



February 2023

PUBLIC HEALTH PREPAREDNESS

HHS Should Plan for Medical Countermeasure Development and Manufacturing Risks

Accessible Version

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.

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.

Contents

GAO Highlights		ii
	Why GAO Did This Study	ii
	What GAO Recommends	ii
	What GAO Found	ii
Letter		1
	Background	4
	HHS Used CIADM Program Funds to Increase Manufacturing Capacity and Provided Relatively Few Funds for Countermeasures Prior to the COVID-19 Pandemic	8
	Underuse of the Sites Prevented Full Development of Manufacturing Capabilities, Affecting COVID-19 Vaccine Production	12
	It Is Unclear How HHS Plans to Address Known Challenges and Future Risks in Its Proposed Program Model	17
	Conclusions	25
	Recommendation for Executive Action	25
	Agency Comments	25
Appendix I: Comments from the Department of Health and Human Services		30
	Text of Appendix I: Comments from the Department of Health and Human Services	32
Appendix II: GAO Contact and Staff Acknowledgments		34
Tables		
	Table 1: Spending on, and Examples of, Base Contract Activities Conducted by Centers for Innovation in Advanced Development and Manufacturing (CIADM) Sites, 2012 through 2021	9
	Table 2: Task Orders Issued to Centers for Innovation in Advanced Development and Manufacturing (CIADM) Sites, Prior to and During the COVID-19 Pandemic, 2012 through 2021	10

Abbreviations

BARDA	Biomedical Advanced Research and Development Authority
BioMaP	National Biopharmaceutical Manufacturing Partnership
CIADM	Centers for Innovation in Advanced Development and Manufacturing
COVID-19	Coronavirus Disease 2019
DOD	Department of Defense
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
OTA	Other Transaction Agreement

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



February 2, 2023

Congressional Committees

The COVID-19 pandemic and other public health emergencies—such as the 2009 H1N1 influenza pandemic and the 2022 mpox outbreak—highlight the threat of widespread illness and death posed by new and emerging infectious diseases.¹ These threats underscore the importance of being able to rapidly develop, manufacture, and distribute medical countermeasures to respond to public health emergencies. Medical countermeasures are drugs, vaccines, and devices to diagnose, treat, prevent, or mitigate the health effects of exposure to a chemical, biological, radiological, or nuclear agent. The Department of Health and Human Services (HHS) is the primary federal department responsible for medical countermeasure development and procurement, and other public health preparedness.

Many factors make it difficult to rapidly develop and manufacture medical countermeasures—referred to in this report as countermeasures—in response to public health emergencies. We have previously reported that, like pharmaceutical products in general, producing countermeasures is time-consuming, complex, and expensive. Unlike most pharmaceutical products, there is no general commercial market for countermeasures used in response to low-probability, high-consequence events. This may reduce incentives for large pharmaceutical companies to invest consistently in these products instead of others that may be more profitable.²

The 2009 H1N1 pandemic raised concerns about the United States' ability to rapidly manufacture needed countermeasures in an emergency, with the federal government acknowledging that it was not able to provide enough vaccines before the pandemic spread through the population.³ Following this pandemic, HHS conducted a review in 2010 of its existing

¹Mpox was formerly known as monkeypox. The World Health Organization recommended the name change in November 2022.

²GAO, *National Preparedness: HHS Has Funded Flexible Manufacturing Activities for Medical Countermeasures, but It Is Too Soon to Assess Their Effect*, [GAO-14-329](#) (Washington, D.C.: Mar. 31, 2014).

³Department of Health and Human Services, *The Public Health Emergency Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs*, (Washington, D.C.: Aug. 2010).

countermeasure efforts. In response to a recommendation in that review, HHS created the Centers for Innovation in Advanced Development and Manufacturing (CIADM) program in 2012. HHS intended that the program would provide both initial and ongoing support to enhance domestic infrastructure and expertise for countermeasure development and manufacturing.

In 2012, HHS awarded funding to three contractors (two biomanufacturing companies and one university) to establish CIADM facilities—hereafter referred to as sites. HHS used the program to support the manufacture of COVID-19 vaccines developed under Operation Warp Speed, but HHS reported that the program had limitations that hindered its effectiveness and that the program did not work as intended.⁴ In 2022, HHS formally announced that it was ending the CIADM program and developing a new program model for rapid countermeasure production that is intended to replace it.⁵

The CARES Act includes a provision for us to report on ongoing monitoring and oversight efforts related to the COVID-19 pandemic.⁶ This report is part of our body of work in response to the CARES Act and related to HHS' leadership and coordination of public health emergencies, which we identified as an area of high risk due to the need to be prepared for, and effectively respond to, future public health threats.⁷ This report focuses on the federal government's efforts related to the CIADM program. Specifically, we:

⁴Operation Warp Speed was a partnership, launched in May 2020, between HHS and the Department of Defense (DOD) to accelerate the development of a COVID-19 vaccine. The program led to the development of three vaccines, two of which began distribution in December 2020. For more information, see GAO, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, [GAO-21-319](#) (Washington D.C.: Feb. 11, 2021); and GAO, *COVID-19: HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues*, [GAO-22-104453](#) (Washington, D.C.: Jan. 19, 2022).

⁵Department of Health and Human Services, *Fiscal Year 2023: Public Health and Social Services Emergency Fund: Justification of Estimates for Appropriations Committee* (Washington, D.C.: Mar. 28, 2022).

⁶Pub. L. No. 116-136, § 19010(b), 134 Stat. 281, 580 (2020). The American Rescue Plan Act of 2021 also includes a provision for us to conduct oversight of the COVID-19 response. Pub. L. No. 117-2, § 4002, 135 Stat. 4, 78. All of GAO's reports related to the COVID-19 pandemic are available on GAO's website at <https://www.gao.gov/coronavirus>.

⁷GAO, *High Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas*, [GAO-21-119SP](#) (Washington, D.C.: Mar. 2, 2021).

1. describe how HHS used CIADM program funds prior to and during the COVID-19 pandemic;
2. describe what challenges affected the CIADM program's effectiveness in developing and manufacturing countermeasures; and
3. examine how HHS plans to use its new program model to address the challenges of countermeasure development faced by the CIADM program.

To describe both (1) how HHS used CIADM program funds prior to and during the COVID-19 pandemic, as well as (2) what challenges affected the CIADM program's effectiveness in developing and manufacturing countermeasures, we reviewed contracts for all three sites and performance documents for two sites active during the COVID-19 response to identify program funding and activities. This documentation included the CIADM contracts between each site and the Biomedical Advanced Research and Development Authority (BARDA), the office within HHS' Administration for Strategic Preparedness and Response that was responsible for oversight of the CIADM program.⁸ We also reviewed orders for services under the CIADM contracts, progress reports submitted by sites to BARDA during the COVID-19 response, and audit reports and documentation from BARDA site visits and inspections related to the CIADM program.

To examine how HHS plans to use its new program model to address the challenges of countermeasure development faced by the CIADM program, we reviewed documentation and presentations evaluating the CIADM program and outlining BARDA's initial plans for the proposed program model.⁹ We assessed BARDA's initial plans against leading practices for risk management, a forward-looking management approach

⁸The Administration for Strategic Preparedness and Response was previously known as the Office of the Assistant Secretary for Preparedness and Response. In July 2022, HHS announced that it would elevate the office from a staff division to a standalone operating division. As part of this change, its name was changed to the Administration for Strategic Preparedness and Response.

⁹Specifically, we reviewed a Request for Information that BARDA released in October 2021 to solicit feedback from biopharmaceutical industry representatives on a new program model (accessed October 28, 2022 from <https://www.medicalcountermeasures.gov/media/38403/barda-rfi-biomap-consortium.pdf>.) We also reviewed a presentation that the Administration for Strategic Preparedness and Response and BARDA made to the Biotechnology Innovation Organization International Convention in June 2022.

that allows agencies to assess threats and opportunities that could affect the achievement of their goals.¹⁰ Risk management involves managing both “risks” (where there is the potential for either a negative or positive outcome in the future), which agencies may or may not be aware of in the present, and “challenges” (actual, known issues or threats agencies have faced in the past or are currently facing). These leading practices include the Office of Management and Budget’s Circular No. A-123, which defines management responsibilities for risk management within federal agencies.¹¹

For all three objectives, we interviewed and reviewed written correspondence with officials at BARDA and each of the three original sites. These discussions provided information about BARDA’s and sites’ experiences in the CIADM program, such as activities the sites undertook during the program and communications between BARDA and the sites about progress and challenges. These discussions also provided insight into what lessons BARDA and the sites learned from these experiences with the CIADM program and how they could be applied to BARDA’s new proposed program model for countermeasure production.

We conducted this performance audit from January 2022 to February 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

HHS is the primary federal department responsible for public health preparedness. Within HHS, the Administration for Strategic Preparedness and Response leads the federal medical and public health response to public health emergencies, including strategic planning and support for developing and securing countermeasures. Within that, BARDA coordinates and supports advanced research and development,

¹⁰GAO, *Enterprise Risk Management: Selected Agencies’ Experiences Illustrate Good Practices in Managing Risk*, [GAO-17-63](#) (Washington, D.C.: Dec. 1, 2016).

¹¹Office of Management and Budget, *OMB Circular No. A-123: Management’s Responsibility for Enterprise Risk Management and Internal Control*, OMB Circular A-123 (Washington, D.C.: Jul. 15, 2016).

manufacturing, and initial procurement of countermeasures and was responsible for overseeing the CIADM program.

HHS created the CIADM program in response to prior challenges in developing countermeasures. Specifically, in its 2010 review of countermeasure efforts, HHS stated that, while the nation did effectively make and test vaccines in response to the 2009 H1N1 pandemic, the vaccines were not broadly available before the virus had spread through the population. This led the agency to conclude that the nation needed faster methods to develop and manufacture vaccines or other countermeasures. HHS reported that its goal for the CIADM program was to support the country's ability to develop and manufacture new countermeasures in a timely manner by constructing facilities that would aid in both short-term emergency and long-term ongoing activities. In the short term, the sites would be able to rapidly produce vaccines for the nation for an emerging disease when a vaccine is available, known as "surge production capacity." In the long term, the sites would provide assistance to larger pharmaceutical manufacturers for developing and producing new countermeasures, which could be accomplished during pandemic or non-pandemic periods.

The CIADM program began in 2012, when BARDA awarded contracts to establish three sites: Emergent Manufacturing Operations of Baltimore LLC (Emergent); CSL Seqirus of Holly Springs, NC (CSL Seqirus); and Texas A&M University System of College Station, TX (Texas A&M).¹² To accomplish the short-term and long-term goals mentioned above, the sites were contracted to provide three types of services as follows.

1. Surge production capacity for influenza pandemic response (at least 50 million finished doses within 4 months of an influenza pandemic).
2. Services to assist in countermeasure development and production, such as production of drug substances for clinical trials. These services, known as "core services," were intended to allow the sites to support those who have existing contracts with BARDA or other government partners.

¹²CSL Seqirus (known as Seqirus until August 2022) was created in 2015 when its parent company, CSL Limited, acquired the influenza vaccine business of Novartis Vaccines and Diagnostics, Inc. of Cambridge, MA, which received the original CIADM award. In December 2016, the government novated the CIADM contract originally awarded to Novartis to CSL Seqirus.

3. Workforce training to enhance and maintain overall U.S. capabilities and expertise to develop and produce countermeasures.

BARDA intended for these activities to improve both the capacity and capability of domestic countermeasure manufacturing. “Capacity” refers to the facilities and infrastructure needed to sustainably develop and produce countermeasures. “Capability” refers to the workforce skills, materials, and quality control systems needed to reliably produce countermeasures at a sufficient scale and level of quality. According to BARDA officials, while the sites were expected to be able to pivot to surge production capacity if needed, the primary capability needed from the sites was core service assistance to countermeasure developers. Specifically, according to BARDA officials, the sites were allowed to use their CIADM program capacity in nonpandemic periods for other activities, including commercial manufacturing, provided that the sites made their influenza vaccine surge capacity available upon request from HHS to respond to a pandemic.¹³ BARDA would monitor the sites through audits and site visits to ensure that the sites were able to meet the terms of their contracts.

Under the CIADM program, each site had a contract, which covered setup activities—such as facility design, construction, and testing—that would allow the sites to build the capacity needed to provide further services. The contracts also included option periods for the three services mentioned above—vaccine surge production capacity, core services, and workforce development.¹⁴ BARDA would assess the sites to determine if they were ready to provide both surge production capacity and core services. Once the sites were deemed ready, they could be awarded task orders to provide those services. BARDA anticipated providing task orders for each of the three types of services throughout the program.

The CIADM program used indefinite delivery/indefinite quantity contracts, a contract type in which the government must order, and the contractor must provide, a minimum agreed-upon quantity of products or services, and the contractor must provide any other quantities ordered by the

¹³While surge capacity at the CIADMs was intended for pandemic influenza vaccine production, BARDA officials also told us this capacity could have been used to manufacture other medical countermeasures, such as an anthrax vaccine, in a public health emergency.

¹⁴Work during the option periods, including for task orders, may have been completed under an indefinite-delivery/indefinite quantity or a cost-plus-fixed-fee contract type.

government up to a stated maximum.¹⁵ Every CIADM site contract was subject to the Federal Acquisition Regulation, which is the principal set of rules for acquiring supplies or services in the federal government. Indefinite delivery/indefinite quantity contracts awarded under the Federal Acquisition Regulation are generally subject to certain requirements intended to provide products or services that have the best value to the government while fulfilling policy objectives. These include standard requirements for competition among vendors and for reporting certain information into a federal procurement database. Requirements can also include further terms and conditions regarding government-unique cost accounting systems and cost data reporting, and rights to intellectual property developed under contracts, among others.

While the CIADM program started with three sites, over the course of the program, the number of participating sites was reduced to one. According to officials from BARDA and the site, one site (CSL Seqirus) reached a mutual agreement with BARDA to end its participation in the CIADM program in 2018, and it did not participate in the response to the COVID-19 pandemic. Another site (Emergent) agreed to stop production from April to July 2021, after the site informed HHS of cross-contamination. A subsequent Food and Drug Administration (FDA) inspection of the site's COVID-19 vaccine production reported observations of non-compliance with current good manufacturing practices that could have led to cross-contamination of one vaccine product with another. BARDA officials said they worked with Emergent to attempt to remedy the issues, but the two sides eventually reached a mutual agreement to terminate Emergent's CIADM contract.¹⁶

In addition, the Department of Defense (DOD) established an advanced development and manufacturing facility focused on developing and manufacturing biological countermeasures to mitigate the health effects of biological agents and naturally occurring diseases on armed forces

¹⁵For additional details on indefinite delivery/indefinite quantity contracts, see GAO, *Federal Contracts: Agencies Widely Used Indefinite Contracts to Provide Flexibility to Meet Mission Needs*, [GAO-17-329](#) (Washington, D.C.: Apr. 13, 2017).

¹⁶United States House of Representatives Select Committee on the Coronavirus Crisis, Committee on Oversight and Reform, *The Coronavirus Vaccine Manufacturing Failures of Emergent Biosolutions* (May 2022).

personnel specifically.¹⁷ While this program is separate from the CIADM program, DOD and HHS officials coordinated to develop their respective facilities, including agency officials serving on each other's contract evaluation panels and governance boards.

HHS Used CIADM Program Funds to Increase Manufacturing Capacity and Provided Relatively Few Funds for Countermeasures Prior to the COVID-19 Pandemic

From 2012 through 2021, BARDA used CIADM program funds to construct or retrofit manufacturing facilities and develop workforce training programs at the sites. BARDA increased the amount of funding to facilities to aid in the response to the COVID-19 pandemic, spending more than it did on countermeasure production prior to the pandemic.

HHS Used CIADM Program Funding to Expand Manufacturing Facilities and Develop Workforce Training Programs

From the CIADM program's start in 2012 through 2021, BARDA used program funds to increase manufacturing capacity at the sites, according to our review of contract documentation and written correspondence with BARDA officials. For example, under their base contracts, the sites constructed new facilities for producing countermeasures, retrofitted existing facilities with newer manufacturing equipment, and developed programs to train a biopharmaceutical workforce in countermeasure manufacturing at the sites, as shown below in table 1. The CIADM program used a public-private partnership model, so both the government and the sites contributed funds, but for all three sites a majority of funds were provided by the government. In total, BARDA provided

¹⁷The DOD facility was operated by Ology Bioservices, Inc. in Alachua, Florida (formerly Nanotherapeutics, Inc.) and became fully operational in 2017. National Resilience, Inc. acquired Ology in April 2021. For more information about the DOD site, see GAO, *Biological Defense: Additional Information That Congress May Find Useful as it Considers DOD's Advanced Development and Manufacturing Capability*, [GAO-17-701](#) (Washington, D.C.: July 17, 2017).

approximately \$400 million in funding to the sites for these base contract activities.

Table 1: Spending on, and Examples of, Base Contract Activities Conducted by Centers for Innovation in Advanced Development and Manufacturing (CIADM) Sites, 2012 through 2021

Dollars

Site	Government spending on base contract activities ^a	Site's cost share on base contract activities	Examples of base contract activities
Emergent Manufacturing Operations of Baltimore LLC	136,664,874	61,955,061	<ul style="list-style-type: none"> Renovated and updated its existing production facilities, which site officials said allowed them to approximately double their production capacity.
CSL Seqirus ^b	89,621,848 ^c	30,929,625	<ul style="list-style-type: none"> Modification of manufacturing process to increase capacity for pandemic influenza vaccine production, as well as establishing clinical trial material fill/finish capacity.
Texas A&M University System	176,664,509	112,024,543	<ul style="list-style-type: none"> Constructed a new facility for flexible manufacturing of vaccines against viruses using insect and mammalian cells. Developed program to train biopharmaceutical staff on manufacturing processes.

Source: GAO analysis of Biomedical Advanced Research and Development Authority (BARDA) contracts and written correspondence, and interviews and written correspondence with CIADM site officials. | GAO-23-105713

^aAs of October 2022, BARDA officials told us that the amounts included for Emergent and CSL Seqirus reflect disbursements to the CIADM sites. Because the CIADM program had not formally ended at this time, the funding amount for Texas A&M reflects obligated amounts.

^bCSL Seqirus (known as Seqirus until August 2022) was created in 2015 when its parent company, CSL Limited, acquired the influenza vaccine business of Novartis Vaccines and Diagnostics, Inc. of Cambridge, MA, which received the original CIADM award. In December 2016, the government novated the CIADM contract originally awarded to Novartis to CSL Seqirus.

^cIn fiscal year 2009, prior to the CIADM program, BARDA awarded approximately \$487 million to Novartis for the construction of an influenza vaccine manufacturing facility in Holly Springs, NC, which has been incorporated into the Novartis CIADM. The contract called for BARDA and Novartis to share the cost of the facility, with BARDA providing about 40 percent and the company paying about 60 percent.

HHS Increased Funding to the Sites to Aid COVID-19 Pandemic Response, Compared to Pre-Pandemic Funding to Produce Countermeasures

HHS provided the CIADM sites with funds to reserve commercial-scale capacity to aid in the response to the COVID-19 pandemic.¹⁸ Specifically,

¹⁸The base contract permitted HHS to unilaterally modify task orders to assign them a priority that allows the government to require preferential acceptance and performance of contracts or orders supporting certain approved national defense programs, such as the COVID-19 response.

as shown in table 2 below, BARDA provided over \$750 million in funding from 2020 through 2021 through two task orders to reserve capacity (i.e., prevent other manufacturing work from occurring) that could be used to produce vaccine candidates and therapeutics as part of the government’s COVID-19 response. The reserved capacity at the two sites that were still participating at the time of the pandemic (Emergent and Texas A&M) was primarily of the equipment purchased and facilities constructed or retrofitted through the CIADM program. BARDA officials said that they paired both sites with vaccine manufacturers to assist the federal government’s response, with officials saying that they did so based on each site’s characteristics and the vaccine developer’s needs.¹⁹ While the sites did produce some vaccine ingredients for the manufacturers, site officials said that they could not determine if ingredients they were contracted to produce were used in vaccines that manufacturers distributed to the public.

Table 2: Task Orders Issued to Centers for Innovation in Advanced Development and Manufacturing (CIADM) Sites, Prior to and During the COVID-19 Pandemic, 2012 through 2021

CIADM site	Prior to COVID-19 Pandemic (2012-2020)		During COVID-19 Pandemic (2020-2021)	
	Government spending on task orders ^a (dollars)	Task order activities	Government spending on task orders ^a (dollars)	Task order activities
Emergent Manufacturing Operations of Baltimore LLC	32,103,568	Five task orders for sites to assist other manufacturers in production of small batches of drug substances for: <ul style="list-style-type: none"> • Ebola virus vaccine (2015-2017) • Purification of monoclonal antibodies for non-clinical use (2015-2016)^b • Zika virus vaccine candidate (2016-2017) • Viral Hemorrhagic Fever therapeutic (2017)^c • Testing and shelf-life extension of adjuvant for pandemic preparedness (2018-2021)^d 	506,369,568	One task order to reserve capacity for commercial-scale production, which was used by another manufacturer to produce one COVID-19 vaccine drug substance.
CSL Seqirus ^e	0	N/A – no task orders issued	-	-

¹⁹According to BARDA officials, the task order funding was used to reserve capacity for vaccine production once viable candidates had emerged. This funding was not directly for vaccine production, since each site contracted separately with the manufacturers to produce vaccines based on manufacturer specifications. In other words, BARDA issued the task orders to hold manufacturing capacity so that it could not be used for alternate purposes.

Letter

CIADM site	Prior to COVID-19 Pandemic (2012-2020)		During COVID-19 Pandemic (2020-2021)	
	Government spending on task orders ^a (dollars)	Task order activities	Government spending on task orders ^a (dollars)	Task order activities
Texas A&M University System	1,054,086	One task order for the technology transfer of anthrax vaccine drug substance (2016-2017). ^f	272,440,877	One task order to reserve capacity for commercial-scale production, which was used by other manufacturers to produce two COVID-19 vaccine candidates.

Source: GAO analysis of Biomedical Advanced Research and Development Authority (BARDA) task orders and written correspondence and CIADM site documentation and written correspondence. | GAO-23-105713

^aAccording to BARDA officials, the spending amounts included for Emergent and Texas A&M reflect disbursements to the CIADM sites.

^bMonoclonal antibodies are laboratory-produced antibodies that act to mimic the immune system's ability to fight off pathogens. They are not vaccines and have traditionally been used as treatments for individuals that are already infected. "Non-clinical use" refers to experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals.

^cViral Hemorrhagic Fevers are a group of diseases that affect many organ systems of the body, damages the overall cardiovascular system, and reduces the body's ability to function on its own. These include yellow fever and dengue fever, among others.

^dAdjuvants are compounds such as aluminum salts that help to enhance the immune response, which are often added to vaccines.

^eCSL Seqirus (known as Seqirus until August 2022) was created in 2015 when its parent company, CSL Limited, acquired the influenza vaccine business of Novartis Vaccines and Diagnostics, Inc. of Cambridge, MA, which received the original CIADM award. In December 2016, the government novated the CIADM contract originally awarded to Novartis to CSL Seqirus.

^f"Technology transfer" refers to the process of transmitting key product information such as product knowledge and experience, manufacturing process, and analytical methods from one entity to another for the purposes of product development and manufacturing.

As shown in table 2, HHS provided funds to the sites through multiple task orders prior to the COVID-19 pandemic, but these task orders were for smaller-scale production. Specifically, BARDA awarded six task orders worth a total of \$33 million. These activities were primarily for manufacturing small batches of drug substances for manufacturing clients, such as for use in clinical trials, and were not intended to be used by the general population. Only two of the three sites received task orders, with one site (CSL Seqirus) receiving no task orders. The 18 months from April 2016 through September 2017 was the only period in which the two sites had ongoing task orders in place at the same time.

Underuse of the Sites Prevented Full Development of Manufacturing Capabilities, Affecting COVID-19 Vaccine Production

BARDA and site officials identified key challenges that prevented the sites from being used to develop their full capability. Specifically, the CIADM sites did not receive consistent funding and production work from HHS or external manufacturing partners. These challenges led to underuse of the facilities and did not allow them to develop capabilities to produce countermeasures in line with the intended goals of the program. While the COVID-19 pandemic drove increased use of the sites and helped them develop additional capabilities, the sites faced difficulties resulting from underuse prior to the pandemic.

According to BARDA and DOD, Inconsistent Funding and Production Work Prior to the COVID-19 Pandemic Prevented Sites from Fully Developing Production Capabilities

BARDA officials told us they intended for the CIADM sites to have regular work in order to ensure that they would maintain an operational state that would allow them to produce countermeasures as needed. However, in 2018, a joint team from BARDA and DOD—known internally as the “Tiger Team”—conducted an internal review of the CIADM program sites and the DOD advanced manufacturing site. The team found significant underuse of all of the sites. Specifically, it found that two of the CIADM sites had none of their available capacity used, and the remaining site had 7 percent used. In comparison, the DOD site was using an estimated 38 percent of its capacity at that time, although BARDA and DOD also considered that site to be significantly underused.

BARDA officials said regular use of site capacity is necessary to ensure that the sites have opportunities to practice and refine manufacturing processes, establish expertise in production, and maintain expertise at a level where they could rapidly produce countermeasures at commercial scale. According to FDA, in order to produce at commercial scale, manufacturing facilities must be able to maintain high quality levels when producing high volumes and conduct numerous rounds of process validation, in line with FDA requirements for current good manufacturing practices (see sidebar). BARDA officials said that without regular use the

sites were not able to build the capabilities needed to be prepared, such as hiring a sufficient number of experienced workers and having enough time to ensure that the equipment could be properly tested and validated for quality control purposes. BARDA officials told us that the sites' experience with clinical trial production in the pre-pandemic task orders they received did not necessarily translate to commercial scale production, such as was needed for the COVID-19 pandemic response. Being able to reliably produce countermeasures at a commercial scale for the national population was the goal of the surge production capacity service envisioned by BARDA.

FDA Inspections and Current Good Manufacturing Practices for Vaccines



The Food and Drug Administration (FDA) ensures the quality of vaccines marketed in the U.S. by monitoring manufacturing facilities' compliance with current good manufacturing practices. Current good manufacturing practices are FDA regulations that contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a product. See 21 C.F.R. Parts 210 and 211 (2021). FDA considers compliance with current good manufacturing practices as part of its review of new product applications, as well as during post-marketing inspections.

Sources: FDA and [GAO-22-105051](#) (information); warut/stock.adobe.com (photo). | GAO-23-105713

BARDA and site officials identified key challenges that prevented the sites from being used to develop their full capability.

- Difficulties attracting manufacturing partners.** The Tiger Team review and BARDA officials found that industry partners were hesitant to use the sites for production. BARDA intended for the sites to maintain work by contracting with countermeasure developers to produce their products. However, two primary factors hindered this work. First, officials from the sites told us that countermeasure manufacturers were hesitant to use site manufacturing space. Specifically, officials from two sites said that industry partners were concerned about the risk of being forced out of the sites when the government later needed the capacity for other reasons.²⁰ Second, the sites did not have an established history of manufacturing FDA-approved countermeasures, and the Tiger Team review found that this inexperience could result in manufacturing delays that could pose a risk to developers' profit incentive for a potential product.²¹ Without external manufacturing partners to provide the sites with regular work, the sites would need to rely on BARDA task orders for work to develop capabilities.
- Lack of sustainment funding from HHS.** BARDA officials said HHS lacked funding to sustain production at the sites, and this limited the CIADM program's effectiveness. As mentioned above, BARDA spent approximately \$4 million per year, on average, on task orders prior to the pandemic; however, maintaining a facility in a ready state requires consistent funding of \$30 to \$60 million per year, according to officials from BARDA and one site we interviewed.

BARDA officials told us that the lack of sustainment funding meant that the agency was limited in its ability to issue regular task orders, monitor sites to provide technical assistance carrying out their contractual obligations, and pay reservation fees to keep facilities in a ready state and reserve unused capacity. Officials from one site told

²⁰BARDA officials noted that this risk is not limited to manufacturers working with BARDA. Under the Defense Production Act, the U.S. government can require any company to prioritize government contracts for medical supplies to address a national emergency. Pub. L. No. 81-774 (1950), codified at 50 U.S.C. §§ 4501 et seq., as amended.

²¹For example, a 2016 study conducted for DOD found that medical countermeasures had little to no commercial market, and the department would not buy sufficient quantities at high enough prices to justify the opportunity cost to large pharmaceutical manufacturers. Thus, delays in manufacturing would result in even fewer quantities being sold, which would have a further negative impact on opportunity cost. See Institute for Defense Analyses, *Cost Benefit Analysis of the DOD Advanced Development and Manufacturing Facility for Medical Countermeasures* (July 2016).

us that this prevented the site from fully staffing its facility. BARDA officials told us that, even though it was bad for the relationships with sites, BARDA avoided officially designating sites as ready to provide core services, as that would have required the agency to pay sustainment fees, for which it did not have funds available.

According to BARDA officials, BARDA sought to request sustainment funding from Congress for the CIADM program, but these were ultimately not included in HHS's budgets for fiscal years 2018 through 2020. BARDA officials also said that funding intended for advanced research and development work was used to support other high priority programs outside of the CIADM program.

BARDA's underuse of the sites also resulted in limited agency oversight of, and unclear communication with, the CIADM sites.

- **Limited BARDA oversight.** Underuse of the sites resulted in BARDA conducting more limited oversight activities. According to BARDA officials, assessing a site's capabilities is difficult without a product in production. Thus, the extent of BARDA's annual audits, site visits, and collection of progress reports and documents from sites depended heavily on whether a task order had been issued to a site to produce a product. According to BARDA officials, sites sent regular reports as outlined in their contracts, and BARDA conducted contractual oversight activities, but, without task orders, the oversight activities were more limited in scope and frequency. For example, officials from one site told us that BARDA had more substantive discussions with them once the site received a task order to produce a product, whereas without a product BARDA was more focused on standard meetings and audits to monitor compliance.
- **Inconsistent BARDA guidance.** The sites did not always receive clear guidance from BARDA on what they were expected to do, according to site officials. Officials from two sites told us that they would make proposals to BARDA, such as identifying potential manufacturing partners for countermeasure development, but could not reach agreement with BARDA officials about how to proceed and would not always receive clear guidance about how to improve the proposals. Officials from one site told us they were unable to start several projects because the site and BARDA could not reach an agreement on project requirements despite multiple proposal revisions. These officials also said the subject matter experts BARDA provided to the site gave inconsistent or conflicting guidance with each other. BARDA officials told us that the program's lack of

sustainment funding limited their ability to provide consistent support and guidance on these proposals.

BARDA officials and officials from one site also said the CIADM program experienced high levels of turnover among the contracting officers at BARDA over the program's duration. These officials said this made the program less efficient due to the new officers' low level of familiarity with their sites' contracts. In the past, we have found that turnover among the contracting workforce leads to lost institutional knowledge and can lead to inefficiencies in the contracting process.²²

Although the COVID-19 Pandemic Response Led to Increased Use of the Sites, Difficulties Resulted from the Prior Underuse

Resources from the federal government's response to the COVID-19 pandemic allowed BARDA to reserve sites' capacity for commercial production of COVID-19 vaccines and therapeutics. This helped address some of the previously mentioned challenges associated with underuse.

- **Task order spending allowed sites to expand operations.** As previously mentioned, BARDA-provided COVID-19 task orders for capacity reservation at the two remaining active sites were worth approximately \$750 million, which was a significant increase from pre-pandemic spending. The funding allowed the sites to reserve capacity and to quickly set up facilities and infrastructure and hire staff to produce vaccine ingredients.
- **Vaccine production increased BARDA oversight of sites.** According to officials from BARDA and the two active sites, BARDA provided more frequent and consistent oversight to the sites as they set up their operations to produce COVID-19 vaccine candidates. BARDA officials told us they provided staff to the two sites remaining in the program to coordinate and provide technical support and held daily calls with both sites to monitor construction efforts, staffing progress, and supply chain logistics. This aimed to ensure that sites could quickly acquire the experience and capability needed to produce vaccines at commercial scale. BARDA officials told us BARDA also conducted extensive review of both sites to assess readiness for vaccine manufacturing activities and to ensure that the sites were compliant with FDA manufacturing requirements. BARDA

²²GAO, *Acquisition Planning: Opportunities to Build Strong Foundations for Better Services Contracts*, [GAO-11-672](#) (Washington D.C.: Aug. 9, 2011).

officials said that they helped both sites with recruitment efforts and provided them with additional staff with laboratory or biomanufacturing expertise to aid with staffing shortages, as well as providing on-site manufacturing experts to work with the sites to improve quality systems. CIADM site officials said that BARDA was much more involved in day-to-day operations during the pandemic and was more helpful.

However, the CIADM program's lack of readiness affected its ability to respond to the COVID-19 pandemic. BARDA officials told us that the sites were not ready to produce high-quality countermeasures reliably at a commercial scale during the pandemic, and were learning in real time. They said that before production could begin during the pandemic, the sites had to create quality systems, which would have already been created and sufficiently tested in a facility that had been regularly producing commercial-scale products. However, BARDA officials said that, because the sites had lacked regular work to develop capability and the associated workforce experience, the sites ran into issues maintaining quality standards when manufacturing COVID-19 vaccines at commercial scale, as illustrated in the following examples.

- Emergent experienced issues related to cross-contamination that led the facility to temporarily shut down and, subsequently, to a mutual agreement with BARDA to terminate the site's contract in November 2021.
- BARDA audits found issues with aspects of the quality systems of Texas A&M's primary subcontractor during the pandemic, such as inconsistent record keeping and deviations from procedure for assessing risks from drug substance manufacturing.

Partially as a result of these problems, none of the CIADM sites were able to manufacture vaccines reliably for the national population in order to meet the program's surge production capacity goal.

It Is Unclear How HHS Plans to Address Known Challenges and Future Risks in Its Proposed Program Model

BARDA has provided some information about how its proposed program model plans to address some challenges experienced by the CIADM program. However, because these plans are not fully developed, it is

unclear how the program model will address or mitigate all known challenges and future risks.

HHS Has Provided Some Information on How Its Proposed Program Model Plans to Address Some CIADM Program Challenges

BARDA officials provided some information on how the agency plans to address challenges experienced by the CIADM program in its proposed new program model, known as the National Biopharmaceutical Manufacturing Partnership (BioMaP). In a June 2022 presentation to industry representatives, BARDA officials said the agency's vision is to establish infrastructure, manufacturing platforms, and a supply chain capable of producing enough vaccines for the entire U.S. population within 130 days—and the global population within 200 days—after identification of a potential pandemic threat.²³ According to BARDA officials, BioMaP will focus on supply chain, industrial base expansion and innovation, and large-scale vaccine drug substance manufacturing.

This program model is expected to use a consortium—a group of members interested in a specific technology area—that will provide the government with a ready pool of stakeholders to innovate in that technology area, according to BARDA officials. Consortium members can include traditional contractors, nontraditional contractors, academic institutions, and non-profit organizations, among others. Under this type of arrangement, members would typically sign a consortium membership agreement (also referred to as articles of collaboration). That agreement could outline information about the consortium's governance structure, membership dues, rules for handling proprietary information within the consortium, principles for handling intellectual property, and other principles that the members agree to when joining the consortium. The consortium may also have a separate entity that manages the consortium.

The President's budget request to Congress for fiscal year 2023 said that consortium members were expected to be established by the end of fiscal year 2022. In October 2022, BARDA officials told us that they planned to

²³This aligns with the goal for vaccine production called for in the 2022 National Biodefense Strategy. See White House, *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* (Washington, D.C.: October 2022).

have the consortium members in place in early fiscal year 2023, but did not provide a timeline for starting manufacturing efforts, as funding was not yet available.

BARDA officials indicated that under current plans for BioMaP, BARDA will use a different contracting structure than it did for the CIADM program, which agency officials said will allow for more flexibility. Specifically, BARDA plans to use a contracting mechanism known as Other Transaction Agreements (OTA).²⁴ The flexibility of OTAs can help agencies address the concerns of nontraditional contractors—entities that do not typically do business with the federal government, such as start-up companies—about the requirements that typically apply to federal procurement contracts.²⁵ BARDA officials told us that they have faced challenges engaging with companies in the past due to the industry’s desire to avoid certain provisions—such as cost accounting standards and audits—that are part of contracts regulated by the Federal Acquisition Regulation, which included the CIADM program contracts. We previously reported that the OTA structure has been used for research, prototyping, and production of new technologies or products with nontraditional companies. However, we have also found risks with the use of this model. For example, OTAs are exempt from the Federal Acquisition Regulation, so they do not require certain procurement contract oversight mechanisms.²⁶

While BARDA has established its plan to use an OTA contract structure for BioMaP, many aspects of the program model remain under

²⁴When an OTA is awarded to a consortium, the task orders resulting from that OTA may be awarded to the members of that consortium. OTAs are not required to include terms and conditions that are typically required when using traditional procurement contracts subject to the Federal Acquisition Regulation, as the CIADM program contracts were. OTAs enable agencies and contract awardees to negotiate terms and conditions specific to each awarded contract or task order. For more information on consortium-based OTAs, see GAO, *Other Transaction Agreements: DOD Can Improve Planning for Consortium Awards*, [GAO-22-105357](#) (Washington, D.C.: Sept. 20, 2022) and [GAO-21-501](#).

²⁵These concerns can be related to requirements establishing a government-unique cost accounting system or losing intellectual property rights, among others. GAO, *COVID-19 Contracting: Actions Needed to Enhance Transparency and Oversight of Selected Awards*, [GAO-21-501](#) (Washington, D.C.: July 26, 2021).

²⁶See, for example, GAO, *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) and *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).

consideration, and the agency is collecting industry feedback. BARDA officials said that the program model will encourage industry participation, and BARDA has proposed a plan for sustainable funding, which were key challenges of the CIADM program. However, industry stakeholders and site officials noted some unaddressed risks. Additionally, the OTA contract structure would introduce its own risks related to the resources and expertise needed to manage the structure. BARDA's proposal has not yet clarified how the program model will work in practice, and industry representatives have expressed concerns about BARDA's plan for the program.

- **Encouraging industry participation.** BARDA officials said that the use of OTA contracting under BioMaP will provide more incentives for industry stakeholders to participate, but industry stakeholders are not as certain. According to BARDA officials and industry stakeholders, the OTA structure allows for flexibilities that could better incentivize manufacturing partner participation.²⁷ BARDA officials said an OTA structure could enable BARDA to identify and attract manufacturing partners that may not ordinarily do business with the government—which they said has been historically challenging in the pharmaceutical field.

BARDA officials said that the new contracting approach could also encourage larger, more established industry partners to participate. According to the officials, these larger manufacturers would be able to maintain a prepared workforce and capability based on their regular commercial work, resulting in BARDA needing to provide less regular funding for the sites.

In response to a BARDA survey, industry stakeholders agreed that the OTA contract structure offers some benefits to encourage industry participation, such as more flexible terms and stronger intellectual property protections. However, industry stakeholders still expressed concerns about industry participation. For example, officials from one CIADM site told us that manufacturers would continue to be hesitant to invest into staff and facilities when they know that the U.S. government can take over their existing capacity during a public health response.

²⁷For instance, the OTA structure allows for more flexible arrangements than can be done under traditional contracting subject to the Federal Acquisition Regulation. These more flexible terms can incorporate commercially acceptable terms, ease infrastructure requirements for proposing and tracking costs, and protect contractors' intellectual property.

- **Providing a sustainable funding source.** BARDA has not identified dedicated funding for BioMaP, raising questions about the viability of the program. The President’s budget request to Congress for fiscal year 2023 identified the program, but did not request funding specifically for BioMaP. However, BARDA officials have said that BioMaP’s proposed funding is accounted for within the White House’s American Pandemic Preparedness Plan, a September 2021 plan from the White House to improve the country’s ability to respond to pandemics.²⁸ According to officials, the plan proposed spending \$81.7 billion for efforts to Prepare for Future Pandemics and Advance Health Security for Other Biological Threats, with \$40 billion of that going to BARDA. BARDA officials indicated that they did not request dedicated funding for BioMaP, but \$10 billion to \$13 billion of the funds for BARDA would be for its manufacturing-related efforts, which would include BioMaP and other programs. BARDA officials told us that they have not developed formal budgets or created acquisition plans for BioMaP, because they are waiting for funding to be secured before doing so.

Industry stakeholders and site officials said that the program needs a source of sustained funding to ensure industry participation and maintain capacity and capability. Industry representatives and site officials said that manufacturers cannot afford to keep manufacturing lines unused for the government’s future use without sustainment funding.

²⁸The American Pandemic Preparedness Plan was announced in September 2021 and aims to transform capabilities to respond rapidly and effectively to any future pandemic or high consequence biological threat by (1) transforming our medical defenses, (2) ensuring situational awareness, (3) strengthening public health systems, (4) building core capabilities, and (5) managing the mission. See White House, *American Pandemic Preparedness: Transforming Our Capabilities* (Washington, D.C.: September 2021).

Other Transaction Agreements (OTA) Use During COVID-19

Most of the COVID-19 OTA dollars were obligated in July 2020 and driven by vaccine awards. Of the \$12.5 billion the Departments of Defense, Health and Human Services (HHS), and Homeland Security obligated for 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. HHS obligated at least \$1.6 billion on COVID-19-related OTAs from March 2020 through March 2021—primarily to help accelerate vaccine development and manufacturing. However, this is an underreported figure because HHS misreported its OTAs as procurement contracts. From November 2020 through March 2021, OTA obligations were comparatively not as significant as earlier in the pandemic. This was, in part, because additional vaccine doses were acquired using procurement contracts instead of OTAs.

Source: [GAO-21-501](#). | [GAO-23-105713](#)

- OTA Structure.** BARDA's contracting workforce may not have the resources and expertise to effectively administer an OTA contract structure as a part of BioMaP. HHS officials have reported that, as of April 2022, BARDA only had half of the contracting staff needed to execute its contract portfolio. We previously reported that, while OTA structures provide more flexibility than traditional contracts subject to the Federal Acquisition Regulation, they are not required to include the same oversight mechanisms used with traditional contracts.²⁹ Because of the lack of the formal structure in traditional contracts, the OTA structure can be more complex to oversee and can require more expertise from contracting officers. We found that HHS has established guidance and training related to the administration of OTA structures, but the agency has not updated its OTA guidance for contracting staff since 2012 to account for any new risks associated with the OTA model.³⁰

While BARDA officials told us the agency has managed OTA structures in the past and their contracting officers gained experience working with OTAs during the pandemic (see sidebar), we found HHS and BARDA also experienced challenges. Specifically, during the COVID-19 pandemic HHS's acquisition workforce did not have the capacity or expertise to manage OTA contracting needs and had to partner with DOD to administer those contracts.

BARDA officials told us that the agency is planning to use a separate consortium management firm to manage the BioMaP consortium. While this could alleviate some risks related to resources and expertise, BARDA's contracting staff would still need to oversee the contract with the consortium management firm. In prior work, we found that HHS's OTA guidance did not include what certain information that contract officers should consider when using consortium management firms, including what enhanced oversight activities may be appropriate, and we recommended that HHS update its OTA guidance.³¹ Therefore, although BARDA has gained more experience managing OTAs, an additional OTA in its portfolio could

²⁹[GAO-22-105357](#).

³⁰According to HHS guidance, contracting officers overseeing an OTA must possess the necessary experience, responsibility, business acumen, and judgment to operate in the relatively unstructured business environment of the OTA without the Federal Acquisition Regulation framework to guide them. These individuals must also receive appropriate OTA training before being delegated authority to administer OTAs. BARDA officials told us that 13 out of approximately 80 BARDA contracting officers were sanctioned to administer OTAs as of August 2022. For more information, see [GAO-21-501](#).

³¹[GAO-21-501](#). As of January 2023, this recommendation remains open.

pose a risk if the agency does not have enough contracting staff or out-of-date guidance in managing a complex structure.

- **Potential challenges with BioMaP’s vision.** BioMaP is still under development, and industry stakeholders and officials from one site expressed confusion about how the program model will work and whether it could face additional challenges. Officials from one site expressed concern about using a model that relies on responding to ad-hoc task orders instead of regular, sustained task orders. The officials told us that, without regular task orders, BioMaP’s consortium would be more of an “on-paper” exercise with partners that would not be regularly producing useful countermeasures. Industry representatives expressed the need for clear communication from BARDA on priority access to facilities.

Industry stakeholders also noted additional barriers to participation, such as technological change and concerns around raw materials and supply chains. From a technological perspective, industry representatives told BARDA that there would need to be limits or constraints on technological changes. One site representative told us that it is not easy to pivot manufacturing platforms quickly, suggesting that BARDA should consider funding a subset of flexible technologies that have redundant capacity that could be drawn upon during a pandemic response.³² Industry representatives also told BARDA that there are already risks to supply chains and uncertainty in lead times that would affect future manufacturing efforts. Additionally, BARDA officials told us that sustaining a biopharmaceutical response infrastructure adequate for multiple different infection or pathogen scenarios must consider supporting a range of manufacturing methodologies, which may need changing over time as technologies improve.

³²For example, as part of the COVID-19 response, the government supported multiple manufacturing technologies during vaccine development in order to mitigate the risk that any one platform or specific vaccine candidate could fail because of problems with safety, efficacy, industrial manufacturability, or scheduling factors. This strategy included two vaccine platforms that had not previously been used in a licensed vaccine, but could theoretically be quickly adapted to COVID-19 and scaled up rapidly (i.e., the mRNA platform and replication-defective live-vector platform), and one platform that had been proven (i.e., the recombinant-subunit-adjuvanted protein platform). For more information, see GAO, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, [GAO-21-319](#) (Washington, D.C.: Feb. 11, 2021).

HHS Has Not Fully Developed Its Plans for How BioMaP Will Address or Mitigate Known Challenges and Future Risks

While BARDA has outlined a framework for its intended BioMaP program model, it is not prepared to address or mitigate known challenges and future risks because BARDA has not yet fully developed its plans for the program model. BARDA officials, site officials, and our previous work have identified risks that could affect BARDA's ability to achieve the goals outlined in BioMaP's vision—some carried over from the CIADM program, and some introduced by the framework for its successor, the BioMaP program model. The results of the CIADM program have shown that building initial capacity is not enough. According to BARDA officials, underuse of the sites posed a significant challenge to the CIADM program's success, as the sites were never able to develop the capability they would have needed to meet the goals of the program.

According to leading practices for risk management, agencies should regularly incorporate risk management activities into their program operations in order to ensure that future risks can be addressed. Specifically, the Office of Management and Budget's Circular A-123 requires federal agencies to integrate risk management activities into their program management to help ensure they are effectively managing risks that could affect the achievement of agency objectives. Then, once initial risks are identified, the circular notes that is important for agencies to regularly re-examine risks to identify new risks or changes to existing risks.

Fully developing a plan to systematically assess and respond to challenges associated with advanced development and manufacturing of medical countermeasure programs would help BARDA ensure it avoids the challenges experienced by the CIADM program. Such a plan would include clearly documenting risks, tracking progress made in addressing risks, estimating resources needed to address risks, and communicating this information to key decision makers, such as HHS leadership and Congress. For example, this plan could include strategies to identify resource needs sufficient to ensure needed domestic capacity is sustained, as BARDA officials noted that a lack of sustained funding for this or a similar program will impede their ability to respond to the next pandemic.

Conclusions

The CIADM program was envisioned as a way to build domestic capacity to rapidly produce countermeasures to save lives during a public health emergency, but the program did not meet its goals. As HHS develops a new program model, appropriate risk planning will be critical to ensuring it can systematically assess, analyze, and respond to known challenges and manage future risks. If HHS does not develop an effective program model, it may not secure the private sector partnerships necessary to provide countermeasure surge manufacturing capacity and capability during future public health emergencies. Without a program that has the capability to build up, maintain, and regularly use domestic countermeasure manufacturing capabilities, HHS risks being unable to meet countermeasure manufacturing goals for future public health emergencies, especially if these emergencies bring about risks that the agency has not planned for, such as those experienced during the COVID-19 response.

Recommendation for Executive Action

The Secretary of Health and Human Services should direct BARDA to, as part of the development of a new program model, incorporate an approach to systematically assess and respond to known challenges and future risks associated with advanced development and manufacturing of countermeasures—including challenges related to funding and risks associated with effectively managing the contracting structure. Such an approach should clearly document program risks, ensure that progress in addressing risks is tracked, estimate needed program resources, and communicate this information to key decision makers. (Recommendation 1)

Agency Comments

We provided a draft of this report to HHS for review and comment. In its written comments, which are reproduced in appendix I, HHS concurred with our recommendation. The agency stated that, while BioMaP is early in development, it will work to ensure the effort aligns with the principles outlined in our recommendation and that it communicates with key decision makers as the effort moves forward. HHS also provided technical comments, which we incorporated as appropriate.

Letter

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, 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 Mary Denigan-Macauley at (202) 512-7114 or deniganmacauleym@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 major contributions to this report are listed in appendix II.

A handwritten signature in black ink that reads "Mary Denigan-Macauley". The signature is written in a cursive style with a long horizontal flourish at the end.

Mary Denigan-Macauley
Director, Health Care

List of Committees

Chairman
Vice Chairman
Committee on Appropriations
United States Senate

Chair
Ranking Member
Committee on Finance
United States Senate

Chair
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

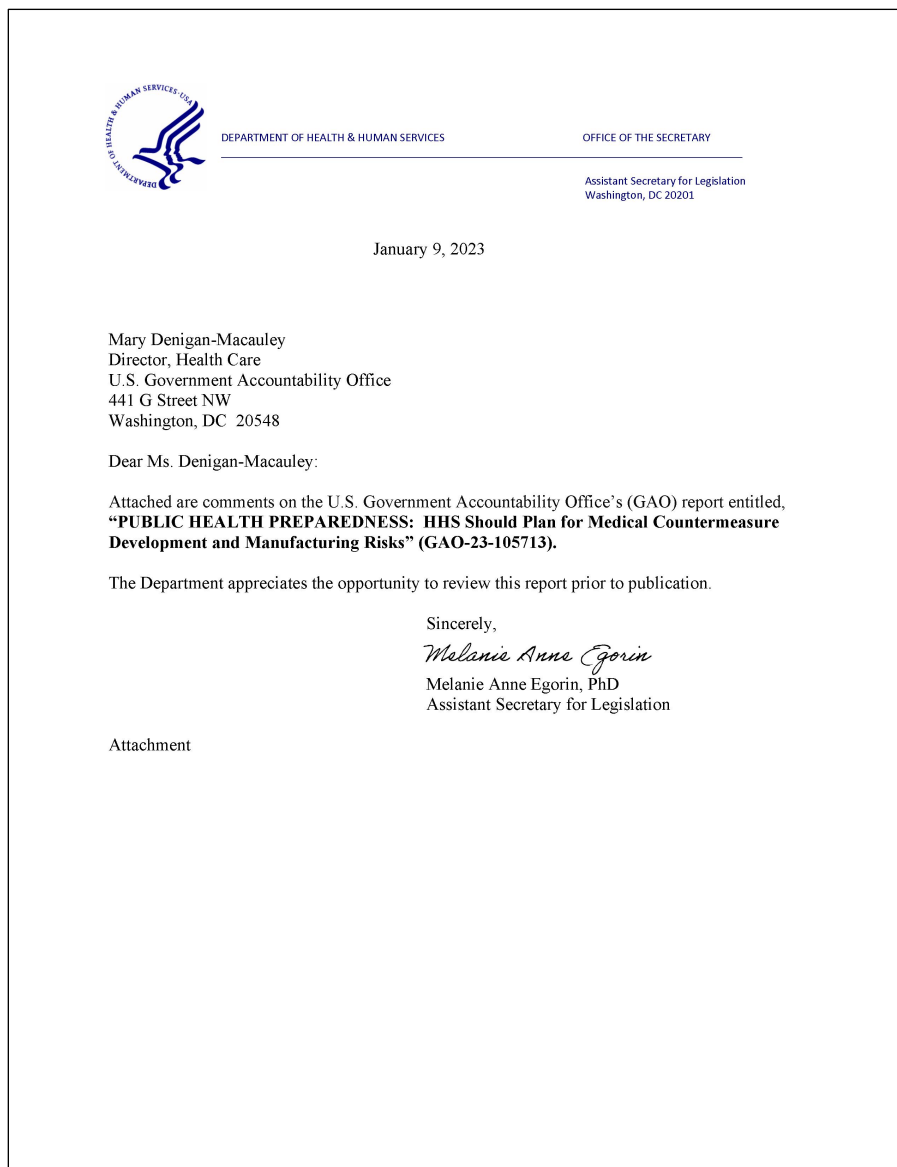
Chairman
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

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

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Mark E. Green, MD
Chairman
The Honorable Bennie G. Thompson
Ranking Member
Committee on Homeland Security
House of Representatives
The Honorable James Comer
Chairman
The Honorable Jamie Raskin
Ranking Member
Committee on Oversight and Accountability
House of Representatives
The Honorable Jason Smith
Chairman
The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
House of Representatives

Appendix I: 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 - PUBLIC HEALTH PREPAREDNESS: HHS SHOULD PLAN FOR MEDICAL COUNTERMEASURE DEVELOPMENT AND MANUFACTURING RISK (GAO-23-105713)

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.

General Comments

Recommendation 1

The Secretary of Health and Human Services should direct BARDA to, as part of the development of a new program model, incorporate an approach to systematically assess and respond to known challenges and future risks associated with advanced development and manufacturing of countermeasures—including challenges related to funding and risks associated with effectively managing the contracting structure. Such an approach should clearly document program risks, ensure that progress in addressing risks is tracked, estimate needed program resources, and communicate this information to key decision makers.

HHS Response

HHS Concurs with GAO's recommendation.

ASPR concurs with this recommendation. ASPR BARDA will work to ensure that the successor to the Centers for Innovation in Advanced Development and Manufacturing Program - the National Biopharmaceutical Manufacturing Partnership (BioMaP) -will align with the GAO recommendation. As GAO notes in the report, BioMaP is still extremely early in development, and ASPR BARDA will work to ensure communication with key decision makers as this effort moves forward.

Text of Appendix I: Comments from the Department of Health and Human Services

January 9, 2023

Mary Denigan-Macauley Director, Health Care

U.S. Government Accountability Office 441 G Street NW

Washington, DC 20548

Dear Ms. Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "PUBLIC HEALTH PREPAREDNESS: HHS Should Plan for Medical Countermeasure Development and Manufacturing Risks" (GAO-23-105713).

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

Sincerely,

Melanie Anne Egorin, PhD Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT - PUBLIC HEALTH PREPAREDNESS: HHS SHOULD PLAN FOR MEDICAL COUNTERMEASURE DEVELOPMENT AND MANUFACTURING RISK GAO-23-105713)

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.

General Comments Recommendation 1

The Secretary of Health and Human Services should direct BARDA to, as part of the development of a new program model, incorporate an approach to systematically

assess and respond to known challenges and future risks associated with advanced development and manufacturing of countermeasures—including challenges related to funding and risks associated with effectively managing the contracting structure. Such an approach should clearly document program risks, ensure that progress in addressing risks is tracked, estimate needed program resources, and communicate this information to key decision makers.

HHS Response

HHS Concurrs with GAO's recommendation.

ASPR concurs with this recommendation. ASPR BARDA will work to ensure that the successor to the Centers for Innovation in Advanced Development and Manufacturing Program - the National Biopharmaceutical Manufacturing Partnership (BioMaP) -will align with the GAO recommendation. As GAO notes in the report, BioMaP is still extremely early in development, and ASPR BARDA will work to ensure communication with key decision makers as this effort moves forward.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Mary Denigan-Macauley, (202) 512-7114, deniganmacauleym@gao.gov

Staff Acknowledgments

In addition to the contact named above, William Hadley (Assistant Director), Matthew Green (Analyst in Charge), Benjamin Feldman, Meg McAloon, Laurie Pachter, Emily Wilson Schwark, Meghan Perez, Janet McKelvey, Claire Li, Michael Dickens, and Roxanna Sun made key contributions to this report.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through our website. Each weekday afternoon, GAO posts on its [website](#) newly released reports, testimony, and correspondence. You can also [subscribe](#) to GAO's email updates to receive notification of newly posted products.

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <https://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

Connect with GAO

Connect with GAO on [Facebook](#), [Flickr](#), [Twitter](#), and [YouTube](#).
Subscribe to our [RSS Feeds](#) or [Email Updates](#). Listen to our [Podcasts](#).
Visit GAO on the web at <https://www.gao.gov>.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact FraudNet:

Website: <https://www.gao.gov/about/what-gao-does/fraudnet>

Automated answering system: (800) 424-5454 or (202) 512-7700

Congressional Relations

A. Nicole Clowers, Managing Director, ClowersA@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548

Strategic Planning and External Liaison

Stephen J. Sanford, Managing Director, spel@gao.gov, (202) 512-4707
U.S. Government Accountability Office, 441 G Street NW, Room 7814,
Washington, DC 20548



Please Print on Recycled Paper.