

# GAO@100 Highlights

Highlights of [GAO-21-265](#), a report to congressional committees

## Why GAO Did This Study

As of January 15, 2021, the U.S. had about 23 million cumulative reported cases of COVID-19 and more than 387,000 reported deaths, according to the Centers for Disease Control and Prevention. The country also continues to experience serious economic repercussions.

Four relief laws, including the CARES Act, were enacted as of November 2020 to provide appropriations to address the public health and economic threats posed by COVID-19. As of November 30, 2020, of the \$2.7 trillion appropriated by these four laws, the federal government had obligated a total of \$1.9 trillion and expended \$1.7 trillion of the COVID-19 relief funds, as reported by federal agencies.

In December 2020, the Consolidated Appropriations Act, 2021, provided additional federal assistance for the ongoing response and recovery.

The CARES Act includes a provision for GAO to report on its ongoing monitoring and oversight efforts related to the COVID-19 pandemic. This report examines the federal government's continued efforts to respond to and recover from the COVID-19 pandemic.

GAO reviewed data, documents, and guidance from federal agencies about their activities and interviewed federal and state officials and stakeholders. GAO completed its audit work on January 15, 2021.

## What GAO Recommends

GAO is making 13 new recommendations for agencies that are detailed in this Highlights and in the report.

View [GAO-21-265](#). For more information, contact A. Nicole Clowers at (202) 512-7114 or [clowersa@gao.gov](mailto:clowersa@gao.gov).

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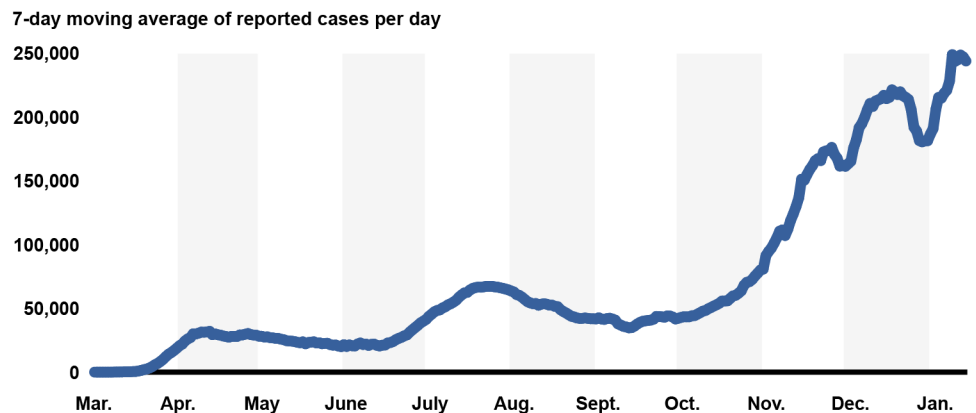
## COVID-19

### Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention

## What GAO Found

Since November 2020, the number of COVID-19 cases in the U.S. has rapidly increased, further straining health care systems across the country. Between December 31, 2020, and January 13, 2021, new reported COVID-19 cases averaged about 225,000 per day—over 7 and 3 times higher than the surges the nation experienced during the spring and summer of 2020, respectively. (See figure.) The country also continues to experience serious economic repercussions and turmoil as a result of the pandemic. As of December 2020, there were more than 10.7 million unemployed individuals, compared to nearly 5.8 million individuals at the beginning of the calendar year. Until the country better contains the spread of the virus, the pandemic will likely remain a significant obstacle to more robust economic activity.

Reported COVID-19 Cases per Day in the U.S., Through January 13, 2021



Source: GAO analysis of Centers for Disease Control and Prevention (CDC) data. | GAO-21-265

As of January 2021, 27 of GAO's 31 previous recommendations remained unimplemented. GAO remains deeply troubled that agencies have not acted on recommendations to more fully address critical gaps in the medical supply chain. While GAO recognizes federal agencies continue to take some steps, GAO underscores the importance of developing a well-formulated plan to address critical gaps for the remainder of the pandemic, especially in light of the recent surge in cases. In addition, implementation of GAO's recommendation concerning the importance of clear and comprehensive vaccine distribution and communication plans remains a work in progress. Moreover, slow implementation of GAO's recommendations relating to program integrity, in particular those made to the Small Business Administration (SBA) and Department of Labor (DOL), creates risk of considerable improper payments, including those related to fraud, and falls far short of transparency and accountability expectations. See appendix III for the status of GAO's past recommendations.

GAO is pleased that the Consolidated Appropriations Act, 2021—enacted in December of 2020—requires a number of actions that are consistent with several of GAO’s prior recommendations, including those related to the medical supply chain, vaccines and therapeutics, and COVID-19 testing. GAO will monitor the implementation of the act’s requirements.

GAO’s new recommendations are discussed below.

#### COVID-19 Testing

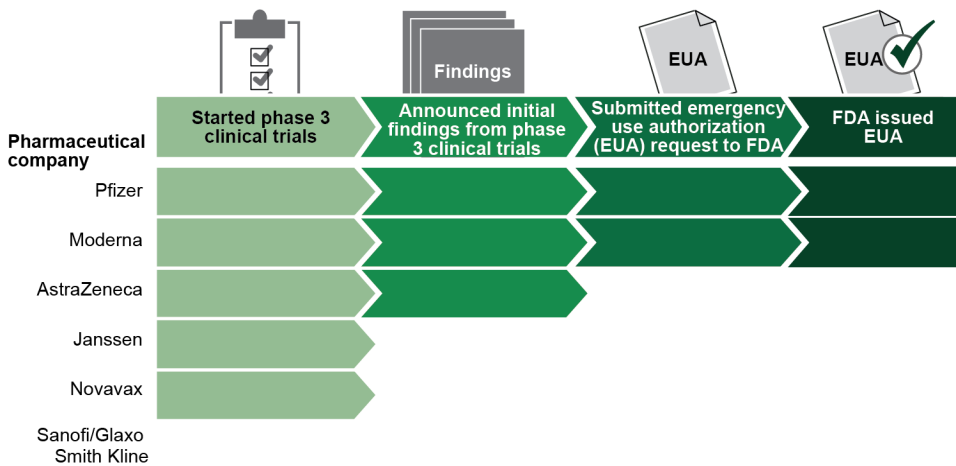
Diagnostic testing for COVID-19 is critical to controlling the spread of the virus, according to the Centers for Disease Control and Prevention. GAO found that the Department of Health and Human Services (HHS) has not issued a comprehensive and publicly available national testing strategy. HHS’s national strategy documents are not comprehensive because they only partially address the characteristics that GAO has found to be desirable in an effective national strategy. For example, testing strategy documents do not always provide consistent definitions and benchmarks to measure progress, not all documents clearly define the problem and risks, and there is limited information on the types of resources required for future needs.

Furthermore, some of the documents have not been made public. While the national testing strategy is formally outlined in a publicly available document, HHS has provided only Congress with the COVID-19 Testing Strategy Reports, which detail the implementation of the testing strategy. Stakeholders who are involved in the response efforts told GAO they were unaware of the existence of a national strategy or did not have a clear understanding of the strategy. Without a comprehensive, publicly available national strategy, HHS is at risk of key stakeholders and the public lacking crucial information to support an informed and coordinated testing response. **GAO is recommending that HHS develop and make publicly available a comprehensive national COVID-19 testing strategy that incorporates all six characteristics of an effective national strategy.** Such a strategy could build upon existing strategy documents that HHS has produced for the public and Congress to allow for a more coordinated pandemic testing approach. HHS partially concurred with this recommendation and agreed that it should take steps to more directly incorporate some of the elements of an effective national strategy.

#### Vaccines and Therapeutics

Multiple federal agencies, through Operation Warp Speed, continue to support the development and manufacturing of vaccines and therapeutics to prevent and treat COVID-19. As of January 8, 2021, two of the six vaccines supported by Operation Warp Speed have been authorized for emergency use, and vaccine distribution and administration have begun. (See figure below). However, distribution and administration fell short of expectations set for the end of the year. As of December 30, 2020, Operation Warp Speed had distributed (shipped) about 12.4 million doses of COVID-19 vaccine and providers reported administering about 2.8 million initial doses, according to Centers for Disease Control and Prevention data. **In September 2020, GAO stressed the importance of having a plan that focused on coordination and communication and recommended that HHS, with the support of the Department of Defense, establish a time frame for documenting and sharing a national plan for distributing and administering COVID-19 vaccine, and among other things, outline an approach for how efforts would be coordinated across federal agencies and nonfederal entities. To date, this recommendation has not been fully implemented. GAO reiterates the importance of doing so.** Effective coordination and communication among federal agencies, commercial partners, jurisdictions, and providers is critical to successfully deploying COVID-19 vaccines and managing public expectations, especially because the initial supply of vaccine has been limited.

Status of Development of Six Operation Warp Speed COVID-19 Vaccine Candidates, as of January 8, 2021



Source: GAO analysis of pharmaceutical company, Operation Warp Speed, and Food and Drug Administration (FDA) information. | GAO-21-265

Medical Supply Chain

The pandemic has highlighted vulnerabilities in the nation’s medical supply chain, which includes personal protective equipment and other supplies necessary to treat individuals with COVID-19. The Strategic National Stockpile (SNS) is an important piece of HHS’s recently developed strategy to improve the medical supply chain to enhance pandemic response capabilities. However, the department has yet to develop a process for engaging about the strategy with key nonfederal stakeholders that have a shared role for providing supplies during a pandemic, such as state and territorial governments and the private sector. GAO’s work has noted the importance of directly and continuously involving key stakeholders, including Congress, in the development of successful agency reforms and helping to harness ideas, expertise, and resources.

**To improve the nation’s response and preparedness for pandemics, GAO recommends that HHS establish a process for regularly engaging with Congress and nonfederal stakeholders—including state, local, tribal, and territorial governments and private industry—as the agency refines and implements its supply chain strategy for pandemic preparedness, to include the role of the SNS.** HHS generally concurred with this recommendation and noted that the department regularly engages with Congress and nonfederal stakeholders. GAO maintains that capitalizing on existing relationships to engage these critical stakeholders as HHS refines and implements a supply chain strategy, to include the role of the SNS, will improve a whole-of-government response to, and preparedness for, pandemics.

In August 2020, the President issued an Executive Order directing agencies to take steps toward the goal of strengthening domestic drug manufacturing and supply chains. Federal agencies have started implementing the Executive Order, but expressed concerns about their ability to implement some of the provisions. In particular, GAO found that federal agencies do not have complete and accessible information to identify supply chain vulnerabilities and to report the manufacturing supply chains of drugs that were procured by the agency.

**To help it identify and mitigate vulnerabilities in the U.S. drug supply chain, GAO recommends that the Food and Drug Administration (FDA) ensure drug manufacturing data obtained are complete and accessible, including by working with manufacturers and other federal agencies, such as the Department of Defense and the Department of Veterans Affairs and, if necessary, seek authority to obtain complete and accessible information.** HHS neither agreed nor disagreed with this recommendation.

COVID-19 Data for Health Care Indicators

The federal government does not have a process to help systematically define and ensure the collection of standardized data across the relevant federal agencies and related stakeholders to help respond to COVID-19, communicate the status of the pandemic with citizens, or prepare for future pandemics. As a result, COVID-19 information that is collected and reported by states and other entities to the federal government is often incomplete and inconsistent. The lack of complete and consistent data limits HHS’s and others’ ability to monitor trends in the burden of the pandemic across states and regions, make informed comparisons between such areas, and assess the impact of public health actions to prevent and mitigate the spread of COVID-19. Further, incomplete and inconsistent data have limited HHS’s and others’ ability to prioritize the allocation of health resources in specific geographic areas or among certain populations most affected by the pandemic.

To improve the federal government’s response to COVID-19 and preparedness for future pandemics, GAO recommends that HHS immediately establish an expert committee comprised of knowledgeable health care professionals from the public and private sectors, academia, and nonprofits or use an existing one to systematically review and inform the alignment of ongoing data collection and reporting standards for key health indicators. HHS partially concurred with this recommendation and agreed that it should establish a dedicated working group or other mechanism with a focus on addressing COVID-19 data collection shortcomings.

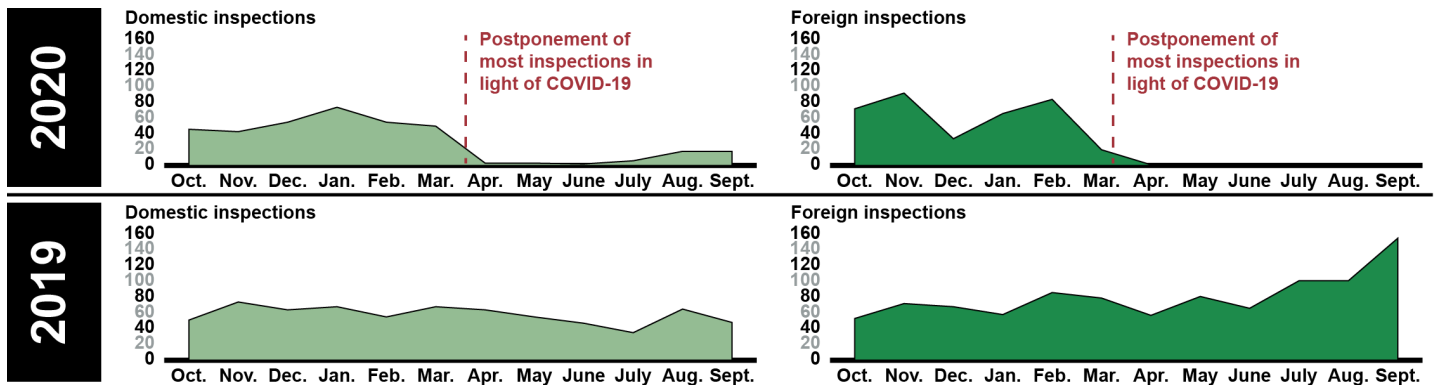
Drug Manufacturing Inspections

FDA is responsible for overseeing the safety and effectiveness of all drugs marketed in the U.S., including those manufactured overseas, and typically conducts more than 1,600 inspections of foreign and domestic drug manufacturing establishments every year. In light of the COVID-19 pandemic, since March 2020, FDA has limited domestic and foreign inspections for the safety of its employees. (See figure below.)

FDA has used alternative inspection tools to maintain some oversight of drug manufacturing quality while inspections are paused, including inspections conducted by foreign regulators, requesting and reviewing records and other information, and sampling and testing. Although FDA has determined that inspections conducted by certain European regulators are equivalent to an FDA inspection, other tools provide useful information but are not equivalent to an FDA inspection. As a result, FDA could be faced with a backlog of inspections, threatening the agency’s goal to maximize inspections prioritized by its risk-based site selection model each year.

GAO recommends that FDA (1) ensure that inspection plans for future fiscal years identify, analyze, and respond to the issues presented by the backlog of inspections that could jeopardize its goal of risk-driven inspections, and (2) fully assess the agency’s alternative inspection tools and consider whether these tools or others could provide the information needed to supplement regular inspection activities or help meet the agency’s drug oversight objectives when inspections are not possible in the future. FDA concurred with both recommendations.

Number of FDA-Conducted Domestic and Foreign Drug Manufacturing Establishment Inspections, Fiscal Years 2019–2020, by Month



Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-21-265

Federal Contracting

Federal agencies are using other transaction agreements to respond to the pandemic, which are contracting mechanisms that can enable agencies to negotiate terms and conditions specific to a project. GAO found that HHS misreports its other transaction agreements related to COVID-19 as procurement contracts, including other transaction agreements with about \$1.5 billion obligated for Operation Warp Speed and other medical countermeasures. HHS’s approach is inconsistent with federal acquisition regulations and limits the public’s insight into the agency’s contract spending. **To ensure consistent tracking and transparency of federal contracting activity related to the pandemic, GAO recommends that HHS accurately report data in the federal procurement database system and provide information that would allow the public to distinguish between spending on other transaction agreements and procurement contracts.** HHS concurred with this recommendation.

Oversight of Worker Safety and Health

GAO identified concerns about federal oversight of worker safety and health amid the COVID-19 pandemic. Specifically, the Occupational Safety and Health Administration (OSHA) has adapted its enforcement methods for COVID-19 to help protect agency employees from the virus and address resource constraints, such as by permitting remote inspections in place of on-site inspections of workplaces. However, gaps in OSHA’s oversight and tracking of its adapted enforcement methods prevent the agency from assessing the effectiveness of its enforcement methods during the pandemic, ensuring that its adapted enforcement methods do not miss violations, and ensuring that employers are addressing certain identified violations.

To improve its oversight, GAO recommends that OSHA (1) develop a plan, with time frames, to implement the agency's oversight processes for COVID-19-adapted enforcement methods, and (2) ensure that its data system includes comprehensive information on use of these enforcement methods to inform these processes. The agency neither agreed nor disagreed with these recommendations.

Additionally, OSHA's data do not include comprehensive information on workplace exposure to COVID-19. For example, OSHA does not receive employer reports of all work-related hospitalizations related to COVID-19, as disease symptoms do not appear within the required reporting time frames. Employers may also face challenges determining whether COVID-19 hospitalizations or fatalities are work-related because of COVID-19's incubation period and the difficulties in tracking the source of exposure. **GAO recommends that OSHA determine what additional data may be needed from employers or other sources to better target the agency's COVID-19 enforcement efforts.** The agency neither agreed nor disagreed with this recommendation.

#### Assistance for Fishery Participants

The CARES Act appropriated \$300 million in March 2020 to the Department of Commerce (Commerce) to assist eligible tribal, subsistence, commercial, and charter fishery participants affected by COVID-19, which may include direct relief payments. After administrative fees were assessed, \$298 million of the \$300 million appropriated was obligated for fishery participants. Widespread restaurant closures in the spring of 2020 led to a decrease in demand for seafood, adversely affecting the fisheries industry.

As of December 4, 2020, all funds had been obligated and only about 18 percent (\$53.9 million) of the CARES Act funding obligated for fishery participants had been disbursed, which is inconsistent with Office of Management and Budget guidance on the importance of agencies distributing CARES Act funds in an expedient manner. Commerce's National Oceanic and Atmospheric Administration (NOAA) officials said they expect that the vast majority of funds will be disbursed to fisheries participants by early 2021. However, the agency does not have the needed information centralized to help ensure that funds are being disbursed expeditiously and efficiently. **GAO recommends that NOAA develop a mechanism to track the progress of states, tribes, and territories in meeting established timelines to disburse funds in an expedited and efficient manner.** NOAA concurred with this recommendation.

#### Program Integrity

GAO continues to identify areas to improve program integrity and reduce the risk of improper payments for programs funded by the COVID-19 relief laws now that federal agencies have obligated a total of \$1.9 trillion and expended \$1.7 trillion of the \$2.7 trillion appropriated for response and recovery efforts as of November 30, 2020. Federal relief programs remain vulnerable to significant risk of fraudulent activities because of the need to quickly provide funds and other assistance to those affected by COVID-19 and its economic effects.

In this report, GAO identifies concerns about overpayments and potential fraud in the unemployment insurance (UI) system, specifically in the federally funded Pandemic Unemployment Assistance (PUA) program, which provides UI benefits to individuals not otherwise eligible for these benefits, such as self-employed and certain gig economy workers. As of January 11, 2021, states that had submitted data to DOL reported more than \$1.1 billion in PUA overpayments from March through December 2020. While DOL requires states to report data on PUA overpayments, as of the beginning of 2021, the agency was not tracking the amount of overpayments recovered, limiting insight into the effectiveness of states' efforts to recoup federal funds. **To better track the recovery of federal funds, GAO recommends that DOL collect data from states on the amount of PUA overpayments recovered.** DOL concurred with this recommendation, and has taken the first step toward implementing it by issuing new guidance and updated instructions for states to report PUA overpayment recovery data.

GAO also remains concerned about SBA's management of internal controls and fraud risks in the Economic Injury Disaster Loans (EIDL) program. COVID-19 relief laws made qualifying small businesses and nonprofit organizations adversely affected by COVID-19 eligible for financial assistance from the EIDL program. Some approval requirements were also relaxed, such as requiring each applicant to demonstrate that it could not obtain credit elsewhere, through December 31, 2021. As of December 31, 2020, SBA officials said they had approved about 3.7 million applications for loans related to COVID-19, totaling about \$200 billion. SBA rapidly processed loans and advances to millions of small businesses affected by COVID-19. GAO's analysis of SBA data shows that the agency approved EIDL loans and advances for potentially ineligible businesses. For example, SBA approved at least 3,000 loans totaling about \$156 million to potentially ineligible businesses in industries that SBA policies state were ineligible for the EIDL program, such as insurance and real estate development, as of September 30, 2020. **GAO recommends that SBA develop and implement portfolio-level data analytics across EIDL loans and advances made in response to COVID-19 as a means to detect potentially ineligible and fraudulent applications.** SBA neither agreed nor disagreed with this recommendation.