVID-19 cases are based on aggregate case reporting to the Centers for Disease Control and Prevention and include probable and confirmed cases as reported by states and jurisdictions. The Centers for Disease Control and Prevention's National Center for Health Statistics COVID-19 death counts in the U.S. are based on provisional counts from death certificate data, which do not distinguish between laboratory-confirmed and probable COVID-19 deaths.

²Pub. L. No. 116-136, §§ 3301, 13006, 134 Stat. at 383, 522.

and DOD acquisition regulations and allows contractors to begin work before all terms and conditions are finalized.³

The CARES Act includes a provision for GAO to conduct a comprehensive audit and review of federal contracting pursuant to authorities provided in the act.⁴ This report is one in a series of reports in response to that provision.⁵ This report examines the extent to which: (1) selected agencies used OTAs in response to COVID-19 and what factors contributed to their use, (2) these COVID-19 OTAs were awarded to consortia and how agencies provided oversight, and (3) selected agencies used and managed undefinitized contracts in response to COVID-19.

To identify the extent to which selected agencies used OTAs in response to COVID-19, we identified all the agencies that reported obligating dollars through OTAs in response to COVID-19 in the Federal

³Pub. L. No. 116-136, § 13005, 134 Stat. at 522. See also Defense Federal Acquisition Regulation Supplement subpt. 217.74.

⁴Pub. L. No. 116-136, § 19010. The CARES Act also requires GAO to, among other things, conduct monitoring and oversight of the exercise of authorities, or the receipt, disbursement, and use of funds made available by law to prepare for, respond to, and recover from the pandemic. We regularly issue government-wide reports on the federal response to COVID-19. For the latest report, see GAO, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, [GAO-21-551](#) (Washington, D.C.: July 19, 2021). Our next government-wide report will be issued in October 2021 and will be available on GAO's website at <https://www.gao.gov/coronavirus>.

⁵For COVID-19 contracting reports, see GAO, *VA COVID-19 Procurements: Pandemic Underscores Urgent Need to Modernize Supply Chain*, [GAO-21-280](#) (Washington, D.C.: June 15, 2021); *COVID-19: Efforts to Increase Vaccine Availability and Perspectives on Initial Implementation*, [GAO-21-443](#) (Washington, D.C.: Apr. 14, 2021); *Defense Production Act: Opportunities Exist to Increase Transparency and Identify Future Actions to Mitigate Medical Supply Chain Issues*, [GAO-21-108](#) (Washington, D.C.: Nov. 19, 2020); *COVID-19 Contracting: Observations on Contractor Paid Leave Reimbursement Guidance and Use*, [GAO-20-662](#) (Washington, D.C.: Sept. 3, 2020); and *COVID-19 Contracting: Observations on Federal Contracting in Response to the Pandemic*, [GAO-20-632](#) (Washington, D.C.: July 29, 2020). We plan to issue future products focused on contractor paid leave reimbursement and agencies' assessment of prospective vendors and contracting lessons learned in response to the pandemic.

Procurement Database System-Next Generation (FPDS-NG), as of March 14, 2021.⁶ These agencies were:

- DOD;⁷
- HHS—specifically, the Office of the Assistant Secretary for Preparedness and Response (ASPR), which includes the Biomedical Advanced Research and Development Authority;⁸ and
- Department of Homeland Security (DHS)—specifically, the Countering Weapons of Mass Destruction Office and the Transportation Security Administration.

We analyzed the FPDS-NG data to identify the types of goods or services procured by DOD, HHS, and DHS using OTAs. We assessed the reliability of the FPDS-NG data by comparing them to OTA documentation and agency-provided data and by performing electronic testing, among other steps, and found the agencies did not accurately report all COVID-19 OTA obligations, which we discuss in the report. We identified additional COVID-19 OTA obligations through agency-provided data and documents. After we corrected the FPDS-NG OTA data for the inaccuracies and underreporting, we determined the data were sufficiently reliable for the purposes of describing agencies' reported OTA obligations in response to COVID-19. We also interviewed officials from the General Services Administration (GSA), which administers FPDS-NG, including the OTA module.

To identify the factors that contributed to DOD, HHS, and DHS using OTAs in selected cases, we selected a nongeneralizable sample of 15 OTAs awarded between February 2020 and October 2020. Our

⁶FPDS-NG is a comprehensive, web-based tool for agencies to report procurement contract actions and is the authoritative source for procurement award data, including dollars obligated on contract actions. It also includes a module for reporting OTAs. In June 2021, FPDS-NG was renamed to FPDS. For the purposes of this report, we refer to the system as FPDS-NG.

⁷While DOD has authority to use OTAs for research, prototyping, and production purposes, this report is focused on OTAs used to support DOD's prototyping and production efforts.

⁸The National Institutes of Health—a part of HHS—did not report awarding any OTAs in response to COVID-19 in FPDS-NG as of March 14, 2021. In May 2021, officials from the National Institutes of Health informed us they had obligated about \$520 million on COVID-19 OTAs as of April 26, 2021. We did not assess the reliability of these data and did not include the \$520 million in our analysis.

selections were based on the highest dollars obligated, representation of all three contracting agencies, and a mix of product or service acquired, among other criteria. When we selected our sample of OTAs in October 2020, the obligations on all COVID-19 OTAs across DOD, HHS, and DHS were 30 percent of total obligations for these three agencies. We selected all seven vaccine OTAs awarded by DOD and HHS, which comprised \$8.9 billion in obligations. We also selected eight nonvaccine OTAs awarded by DOD, HHS, and DHS, which accounted for an additional \$1.2 billion in obligations. Combined, these 15 OTAs accounted for 81 percent of all obligations on COVID-19 OTAs as of March 14, 2021. For these selected cases, we analyzed OTA documents, such as written determinations for OTA use, and interviewed agreements officers—federal employees with the authority to bind the government by signing an OTA—and program officials. As part of our analysis, we determined the extent to which these OTAs used available CARES Act flexibilities. In addition, we reviewed agencies' OTA policies and guidance and interviewed contracting policy officials at DOD, HHS, and DHS.

To identify the extent to which DOD, HHS, and DHS awarded OTAs to consortia in response to COVID-19, we analyzed the same data available in the OTA module of FPDS-NG discussed above by vendor. We supplemented this analysis with reviews of publicly available information and OTA documents. Of the 15 OTA cases we reviewed, six were awarded to consortia by DOD. To determine how DOD provided oversight for these six OTAs, we analyzed OTA documents and interviewed agreements officers and program officials. We reviewed DOD, HHS, and DHS policies related to OTAs awarded to consortia and these agencies' reports to congressional committees regarding OTA use. We also interviewed officials from Advanced Technology International (ATI), the consortium management firm that received the majority of COVID-19 OTA obligations according to FPDS-NG data.

To identify the extent to which DOD, HHS, and DHS used undefinitized contracts in response to COVID-19, we analyzed data available in the procurement contract module of FPDS-NG as of March 14, 2021. For the purposes of our data analysis, undefinitized contract obligations are associated with contract actions identified in FPDS-NG as undefinitized, which includes letter contracts. DOD, HHS, and DHS accounted for 96 percent of all COVID-19-related undefinitized contract obligations reported across the federal government over the time frame of our

review.⁹ We analyzed the FPDS-NG data to identify the types of goods or services procured by DOD, HHS, and DHS using undefinitized contracts. We assessed the reliability of the FPDS-NG data by comparing them to contract documentation and agency-provided data and performing electronic testing, among other steps, and determined that they were sufficiently reliable for the purposes of describing agencies' reported undefinitized obligations in response to COVID-19.

To identify how DOD, HHS, and DHS managed selected undefinitized contracts, we selected a nongeneralizable sample of three undefinitized contracts awarded between February 2020 and October 2020. Our selections were based on the highest dollars obligated, representation of the contracting agencies with the majority of undefinitized contract obligations (DOD and HHS), and a mix of product or service acquired, among other criteria. When we selected our sample of undefinitized contracts, the obligations on all COVID-19 undefinitized contracts across the three agencies were 6 percent of their total obligations during this time frame. The three undefinitized contracts we selected were awarded by DOD and HHS and had combined obligations of \$509 million, or about 10 percent of all COVID-19 undefinitized contract obligations. For these selected cases, we analyzed contract documents, such as written determinations and award documents, and interviewed contracting officers and program officials. As part of our analysis, we determined the extent to which DOD used available CARES Act flexibilities for its undefinitized contracts. In addition, we reviewed federal acquisition regulations, agencies' federal acquisition regulation supplements, and agency policies and guidance related to undefinitized contracts. We also interviewed contracting policy officials at DOD, HHS, and DHS.

For additional information on our objectives, scope, and methodology, see appendix I.

We conducted this performance audit from August 2020 to July 2021 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

⁹On April 12, 2021, in response to our review, HHS corrected information for an undefinitized contract we reviewed by revising nine actions from being incorrectly identified as undefinitized to correctly identified as definitized. We updated our March 14, 2021 data analysis, which resulted in a reduction of HHS undefinitized contract obligations by \$120 million.

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

Background

Every agency has inherent authority to award procurement contracts—contracts subject to the Federal Acquisition Regulation (FAR)—to procure goods or services for its own use. However, agencies must receive specific authority through legislation to award OTAs, which are not subject to the FAR. Undefined contracts are procurement contracts subject to the FAR but have certain requirements related to their use.

Overview of Other Transaction Agreements

OTAs are not required to include terms and conditions that are typically required when using procurement contracts subject to the FAR. They enable agencies and companies to start with a “blank sheet of paper” to negotiate contractual terms and conditions specific to the OTA. This flexibility can help agencies address concerns from nontraditional contractors—entities that do not typically do business with the federal government such as start-up companies—about requirements that apply to federal procurement contracts. These concerns can include establishing a government-unique cost accounting system or losing intellectual property rights, among others.¹⁰ Our prior work found that OTAs with nontraditional companies have been used for research, prototyping, and production of new technologies or products.¹¹ We also found, however, risks with the use of OTAs regarding reduced accountability and transparency, in part, because they are exempt from

¹⁰GAO, *Military Acquisitions: DOD Is Taking Steps to Address Challenges Faced by Certain Companies*, [GAO-17-644](#) (Washington, D.C.: July 20, 2017).

¹¹GAO, *Army Modernization: Army Should Improve Use of Alternative Agreements and Approaches by Enhancing Oversight and Communication of Lessons Learned*, [GAO-21-8](#) (Washington, D.C.: Oct. 1, 2020); *Defense Acquisitions: DOD’s Use of Other Transactions for Prototype Projects Has Increased*, [GAO-20-84](#) (Washington, D.C.: Nov. 22, 2019); and *Federal Acquisitions: Use of ‘Other Transaction’ Agreements Limited and Mostly for Research and Development Activities*, [GAO-16-209](#) (Washington, D.C.: Jan. 7, 2016).

the FAR and related oversight mechanisms that apply to procurement contracts.¹²

Congress provided the agencies in our review the authority to use OTAs, and each authority is unique to the agency:

- **DOD.** DOD generally has department-wide authority to award OTAs for research, prototyping, and production purposes. Specifically, DOD can use OTAs to carry out certain prototype projects, including those that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by DOD. DOD may not enter into a prototype OTA unless at least one of four conditions is met. The conditions are related to participation by a nontraditional defense contractor, nonprofit research institution or small business participation; cost sharing; or senior procurement executive approval.¹³ Congress did not define a prototype project in statute, but DOD's November 2018 OTA guide defined a prototype project as addressing certain needs, such as a proof of concept, model, and novel application of commercial technologies for defense purposes. DOD can also award follow-on production OTAs—without using competitive procedures—to the participants of a competitively awarded prototype OTA, provided several conditions are met, such as successful completion of the prototype.¹⁴

¹²GAO, *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention*, [GAO-21-265](#) (Washington, D.C.: Jan. 28, 2021); *Transportation Security Administration: After Oversight Lapses, Compliance with Policy Governing Special Authority Has Been Strengthened*, [GAO-18-172](#) (Washington, D.C.: Dec. 21, 2017); *Department of Homeland Security: Further Action Needed to Improve Management of Special Acquisition Authority*, [GAO-12-557](#) (Washington, D.C.: May 8, 2012); and *Department of Homeland Security: Improvements Could Further Enhance Ability to Acquire Innovative Technologies Using Other Transaction Authority*, [GAO-08-1088](#) (Washington, D.C.: Sept. 23, 2008).

¹³National Defense Authorization Act for Fiscal Year 2016, Pub. L. No. 114-92, § 815 (2015), codified at 10 U.S.C. § 2371b. For purposes of DOD OTAs, a nontraditional defense contractor is an entity that is not performing on any DOD contract or subcontract that is subject to full coverage under the cost accounting standards prescribed by certain statutes and regulations, and has not performed on such a contract or subcontract for at least 1 year before DOD's solicitation for the OTA. 10 U.S.C. § 2302(9). The OTA authorities for HHS, the Transportation Security Administration, and DHS's Countering Weapons of Mass Destruction Office did not include statutory definitions of nontraditional contractors.

¹⁴10 U.S.C. § 2371b(f).

Further, DOD agreements officers can award certain higher-dollar prototype OTAs if senior DOD contracting officials approve the OTAs in writing.¹⁵ For example, for most DOD entities, OTAs expected to cost more than \$100 million but not more than \$500 million may only be carried out if the senior procurement executive makes a written determination that certain statutory requirements will be met and that use of OTA authority is essential to promoting the success of the prototype project.¹⁶ OTAs expected to cost more than \$500 million may only be carried out if the Under Secretary of Defense for Research and Engineering or the Under Secretary of Defense for Acquisition and Sustainment makes a written determination that certain statutory requirements will be met and that the use of OTA authority is essential to meet critical national security objectives. DOD must also notify the congressional defense committees in writing of any OTAs expected to cost more than \$500 million at least 30 days before the OTA authority is exercised.

- **HHS.** Two of HHS's components have authority to award OTAs: ASPR, which leads the nation's response to public health emergencies and includes the Biomedical Advanced Research and Development Authority, and the National Institutes of Health, which is composed of 27 institutes and centers, each with a specific agenda.¹⁷ ASPR's OTA authority supports advanced research and development for medical countermeasures, such as vaccines and therapeutics.¹⁸ Several programs and types of projects within the National Institutes of Health have OTA authority, such as a program focused on researching heart, lung, and blood diseases.¹⁹

ASPR's agreements officers can award OTAs expected to cost more than \$100 million if the HHS Assistant Secretary for Financial

¹⁵10 U.S.C. § 2371b(a)(2).

¹⁶In the case of the Defense Advanced Research Projects Agency or the Missile Defense Agency, the agency director must make the written determination.

¹⁷To fulfill its mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability, the National Institutes of Health funds research related to life processes and many diseases and conditions.

¹⁸42 U.S.C. § 247d-7e(c)(5)(A).

¹⁹42 U.S.C. § 285b-3; Consolidated and Further Continuing Appropriations Act, 2015, Pub. L No. 113-235, div. G, title II, § 213,128 Stat. 2487 (2014); 42 U.S.C. § 284n; and 42 U.S.C. § 287a.

Resources makes a written determination that use of such authority is essential to promoting the success of the project.²⁰

- **DHS.** Two of DHS's components each have unique, unrestricted authorities to award OTAs to carry out their missions: the Countering Weapons of Mass Destruction Office and the Transportation Security Administration.²¹ DHS also awards OTAs for research and prototyping efforts across the department.

The CARES Act removed certain requirements related to the use of OTAs for DOD and HHS ASPR in response to COVID-19, which we refer to as CARES Act flexibilities for the purposes of our report.²² These flexibilities allow for delegation of OTA award approval to lower-level contracting officials and changes to congressional notification requirements. Specifically, for DOD:

- Senior procurement executives can delegate approval of written determinations to other officials for prototype OTAs expected to cost more than \$100 million but not more than \$500 million.
- The Under Secretary of Defense for Research and Engineering and the Under Secretary of Defense for Acquisition and Sustainment can delegate approval of written determinations to other officials for prototype OTAs expected to cost more than \$500 million.
- DOD can notify the congressional defense committees in writing of prototype OTAs expected to cost more than \$500 million as soon as practicable after the OTA is awarded instead of at least 30 days before the OTA authority is exercised.

Additionally, during a public health emergency, ASPR can award advanced research and development OTAs expected to cost more than \$100 million without a written determination from the HHS Assistant Secretary for Financial Resources. The CARES Act did not provide HHS's National Institutes of Health or DHS with additional OTA flexibilities.

²⁰42 U.S.C. § 247d-7e(c)(5)(A)(ii).

²¹6 U.S.C. § 596 and 49 U.S.C. § 114(m).

²²Pub. L. No. 116-136, §§ 3301, 13006, 134 Stat. at 383, 522.

DOD and DHS have established policies requiring the reporting of certain OTAs into FPDS-NG, in part to help address certain statutory reporting requirements.²³ DHS, for example, established policies requiring reporting of research and prototype and Transportation Security Administration OTAs to FPDS-NG.²⁴ Transportation Security Administration officials stated that they report OTAs to FPDS-NG to also assist with understanding the workload involved in awarding and administering OTAs. HHS ASPR reports its use of OTAs to FPDS-NG while the National Institutes of Health does not.

Overview of Undefined Contracts

To help meet urgent needs, agencies can use undefined contracts to authorize contractors to begin work and incur costs before reaching final agreement on contract terms and conditions.²⁵ Before these contracts are finalized, they are called undefined. In contrast, a defined contract is one in which all terms and conditions, including price, are agreed to by the parties to the contract at the time of contract award. We previously found that undefined contracts may be risky for the government.²⁶ In particular, the government may incur unnecessary costs if requirements change before the contract is defined.

²³The Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 required certain improvements to FPDS-NG, including the collection of data on certain OTAs. Pub. L. No. 110-417, § 874 (2008). DOD does not report its use of research OTAs to FPDS-NG. Instead, DOD requires their use to be reported to the Defense Assistance Awards Data System, a system used to track assistance awards, including grants.

²⁴According to DHS officials, DHS requires research and prototype OTAs (issued pursuant to 6 U.S.C. § 391) to be reported in FPDS-NG in accordance with section 874 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009. DHS does not require Countering Weapons of Mass Destruction OTAs (issued pursuant to 6 U.S.C. § 596) to be entered into FPDS-NG but still enters these OTAs into FPDS-NG.

²⁵For the purposes of our report, we define undefined contracts to include letter contracts (a preliminary contract that authorizes the contractor to begin work immediately) pursuant to FAR § 16.603. In addition, we define undefined contracts to include what DOD refers to as “undefined contract actions,” which includes any contract action for which the contract terms, specifications, or price are not agreed upon before performance has begun under the action. These actions include letters contracts, undefined task or delivery orders issued against a pre-established umbrella contract, and undefined modifications for additional supplies or services to an existing contract. Defense Federal Acquisition Regulation Supplement subpt. 217.74.

²⁶GAO, *Defense Contracting: DOD Has Enhanced Insight into Undefined Contract Action Use, but Management at Local Commands Needs Improvement*, [GAO-10-299](#) (Washington, D.C.: Jan. 28, 2010).

To help minimize these risks:

- The FAR generally requires letter contracts—a type of undefinitized contract—to include a schedule that provides for definitization within 180 days of the contract award or before completion of 40 percent of the work to be performed, whichever occurs first.²⁷ HHS and DHS are subject to the undefinitized contract requirements in the FAR as well as agency-specific acquisition regulations and policies.
- Additionally, DOD may only enter an undefinitized contract if it requires definitization of the contractual terms, specifications, and price within 180 days of the contractor submitting a qualifying proposal—a proposal that contains sufficient information to enable DOD to conduct meaningful analyses and audits—or before more than 50 percent of the estimated contract price is obligated, whichever occurs first.²⁸

The CARES Act allows DOD to waive time frames to definitize undefinitized contracts and to waive limitations on the amounts that can be obligated before the undefinitized contract is definitized, which we refer to as CARES Act flexibilities for the purposes of our report.²⁹ The CARES Act did not provide HHS or DHS with additional flexibilities for undefinitized contracts.

²⁷FAR § 16.603. For the purposes of our report, we refer to letter contracts as undefinitized contracts.

²⁸For the purposes of our report, we refer to the negotiated overall ceiling price and not-to-exceed price in DOD's undefinitized contracts, as well as the proposed estimated cost in HHS's undefinitized contracts, as the estimated contract price. For DOD, if a contractor submits a qualifying proposal to definitize the undefinitized contract before 50 percent of the not-to-exceed price is obligated, the limitation on obligations can be increased to 75 percent of the estimated contract price. 10 U.S.C. § 2326(b) and Defense Federal Acquisition Regulation Supplement subpt. 217.74. See also HHS Acquisition Policy, Guidance and Instructions § 316.603-70.

²⁹Pub. L. No. 116-136, § 13005, 134 Stat. at 522.

Agencies Obligated At Least \$12.5 Billion on OTAs to Quickly Respond to COVID-19 but Did Not Accurately Report All Awards

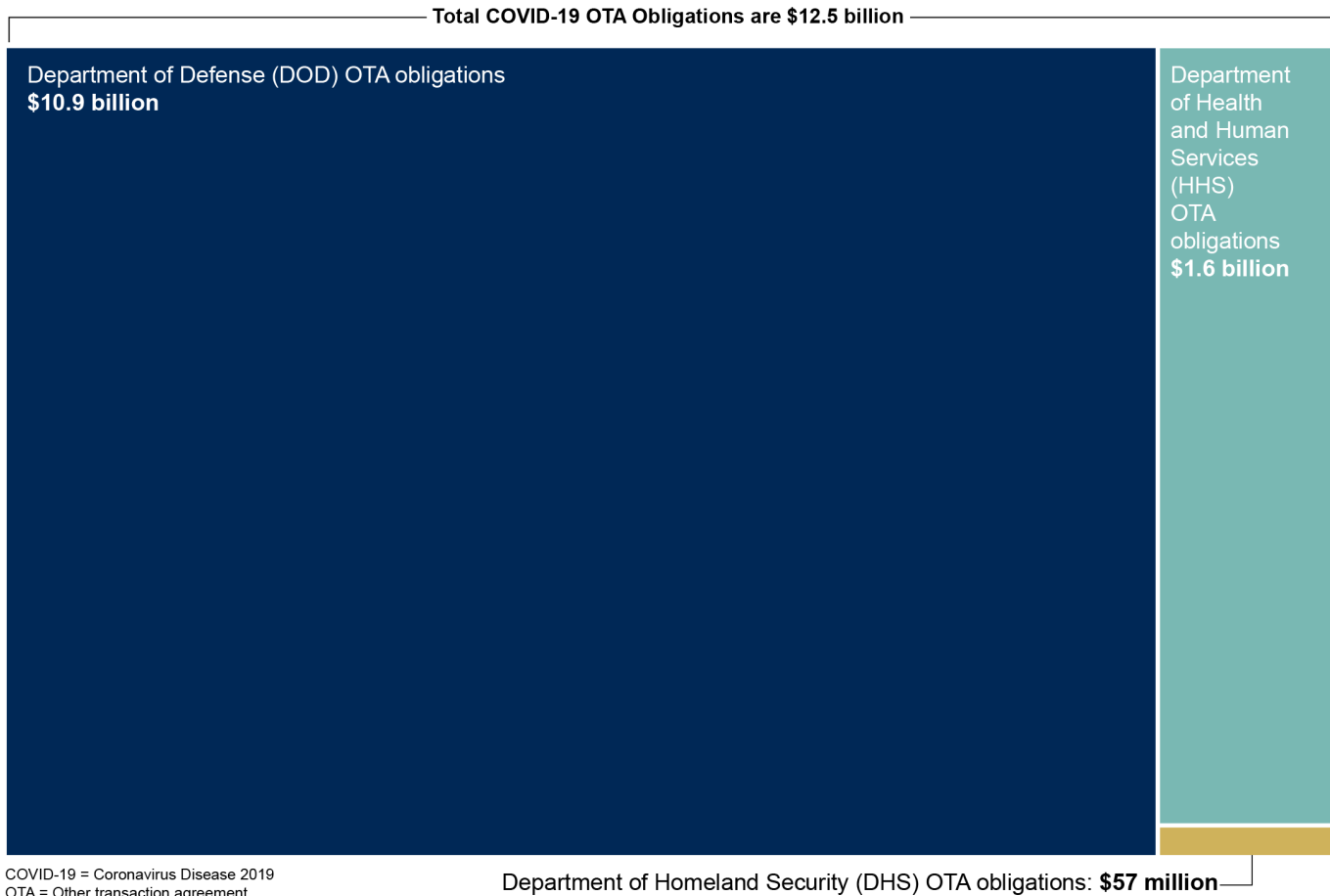
DOD, HHS, and DHS obligated at least \$12.5 billion on COVID-19-related OTAs from March 2020 through March 2021, primarily to help accelerate vaccine development and manufacturing. However, of that \$12.5 billion, at least \$1.6 billion was underreported because HHS misreported its OTAs as procurement contracts, while DOD and DHS did not accurately identify certain OTAs as COVID-19-related. In addition, agency officials cited timeliness of award as the main factor contributing to OTA use but also noted that the OTA required less administrative work and facilitated engagement with nontraditional contractors.

Agencies Made Significant Use of OTAs for Vaccine Development and Manufacturing

Our analysis of FPDS-NG and agency-provided data found that DOD, HHS, and DHS obligated at least \$12.5 billion on OTAs in response to COVID-19 as of March 2021 (see fig. 1).³⁰

³⁰Prior to March 2020, DHS awarded OTAs in response to COVID-19. These OTAs accounted for \$8 million in obligations or 0.07 percent of all COVID-19 OTA obligations and are included in our analysis.

Figure 1: DOD, HHS, and DHS Other Transaction Agreement Obligations in Response to Coronavirus Disease 2019 as of March 14, 2021



COVID-19 = Coronavirus Disease 2019
 OTA = Other transaction agreement

Source: GAO analysis of Federal Procurement Data System-Next Generation (FPDS-NG) data and information from DOD, HHS, and DHS. | GAO-21-501

Note: We corrected the FPDS-NG data by adding \$1.6 billion in obligations the agencies did not accurately report as COVID-19 OTAs. Our analysis did not include data that are not reported in FPDS-NG because we did not assess the reliability of these data.

These three agencies' obligations on OTAs for COVID-19 have been significant when compared with both of their OTA obligations in prior years and their COVID-19 procurement contract obligations. For example:

- **OTA obligations in prior years.** Obligations reported on OTAs across the three agencies increased from \$2.4 billion in fiscal year

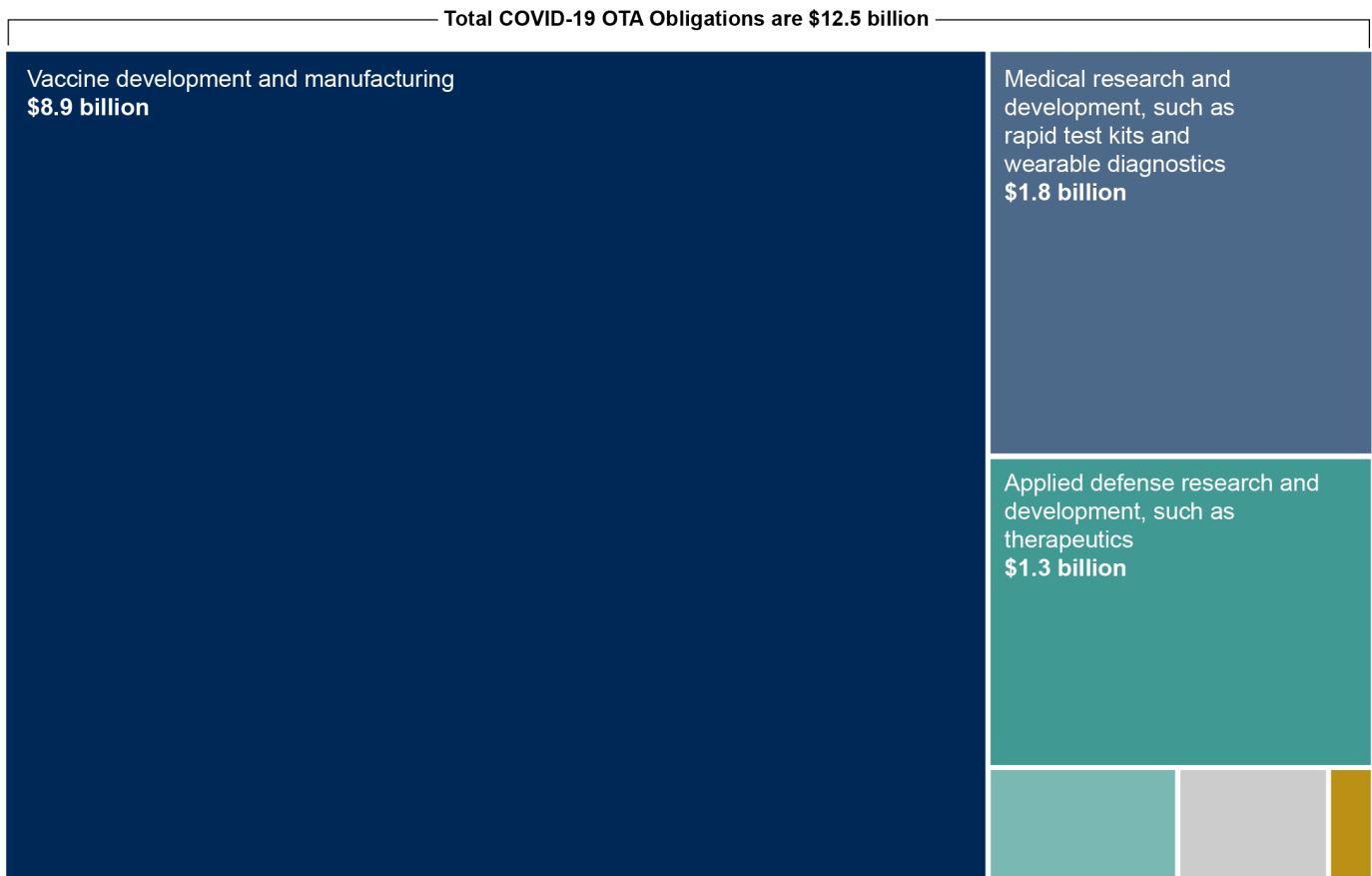
2017 to \$7.8 billion in fiscal year 2019.³¹ In comparison, from March 2020 to March 2021, their OTA obligations were \$12.5 billion for the COVID-19 response alone.

- **OTA obligations as a proportion of total obligations.** The three agencies have obligated \$54.7 billion in response to COVID-19 using both OTAs and procurement contracts. The \$12.5 billion those agencies have obligated on OTAs for COVID-19 represents about 23 percent of the total obligations. In comparison, in fiscal year 2019, prior to the COVID-19 pandemic, their OTA obligations accounted for 2 percent of total obligations.

Of the \$12.5 billion obligated on COVID-19 OTAs, \$8.9 billion or 71 percent was for vaccine development—including clinical trials—and manufacturing efforts. The remaining \$3.6 billion was for medical research and development and other nonvaccine products and services (see fig. 2).

³¹Our fiscal year 2017 through 2019 analysis generally did not include data that are not reported in the FPDS-NG OTA module, such as OTA obligations from the National Institutes of Health, because we did not assess the reliability of these data. However, we supplemented our analysis of FPDS-NG data by including data on OTA obligations provided by HHS ASPR.

Figure 2: Top COVID-19 Products and Services Acquired by DOD, HHS, and DHS Using OTAs as of March 14, 2021



COVID-19 = Coronavirus Disease 2019
 DHS = Department of Homeland Security
 DOD = Department of Defense
 FPDS-NG = Federal Procurement Data System-Next Generation
 HHS = Department of Health and Human Services
 OTA = Other transaction agreement

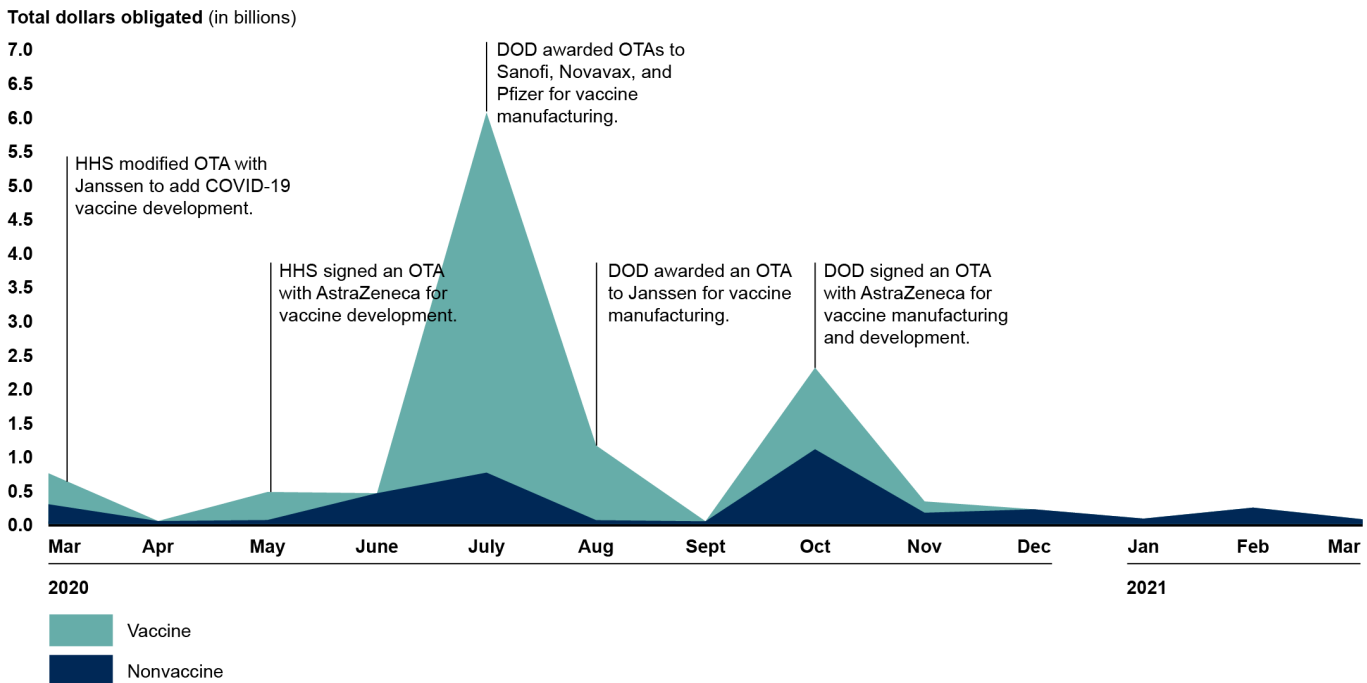
Diagnostic substances and test kits: **\$232 million**
 All other products and services, including airport screening: **\$184 million**
 Drugs and biologicals: **\$51 million**

Source: GAO analysis of FPDS-NG data and information from DOD, HHS, and DHS. | GAO-21-501

Note: We corrected the FPDS-NG data by adding \$1.6 billion in obligations the agencies did not accurately report as COVID-19 OTAs. Our analysis did not include data that are not reported in FPDS-NG because we did not assess the reliability of these data.

Most of the COVID-19 OTA dollars were obligated in July 2020 and driven by vaccine awards. From November 2020 through March 2021, OTA obligations were comparatively not as significant as earlier in the pandemic, in part because additional vaccine doses were acquired using procurement contracts instead of OTAs (see fig. 3).

Figure 3: Coronavirus Disease 2019 (COVID-19) OTA Obligations by Vaccine and Nonvaccine Awards from March 2020 through March 2021



Source: GAO analysis of Federal Procurement Data System-Next Generation (FPDS-NG) data and information from Department of Defense (DOD), Department of Health and Human Services (HHS), and Department of Homeland Security. | GAO-21-501

Note: We corrected the FPDS-NG data by adding \$1.6 billion in obligations the agencies did not accurately report as COVID-19 other transaction agreements (OTA). Our analysis did not include data that are not reported in FPDS-NG because we did not assess the reliability of these data.

Agencies Did Not Accurately Reflect All Dollars Obligated on COVID-19 OTAs

HHS, DOD, and DHS reported obligating \$10.9 billion on COVID-19 OTAs in FPDS-NG. However, our analysis of FPDS-NG and agency-provided data, as well as OTA documentation, found these three agencies actually obligated at least \$12.5 billion on COVID-19 OTAs—a \$1.6 billion difference. In addition to this \$1.6 billion, HHS’s National Institutes of Health officials told us they obligated about \$520 million on COVID-19 OTAs, which were not reported in FPDS-NG.

HHS ASPR was responsible for a majority of the inaccurate reporting of COVID-19 OTA dollars. We previously found in January 2021 that HHS ASPR misreported its COVID-19 OTAs as procurement contracts because it reports OTAs into the procurement module of FPDS-NG.³²

³²GAO-21-265.

Based on our analysis of FPDS-NG data as of March 14, 2021, ASPR continues to misreport these OTAs, which have about \$1.55 billion in obligations. ASPR's approach of reporting OTAs in the procurement module is inconsistent with the FAR. Agencies can only report OTAs in FPDS-NG under certain conditions, such as if the OTAs can be segregated from procurement contract actions and written approval from the FPDS program office is obtained.³³ For example, DOD and DHS report certain OTAs in a separate OTA module of FPDS-NG.³⁴

Furthermore, ASPR's approach does not provide a way for FPDS-NG users to systematically identify which actions are OTAs. FPDS-NG reflects overreporting of ASPR's COVID-19 procurement contracts by \$1.55 billion and no dollars obligated on ASPR's COVID-19 OTAs in the OTA module. In January 2021, we recommended that ASPR should accurately report data in FPDS-NG and provide information that would allow the public to distinguish between spending on OTAs and procurement contracts.³⁵ ASPR concurred with our recommendation. As of April 2021, ASPR officials stated that they have discussed within ASPR the need to consistently identify OTAs in FPDS-NG and explored how their contract writing system may interface with the FPDS-NG OTA module in the future. ASPR officials added that, in the meantime, they have identified OTAs in the procurement module by manually adding designators such as "OTA" or "other transaction agreement" into the description of requirement data field. We will continue to monitor ASPR's efforts to implement our recommendation.

Separately, DOD and DHS reported their COVID-19 OTAs in the FPDS-NG OTA module but did not accurately identify certain OTAs and associated dollars as COVID-19-related. Specifically:

- In November 2020, DOD obligated \$52.5 million on the Pfizer vaccine OTA but did not identify these dollars as COVID-19-related.
- From February 2020 through September 2020, DHS's Countering Weapons of Mass Destruction Office obligated \$25.5 million on two OTAs for COVID-19 screening at airports and ports of entry but did

³³FAR § 4.601; 4.603(b); and 4.606(a).

³⁴As noted earlier, DOD and DHS are generally not required by statute or regulation to report OTAs into FPDS-NG but have established policies requiring such reporting for certain OTAs.

³⁵[GAO-21-265](#).

not identify these OTAs as COVID-19-related.

Additionally, the National Institutes of Health did not report awarding any OTAs in response to COVID-19 in FPDS-NG, as it is not required to do so by statute or policy. In May 2021, National Institutes of Health officials told us they obligated about \$520 million on COVID-19 OTAs as of April 2021.³⁶ Officials told us that while they do not report their use of OTAs to FPDS-NG, they plan to report these OTAs to the Tracking Accountability in Government Grants System—a database used by HHS to track grant awards—starting in summer 2021. Officials stated that such reporting will allow the National Institutes of Health to submit its OTA data to USAspending.gov—a public-facing website that tracks federal spending on procurement and assistance awards. According to officials, the National Institutes of Health has not included information on OTAs in USAspending.gov in the past.

Transparency in federal spending is desired by policymakers and the public. For example, the Federal Funding Accountability and Transparency Act of 2006—which established USAspending.gov—and the Digital Accountability and Transparency Act of 2014 require agencies to disclose spending data on certain federal awards, including contracts and grants.³⁷ While an agency official—in response to public inquiries on the availability of OTA data on USAspending.gov—noted that the acts are not applicable to OTAs, the Digital Accountability and Transparency Act of 2014 aims to establish government-wide data standards to provide consistent, reliable, and searchable spending data that are displayed accurately for taxpayers and policymakers. Additionally, federal internal control standards state that an agency’s management should design information systems and externally communicate quality information to achieve objectives and address related risks.³⁸

DOD, DHS, and HHS currently do not use a systematic approach to consistently and accurately track OTAs awarded in response to COVID-

³⁶We did not assess the reliability of the data provided by the National Institutes of Health or include them in our analysis.

³⁷Pub. L. No. 113-101, 128 Stat. 1146 (May 9, 2014). The Digital Accountability and Transparency Act of 2014 amended the Federal Funding Accountability and Transparency Act of 2006. Pub. L. No. 109-282, 120 Stat. 1186 (Sept. 26, 2006), codified at 31 U.S.C. § 6101 note.

³⁸GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

19 or other national interest events and the associated dollars obligated. Based on our March 2021 analysis, only DOD and DHS reported their COVID-19 OTAs to the FPDS-NG OTA module—a government data system available for agencies to report OTA actions and associated obligations. As noted earlier, while HHS ASPR reported its COVID-19 OTAs to FPDS-NG, it continues to misreport them in the procurement module.

Even if agencies consistently required that their OTA awards be reported to the FPDS-NG OTA module, the module does not have a systematic way for agencies to identify an OTA as COVID-19-related. The procurement contract module of FPDS-NG, in contrast, includes a National Interest Action data field that allows tracking of COVID-19 contracts. According to Office of Management and Budget guidance, National Interest Action codes are used in the procurement module to consistently collect data on contract actions related to emergency or contingency responses or other nationally significant events.³⁹ Examples of past national interest events tracked by these codes include Hurricanes Katrina, Harvey, Irma, Florence and Michael; Operation Enduring Freedom; and the 2014 Ebola outbreak in West Africa.

In March 2020, GSA added a National Interest Action code to track acquisition costs of federal agencies involved in the response to COVID-19.⁴⁰ The Office of Management and Budget later broadened the application of this code, noting that the use of such codes contributes to transparency in tracking of COVID-19-related procurement actions in FPDS-NG.⁴¹ As noted earlier, HHS ASPR continues to misreport its OTAs in the procurement module of FPDS-NG. Because the National Interest Action code data field is available in the procurement module, FPDS-NG users are able to identify which HHS ASPR OTAs are COVID-19-related

³⁹Office of Management and Budget, Office of Federal Procurement Policy, *Memorandum for Chief Acquisition Officers, Senior Procurement Executives: Emergency Acquisitions Guide* (Washington, D.C.: Jan. 14, 2011).

⁴⁰Office of Management and Budget, *Memorandum to the Heads of Executive Departments and Agencies: Managing Federal Contract Performance Issues Associated with the Novel Coronavirus (COVID-19)*, M-20-18 (Washington, D.C.: Mar. 20, 2020).

⁴¹Office of Management and Budget, *Memorandum for the Heads of Departments and Agencies: Implementation Guidance for Supplemental Funding Provided in Response to the Coronavirus Disease 2019 (COVID-19)*, M-20-21 (Washington, D.C.: Apr. 10, 2020).

using this code if ASPR identifies the awards as OTAs in the description of requirement field.

GSA administers the Integrated Award Environment, a government-wide initiative that includes a suite of federal award data systems, including FPDS-NG and its OTA module.⁴² According to the Integrated Award Environment's governing charter, the initiative's mission includes simplifying, unifying, and streamlining the federal award process for government agencies, which it achieves through changes to a portfolio of government-wide online systems. The initiative has a change control board, which includes 24 voting members from agencies identified in the Chief Financial Officer Act—including DOD, DHS, HHS, and GSA. Any revisions to FPDS-NG must be approved by a majority of the agencies that are voting members.

According to GSA officials, as of April 2021, no agency requested to add the National Interest Action data element to the OTA module. GSA officials explained that not all of the agencies use the OTA module. However, because updates to the FPDS-NG system and other Integrated Award Environment systems are collectively funded by all 24 agencies, each agency has a vote in how the funding is spent and what system changes are prioritized. GSA is currently leading an effort to modernize the Integrated Award Environment systems, including FPDS-NG, which may offer an alternative system and process for reporting on OTAs. However, GSA officials did not have time frames for when the new system will be implemented.

Adding a National Interest Action data field to the OTA module is one option for tracking OTAs used for national emergencies such as the pandemic response. Without this or another systematic approach, policy makers and the public will continue to lack insight into the extent to which agencies are using OTAs to respond to national emergencies.

Additionally, due to a lack of a systematic way to identify national interest events for OTA awards, agencies take different approaches over how and whether they distinguish COVID-19 OTAs from other OTAs. In March 2020, DOD issued guidance informing contracting personnel that the OTA

⁴²The Integrated Award Environment is a GSA-managed presidential e-government initiative established in 2002.

module does not have a National Interest Action data field and instructed them to enter “COVID-19” in the description of requirement data field.⁴³

DHS, however, does not have guidance on how COVID-19 OTAs should be specifically identified in the OTA module. While DHS’s March 2020 National Interest Action code guidance emphasizes the importance of all DHS-related FPDS-NG actions being promptly and correctly coded as COVID-19 for congressional oversight, it does not include information on how OTAs should be specifically coded.⁴⁴ Without such guidance, public users of FPDS-NG will not have an accurate understanding of the extent to which DHS used OTAs in response to COVID-19.

Timeliness among Top Factors Cited for OTA Use in Response to COVID-19

DOD and HHS Used OTAs to Help Expedite Large Vaccine Awards

DOD and HHS officials cited the timeliness of awards as one of the main factors for using OTAs for COVID-19 vaccine development and manufacturing. Vaccine development efforts included clinical trials that evaluated the product’s safety, efficacy, proposed doses, schedule of immunizations, and methods of delivery in volunteers. Vaccine manufacturing efforts included large-scale production of hundreds of millions of doses that met the Food and Drug Administration’s regulatory standards for ensuring pharmaceutical quality. According to OTA justification documents and DOD officials, OTAs offered streamlined competitive processes for evaluation and selection of awardees. Seven OTAs awarded by either HHS or DOD accounted for all \$8.9 billion in OTA obligations on vaccine development and manufacturing (see table 1).

⁴³Department of Defense, Office of the Under Secretary of Defense for Acquisition and Sustainment, *Reporting COVID-19 Related Actions to the Federal Procurement Data System* (Washington, D.C.: Mar. 31, 2020).

⁴⁴Department of Homeland Security, Chief Procurement Officer, *Increasing Thresholds for Procurements Supporting Coronavirus (COVID-19) Response and Recovery* (Washington, D.C.: Mar. 17, 2020).

Table 1: Dollars Obligated on OTAs Awarded by DOD and HHS for COVID-19 Vaccine Development and Manufacturing by Manufacturer as of March 14, 2021

Contracting agency	Vaccine manufacturer (effort)	Total dollars obligated (\$)
HHS ASPR	Janssen (development and clinical studies)	1.1 billion
DOD Army	Janssen (manufacturing)	1.0 billion
HHS ASPR	AstraZeneca (development)	0.126 billion
DOD Army	AstraZeneca (manufacturing)	1.2 billion
DOD Army	Sanofi (manufacturing)	1.8 billion
DOD Army	Novavax (manufacturing)	1.6 billion
DOD Army	Pfizer (manufacturing)	2.03 billion
Total		8.9 billion

ASPR - Office of the Assistant Secretary for Preparedness and Response
 COVID-19 - Coronavirus Disease 2019
 DOD - Department of Defense
 FPDS - NG - Federal Procurement Data System-Next Generation
 HHS - Department of Health and Human Services
 OTA - Other transaction agreement

Source: GAO analysis of FPDS-NG data and information from DOD and HHS. | GAO-21-501

Note: We corrected the FPDS-NG data by adding \$1.3 billion in obligations the agencies did not accurately report as COVID-19 OTAs. Our analysis did not include data that are not reported in FPDS-NG because we did not assess the reliability of these data.

More broadly, OTAs have played a significant role in the joint effort between DOD and HHS to expedite the acquisition and development of COVID-19 vaccine candidates—previously known as the Operation Warp Speed effort.⁴⁵ For example, the seven vaccine OTAs we reviewed accounted for 43 percent of the \$20.5 billion obligated by DOD and HHS on vaccine development and manufacturing as of March 14, 2021.⁴⁶

The award times for the COVID-19 vaccine OTAs were generally shorter than award times for OTAs and procurement contracts we reviewed in our prior work in 2018 and 2019. We defined award times as the time from the contracting office releasing a solicitation until the time the government

⁴⁵As of January 20, 2021, the federal government no longer uses the name Operation Warp Speed, but the DOD and HHS partnership has continued. DOD and HHS’s partnership was formalized through a memorandum of understanding between the two departments. For more information on COVID-19 vaccines, see [GAO-21-443](#).

⁴⁶The remaining \$11.4 billion in obligations were on contract vehicles outside the scope of this review. For example, these vehicles included \$5.3 billion in procurement contracts awarded to Moderna for vaccine development.

awarded the OTA. Specifically, for the six vaccine OTAs awarded in response to a COVID-19 solicitation, the award times ranged from 27 days to about 8 months, with a median of 54 days.⁴⁷ For non-COVID-19 OTAs, in November 2019, we found that award times for a nongeneralizable sample of 11 DOD prototype OTAs ranged from 45 days to about 1 year, with a median of nearly 10 months.⁴⁸ For procurement contracts, in July 2018, we found that the award time for 129 weapon systems-related contracts ranged from less than a month to over 4 years, with a median of about 9 months.⁴⁹

DOD and HHS employed several contracting methods to further expedite the award of the seven vaccine OTAs (see table 2).

⁴⁷We excluded from our analysis of award times the ASPR-awarded OTA to Janssen because it was awarded prior to the COVID-19 pandemic. The six OTAs included in our analysis were five awarded by Army Contracting Command to Janssen, Sanofi, Novavax, Pfizer, and AstraZeneca, and one awarded by ASPR to AstraZeneca. Both of the AstraZeneca OTAs—one awarded in May 2020 and the other in October 2020—were in response to the same solicitation issued in March 2020.

⁴⁸[GAO-20-84](#).

⁴⁹GAO, *Defense Contracts: DOD Should Develop a Strategy for Assessing Contract Award Time Frames*, [GAO-18-467](#) (Washington, D.C.: July 16, 2018).

Table 2: Methods Used by DOD and HHS in Awarding OTAs to Help Expedite COVID-19 Vaccine Development and Manufacturing

Methods to expedite award of OTAs	Contracting agency / vaccine manufacturer						
	Army / Janssen	HHS ASPR / Janssen	Army / AstraZeneca	HHS ASPR / AstraZeneca	Army / Sanofi	Army / Novavax	Army / Pfizer
DOD and HHS partnership	✓	X	✓	X	✓	✓	✓
DOD OTA award that continues work of previously awarded HHS OTA	✓	X	✓ ^a	X ^a	X	X	X
Modified existing OTA to add projects	✓	✓	X	X	✓	✓	✓
Awarded OTAs without finalized terms and conditions	X	X	✓	✓	✓	✓	X
Delegated approval to lower-level management review pursuant to the CARES Act	✓	X	✓	X	✓	✓	✓
Congressional notification requirement not provided in advance pursuant to the CARES Act	✓	X	✓	X	✓	✓	✓

Legend:

✓ = yes

X = no or not applicable

ASPR - Office of the Assistant Secretary for Preparedness and Response

COVID-19 - Coronavirus Disease 2019

DOD - Department of Defense

HHS - Department of Health and Human Services

OTA - other transaction agreement

Source: GAO analysis of DOD and HHS OTA documentation and testimonial information from officials. | GAO-21-501

^aArmy officials stated that their October 2020 OTA award to AstraZeneca replaced and finalized the OTA that HHS ASPR had awarded in May 2020.

The methods used by DOD and HHS to expedite vaccine development and manufacturing in their OTA awards are further illustrated below:

- **DOD and HHS partnership.** According to DOD and HHS officials, HHS partnered with DOD to leverage DOD’s OTA authorities and acquisition workforce capacity, which HHS lacked. First, HHS ASPR’s OTA authority is limited to advanced research and development, while

DOD's OTA authority allows for research, prototyping, and production efforts. However, while DOD awarded five vaccine prototype OTAs, it did not award any follow-on vaccine production OTAs as of March 2021. For example, to acquire an additional 200 million Pfizer vaccine doses after the initial 100 million acquired under the prototype OTA, DOD awarded \$4 billion in procurement contracts. DOD officials explained that, when they began negotiating the follow-on contracts with Pfizer for additional doses in December 2020, Pfizer had not yet fully demonstrated its prototyping efforts under the OTA—namely, delivering 100 million doses. Successful prototype project completion is one of the conditions that must be met to award a follow-on production OTA without being required to use competitive procedures.⁵⁰

Second, according to senior HHS contracting officials, the contracting needs resulting from COVID-19 overwhelmed HHS's acquisition workforce both in terms of capacity and expertise. In March 2021, a third-party company assessed the office of HHS's senior procurement executive and found the office does not have sufficient staffing. Additionally, the assessment noted that the office had limited funding for acquisition staffing and did not provide sufficient oversight of contracts and the acquisition workforce. Further, the assessment found HHS had outdated contracting policies.

- **DOD OTA awards that continue work of previously-awarded HHS OTAs.** As part of the DOD and HHS partnership, Army Contracting Command awarded OTAs that continued COVID-19 work started under OTAs awarded by ASPR. For example, in May 2020, ASPR awarded AstraZeneca an OTA for vaccine development without finalized terms and conditions, in anticipation of another OTA award that would replace it. In October 2020, Army Contracting Command awarded a \$1.2 billion prototype OTA that built upon AstraZeneca's efforts in developing and manufacturing the vaccine under ASPR's OTA. After Army Contracting Command awarded the OTA to AstraZeneca, ASPR terminated its OTA, which had \$126 million in obligations.
- **DOD and HHS modified existing OTAs to add projects.** For four of the vaccine OTAs, Army Contracting Command modified an existing OTA for COVID-19 prototype projects awarded to Janssen, Sanofi, Novavax, and Pfizer.⁵¹ ASPR also modified an OTA previously

⁵⁰10 U.S.C. 2371b(f)(2)(B).

⁵¹Janssen is a pharmaceutical subsidiary of Johnson & Johnson.

awarded to Janssen to include COVID-19 vaccine development in the scope. A senior ASPR official explained that Janssen's existing OTA provided HHS with the flexibility to quickly pivot from an existing portfolio of vaccines to focus on COVID-19, which would not have been possible under a procurement contract.

- **DOD and HHS awarded OTAs without finalized terms and conditions.** In July and October 2020, Army Contracting Command made vaccine awards to Sanofi, Novavax, and AstraZeneca that were not finalized. DOD senior contracting officials stated that doing so allowed the vaccine manufacturers to initiate work quickly. According to Army Contracting Command officials, examples of terms and conditions not finalized included the total project costs and elements of project scope, including the clinical trials. According to officials, all three OTAs were finalized in December 2020, 2 to 5 months after the awards. As noted earlier, ASPR also awarded an OTA to AstraZeneca without finalized terms and conditions, such as what intellectual property rights the government would receive. ASPR officials stated that this approach allowed AstraZeneca to initiate work quickly.
- **DOD used CARES Act flexibility to delegate approval of OTAs to lower-level management review.** Of the six vaccine OTAs that met the dollar thresholds to use CARES Act flexibilities for the initial award, five used the flexibility that allowed lower-level contracting officials to approve the OTAs.⁵² Specifically, the Army's senior procurement executive, rather than the Under Secretary of Defense for Research and Engineering or the Under Secretary of Defense for Acquisition and Sustainment, approved the written determinations for these five OTAs.⁵³
- **DOD used CARES Act flexibility to provide congressional notifications after awards.** All five vaccine OTAs awarded by DOD used the CARES flexibility to notify the congressional defense committees in writing of these OTAs after they were awarded (rather than the typical requirement of notification at least 30 days before

⁵²ASPR awarded an OTA to Janssen in August 2017, prior to passage of the CARES Act in March 2020. The CARES Act flexibility was not used for the initial award. Pub. L. No. 116-136, § 3301.

⁵³The five OTAs that met the \$500 million estimated cost threshold and used the CARES Act flexibility related to approval delegation from the Under Secretary of Defense for Research and Engineering or the Under Secretary of Defense for Acquisition and Sustainment to other officials for prototype OTAs were the Janssen, AstraZeneca, Pfizer, Novavax, and Sanofi OTAs.

award).⁵⁴ For all five vaccine OTAs, DOD notified the committees within 1 week of award.

Additionally, the written justifications for four of the vaccine OTAs cited the flexibility to negotiate individualized OTA language and unique terms and conditions that would not have been possible under a procurement contract as factors contributing to the use of OTAs. For example, DOD officials cited flexible payment terms through milestone payment schedules, flexible termination provisions, and custom rights for intellectual property, technical data, and regulatory deliverables.

DOD, HHS, and DHS Cited Timeliness and Other Factors for Nonvaccine OTAs

Factors that contributed to agencies using OTAs for the eight selected nonvaccine efforts included (1) timeliness of awards, (2) a more flexible process which requires less administrative work, (3) engaging nontraditional contractors, and (4) the ability to use cost-sharing or additional funding streams (see table 3).

Table 3: Cited Benefits of Using OTAs for Selected Nonvaccine COVID-19 Efforts Cited by DOD, HHS, and DHS

Cited Benefits of OTAs	Nonvaccine OTA							
	Army crisis response technology	Army rapid test kits	Army wearable COVID-19 detection	Army Regeneron therapeutic	HHS ASPR Regeneron therapeutic	Air Force 3D printing	DHS airport and port screening	DHS airport cleaning
Timeliness of awards	✓	✓	✓	✓	✓	X	✓	✓
More flexible process or less administrative work	✓	✓	✓	✓	✓	✓	✓	✓
Nontraditional contractor engagement	✓	✓	✓	✓	✓	✓	✓	✓
Cost-sharing or use of additional funding streams	X	X	X	X	✓	✓	X	X

Legend:

✓ = yes

X = no or not applicable

ASPR - Office of the Assistant Secretary for Preparedness and Response

COVID-19 - Coronavirus Disease 2019

DHS - Department of Homeland Security

DOD - Department of Defense

HHS - Department of Health and Human Services

OTA - Other transaction agreement

Source: GAO analysis of DOD and HHS OTA documentation and testimonial information from officials. | GAO-21-501

⁵⁴Pub. L. No. 116-136, § 13006(b).

The factors that contributed to the use of OTAs are further illustrated in the examples below.

- **Timeliness of awards.** Contracting officials noted that the OTAs allowed them to successfully execute efforts in weeks, whereas a procurement contract would generally take months to award.⁵⁵ For example, in February 2020, the DHS Countering Weapons of Mass Destruction Office noncompetitively awarded a \$23 million OTA for COVID-19 screening at airports and ports of entry within 1 day of receiving the requirement. DHS officials stated that the contractor began work based on a verbal agreement and then signed a written OTA award 24 days later. In another example, ASPR's approval document for an OTA awarded to Regeneron for therapeutics against emerging infectious diseases noted significant time savings as a benefit of using OTAs. According to the approval document, the OTA allowed for the immediate replacement of underperforming assets within a therapeutics portfolio with a promising new candidate, which resulted in an estimated savings of up to 9 months and hundreds of hours of government effort. ASPR officials explained that under a procurement contract, terminating work and adding scope can take longer given the additional FAR requirements that must be met to do so, such as those related to terminations or competition for modifications that change the scope of work.
- **More flexible contracting process and less administrative work.** According to officials interviewed and the approval documents for all eight OTAs we reviewed, OTAs have a more flexible process and require less administrative work than procurement contracts. For example, in April 2020, Army Contracting Command modified an existing production OTA for a suite of communication capabilities used in national emergencies to include \$11 million for use of such capabilities at COVID-19 testing sites.⁵⁶ Army Contracting Command officials noted that these OTAs required less administrative work to execute, including less required documentation than a procurement contract.

⁵⁵DOD and Transportation Security Administration officials stated that OTA awards are not always faster to award than procurement contracts.

⁵⁶Army Contracting Command officials awarded this production OTA to Augustine Consulting, Inc. upon the successful completion of their prototype under a separate prototype OTA. According to FPDS-NG data as of October 2020, this OTA was the only production OTA awarded by DOD, which in part covered some of the communications equipment used for the COVID-19 response.

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- **Nontraditional contractor engagement.** Most of the nonvaccine OTAs in our review were awarded to nontraditional contractors. For example, in August and September 2020, the Army Medical Research Acquisition Activity awarded OTAs with combined total obligations of \$19.2 million for seven nontraditional contractors to develop COVID-19 wearable diagnostic devices. Army Medical Research Acquisition Activity officials told us the OTAs enabled them to engage with commercial companies that do not normally do business with DOD. One such example is Fitbit. Army officials stated that military work does not typically fit into Fitbit’s business model, but it entered into an OTA for diagnostic devices. Similarly, HHS officials stated that many biomedical research and development organizations are unable or unwilling to agree to some government conditions in procurement contracts, which they perceive to be burdensome.

In another example, in October 2020, Army Contracting Command awarded a \$481 million OTA to Cue Inc. for rapid COVID-19 detection testing kits, which were the official test kits for the National Basketball Association. Army Contracting Command officials told us that the OTA provided a collaborative “training wheels” type of arrangement. This allowed Cue Inc. to learn how to be a government contractor and allowed the government to learn how to use Cue Inc.’s new technology, which would not have been possible under a traditional contracting mechanism.

- **OTAs allowed for cost-sharing and ability to use additional funding streams.** Cost-sharing on an OTA occurs when a portion of the total cost is paid by sources other than the federal government. For example, in September 2020, the Air Force awarded an OTA with \$4.3 million in obligations to Essentium Inc. that was used to support the defense industrial base for 3D printing capabilities. The Air Force plans to leverage this 3D printing capability to address maintenance and obsolescence issues in aircraft. In April 2021, we found that COVID-19 exacerbated challenges at Air Force depots, such as having too few materials to finish work.⁵⁷

Air Force officials explained that this OTA award helped increase cash flow to the contractor to offset financial distress caused by COVID-19. The Air Force awarded this OTA through a small business innovation research pilot program, which has a cost-sharing requirement. Specifically, the program has a matching-funds requirement: For

⁵⁷GAO, *Depot Maintenance: DOD Should Improve Pandemic Plans and Publish Working Capital Fund Policy*, [GAO-21-103](#) (Washington, D.C.: Apr. 6, 2021).

every dollar of small business innovation research funding provided, nonfederal sources must fund one dollar, and a private third-party must fund two dollars. Air Force officials stated that accommodating this cost-sharing requirement was a fundamental reason and benefit for using an OTA for the effort.

Similar to the vaccine OTAs, two of the nonvaccine OTAs—Army Contracting Command’s Regeneron therapeutics and COVID-19 rapid test kit OTAs—used the CARES Act flexibility to delegate approval to lower-level management reviews.⁵⁸ The Army’s head of contracting activity—rather than the senior procurement executive—approved the written determinations for both OTAs. Five nonvaccine OTAs we reviewed did not use the CARES Act flexibility because they were (1) awarded by DHS, which did not receive OTA flexibilities under the CARES Act; or (2) below the relevant dollar thresholds. The remaining nonvaccine OTA was awarded prior to the flexibilities being granted.

Majority of COVID-19 OTA Obligations Awarded through Consortia, but Transparency and Oversight Are Limited

DOD awarded about 58 percent of the \$12.5 billion in COVID-19 OTA obligations to members of consortia through a single consortium management firm, but agencies did not report which members received the awards and do not have policies that address the need for enhanced oversight of firm-managed consortia OTAs. DOD, HHS, and DHS did not publicly report which consortium members received OTA awards because of limitations with FPDS-NG, which reduces the transparency of these OTAs. In addition, consortium management firms can provide acquisition-support services for OTA awards that require heightened management attention from the government. However, DOD and HHS policies do not address mitigation of this known risk.

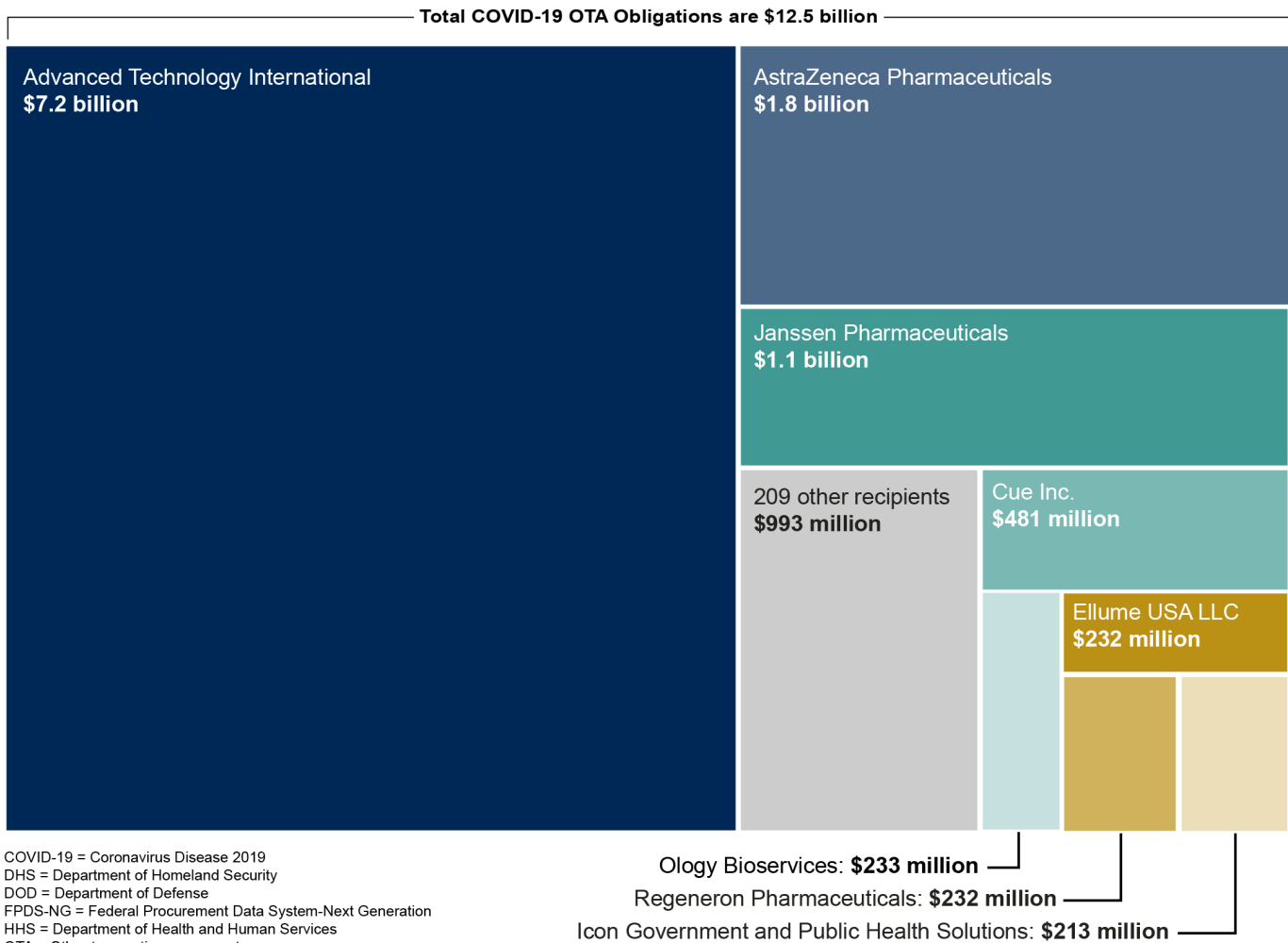
\$7.2 Billion of OTA Obligations Awarded through One Consortium Management Firm

According to FPDS-NG, the top recipient of COVID-19 OTA obligations was Advanced Technology International (ATI), a consortium management firm (see fig. 4).⁵⁹

⁵⁸These two OTAs met the \$100 million cost threshold to use DOD’s CARES Act flexibility related to the senior procurement executives delegating approval of written determinations to other officials. Pub. L. No. 116-136, § 13006(a).

⁵⁹According to its website, ATI manages 21 different consortia—15 through OTAs and six through procurement contracts.

Figure 4: Top Recipients of COVID-19 OTA Obligations as of March 14, 2021



Source: GAO analysis of FPDS-NG data and information from DOD, HHS, and DHS. | GAO-21-501

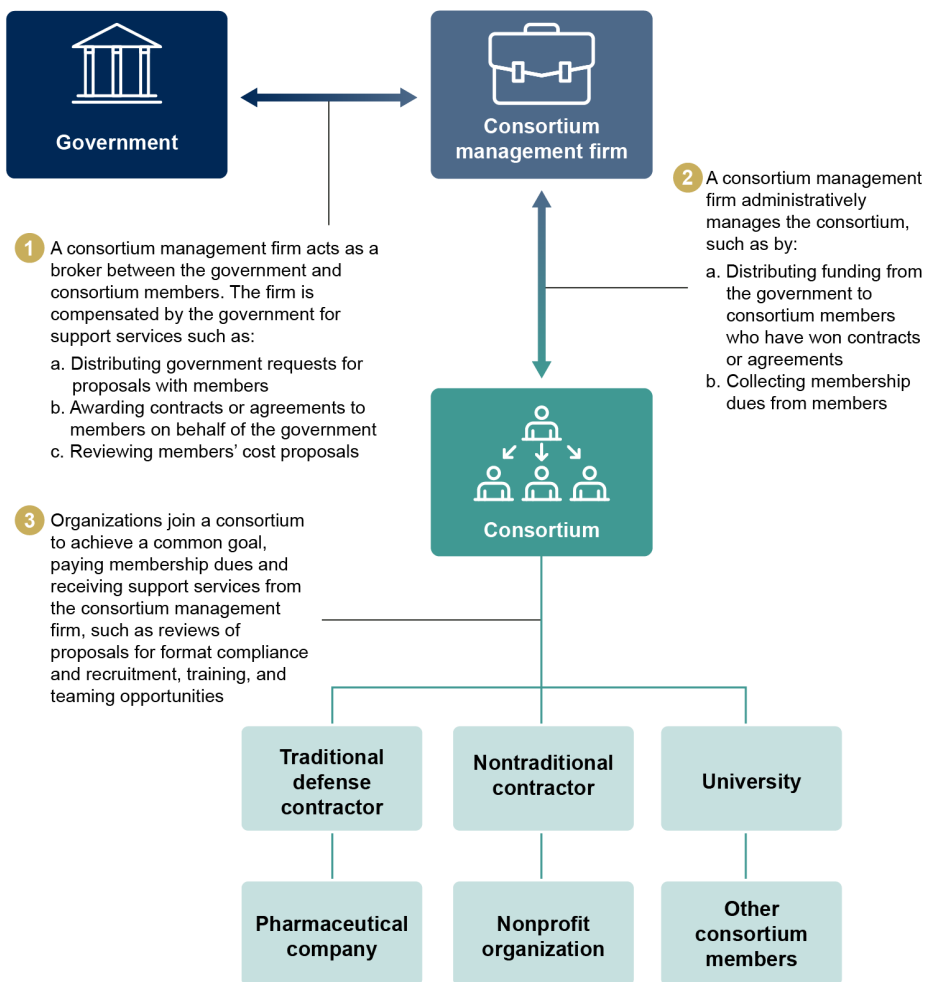
Note: We corrected the FPDS-NG data by adding \$1.6 billion in obligations the agencies did not accurately report as COVID-19 OTAs. Our analysis did not include data that are not reported in FPDS-NG because we did not assess the reliability of these data.

Prior to the COVID-19 response, OTA awards to ATI accounted for \$3.5 billion, or 49 percent of the obligations on DOD’s prototype OTA awards from fiscal years 2016 through 2018.⁶⁰

⁶⁰GAO-20-84.

A consortium is comprised of members which can include traditional contractors, nontraditional companies, nonprofit organizations, and academic institutions interested in a specific topic area. A consortium can be established to provide the government a pool of stakeholders to further innovate in that topic area. According to ATI staff, some of these consortium members may be less experienced in contracting with the government. A consortium management firm may administratively manage the consortium and act as a liaison or broker between the members and the government in OTA awards (see fig. 5).

Figure 5: Notional Depiction of Relationships for One Type of Consortium Other Transaction Agreement Model



Source: GAO analysis of Department of Defense information and Advanced Technology International (data); iierlok_xolms/stock.adobe.com (images). | GAO-21-501

As a consortium management firm, ATI manages multiple consortia. ATI provides administrative support services that facilitate the contracting process and does not perform prototype or production work under OTAs. For example, ATI receives requests for prototype proposals from DOD and distributes them to consortium members through an ATI-managed solicitation system. ATI then reviews consortium members' proposals to ensure all required documentation is complete before submitting it to DOD. ATI, on behalf of the consortia, also negotiates the terms and conditions of base or "umbrella" OTA awards between DOD and consortium members when such an approach is used. The base OTA provides terms and conditions that generally apply to all project OTAs awarded and serves as a starting point for negotiations between DOD and consortium member awardees. For the six OTAs awarded through ATI in our review, DOD paid ATI for its services under a cost-plus-fixed-fee structure to assist in executing OTAs, which include acquisition support services. Separately, consortium members pay dues to the consortium.

For the COVID-19 response, three consortia managed by ATI have received OTA awards: the Medical Chemical, Biological, Radiological and Nuclear Defense Consortium (hereafter referred to as the medical defense consortium), the Medical Technology Enterprise Consortium (hereafter referred to as the medical technology consortium), and the Countering Weapons of Mass Destruction Consortium.⁶¹ According to DOD and ASPR officials, awarding OTAs to consortia provided two main benefits to the government for responding to COVID-19: a ready supply of organizations interested in the subject matter and faster negotiation times due to streamlined solicitation and selection procedures. For example:

- **Medical defense consortium.** In April 2016, Army Contracting Command awarded a 20-year base OTA with an estimated ceiling of \$10 billion to the medical defense consortium through ATI. This OTA was for conducting research and development into medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel. From this base OTA, Army Contracting Command awarded four vaccine OTAs and one therapeutic OTA. According to DOD officials, the base OTA's terms and conditions provided a starting point for negotiations, which expedited the negotiation process. The average award time for the five medical defense consortium OTAs was 45 days.

⁶¹ATI waived its fixed fee for all COVID-19 awards.

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- **Medical technology consortium.** In August 2015, Army Medical Research Acquisition Activity awarded a 10-year base OTA to ATI to help establish a medical technology consortium that could perform on future OTA projects.⁶² The projects include conducting research, development, and testing leading to technology demonstrations in the biomedical sciences and related fields to maintain and improve service member health and performance. Army Medical Research Acquisition Activity officials explained that the OTA consortium model allows them to engage with medical companies that are not accustomed to and generally do not want to navigate the government procurement process. These officials also stated that ATI can rapidly distribute their government solicitations to a pool of more than 300 medical technology consortium members that are already aware of or engaged in work compatible with the activity's needs.

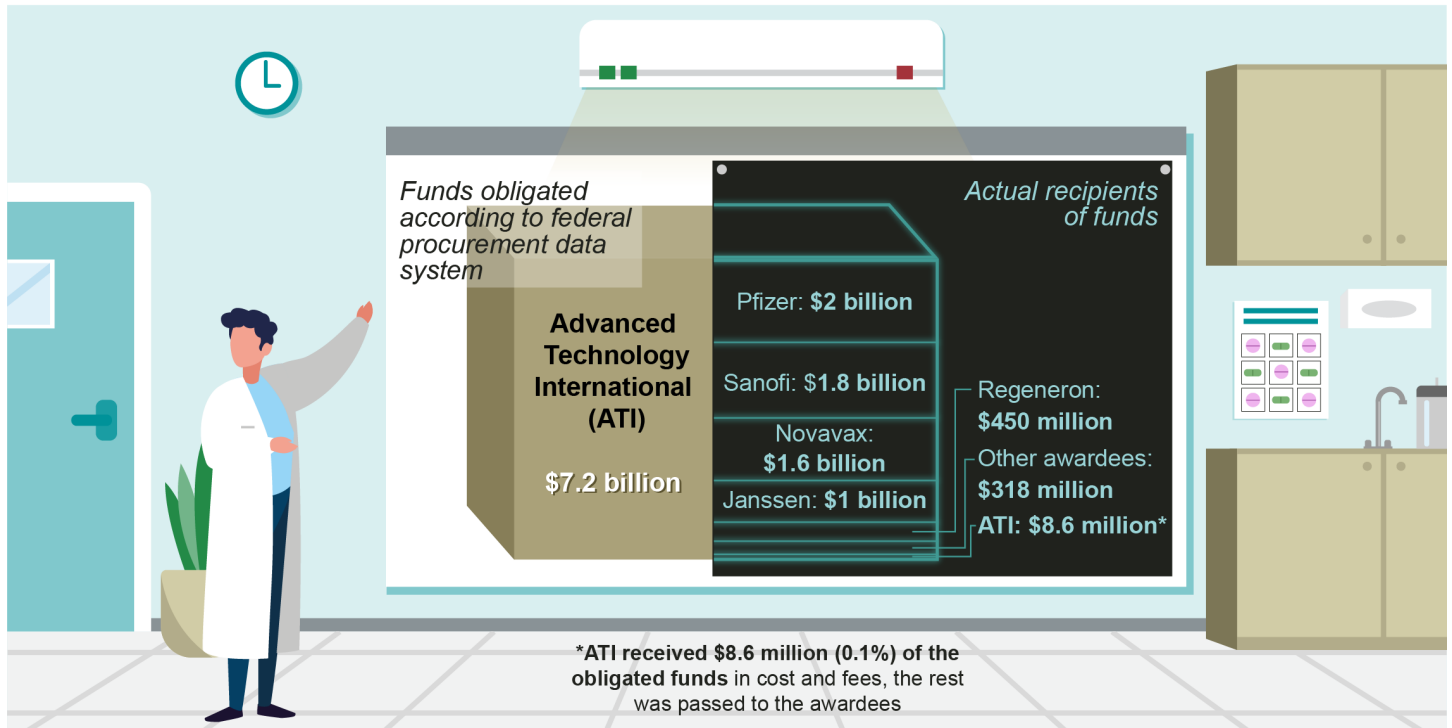
Additionally, ASPR officials stated that while they previously did not award many OTAs to consortia, they were interested in expanding their use as a result of their positive experience with DOD and the medical defense consortium. Specifically, ASPR officials stated that consortia provide a ready pool of companies to respond to requests for proposals.

Agencies Generally Do Not Report Data on Consortium Members Receiving OTA Awards

When federal agencies award OTAs to consortia, they do not report which consortium members received the awards because the OTA module of FPDS-NG does not currently have the capability to allow for this reporting. Instead, the OTA module tracks the top-level awardee—the consortium or consortium management firm—but is opaque beyond that. For example, our analysis of FPDS-NG data showed ATI receiving \$7.2 billion in OTA obligations in response to COVID-19. However, our analysis of OTA award documentation, publicly available data, and data provided by ATI found that the majority of that funding was distributed to five OTA awardees who performed the work. ATI received about 0.12 percent of the obligations to fund its support services (see fig. 6).

⁶²According to ATI officials, after the medical technology consortium was established as a legal entity, the OTA was novated or transferred to the consortium on August 31, 2016.

Figure 6: Coronavirus Disease 19 Other Transaction Agreement Awardees and Obligations in Federal Procurement Database Compared to Awardees Who Actually Received Funds as of March 14, 2021



Source: GAO analysis of Federal Procurement Data System-Next Generation data, data and other transaction agreement documents from the Department of Defense, and data from Advanced Technology International. (data); djvstock/stock.adobe.com (doctor image). | GAO-21-501

In another example, analysis of FPDS-NG data showed the medical technology consortium—which is managed by ATI—received \$19.2 million for the wearable COVID-19 diagnostics OTA award. Our analysis of OTA documents for this project found that seven nontraditional defense contractors—the University of California, San Francisco; Diomics; Silbel; Philips; Empatica; Sempulse; and Fitbit—each received from \$1.8 million to \$5.2 million to perform the work.⁶³ The medical technology consortium and ATI did not receive any of the \$19.2 million. Instead, ATI received a separate payment of about \$885,000 to reimburse OTA-execution costs,

⁶³The request for prototype proposal for this OTA was open to both members and nonmembers of the medical technology consortium. The request for prototype proposals further noted that, if a nonmember submitted a proposal that was selected by the government, the nonmember was required to join the consortium to receive an OTA award. The medical technology consortium is administratively managed by ATI but is separately identified in FPDS-NG, unlike the medical defense consortium.

which was awarded under the base OTA and not identified as COVID-19-related.

ATI staff told us that the FPDS-NG OTA data overstate how much ATI has received, making it appear that ATI retains billions in funding for its services. ATI staff stated that the way the government reports OTA data into FPDS-NG does not accurately capture ATI's role. For the OTAs awarded through ATI, the government selects which consortium members receive awards and the amount of those awards. To this end, ATI's consortia websites provide some information on the consortium members who received awards and the amounts each member received by solicitation.

In November 2019, we found similar OTA data system limitations, and DOD officials at that time stated they were working to address them.⁶⁴ In April 2021, the DOD Inspector General also found that FPDS-NG did not provide insight into consortium member awardees for non-COVID-19 OTAs awarded through consortia, among other data limitations.⁶⁵ The DOD Inspector General recommended that DOD coordinate with GSA to update FPDS-NG to more accurately capture data related to OTAs awarded through consortia. DOD concurred with the recommendation and stated that it was requesting FPDS-NG updates through the Integrated Award Environment.

In April 2021, DOD officials told us they were proposing two changes to the OTA module—one that would allow tracking of whether an OTA was awarded to a consortium or not and one that would allow tracking of which consortium members performed work on the OTA. However, DOD officials added that they face challenges implementing changes related to adding the capability to track consortium members. One challenge is that FPDS-NG changes are resource-constrained and must be prioritized by a majority of the Integrated Award Environment governing board. As noted earlier, the board includes DOD, DHS, HHS, and GSA. Another issue is that more broadly, GSA is leading an effort to revamp how federal contractors are identified and tracked, which is to be completed by April 2022. DOD officials explained that they may wait until this tracking effort is implemented before adding the capability to track consortium member awardees for OTAs. While DOD's proposed changes to the FPDS-NG

⁶⁴GAO-20-84.

⁶⁵Department of Defense Inspector General, *Audit of Other Transactions Awarded Through Consortia*, DODIG-2021-077 (Alexandria, VA: Apr. 21, 2021).

OTA module could provide the necessary insight into consortium member awardees, these changes may not be prioritized by the Integrated Award Environment given other competing demands for FPDS-NG and other system changes.

Until the agencies have the capability to systematically track the consortium members who received OTAs, information on the consortium member awardees could be included in the description of requirement field in the OTA module. As of April 2021, DOD, HHS, and DHS indicated they have not required agreement officers to do so.

Additionally, agencies do not consistently provide this type of information to congressional decision makers. For example, DOD's fiscal year 2019 report on the use of OTAs submitted to the congressional defense committees includes information on whether OTAs were awarded to a consortium but does not include information on the consortium member awardees.⁶⁶ In contrast, DHS's fiscal year 2019 report on OTAs submitted to the congressional homeland security committees includes some information on consortium members who received OTA awards.⁶⁷ However, DHS's OTA reports are not published, so taxpayers do not have insight into which consortium members have received OTA awards from DHS. According to HHS officials, HHS did not have a requirement to report on its OTA use to congressional committees prior to the pandemic and thus also has not provided OTA consortia awardee information to congressional decision makers.⁶⁸

According to DOD, HHS, and DHS policies, one of the primary objectives of agencies for using OTAs is to build new relationships with entities that may not ordinarily do business with the government, such as start-up companies. Further, federal standards for internal controls state that an

⁶⁶Department of Defense, Office of the Under Secretary of Defense for Acquisition and Sustainment, *Report to Congress on the Use of Other Transactions (OT) Authority for Prototype Projects in FY 2019 and First Quarter of FY 2020* (Washington, D.C.: Apr. 16, 2020).

⁶⁷Department of Homeland Security, Office of the Chief Procurement Officer, *Other Transaction Authority, Fiscal Year 2019* (Washington, D.C.: Nov. 4, 2020).

⁶⁸The CARES Act requires HHS to provide a report to the certain congressional committees on the funds used for OTAs using certain CARES Act flexibilities after expiration of the public health emergency declaration. Pub. L. No. 116-136, §§ 3301.

agency's management should externally communicate quality information to achieve its objectives and related risks.⁶⁹

Without transparency on the awardees who are performing the work on OTAs awarded to consortia, congressional decision makers and taxpayers have limited insight into the extent to which agencies are achieving one of the purposes of awarding OTAs— attracting nontraditional contractors.

DOD and HHS Policies Do Not Address Risks for Consortium OTAs That Need Heightened Management Attention

When consortium management firms perform acquisition-support services—activities that closely support inherently governmental functions—they often require heightened management attention. For all six OTAs that DOD awarded through ATI in our review, documentation of DOD's analysis of risks or mitigation steps related to this heightened attention was lacking.

According to the Office of Federal Procurement Policy's Policy Letter 11-01, inherently governmental functions refer to functions that are so intimately related to the public interest, they are required to be performed by federal employees.⁷⁰ One example of such a function is the determination of whether prices are fair and reasonable when awarding contracts. Additionally, the policy letter identifies categories of service functions that are not considered inherently governmental and that agencies are allowed to contract for but that require heightened management attention because they are closely associated with the performance of inherently governmental functions. These types of service functions may require enhanced attention because of the possibility that contractors may inappropriately influence the government's authority, control, and accountability for decisions.

According to the policy letter, an agency can determine that contractor performance of such a service function is appropriate. However, for all procurements of services above the simplified acquisition threshold where the contracted function is closely associated with an inherently governmental function, the agency should identify—during the acquisition planning phase—risk mitigation steps to oversee and manage the

⁶⁹GAO-14-704G.

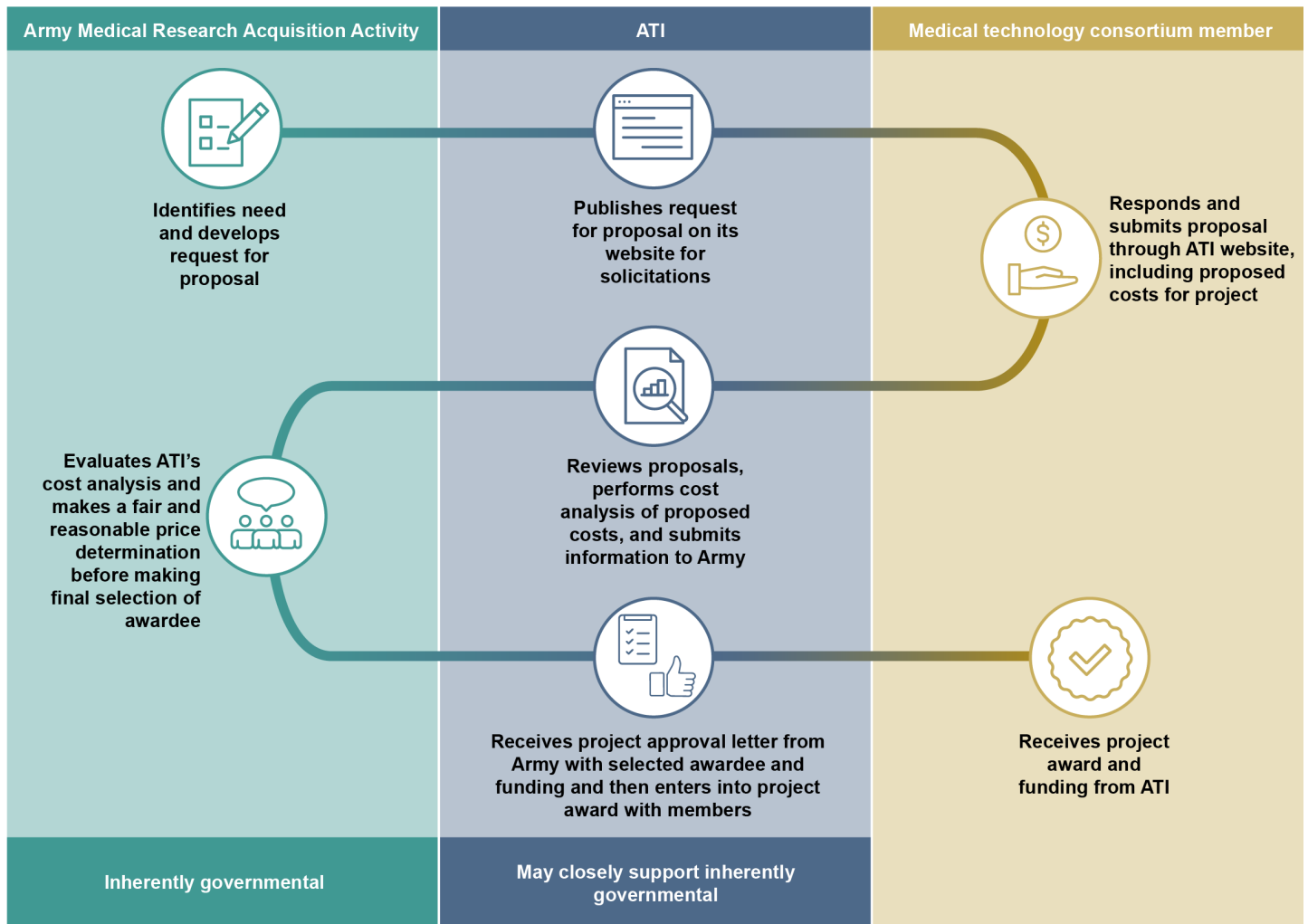
⁷⁰Office of Management and Budget, Office of Federal Procurement Policy, *Performance of Inherently Governmental and Critical Functions*, Policy Letter 11-01, 76 Fed. Reg. 56,227 (Sept. 12, 2011).

contractor's activities.⁷¹ Specifically, the agency should document in the contract file an analysis that establishes that the agency has sufficient capacity and capability to give special management attention to contractor performance and limit or guide the contractor's discretion, among other analyses.

As noted earlier, consortium management firms such as ATI can provide acquisition-support services to the government that closely support inherently governmental functions. For the six consortium OTAs in our review, ATI's acquisition-support responsibilities are outlined in the terms and conditions of the base OTAs, which generally apply to the OTAs awarded to consortia members. ATI's acquisition-support responsibilities for the COVID-19 wearable diagnostic devices OTA are outlined in the terms and conditions associated with the August 2015 base OTA awarded to the medical technology consortium. ATI provided services that may closely support inherently governmental functions for the wearable diagnostics OTA, such as analyzing consortium members' cost proposals (see fig. 7).

⁷¹The simplified acquisition threshold is generally \$250,000. In certain situations, for domestic purchases, this threshold can be increased to \$800,000. For example, the Office of Management and Budget noted that the President's emergency declaration related to COVID-19 allowed the simplified acquisition threshold to be increased. Currently, the simplified acquisition threshold for these purposes is \$800,000.

Figure 7: Examples of Services Performed by Advanced Technology International that May Closely Support Inherently Governmental Functions for a Coronavirus Disease 2019 Wearable Diagnostics Other Transaction Agreement



Source: GAO analysis of Army Medical Research Acquisition Activity and Advanced Technology International (ATI) information (data); iierlok_xolms/stock.adobe.com (images). | GAO-21-501

The Army Medical Research Acquisition Activity agreements officer responsible for the wearable diagnostic devices OTA stated that, while ATI provided services that closely supported inherently governmental functions, the government ultimately retained control over its inherently governmental decisions. The agreements officer noted that he monitored ATI's performance to help ensure everyone "stayed in their lanes." For example, ATI conducted a cost analysis of the consortium members' cost proposals by reviewing proposed labor rates and comparing them to

market rates, noting that the proposals provided sufficient cost data and were an adequate basis for award. The Army agreements officer then reviewed ATI's cost analysis and determined the costs to be fair and reasonable to the government. However, the agreements officer acknowledged that the Army Medical Research Acquisition Activity has limited contracting capacity, citing increased use of medical technology consortium OTA awards. ATI provides assistance in the government's evaluation process by providing cost analysis, which the agreements officer reviews, and administrative support. The agreements officer also confirmed that neither the base nor project OTA files included an assessment of the extent to which ATI was closely supporting inherently governmental functions or any enhanced management steps that needed to be planned for or taken to oversee ATI's performance of these activities. Since our review, Army officials plan to develop a process to measure and report on the consortium management's firm performance and a related quality assurance surveillance plan for the medical technology consortium OTA.

For the five OTAs that Army Contracting Command awarded through ATI to medical defense consortium members, Command officials also did not document an assessment of the extent to which ATI was closely supporting inherently governmental functions or any related enhanced management steps for overseeing ATI's performance in either the base or project OTAs. When we discussed this issue with an Army Contracting Command official in May 2021, the official told us that, upon review of the policy letter, it did not appear that ATI provides services that closely support inherently governmental functions. The official added that the agreement officers, agreement officer's representatives, and program officials responsible for these OTAs provide oversight of ATI's performance. A Command official also noted that the government's oversight responsibilities were reviewed and discussed during the acquisition planning phase, and that ATI performs services after receiving approval or authorization from an agreement officer or agreement officer's representative. Army Contracting Command has highlighted in its OTA training various acquisition support services provided by consortium management firms that could closely support inherently governmental functions, which are permitted. Specifically, typical consortium management duties include preparing requests for proposals; negotiating, awarding, and administering project OTAs; and project invoice receipt and payments. However, the training emphasized that the firms cannot perform inherently governmental functions. For the five medical defense consortium OTAs, ATI issued Army Contracting Command's request for proposals, entered into project OTAs on behalf of the government, and

distributed funding to the OTA awardees. Without conducting and documenting an assessment of ATI's responsibilities, Army Contracting Command missed an opportunity to determine the extent to which ATI's services closely supported inherently governmental functions and to take any necessary steps to mitigate potential risks.

HHS's September 2012 and DOD's November 2018 OTA guides do not include information that agreements officers should consider when considering the use of a consortium management firm to support acquisition-related activities that could closely support inherently governmental functions.⁷² The HHS OTA guide acknowledges that the roles and responsibilities of the participants in an OTA awarded through a consortium should be documented. However, the guide does not discuss the role of a consortium management firm specifically. HHS officials noted that they do not currently make much use of consortium management firms. However, as noted above, HHS officials stated they are interested in increasing use of consortiums in the future, which may lead to increased use of consortium management firms. Officials from DOD's Office of Defense Pricing and Contracting—the office responsible for updating DOD's OTA guide—noted that they are aware of risks associated with the functions provided by consortium management firms, such as performing services that closely support inherently governmental functions. Officials stated they are planning to update the DOD OTA guide to address such risks but did not offer time frames for when the update would be completed.

HHS's and DOD's guides also do not address what agreements officers should do after award to help ensure consortium management firms are not performing inherently governmental functions when they closely support such functions. For example, the guides do not direct agencies to monitor their oversight of consortium management firm activities to ensure they have sufficient capacity and capability to provide such oversight as needed. In contrast, DHS's July 2019 OTA guide states that agreements officers should, before and after award, ensure that consortium management firms are not performing inherently

⁷²Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Acquisition Management, Contracts and Grants, Biomedical Advanced Research and Development Authority, *Other Transaction Authority Guide and Standard Operating Procedure* (Sept. 2012) and Department of Defense, Office of the Under Secretary of Defense for Acquisition and Sustainment, *Other Transactions Guide, Version 1.0* (Nov. 2018).

governmental functions.⁷³ The guide notes that the agreements officer should review the proposed scope of work of consortium management firms to identify functions that could be deemed inherently governmental and ensure that the OTA specified that the performance of such activities are conducted with sufficient federal involvement.

Without guidance on information that agreements officers should consider prior to awarding OTAs through consortia in which consortium management firms support acquisition-related activities, DOD and HHS agreements officers may not fully consider the range of actions they should take to mitigate risks of consortium management firms if they perform functions that closely support inherently governmental functions.

DOD, HHS, and DHS Obligated \$4.7 Billion on Undefined Contracts, but Contract Finalization Varied in Selected Cases

From March 2020 through March 2021, DOD, HHS, and DHS obligated \$4.7 billion on undefinitized contracts in response to COVID-19 and definitized these contracts to varying degrees for the selected cases we reviewed. A majority of the \$4.7 billion in contract obligations was for medical equipment and testing, hospital construction, drugs and biologicals, and support of the defense industrial base. DOD officials cited the ability to quickly award undefinitized contracts as a major benefit during COVID-19, while HHS and DHS used undefinitized contracts to a lesser extent.

Undefinitized Contracts Used to Acquire Medical Supplies and Services, Construct Hospitals, and Support Industrial Base

From March 2020 to March 2021, obligations on DOD, HHS, and DHS undefinitized contracts in response to COVID-19 increased from \$250.3 million to about \$4.7 billion. These undefinitized contract obligations comprised about 11 percent of COVID-19 procurement contract obligations across these three agencies as of March 14, 2021, with DOD accounting for the majority (see table 4).

⁷³Department of Homeland Security, Office of the Chief Procurement Officer, *Other Transactions for Research and Prototype Projects Guide* (July 11, 2019).

Table 4: DOD, HHS, and DHS Undefinitized Contract Obligations in Response to Coronavirus Disease 2019 as of March 14, 2021

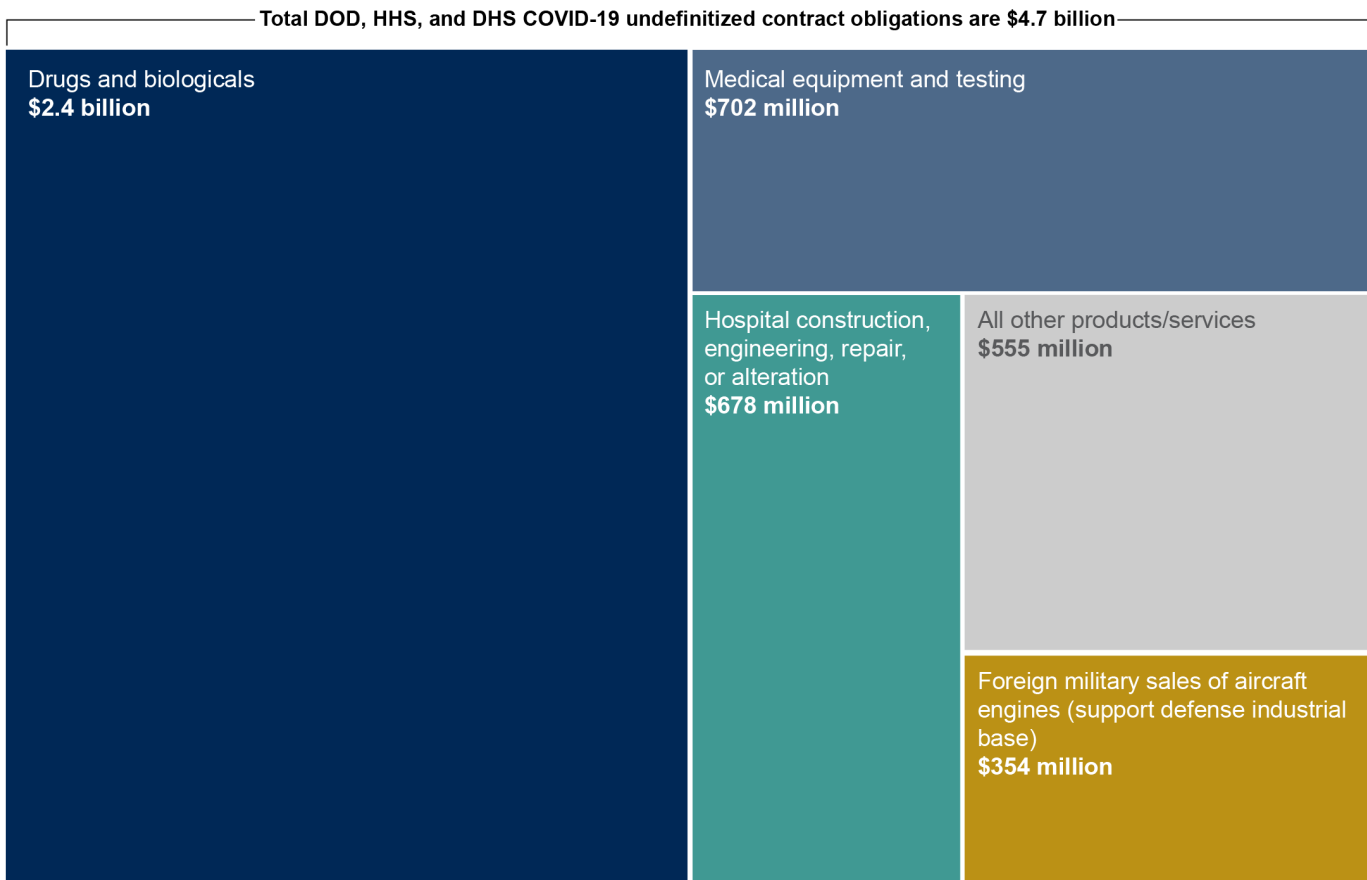
Agency	Undefinitized contract obligations (\$)	Procurement contract obligations (\$)	Undefinitized contract obligations as a percentage of procurement contract obligations (%)
Department of Defense (DOD)	4 billion	24.1 billion	17
Department of Health and Human Services (HHS)	668 million	16 billion	4
Department of Homeland Security (DHS)	12 million	2.2 billion	1
Total	4.7 billion	42.2 billion	11

Source: GAO analysis of Federal Procurement Data System-Next Generation data. | GAO-21-501

This 11 percent is slightly higher than in fiscal years 2017 through 2019, when obligations on DOD, HHS, and DHS’s undefinitized contracts accounted for 8 to 10 percent of procurement contract obligations in each year.

Most of the COVID-19 obligations on undefinitized contracts awarded by DOD, HHS, and DHS were used to acquire medical equipment, testing, and drugs and biologicals; construct or alter hospitals; and support the defense industrial base (see fig. 8).

Figure 8: Top COVID-19 Products and Services Acquired by DOD, HHS, and DHS Using Undefinitized Contracts as of March 14, 2021



COVID-19 = Coronavirus Disease 2019
 DHS = Department of Homeland Security
 DOD = Department of Defense

FPDS-NG = Federal Procurement Data System-Next Generation
 HHS = Department of Health and Human Services

Source: GAO analysis of FPDS-NG data and information from DOD, HHS, and DHS. | GAO-21-501

Note: Under the foreign military sales program, foreign governments pay the U.S. government to acquire defense articles and services on their behalf.

According to DOD officials, undefinitized contracts have been helpful in addressing COVID-19 because they allowed contractors to begin work immediately while they finalized negotiations. A senior DOD official stated that the ability to award an undefinitized contract on the same day that the agency receives funding is a powerful tool for responding to COVID-19. HHS officials stated that they did not make significant use of undefinitized contracts, in part, because many of their early purchases were for commercial products, which did not require undefinitized terms and conditions. DHS contracting policy officials stated that they did not make

significant use of undefinitized contracts because they are not a preferred contracting mechanism within the department.

Following is additional information on the three undefinitized contracts we reviewed:

- **U.S. Army Corps of Engineers' undefinitized contract for an alternative care facility.** In March 2020, the Army Corps awarded a firm-fixed-price undefinitized contract with an estimated contract price of \$101 million to Turner Construction, nearly 1 week after issuing the request for proposal. The contract was used to construct a temporary COVID-19 alternative care facility at Stony Brook University in New York.⁷⁴ According to a senior Army Corps official, the use of an undefinitized contract was imperative to building the facility as quickly as possible. When the Army Corps awarded the contract, terms and conditions such as the type, quantity, and location of equipment and structures had not yet been definitized.

In May 2020, after the contract was definitized and the contractor completed construction of the facility, the State of New York took control of the facility. According to Army Corps officials, the facility was ready to be occupied when they turned it over to the State of New York. Army Corps officials emphasized that the State of New York did not require the facility to be permanent or designed to withstand adverse weather conditions. According to a senior Army Corps official, after construction completion, the facility experienced snow damage, wind damage, generator issues, and mold growth. The contractor maintained an on-site presence and worked with the Army Corps and the State of New York to resolve issues covered by the contractor's warranty during the 6-month warranty period. After the warranty period ended, the facility continued to experience weather-related damage and could no longer be occupied. The State of New York ultimately decided that the facility was not needed for patients, and the facility was never used. As of March 2021, the Army Corps

⁷⁴The facility was one of multiple facilities constructed throughout the U.S. by the Army Corps with disaster relief funding from the Federal Emergency Management Agency to help supplement the lack of capacity of existing hospitals. In April 2021, the DOD Inspector General reviewed the Army Corps' management of definitization timelines, fair and reasonable price determinations, and profits adjusted for costs incurred for 30 alternative care facility undefinitized contracts. For more information, see Department of Defense Inspector General, *Audit of the U.S. Army Corps of Engineers Use of Undefinitized Contract Actions for the Conversion of Alternate Care Sites in Response to the Coronavirus Disease—2019 Pandemic*, DODIG-2021-074 (Alexandria, VA: Apr. 7, 2021).

obligated \$155 million for this effort, which included an additional \$54 million above the initial estimated price for items not included in the initial contract. These items included tents for putting on and taking off personal protective equipment.

- **ASPR undefinitized contract for convalescent plasma.** In March 2020, ASPR awarded a \$750,000 undefinitized contract to the American Red Cross to start initial work for recruiting, collecting, and distributing convalescent plasma from individuals who have COVID-19 antibodies. ASPR awarded the undefinitized contract on the same day the program office received this requirement. ASPR officials stated that the undefinitized contract allowed the American Red Cross to begin work before officials had information on the delivery schedule or full scope of work. ASPR officials explained that none of the terms and conditions were definitized at the time of award because they did not have information on (1) the number of individuals who would be willing to donate plasma or (2) the start-up costs, such as marketing costs to recruit donors and the costs associated with the additional personal protective equipment needed to collect plasma from COVID-19 patients. These officials also noted that the requirement was extraordinary and urgent because no other therapeutic options were available at the time.

According to ASPR officials, when they definitized the contract in June 2020, the American Red Cross had already completed the necessary start-up work. According to ASPR officials, as of January 2021, the American Red Cross had collected over 142,000 units—at 200 milliliters per unit—of COVID-19 convalescent plasma and provided at least 1 unit of plasma to over 1,200 hospitals. As of March 2021, ASPR had obligated \$120 million for this effort.

- **Air Force undefinitized contracts for aircraft engines.** In April 2020, the Air Force awarded four firm-fixed-price undefinitized contracts with a combined estimated total contract price of \$707 million to General Electric Aviation for foreign military sales of F110 engines to Slovakia, Bulgaria, Qatar, and Taiwan.⁷⁵ Prior to the COVID-19 pandemic, the Air Force had already planned to award

⁷⁵The foreign military sales program is an acquisition process through which the U.S. government procures military equipment, training, and other services on behalf of foreign governments. The Arms Export Control Act authorizes the sale of defense articles and services to eligible foreign customers under this program, which is one of multiple security cooperation programs that provide for the transfer of defense articles and services to foreign governments.

undefinitized contracts for sales to Slovakia and Bulgaria because of the long-lead times for production.⁷⁶ COVID-19, however, caused a significant decrease in worldwide commercial airline travel, which created unprecedented challenges for aerospace companies reliant on commercial sales, including General Electric. As a result, General Electric requested that the Air Force also award undefinitized contracts for sales of engines to Qatar and Taiwan, as well as advance payments on all four undefinitized contracts.

The Air Force approved the requests, and according to Air Force officials, the only term not definitized at the time of award was the final negotiated price. Air Force officials explained that using undefinitized contracts for foreign military sales is a common practice because this allows the contractor to start work while the government works with the foreign nation on country-specific requirements. Similarly, we have previously found that DOD used undefinitized contracts for foreign military sales to help reduce schedule risk by allowing the work to start earlier than under a definitized contract.⁷⁷

Timing of Definitization and Amount Obligated Prior to Definitization

Table 5 shows the timing of definitization and the amounts obligated for the three undefinitized contracts we reviewed.

⁷⁶Long-lead items include aircraft engines, which need to be procured early to reduce production lead times and ensure that planned production schedules are maintained for the related end item—the aircraft.

⁷⁷GAO, *Foreign Military Sales: Expanding Use of Tools to Sufficiently Define Requirements Could Enable More Timely Acquisitions*, [GAO-17-682](#) (Washington, D.C.: Aug. 14, 2017).

Table 5: Definitization Timing and Amounts Obligated for Selected Unfinalized Contracts Awarded in Response to Coronavirus Disease 2019 (COVID-19)

Description of unfinalized contract and the contracting agency	Time between award and definitization	Amount obligated prior to definitization
Alternative care facility in Stony Brook, New York (U.S. Army Corps of Engineers)	22 days	\$101 million or 100 percent of the estimated contract price ^a
COVID-19 convalescent plasma (Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response)	72 days	\$750,000 or 100 percent of the initial estimated contract price ^b
Foreign military sales of F110 engines to support defense industrial base (Air Force) ^c	Not applicable – not yet definitized as of April 12, 2021, 349 days after award	\$354 million or 50 percent of the estimated contract price

Source: GAO analysis of Department of Defense and Department of Health and Human Services information. | GAO-21-501

^aThe CARES Act grants additional flexibilities for DOD to waive certain limitations on the amounts that can be obligated before the contract is definitized.

^bThe initial estimated contract price of \$750,000, obligated at the time of award, was ultimately less than 1 percent of the total obligated amount on the unfinalized contract as of March 14, 2021 (\$120 million).

^cThe Air Force took actions to increase cash flow to the contractor to offset financial distress caused by COVID-19.

Agency officials provided additional context for the obligation amounts and timing of definitization for these three unfinalized contracts:

- Pursuant to the CARES Act, the Army Corps’ head of contracting activity approved a class waiver that removed certain statutory and regulatory limitations on obligations for all alternative care facility unfinalized contracts, including the Stony Brook contract.⁷⁸ Specifically, the waiver permitted Army Corps contracting personnel to obligate 100 percent of the estimated contract price prior to definitization. According to the determination, the Army Corps was the only entity with the capacity to build the temporary medical infrastructure needed to support rapid response to COVID-19. The determination further noted that definitizing the unfinalized contract at 50 percent of the estimated contract price (or 75 percent with a qualifying proposal from the contractor) would have risked unacceptable construction delay for this significant and high priority mission.

⁷⁸Pub. L. No. 116-136, § 13005, 134 Stat. at 522.

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- For the COVID-19 convalescent plasma undefinitized contract, ASPR officials explained that they determined the initial estimated contract price to be \$750,000 and obligated this full amount at award. As noted earlier, ASPR officials did not have information related to the price per unit, quantities, or start-up costs. As a result, they did not include a total estimated contract price in their justification for using an undefinitized contract, which is inconsistent with HHS's acquisition procedures.⁷⁹ ASPR officials explained that given the urgency of the requirement and lack of information, including an estimated cost for the total effort was not feasible at the time. According to ASPR officials, the senior officials responsible for approving the undefinitized contract knew that the total effort would be greater than the initial \$750,000 and that the risks of starting the undefinitized contract without key information far outweighed risks of waiting for more information given the lives being lost to COVID-19. ASPR officials definitized the contract after obligating the initial \$750,000, which accounted for less than 1 percent of the \$120 million obligated on the contract as of March 14, 2021.
 - For the four foreign military sales undefinitized contracts, Air Force officials stated that they had not yet definitized the contracts 349 days after award because General Electric had not yet submitted a qualifying proposal. DOD may only enter into an undefinitized contract if it requires definitization of contractual terms, specifications, and price within 180 days after the contractor submits a qualifying proposal for definitization or before obligating 50 percent of the estimated contract price, whichever occurs earlier.⁸⁰ The CARES Act allowed DOD to waive these requirements. However, the Air Force has not elected to waive these requirements for the four foreign military sales undefinitized contracts.⁸¹

Conclusions

Federal contracting—including OTAs—plays a critical role in the nation's response to COVID-19 by accelerating the development of vaccines and the procurement of vital goods and services. It is imperative for the public and congressional decision makers to understand the significant role that OTAs play and how they can be leveraged in the future, especially if another national emergency calls for the expanded use of such tools. Government-wide systems can improve OTA reporting, but only if

⁷⁹Department of Health and Human Services; Health and Human Services Acquisition Regulation; Policy, Guidance, and Instructions § 316.603-70.

⁸⁰10 U.S.C. § 2326(b).

⁸¹Pub. L. No. 116-136, § 13005, 134 Stat. at 522.

agencies collectively prioritize and implement these changes. Further, it is also critical that agencies provide greater insight and oversight on consortium management firms that may perform functions that are closely associated with inherently governmental functions. This will contribute to greater transparency and help ensure that the firms do not perform inherently governmental functions.

Recommendations for Executive Action

We are making a total of 14 recommendations, including four to DOD, four to DHS, two to GSA, and four to HHS. Specifically:

The Secretary of Defense—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to consistently and accurately track other transaction agreements used for national interest events and the associated dollars obligated. (Recommendation 1)

The Secretary of Homeland Security—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to consistently and accurately track other transaction agreements used for national interest events and the associated dollars obligated. (Recommendation 2)

The Secretary of Health and Human Services—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to consistently and accurately track other transaction agreements used for national interest events and the associated dollars obligated. (Recommendation 3)

The Administrator of the General Services Administration—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to consistently and accurately track other transaction agreements used for national interest events and the associated dollars obligated. (Recommendation 4)

Until a systematic approach to consistently and accurately track other transaction agreements used for national interest events is implemented, the Secretary of Homeland Security should update Department of Homeland Security guidance to clarify how other transaction agreements awarded in response to COVID-19 should be designated when reporting

in the other transaction agreement module of the Federal Procurement Data System-Next Generation. (Recommendation 5)

The Secretary of Defense—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to track the consortium members performing for each other transaction agreement awarded through a consortium or consortium management firm. (Recommendation 6)

The Secretary of Homeland Security—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to track the consortium members performing for each other transaction agreement awarded through a consortium or consortium management firm. (Recommendation 7)

The Secretary of Health and Human Services—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to track the consortium members performing for each other transaction agreement awarded through a consortium or consortium management firm. (Recommendation 8)

The Administrator of the General Services Administration—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to track the consortium members performing for each other transaction agreement awarded through a consortium or consortium management firm. (Recommendation 9)

Until a systematic approach to track consortium members for other transaction agreements awarded through a consortium or consortium management firm is implemented, the Secretary of Defense should provide information to the public and congressional decision makers on the consortium members performing on each other transaction agreement awarded through a consortium or consortium management firm, such as by including this information in the description of requirement field in the other transaction agreement module of the Federal Procurement Data System-Next Generation. (Recommendation 10)

Until a systematic approach to track consortium members for other transaction agreements awarded through a consortium or consortium management firm is implemented, the Secretary of Health and Human Services should direct the Office of the Assistant Secretary for Preparedness and Response to provide information to the public and congressional decision makers on the consortium members performing on each other transaction agreement awarded through a consortium or consortium management firm, such as by including this information in the description of requirement field in the other transaction agreement module of the Federal Procurement Data System-Next Generation. (Recommendation 11)

Until a systematic approach to track consortium members for other transaction agreements awarded through a consortium or consortium management firm is implemented across agencies, the Secretary of Homeland Security should provide information to the public on the consortium members performing on each other transaction agreement awarded through a consortium or consortium management firm, such as by including this information in the description of requirement field in the other transaction agreement module of Federal Procurement Data System-Next Generation. (Recommendation 12)

The Secretary of Defense should direct the Director of Defense Pricing and Contracting to update the Department of Defense's other transaction agreement guidance to include what agreement officers should consider when planning to use a consortium management firm to support acquisition-related activities, such as assessing the extent to which a consortium management firm is closely supporting inherently governmental functions and, for firms that do so, what enhanced management oversight activities are appropriate, if any. (Recommendation 13)

The Secretary of Health and Human Services should direct the Assistant Secretary for Preparedness and Response to update the Department of Health and Human Services' other transaction agreement guidance to include what agreement officers should consider when planning to use a consortium management firm to support acquisition-related activities, such as assessing the extent to which a consortium management firm is closely supporting inherently governmental functions and, for firms that do so, what enhanced management oversight activities are appropriate, if any. (Recommendation 14)

Agency Comments and Our Evaluation

We provided a draft of this report to DOD, HHS, DHS, and GSA for review and comment. In written comments provided by DOD, HHS, DHS, and GSA (reproduced in appendices II, III, IV, and V), the agencies concurred with 11 of the 14 recommendations. Specifically, DOD concurred with three of four recommendations, HHS concurred with all four, DHS concurred with two of four, and GSA concurred with both recommendations. The agencies generally provided steps they plan to take to address these recommendations. As discussed further below, DOD partially concurred with one recommendation, and DHS did not concur with two recommendations—all three related to consistently and accurately tracking OTAs awarded in response to national interest events and dollars obligated.

DOD concurred with recommendations 6, 10, and 13 and described its plans to address these recommendations in its written comments. DOD partially concurred with the first recommendation regarding consideration to prioritize the development and implementation of a systematic approach to consistently and accurately track OTAs used for national interest events and the associated dollars obligated. In its written comments, DOD noted that it understands the importance of being able to quickly identify awards made in support of national emergencies, such as the response to the COVID-19 pandemic, for the public. DOD further notes that the federal response to COVID-19 is very unique, and it is unlikely that OTAs will be used to respond to national emergencies, natural disasters, or contingency actions in the future. As a result, DOD stated it does not believe expending resources on system changes to FPDS-NG is warranted.

However, as we noted in our report, prior to the start of the pandemic, DOD, DHS, and HHS increased their use of OTAs from \$2.4 billion in fiscal year 2017 to \$7.8 billion in fiscal year 2019, or a 225 percent increase. Further, in response to COVID-19, agencies obligated about \$12 billion on OTAs for research, development, and manufacturing purposes. As future national emergencies arise—whether they are natural disasters, contingency operations, or another health crisis—OTAs will likely play a role in such events.

Through the Integrated Award Environment's change control board, agencies have an opportunity to lay the groundwork for better transparency on OTA awards for national interest events in the future. In its written comments, DOD also noted that a process-based approach, rather than FPDS-NG system changes, could help track such OTAs, and that it would work with the Integrated Award Environment's change control board to consider different approaches for identifying OTA awards in the future. As the recommendation did not specify that the systematic

tracking should be accomplished through FPDS-NG changes, we believe that DOD's planned actions could meet the intent of the recommendation.

HHS concurred with recommendations 3, 8, 11, and 14 and described its plans to address these recommendations in its written comments. In its response, HHS shared plans to work in coordination with DOD and DHS to prioritize the development of a systematic approach to consistently and accurately track OTAs used for national interest events and to track the consortium members performing for each OTA awarded through a consortium or consortium management firm.

DHS concurred with recommendations 7 and 12 and described its plans to address these recommendations in its written comments. DHS did not concur with the second recommendation regarding consideration to prioritize the development and implementation of a systematic approach to consistently and accurately track OTAs used for national interest events and the associated dollars obligated. In its written comments, DHS noted that only its research and prototype OTAs are required by statute to be reported in FPDS-NG. However, the primary purpose of the recommendation is to increase accuracy and transparency for the public to better understand the use of OTAs and dollars obligated, regardless of what is required by statute to be publicly reported. Regardless of what OTAs are required to be reported, DHS reported its use of OTAs to FPDS-NG, and the reporting was inaccurate. As we noted in our report, DHS obligated \$57 million on COVID-19 OTAs, and of that, \$25.5 million or about 45 percent had not been accurately identified by DHS as COVID-19-related. Further, none of the \$57 million on DHS's COVID-19 OTAs were research and prototype OTAs. Instead, all of DHS's COVID-19 OTAs were awarded by either the Countering Weapons of Mass Destruction Office or Transportation Security Administration for services, such as airport screening and cleaning. The discrepancy between what DHS is statutorily required to report and what it actually reports for OTAs underscores the inconsistency of reporting within DHS and the need for quality information about OTA use and dollars in response to national interest events.

In its response, DHS stated that if there is future use of OTAs in response to a national interest event, DHS will issue instructions on how to identify those actions when reporting to FPDS-NG is required. We believe there are shortcomings to such an approach. The lack of a systematic approach is, in part, why there was inaccurate reporting of COVID-19 OTAs. While it is not possible to anticipate the types of national interest events that may arise in the future, DHS has an opportunity to approach OTA reporting in a proactive rather than reactive manner.

DHS's response also noted that FPDS-NG is used for reporting summary level details of awards rather than dollars. However, this is an inaccurate portrayal of FPDS-NG. FPDS-NG is the authoritative source for contracting data, which includes dollars obligated on contract actions, and is used by federal agencies to create reports to the President, the Congress, GAO, federal agencies, and the public. As we noted in our report, DHS obligated \$57 million on OTAs in response to COVID-19 based on FPDS-NG data. In addition, FPDS-NG is a public database that provides insight into summary-level OTA spending (agencies have not reported data on OTAs in USAspending.gov). The recommendation is meant to start a dialogue among the Integrated Award Environment's change control board agencies to weigh the costs and benefits of a systematic approach to allow accurate and consistent tracking of OTA obligations for decision makers and the public.

While DHS requests the recommendation be resolved and closed, given the reasons that we cited above, we continue to believe that DHS should consider prioritizing the development and implementation of a systematic approach to accurately and consistently track OTAs used for national interest events and the associated dollars obligated.

DHS also did not concur with the fifth recommendation regarding updating DHS guidance to clarify how OTAs awarded in response to COVID-19 should be designated when reporting in the OTA module of FPDS-NG. In its response, DHS noted that additional guidance is not necessary because designation of OTAs is addressed in its July 2019 OTA guide, and that only research and prototype OTAs are required to be reported in FPDS-NG. However, DHS's response does not address the primary purpose of the recommendation—to provide the public with better transparency on the dollars obligated on COVID-19 OTAs. First, DHS's July 2019 OTA guide pre-dates COVID-19 and thus does not address how DHS should identify COVID-19 OTAs. Further, as noted above, regardless of what DHS is required to report in FPDS-NG, it did not accurately identify 45 percent of reported OTA dollars as COVID-19-related.

DHS's response noted that DHS voluntarily entered all of its Countering Weapons of Mass Destruction OTAs into FPDS-NG in response to COVID-19. However, without guidance to contracting personnel, it is likely that there will continue to be errors in reporting. As we noted in our report, part of the reason why DHS did not accurately identify \$25.5 million in OTAs as COVID-19-related is because DHS lacks guidance instructing contracting personnel to do so. In its response, DHS also noted that it maintains an internal OTA data collection and tracking log to ensure

OTAs are being documented. While this may be a helpful agency management tool, such information is not publicly available and does not provide the public with transparency into DHS's COVID-19 OTAs.

While DHS requests the recommendation be resolved and closed, given the reasons that we cited above, we continue to believe that DHS should update DHS guidance to clarify how OTAs awarded in response to COVID-19 should be designated when reporting in the OTA module of FPDS-NG.

GSA concurred with recommendations 4 and 9 and described its plans to address these recommendations in its written comments. In its response, GSA recognized that policy drives the Integrated Award Environment system functionality and noted it will collaborate with executive branch stakeholders to clarify existing policy guidance on agency reporting requirements for OTAs. GSA also noted it will work with the Integrated Award Environment's change control board to identify opportunities to enhance OTA tracking and reporting compliance.

DOD, HHS, and DHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Administrator of the General Services Administration, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, and other interested parties. 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 makm@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 the report are listed in appendix VI.



Marie A. Mak
Director, Contracting and National Security Acquisitions

List of Committees

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

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Patty Murray
Chair
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

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

The Honorable Rosa L. DeLauro
Chairwoman
The Honorable Kay Granger
Ranking Member
Committee on Appropriations
House of Representatives

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Bennie G. Thompson
Chairman
The Honorable John Katko
Ranking Member
Committee on Homeland Security
House of Representatives

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

The Honorable Richard E. Neal
Chairman
The Honorable Kevin Brady
Republican Leader
Committee on Ways and Means
House of Representatives

Appendix I: Objectives, Scope, and Methodology

This report examines the extent to which: (1) selected agencies used other transaction agreements (OTA) in response to Coronavirus Disease 2019 (COVID-19), and what factors contributed to their use, (2) these COVID-19 OTAs were awarded to consortia and how agencies provided oversight, and (3) selected agencies used and managed undefinitized contracts in response to COVID-19.

To identify the extent to which selected agencies used OTAs in response to COVID-19, we identified all the agencies that reported obligating dollars through OTAs in response to COVID-19 in the Federal Procurement Database System-Next Generation (FPDS-NG).¹ These agencies were:

- Department of Defense (DOD);²
- Department of Health and Human Services (HHS)—specifically, the Office of the Assistant Secretary for Preparedness and Response (ASPR), which includes the Biomedical Advanced Research and Development Authority;³ and
- Department of Homeland Security (DHS)—specifically, the Countering Weapons of Mass Destruction Office and the Transportation Security Administration.

We analyzed data available in the OTA module of FPDS-NG as of March 14, 2021 and identified OTAs and associated obligations by searching for “coronavirus” and “COVID-19” in the description of requirement data field. We analyzed the FPDS-NG data to identify the types of goods or services procured by DOD, HHS, and DHS using OTAs. We assessed the reliability of the FPDS-NG data by reviewing existing information about the FPDS-NG system and the data it collects, such as the data dictionary and data validation rules; performing electronic testing; and comparing reported data to agency-provided data and OTA documents. We

¹FPDS-NG is a comprehensive, web-based tool for agencies to report procurement contract actions and is the authoritative source for procurement award data, including dollars obligated on contract actions. It also includes a module for reporting OTAs.

²While DOD can use OTAs for research, prototyping, and production purposes, this report is focused only on OTAs used to support prototyping and production efforts.

³The National Institutes of Health—a part of HHS—did not report awarding any OTAs in response to COVID-19 in FPDS-NG as of March 14, 2021. In May 2021, officials from the National Institutes of Health informed us they had obligated about \$520 million on COVID-19 OTAs as of April 26, 2021. We did not assess the reliability of these data and did not include the \$520 million in our analysis.

determined that the control activities component of internal controls was significant to this objective, along with the principle that management should design information systems and related control activities to achieve objectives and respond to risks. We also determined that the information and communication component of internal controls was significant to this objective, along with the principle that management should externally communicate quality information to achieve objectives. We assessed the FPDS-NG OTA module system and its ability to accurately provide quality data on the actions and associated obligations for COVID-19 OTAs and the extent to which this information was communicated to congressional decision makers and the public. We found the agencies did not accurately report all COVID-19 OTA obligations, which we further discuss in the report. We identified additional COVID-19 OTA obligations through agency-provided data and documents. After we corrected the FPDS-NG OTA data for the inaccuracies and underreporting, we determined the data were sufficiently reliable for the purposes of describing agencies' reported OTA obligations in response to COVID-19. We also interviewed officials from the General Services Administration (GSA), which administers FPDS-NG, including the OTA module.

To identify the factors that contributed to DOD, HHS, and DHS using OTAs in selected cases, we selected a nongeneralizable sample of 15 OTAs awarded between February 2020 and October 2020 based on the FPDS-NG data, using the following criteria:⁴

- Highest dollars obligated
- Representation of all three contracting agencies
- Mix of product or service acquired
- Vendor, including consortium participation
- Justification for OTA use (nontraditional contractor participation, cost sharing, exceptional circumstance)
- Type of OTA (prototype or production)
- OTAs with potential data reliability concerns, including those identified by agencies as COVID-19-related but were not identified as COVID-19 in FPDS-NG

⁴Our selected OTAs included those awarded prior to February 2020 but were modified between February 2020 and October 2020 to include COVID-19 work.

Appendix I: Objectives, Scope, and Methodology

When we selected our sample of OTAs in October 2020, the obligations on OTAs across DOD, HHS, and DHS were 30 percent of total obligations on all contracting mechanisms—OTAs and procurement contracts—for these three agencies.

We selected seven vaccine OTAs, which comprised all obligations on COVID-19 vaccine OTAs. We also selected eight nonvaccine OTAs. See table 6 for details on the OTAs we selected.

Table 6: Selected COVID-19 Other Transaction Agreements (OTA)

Agency / component - vendor (consortium participation)	OTA number	Description	Obligations as of March 14, 2021 (\$)
HHS / ASPR - Janssen (not through a consortium)	HHSO100201700018C	COVID-19 vaccine development and clinical studies	1.1 billion
DOD / Army Contracting Command - Janssen (through a consortium)	W15QKN1691002 P000081	COVID-19 vaccine manufacturing	1 billion
HHS / ASPR - AstraZeneca (not through a consortium)	75A50120C00114	COVID-19 vaccine development	126 million
DOD / Army Contracting Command - AstraZeneca (not through a consortium)	W15QKN2191003	COVID-19 vaccine development and manufacturing	1.2 billion
DOD / Army Contracting Command - Sanofi (through a consortium)	W15QKN1691002 P000078	COVID-19 vaccine manufacturing	1.8 billion
DOD / Army Contracting Command - Novavax (through a consortium)	W15QKN1691002 P000074 ^a	COVID-19 vaccine manufacturing	1.6 billion
DOD / Army Contracting Command - Pfizer (through a consortium)	W15QKN1691002 P000076	COVID-19 vaccine manufacturing	2 billion
DOD / Army Contracting Command - Cue Inc. (not through a consortium)	W911NF2190001	Nonvaccine: increase domestic production capacity of COVID-19 rapid detection test kits	481 million
DOD / Army Medical Research Acquisition Activity – University of California, San Francisco / Empatica / Sempulse / Fitbit / Diomics / Silbel / Philips (through a consortium)	W81XWH2090015	Nonvaccine: the development of wearable diagnostics for COVID-19 detection	19.2 million
DHS / Countering Weapons of Mass Destruction - American Medical Response (not through a consortium)	70RWMD20T00000006	Nonvaccine: COVID-19 screening at U.S. Customs and Border Protection federal inspection stations within ports of entry	23 million
DHS / Transportation Security Administration - City of Atlanta, Department of Aviation (not through a consortium)	HSTS0116HRES950	Nonvaccine: COVID-19 cleaning and sanitation at the Atlanta Airport	4.9 million

Appendix I: Objectives, Scope, and Methodology

Agency / component - vendor (consortium participation)	OTA number	Description	Obligations as of March 14, 2021 (\$)
DOD / Air Force - Essentium Inc. (not through a consortium)	FA86492099135	Nonvaccine: 3D printing for replacement parts to support the industrial base ^b	4.25 million
DOD / Army Contracting Command - Augustine Consulting, Inc. (not through a consortium)	W91CRB2090001	Nonvaccine: crisis response communication kit	11 million
HHS / ASPR - Regeneron Pharmaceuticals (not through a consortium)	HHSO100201700020C	Nonvaccine: COVID-19 therapeutic development	231 million
DOD / Army Contracting Command - Regeneron Pharmaceuticals, Inc. (through a consortium)	W15QKN1691002 P00074 ^a	Nonvaccine: large scale manufacturing of COVID-19 therapeutic	450 million

ASPR - Office of the Assistant Secretary for Preparedness and Response
 COVID-19 - Coronavirus Disease 2019
 DHS - Department of Homeland Security
 DOD - Department of Defense
 HHS - Department of Health and Human Services

Source: GAO review of Federal Procurement Data System-Next Generation and agency information. | GAO-21-501

^aThe OTA modification included two awards—one to Novavax and one to Regeneron.

^bThe Air Force took actions to increase cash flow to the contractor to offset financial distress caused by COVID-19.

The seven selected vaccine OTAs awarded by DOD and HHS account for all \$8.9 billion obligated on COVID-19 vaccine OTAs. The selected eight nonvaccine OTAs awarded by DOD, HHS, and DHS accounted for an additional \$1.2 billion in COVID-19 obligations. Combined, these 15 OTAs accounts for 81 percent of all obligation on COVID-19 OTAs as of March 14, 2021. For these selected cases, we analyzed OTA documents, such as written determinations for OTA use, solicitation documents, and award documents, and interviewed agreements officers and program officials. As part of our analysis, we determined the extent to which these OTAs used available CARES Act flexibilities. In addition, we reviewed agencies’ OTA policies and guidance and interviewed contracting policy officials at DOD, HHS, and DHS.

To identify the extent to which DOD, HHS, and DHS awarded OTAs to consortia in response to COVID-19, we analyzed the same data available in the OTA module of FPDS-NG as discussed above but by vendor, and we supplemented this analysis with reviews of publicly available information and OTA documents. We determined that the information and communication component of internal controls was significant to this objective, along with the principle that management should externally

communicate quality information to achieve objectives. We assessed DOD's, HHS's, and DHS's efforts to provide quality data on the consortium members who performed significant work on OTAs to congressional decision makers and the public. Of the 15 selected OTA cases we reviewed, six were awarded to consortia, all by DOD. To determine how DOD provided oversight for these six OTAs, we analyzed OTA documents and interviewed agreements officers and program officials to identify the extent to which these OTAs included analysis required by the Office of Federal Procurement Policy's Policy Letter 11-01 when contractors perform work closely associated with inherently governmental functions.⁵ We reviewed DOD, HHS, and DHS policies related to OTAs awarded to consortia and these agencies' reports to congressional committees regarding OTA use. We also interviewed officials from Advanced Technology International (ATI), the consortium management firm that received the majority of COVID-19 OTA obligations according to FPDS-NG data.

To identify the extent to which DOD, HHS, and DHS used undefinitized contracts in response to COVID-19, we analyzed data available in the procurement contract module of FPDS-NG as of March 14, 2021.⁶ We primarily identified these contract actions and associated obligations related to the COVID-19 response by using the National Interest Action code and supplementing this analysis by searching for "coronavirus" and "COVID-19" in the description of requirement data field.⁷ For the purposes of our analysis, undefinitized contract obligations are associated with contract actions identified in FPDS-NG as undefinitized, which includes letter contracts. DOD, HHS, and DHS accounted for 96 percent of all COVID-19-related undefinitized contract obligations reported across the federal government in FPDS-NG over the time frame of our review, or \$4.9 billion. We analyzed the FPDS-NG data to identify the types of goods or services procured by DOD, HHS, and DHS using undefinitized

⁵Office of Management and Budget, Office of Federal Procurement Policy, *Performance of Inherently Governmental and Critical Functions*, Policy Letter 11-01, 76 Fed. Reg. 56,227 (Sept. 12, 2011).

⁶On April 12, 2021, in response to our review, HHS corrected information for an undefinitized contract we reviewed by revising nine actions from being incorrectly identified as undefinitized to correctly identified as definitized. We incorporated these revisions into our March 14, 2021 data analysis, which resulted in a reduction of HHS undefinitized contract obligations by \$120 million.

⁷National Interest Action codes were established in 2005 after Hurricane Katrina with the purpose of tracking federal procurements for specific disasters, emergencies, or contingency events.

contracts. We assessed the reliability of the FPDS-NG data by reviewing existing information about the FPDS-NG system and the data it collects, such as the data dictionary and data validation rules; performing electronic testing, and comparing reported data to source documents. We determined the FPDS-NG data were sufficiently reliable for the purposes of describing agencies' reported undefinitized contract obligations in response to COVID-19.

To identify how DOD, HHS, and DHS managed selected undefinitized contracts, we selected a nongeneralizable sample of three undefinitized contracts awarded between February 2020 and October 2020 based on the FPDS-NG data, using the following criteria:

- Highest dollars obligated
- Representation of the contracting agencies with the majority of undefinitized contract obligations (DOD and HHS)
- Mix of product or service acquired
- Definitization status and schedule
- Percentage of work completed before definitization
- Vendor
- Extent competed

When we selected our sample of undefinitized contracts, the obligations on undefinitized contracts across the three agencies were 6 percent of total obligations on all contracting mechanisms—OTAs and procurement contracts.

See table 7 for details on the undefinitized contracts we selected.

Appendix I: Objectives, Scope, and Methodology

Table 7: Selected COVID-19 Undefined Contracts

Agency / component - vendor	Contract number	Description	Obligations as of March 14, 2021 (\$)
DOD / Air Force - General Electric Company	FA862618D0029 (base award), FA862620F0026 (delivery order), FA862620F0027 (delivery order), FA862620F0028 (delivery order), FA862620F0029 (delivery order)	Foreign military sales of jet engines to four countries to support the defense industrial base ^a	353.6 million
DOD / Army Corps of Engineers - Turner Construction Company	W912DS20C0008	Construct an alternative care facility in Stony Brook, New York	154.6 million
HHS / ASPR - American Red Cross	75A50120C00045	Convalescent plasma coordination and distribution	120.3 million ^b

ASPR - Office of the Assistant Secretary for Preparedness and Response
 COVID-19 - Coronavirus Disease 2019
 DOD - Department of Defense
 HHS - Department of Health and Human Services

Source: GAO review of Federal Procurement Data System-Next Generation and agency information. | GAO-21-501

^aThe Air Force took actions to increase cash flow to the contractor to offset financial distress caused by COVID-19.

^bOf the \$120.3 million in obligations, HHS obligated \$750,000 prior to definitizing or finalizing the contract and \$119.6 million after definitizing the contract.

The three undefinitized contracts we selected were awarded by DOD and HHS and had combined undefinitized contract obligations of \$509 million or about 10 percent of all COVID-19 undefinitized contract obligations. For these selected cases, we analyzed contract documents, such as written determinations and award documents, and interviewed contracting officers and program officials. As part of our analysis, we determined the extent to which DOD used available CARES Act flexibilities for its undefinitized contracts. In addition, we reviewed the Federal Acquisition Regulation, agencies' federal acquisition regulation supplements, and agency policies and guidance related to undefinitized contracts. We also interviewed contracting policy officials at DOD, HHS, and DHS.

We conducted this performance audit from August 2020 to July 2021 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.

Appendix II: Comments from the Department of Defense



ACQUISITION
AND SUSTAINMENT

OFFICE OF THE UNDER SECRETARY OF DEFENSE

3000 DEFENSE PENTAGON
WASHINGTON, DC 20301-3000

Ms. Marie Mak
Director, Contracting and National Security
U.S. Government Accountability Office
441 G Street, NW
Washington DC 20548

Dear Ms. Mak,

This is the Department of Defense response to GAO Draft Report GAO-21-501, "COVID-19 CONTRACTING: Actions Needed to Enhance Transparency and Oversight of Selected Awards," dated June 4, 2021 (GAO Code 104497).

Enclosed is the Department's response to the subject report. My point of contact is Mr. Gregory Snyder who can be reached at gregory.d.snyder.civ@mail.mil and or 703-614-0719.

Sincerely,

TENAGLIA Digitally signed by
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154945926 Date: 2021.07.09
10:50:34 -04'00'

John M. Tenaglia
Principal Director,
Defense Pricing and Contracting

Enclosure:
As stated

Enclosure

GAO DRAFT REPORT DATED JUNE 4, 2021
GAO-21-501 (GAO CODE 104497)

“COVID-19 CONTRACTING: ACTIONS NEEDED TO ENHANCE TRANSPARENCY
AND OVERSIGHT OF SELECTED AWARDS”

DEPARTMENT OF DEFENSE COMMENTS
TO THE GAO RECOMMENDATION

DoD RECOMMENDATION 1: The Secretary of Defense—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to consistently and accurately track Other Transaction Authorities (OTAs) used for national interest events and the associated dollars obligated. (Recommendation 1)

DoD RESPONSE: Partially Concur. The Department understands the importance of being able to quickly identify awards made in support of national emergencies, such as the response to the COVID-19 pandemic, for the public. However, in addition to an approach that would change the Federal Procurement Data System (FPDS) as recommended, DoD believes there are process-based approaches that could satisfy the need for identifying related Other Transactions for Prototypes / Production awards that would not require additional resources at FPDS or the agency-level to implement. Notwithstanding the very unique COVID-19 pandemic federal response, it is unlikely that Other Transactions for Prototypes / Production would routinely be used in the future to respond to other National Emergencies, natural disasters, or contingency actions; and, as such, expending resources on system changes to FPDS and agency contract writing systems may not be warranted. Regardless, DoD will work with the agency members of the change control board as necessary to consider different approaches and develop a standard framework for how agencies can identify applicable Other Transactions for Prototype / Production awards in the future.

DoD RECOMMENDATION 2: The Secretary of Defense—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to track the consortium members performing for each OTA awarded through a consortium or consortium management firm. (Recommendation 6)

DoD RESPONSE: Concur. The Department recognizes the need to more easily identify the individual consortium member performing on an order awarded to the consortium. DoD will work with the federal change control board to propose a method for doing so as part of reporting OTs for Prototypes/Production to the FPDS.

DoD RECOMMENDATION 3: Until a systematic approach to track consortium members for OTAs awarded through a consortium or consortium management firm is implemented, the Secretary of Defense should provide information to the public and congressional decision makers

**Appendix II: Comments from the Department
of Defense**

2

on the consortium members performing on each OTA awarded through a consortium or consortium management firm, such as by including this information in the description of requirement field in the OTA module of FPDS-Next Generation. (Recommendation 10)

DoD RESPONSE: Concur: The Department will provide instruction for users to include the names of the consortium member awardees of discrete sub-Prototype/Production OTs in the description of requirements field until planned system updates can be implemented in the FPDS OTA module.

DoD RECOMMENDATION 4: The Secretary of Defense should direct the Principal Director, Defense Pricing and Contracting, to update DOD's OTA guidance to include what agreement officers should consider when planning to use a consortium management firm to support acquisition-related activities, such as assessing the extent to which a consortium management firm is closely supporting inherently governmental functions and, for firms that do so, what enhanced management oversight activities are appropriate, if any. (Recommendation 13)

DoD RESPONSE: Concur: Defense Pricing and Contracting will provide guidance in the OT Guide update on factors the acquisition teams should consider when planning to use a consortium management firm (CMF). The guidance will address appropriate management oversight and risk mitigation procedures to be put in place to ensure inherent government functions are not performed by the CMF.

Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

June 29, 2021

Marie A. Mak
Director, Contracting and National Security Acquisitions
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Mak:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*COVID-19 CONTRACTING: Actions Needed to Enhance Transparency and Oversight of Selected Awards*" (Job code 104497/GAO-21-501).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Hild".

Jeff Hild
Acting Assistant Secretary for Legislation
Principal Deputy Assistant Secretary for Legislation

Attachment

**Appendix III: Comments from the Department
of Health and Human Services**

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — COVID-19 CONTRACTING: ACTIONS NEEDED TO ENHANCE TRANSPARENCY AND OVERSIGHT OF SELECTED AWARDS (GAO-21-501)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation 3

The Secretary of Health and Human Services—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to consistently and accurately track OTAs used for national interest events and the associated dollars obligated.

HHS Response

HHS concurs with GAO's recommendation. HHS, in coordination with DoD and DHS, will submit to the IAE CCB the recommendation to prioritize the development of a systematic approach to consistently and accurately track OTAs used for national interest events and the associated dollars obligated for their implementation Government-wide.

Recommendation 8

The Secretary of Health and Human Services—in coordination with the change control board governing the Integrated Award Environment—should consider prioritizing the development and implementation of a systematic approach to track the consortium members performing for each OTA awarded through a consortium or consortium management firm.

HHS Response

HHS concurs with GAO's recommendation. HHS, in coordination with DoD and DHS, will submit to the IAE CCB the recommendation to prioritize the development of a systematic approach to track the consortium members performing for each OTA awarded through a consortium or consortium management firm for their implementation Government-wide.

Recommendation 11

Until a systematic approach to track consortium members for OTAs awarded through a consortium or consortium management firm is implemented, the Secretary of Health and Human Services should direct the Office of the Assistant Secretary for Preparedness and Response to provide information to the public and congressional decision makers on the consortium members performing on each OTA awarded through a consortium or consortium management firm, such as by including this information in the description of requirement field in the OTA module of FPDS-NG. (Recommendation 11)

HHS Response

HHS concurs with GAO's recommendation.

**Appendix III: Comments from the Department
of Health and Human Services**

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED — COVID-19 CONTRACTING: ACTIONS NEEDED TO ENHANCE TRANSPARENCY AND OVERSIGHT OF SELECTED AWARDS (GAO-21-501)

Recommendation 14

The Secretary of Health and Human Services should direct the Assistant Secretary for Preparedness and Response to update HHS's OTA guidance to include what agreement officers should consider when planning to use a consortium management firm to support acquisition-related activities, such as assessing the extent to which a consortium management firm is closely supporting inherently governmental functions and, for firms that do so, what enhanced management oversight activities are appropriate, if any. (**Recommendation 14**)

HHS Response

HHS concurs with GAO's recommendation.

Appendix IV: Comments from the Department of Homeland Security

U.S. Department of Homeland Security
Washington, DC 20528



**Homeland
Security**

June 25, 2021

Marie A. Mak
Director, Contracting and National Security Acquisitions
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Re: Management Response to Draft Report GAO-21-501, "COVID-19 CONTRACTING: Actions Needed to Enhance Transparency and Oversight of Selected Awards"

Dear Ms. Mak:

Thank you for the opportunity to comment on this draft report. The U.S. Department of Homeland Security (DHS or the Department) appreciates the U.S. Government Accountability Office's (GAO) work in planning and conducting its review and issuing this report.

The Department is pleased to note the GAO's recognition that DHS's Other Transactions (OT) policy provides for enhanced oversight of the activities consortium management firms may perform in close support of inherently governmental functions, which reduces the risk of inappropriate influence on government decisions.

DHS remains committed to, among other things: (1) procurement of vital goods and services; (2) reporting accuracy, accountability, transparency in federal spending; and (3) mitigating the potential risks associated with contractors performing acquisition support services.

The draft report contained fourteen recommendations, including four for DHS, two with which the Department concurs, and two with which we non-concur. Attached find our detailed response to each recommendation. DHS previously submitted technical comments addressing several accuracy and contextual issues under a separate cover for GAO's consideration.

Again, thank you for the opportunity to review and comment on this draft report. Please feel free to contact me if you have any questions. We look forward to working with you again in the future.

Sincerely,

JIM H
CRUMPACKER

Digitally signed by JIM H
CRUMPACKER
Date: 2021.06.25 07:08:32 -04'00'

JIM H. CRUMPACKER, CIA, CFE
Director
Departmental GAO-OIG Liaison Office

Attachment

**Attachment: Management Response to Recommendations
Contained in GAO-21-501**

GAO recommended that the Secretary of Homeland Security:

Recommendation 2: In coordination with the change control board governing the Integrated Award Environment—consider prioritizing the development and implementation of a systematic approach to consistently and accurately track OTAs [Other Transaction Agreements] used for national interest events and the associated dollars obligated.

Response: Non-Concur. The DHS Office of the Chief Procurement Officer (OCPO) does not support prioritizing the development and implementation of a systematic approach to track OTAs used for national interest events and the associated dollars obligated within the Federal Procurement Data System-Next Generation (FPDS-NG). Only OTAs for research and development and prototype projects issued pursuant to 10 U.S.C. § 2371, “Research Projects: Transactions Other Than Contracts and Grants,” are statutorily required to be reported in FPDS-NG, and these OTAs are rarely used in response to national interest events. Further, FPDS-NG is used to report summary level detail of awards, not dollars. Nevertheless, if there is future use of OTAs in response to a national interest event, OCPO will issue instructions on how to identify those actions when reporting to FPDS-NG is required.

DHS requests that the GAO consider this recommendation resolved and closed.

Recommendation 5: Until a systematic approach to consistently and accurately track OTAs used for national interest events is implemented, update DHS guidance to clarify how OTAs awarded in response to COVID-19 should be designated when reporting in the OTA module of FPDS-NG.

Response: Non-concur. The OCPO does not agree that additional guidance is necessary, as the designation of OTAs is already addressed in current guidance. Specifically, the FPDS-NG reporting guidance contained in the DHS Other Transactions for Research and Prototype Projects Guide, dated July 2019, (OT Guide) referenced throughout GAO’s draft report is only applicable to OTAs issued pursuant to section 831 of the Homeland Security Act (HSA) of 2002, Public Law 107-296, (6 U.S.C. § 391), and does not extend to the Countering Weapons of Mass Destruction (CWMD) Office’s special authority under the HSA of 2002, Public Law 107-296, § 1926 (as added by Public Law No. 115-387, § 2(a)(5), (8) (2018)) (6 U.S.C. 596(1)). Nor does the FPDS-NG reporting guidance extend to the Transportation Security Administration’s (TSA’s) unique OT authority under 49 U.S.C. § 106(l)(6), 114(m).

While OTAs issued pursuant to CWMD's and TSA's authorities are not required by statute to be reported in FPDS-NG, OTAs awarded pursuant to section 831 of the HSA are required, pursuant to section 874 of the Duncan Hunter National Defense Authorization Act (NDAA) for Fiscal Year 2009 (Public Law 110-417).

Accordingly, DHS included FPDS-NG reporting instructions in the OT Guide to implement section 874 of the Duncan Hunter NDAA. While the OCPO voluntarily entered all its CWMD COVID-19 OTAs into FPDS-NG in response to the public health emergency, it was not required to do so. DHS does, however, require Contracting Activities delegated with section 831 of the HSA and CWMD's OT authorities to maintain an internal OT data collection and tracking log to ensure OTAs are being documented, and that OTAs comply with statutory and policy requirements. Consequently, the current log contains information such as the identification of the awardee, the effective date, funding, and the objectives of the OTA. The DHS OCPO Office of Procurement Operations (OPO) is the only Contracting Activity authorized to execute OTAs pursuant to CWMD's OT authority. OPO has documented all the CWMD OTAs in this log and has identified them as COVID-19 related when applicable.

DHS requests that the GAO consider this recommendation resolved and closed.

Recommendation 7: In coordination with the change control board governing the Integrated Award Environment—consider prioritizing the development and implementation of a systematic approach to track the consortium members performing for each OTA awarded through a consortium or consortium management firm.

Response: Concur. In keeping with the processes of the change control board governing the Integrated Award Environment, the Department of Defense requested a change to the system to allow identification of consortia for each OTA in February 2021. The DHS OCPO will consider this change when it is brought up for governance consideration but is not yet able to identify an estimated completion date for this action, as it is dependent on the General Services Administration's governance process. Estimated Completion Date (ECD): To Be Determined.

Recommendation 12: Until a systematic approach to track consortium members for OTAs awarded through a consortium or consortium management firm is implemented across agencies, provide information to the public on the consortium members performing on each OTA awarded through a consortium or consortium management firm, such as by including this information in the description of requirement field in the OTA module of FPDS-NG.

Response: Concur. The DHS OCPO will issue a policy memorandum directing authorized Contracting Activities to identify consortium members performing OTAs in the description field of the OTA module in FPDS-NG for all OTAs that are required to be reported in the system. ECD: September 30, 2021.

Appendix V: Comments from the General Services Administration

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The Administrator

June 30, 2021

The Honorable Gene L. Dodaro
Comptroller General of the United States
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Dodaro:

The U.S. General Services Administration (GSA) appreciates the opportunity to review and comment on the draft report, "COVID-19 Contracting Actions Needed to Enhance Transparency and Oversight of Selected Awards."

In the draft report, the Government Accountability Office (GAO) issued the following recommendations to GSA:

- Recommendation 4: GAO recommends the Administrator of General Services Administration, in coordination with the change control board governing the Integrated Award Environment, should consider prioritizing the development and implementation of a systematic approach to consistently and accurately track other transaction agreements (OTA) used for national interest events and the associated dollars obligated.
- Recommendation 9: GAO recommends that the Administrator of General Services Administration, in coordination with the change control board governing the Integrated Award Environment, should consider prioritizing the development and implementation of a systematic approach to track the consortium members performing for each OTA awarded through a consortium or consortium management firm.

GSA concurs with both Recommendations 4 and 9. Recognizing that policy drives the system functionality of the Integrated Award Environment (IAE), the IAE Program Management Office (PMO), in coordination with GSA's Office of Government-wide Policy, will collaborate with executive branch stakeholders to clarify existing policy guidance on agency reporting requirements for OTAs. Following that clarification, the IAE PMO will work with the IAE Change Control Board to identify opportunities to enhance OTA tracking and reporting compliance.

If you have any additional questions or concerns, please do not hesitate to contact me or Gianelle E. Rivera, Associate Administrator, Office of Congressional and Intergovernmental Affairs, at (202) 501-0563.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kale".

Katy Kale
Acting Administrator

cc: Marie A. Mak, Director, Contracting and National Security Acquisitions, GAO

U.S. General Services Administration
1800 F Street NW
Washington, DC 20405
www.gsa.gov

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

Marie A. Mak, 202-512-4841 or makm@gao.gov

Staff Acknowledgments

In addition to the contact named above, Penny Berrier (Assistant Director), Claire Li (Analyst in Charge), Ryan F. Braun, and Adie Lewis were principal contributors. In addition, the following people made contributions to this report: Vinayak Balasubramanian, Lorraine Ettaro, Laura Greifner, Kurt Gurka, Julia Kennon, Edward J. SanFilippo, and Roxanna T. Sun.

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