

# GAO Highlights

Highlights of [GAO-23-105713](#), a report to congressional committees

## Why GAO Did This Study

The COVID-19 pandemic and other recent public health emergencies highlight the threat of widespread illness and death posed by new and emerging infectious diseases. GAO has designated HHS's leadership and coordination of public health emergencies as a high-risk area due to the need to be prepared for, and effectively respond to, future public health threats.

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 (1) how HHS used CIADM program funds prior to and during the COVID-19 pandemic, (2) what challenges affected the CIADM program's effectiveness in developing and manufacturing countermeasures, and (3) how HHS plans to use its new program model to address the challenges of the CIADM program.

To address these objectives, GAO examined HHS documents and leading practices for managing program risks and interviewed and reviewed written correspondence with representatives from HHS and the three CIADM sites.

## What GAO Recommends

GAO is recommending that HHS incorporate into the development of its new program model an approach to systematically assess, and respond to, known challenges and risks associated with advanced development and manufacturing of medical countermeasures. We provided a draft of this report to HHS for review and comment. HHS concurred with our recommendation.

View [GAO-23-105713](#). For more information, contact Mary Denigan-Macauley at (202) 512-7114 or [deniganmacauleym@gao.gov](mailto:deniganmacauleym@gao.gov).

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## PUBLIC HEALTH PREPAREDNESS

### HHS Should Plan for Medical Countermeasure Development and Manufacturing Risks

## What GAO Found

In 2012, the Department of Health and Human Services (HHS) established a program to improve domestic infrastructure and expertise to produce medical countermeasures—such as drugs and vaccines—in response to public health emergencies. This program, known as the Centers for Innovation in Advanced Development and Manufacturing (CIADM), was originally composed of three sites responsible for, among other things, rapidly producing countermeasures for a pandemic. During the period prior to the COVID-19 pandemic, HHS funded the sites to produce small batches of drug substances for other manufacturers. During the COVID-19 pandemic, HHS provided increased funding to reserve capacity to produce products at a larger scale to aid the pandemic response. However, HHS said that the sites faced challenges reliably producing products at a larger scale, such as poor quality control, that led to the eventual shutdown of one site due to cross-contamination.

An internal HHS review found that a lack of regular manufacturing work from either HHS or other manufacturers prevented the sites from developing the capability to rapidly produce countermeasures at a large scale as the program intended. HHS and site officials identified several reasons for this underuse, including a lack of dedicated funding from HHS and challenges attracting external manufacturers to use the sites for countermeasure production.

HHS is ending the CIADM program and plans to transition to a new program model—the National Biopharmaceutical Manufacturing Partnership (BioMaP). BioMaP is early in its development, and it is unclear how BioMaP will address some of the challenges faced by the CIADM program, as in the following examples.

- BioMaP is expected to use a different contracting structure intended to provide more incentives for industry partners to participate. However, this different structure requires additional expertise to manage effectively. Moreover, HHS told GAO that its contracting staff had previously faced resource challenges using this different contracting structure for other programs during the COVID-19 pandemic. HHS officials said in April 2022 that the agency has half the contracting staff needed to manage its contracting portfolio. This creates the risk that the agency may not have enough resources and expertise to manage this different structure effectively.
- HHS does not have a sustainable source of funding for the new program model, and it has not yet developed detailed plans or budgets. HHS officials said that, without sustained funding for BioMaP or a similar program, the agency would be unprepared to respond to the next pandemic.

As HHS is developing its plans for a new program model for countermeasure production, incorporating an approach to address these challenges and risks would provide HHS with greater assurance that it can avoid repeating the challenges of the CIADM program.