United States Government Accountability Office

Report to Congressional Committees

July 2017

BIOLOGICAL DEFENSE

Additional Information That Congress May Find Useful as It Considers DOD's Advanced Development and Manufacturing Capability

GAO-17-701

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GAO Highlights

Highlights of GAO-17-701, a report to congressional committees

Why GAO Did This Study

DOD has long expressed concerns about its ability to acquire and maintain the capability to research, develop, and manufacture medical countermeasures (e.g., vaccines) against biological warfare threat agents, toxins, and endemic diseases. In 2013, DOD partnered with a private-sector biopharmaceutical company to develop an ADM facility with the capability to use disposable equipment enabling timely changes in a production line for medical countermeasures. The facility was fully operational in March 2017, and DOD can now renew its contract for 2-year periods through 2024.

Congress included a provision in the National Defense Authorization Act for Fiscal Year 2016 that DOD, among other things, submit a report to Congress addressing six required elements regarding DOD's ADM facility. DOD submitted its report in October 2016. The act also contained a provision that GAO review the report. GAO describes (1) the information that DOD included in its report to address the six required elements and (2) presents additional information related to the elements that may be useful to Congress in its oversight role. GAO compared DOD's report and cost-benefit analysis with the legislatively required elements and analyzed documents from DOD, HHS, and their private-sector partners. This is a public version of a sensitive report issued in May 2017. Information DOD and HHS deemed sensitive has been omitted.

What GAO Recommends

GAO is not making recommendations in this report. GAO incorporated agency technical comments, as appropriate.

View GAO-17-701. For more information, contact Joseph W. Kirschbaum, (202) 512-9971 or KirschbaumJ@gao.gov

What GAO Found

The Department of Defense (DOD) included in its October 2016 report to Congress information that addressed each of the six required elements regarding the department's public-private partnership to construct a facility with an advanced development and manufacturing (ADM) capability. In its report to Congress, DOD addressed the six elements that included, among other things: (1) a description of the ADM facility and its capabilities and an explanation of the origin of the ADM capability requirement; (2) information on some of the program goals, high-level performance metrics, and estimated completion costs along with a statement that DOD is not requesting procurement or operations and maintenance funds in the future years defense program for the ADM facility and that sustainment costs will come from existing medical countermeasure programs; (3) a copy of a 2009 analysis of alternatives conducted for the Secretaries of Defense and Health and Human Services (HHS) that DOD stated justifies the ADM capability; (4) and (5) combined, an independent analysis of the incremental cost and benefits, schedule, and performance of continued DOD investment in its ADM facility; and (6) the department's medical countermeasures production plans for the ADM facility.

GAO identified additional information related to these elements that may be useful for congressional oversight. This information may be particularly useful as DOD decides whether and how to renew its contract for 2-year option periods with the contractor that constructed the ADM facility. First, DOD's sustainment payments for priority access to the ADM capability will be budgeted as a cost of developing medical countermeasures (e.g., vaccines), a funding structure similar to the model used with DOD-owned laboratories, according to DOD officials. Second, discussions with officials indicate that the total costs to the ADM capability contractor to operate and maintain the ADM facility, which are separate from and in addition to the costs in the initial contract with DOD for building the facility, were not fully known at the time of DOD's report and are not fully covered by the DOD-provided sustainment payments. However, GAO learned that the contractor and DOD have taken some initial steps toward bringing additional funded work to the DOD ADM capability, which may help to reduce DOD's sustainment payments under the contract options. Third, the three HHS facilities were not analyzed as alternatives to the DOD ADM facility, although HHS officials said that DOD could separately contract for medical countermeasures with any of HHS's facilities, either independently or through existing HHS contracts. Officials from DOD's ADM program office stated that the HHS facilities are not appropriate for DOD's needs—because they are large dedicated facilities designed primarily to address pandemic influenza threats. However, an official from one of the three HHS facilities informed us that they currently produce medical countermeasures for DOD. An official with the ADM program office said that DOD is represented on the governing board for the HHS Centers for Innovation in Advanced Development and Manufacturing and is aware of what HHS is doing there, so this information can be taken into consideration along with ADM performance and utilization metrics as DOD considers future contract extensions for the ADM capability.

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Abbreviations

ADM	advanced development and manufacturing
BSL	biological safety level
CIADM	Center for Innovation in Advanced Development and Manufacturing
DOD	Department of Defense
HHS	Department of Health and Human Services

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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July 17, 2017

Congressional Committees

The Department of Defense (DOD) has long expressed concerns about its ability to acquire and maintain the capability to research, develop, and manufacture medical countermeasures—vaccines, drugs, and diagnostics—against biological warfare threat agents, toxins, and endemic diseases in areas where warfighters are deployed.[1] These concerns stem from the challenges associated with attracting large and experienced private-sector pharmaceutical manufacturers to produce DOD-specific medical countermeasures.[2] These challenges include, but are not limited to, overcoming the manufacturers' concerns about low profitability, intellectual property rights, the lack of a long-term commitment from DOD, complying with the Federal Acquisition Regulation, and restrictions on exporting medical countermeasures. Specifically, a recent study conducted for DOD said that DOD medical countermeasures have little or no commercial market, and DOD will not buy sufficient quantities at high enough prices to justify the opportunity cost to large pharmaceutical manufacturers.[3] Even during a crisis, large, dedicated production lines from these private-sector manufacturers would not be readily convertible to produce DOD medical countermeasures. Small biopharmaceutical companies often originate the innovations needed for DOD medical countermeasures, but lack the experience and capability to develop the production processes beyond laboratory scale and also do not conduct the clinical trials required for licensure by the Food and Drug Administration. As a result, according to DOD's Joint Program Executive Office for Chemical and Biological Defense, DOD's reliance on small innovator biopharmaceutical companies resulted in a lack of Food and Drug Administration regulatory and manufacturing

[1] See Institute for Defense Analyses, *Cost Benefit Analysis of the DOD Advanced Development and Manufacturing Facility for Medical Countermeasures* (July 2016) and University of Pittsburgh Medical Center, *Ensuring Biologics Advanced Development and Manufacturing Capability for the United States Government: A Summary of Key Findings and Conclusions* (Pittsburgh, PA: Oct. 6. 2009).

[2] See DOD, Abaie, Michael, *Acquisition Strategy and Plan for Advanced Development and Manufacturing Prototype Capability for Medical Countermeasures*, (Washington, D.C.: Aug. 25, 2011).

[3] See Institute for Defense Analyses, *Cost Benefit Analysis of the DOD Advanced Development and Manufacturing Facility for Medical Countermeasures* (July 2016).

experience, schedule slips, increased costs, and a lack of access to manufacturing infrastructure.

In 2014, we reported that DOD had started planning to develop an advanced development and manufacturing (ADM) facility in 2012 with the capability to produce medical countermeasures such as vaccines and other therapeutics using "flexible technologies."[4] DOD formally contracted for a public-private partnership with a private-sector biopharmaceutical company in March 2013 to construct the ADM facility. We noted in the 2014 report that the Department of Health and Human Services (HHS) also had contracted for three facilities—Centers for Innovation in Advanced Development and Manufacturing (CIADM)—with the capability to produce medical countermeasures using flexible technologies. According to officials with DOD's Chemical and Biological Defense Program, DOD's ADM facility became fully operational in March 2017. According to HHS's Office of the Assistant Secretary for Preparedness and Response, as of April 2017, it was yet to be determined when the three CIADMs would be fully operational, as this includes establishing their pandemic flu surge capacity. HHS officials said that all three CIADMs have been capable of responding to core services task orders since early 2014. In our 2014 report, we reported that DOD and HHS had established a memorandum of understanding to facilitate collaboration at their facilities for advanced development and manufacturing and recommended, among other things, that DOD develop and implement a process to update and validate DOD's list of biological threats.[5] DOD concurred with the recommendation but had not fully implemented it at the time of our review.[6]

[4] See *Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization*, GAO-14-442 (Washington, D.C.: May 15, 2014). According to DOD's contract for the ADM capability, "flexible technologies" are single-use, disposable equipment used in flexible or agile manufacturing, which is a combination of manufacturing technology, processes, tools, and training that are structured to enable prompt and timely changes in a production line.

[5] GAO-14-442.

[6] In February 2015, DOD established a working group to ensure that the Chemical and Biological Defense Program's medical portfolio is addressing the highest priority threats considering available candidates and resources. As of March 2017, DOD was still updating DOD Directive 5160.05E, *Roles and Responsibilities Associated with the Chemical and Biological Defense Program (CBDP)* (Oct. 9, 2008), the governing guidance for the Chemical and Biological Defense Program.

Because of cost and schedule overruns and the apparent overlap of DOD and HHS efforts to establish ADM capabilities, Congress included a provision in the National Defense Authorization Act for Fiscal Year 2016 that DOD conduct an independent cost-benefit analysis of DOD's ADM facility and report the results, among other things, before all authorized fiscal year 2016 research, development, test, and evaluation funds for this facility could be released to the department.[7]

DOD submitted its report, *Department of Defense Advanced Development and Manufacturing Capability Report*, to Congress on October 17, 2016.[8] The act also contained a provision that we review DOD's report. In our report we (1) describe the information that DOD included in its report to address the six elements required by the National Defense Authorization Act for Fiscal Year 2016 and (2) present additional information related to each element that may be useful to Congress in its oversight role regarding DOD's ADM capability.

This report is a public version of a sensitive report that we issued in May 2017.[9] DOD and HHS deemed some of the information in our May report to be sensitive, which must be protected from public disclosure. Therefore, this report omits sensitive information about DOD's ADM facility and HHS's three CIADM facilities from the appendices. Although the information provided in this report is more limited, the report addresses the same objectives as the sensitive report and uses the same methodology.

To address our objectives, we compared the six elements required by the National Defense Authorization Act for Fiscal Year 2016 with the report DOD provided to Congress to meet the congressional mandate and with the cost-benefit analysis included in the 2016 DOD-commissioned Institute for Defense Analyses report that DOD also submitted to

[7] National Defense Authorization Act for Fiscal Year 2016, Pub. L. No. 114-92, § 221 (2015). DOD officials told GAO that there were no direct, dedicated fiscal year 2016 funds for DOD's ADM facility.

[8] DOD, *Department of Defense Advanced Development and Manufacturing Capability Report* (Oct. 17, 2016).

[9] GAO, *Biological Defense: Additional Information That Congress May Find Useful as It Considers DOD's Report on Its Advanced Development and Manufacturing Capability*, GAO-17-297SU (Washington, D.C.: May 4, 2017).

Congress.[10] We obtained documents from and conducted interviews with analysts from the Institute for Defense Analyses to corroborate our understanding of their DOD-commissioned study. Additionally, we obtained documents from and conducted interviews with officials from DOD, HHS, and the ADM and CIADM contractors regarding the information that DOD had provided in its report and to determine what, if any, other information related to the six required elements might be useful to Congress. Finally, we conducted site visits at the following facilities to compare the capabilities of the DOD ADM facility with the capabilities of the three HHS CIADM facilities: (1) DOD's ADM facility operated by Nanotherapeutics, Inc. in Alachua, Florida; (2) HHS's CIADM facility operated by the Texas A&M University System in College Station, Texas; and (3) HHS's CIADM facility operated by Emergent BioSolutions, Inc., in Baltimore, Maryland. Due to ongoing sensitive contract negotiations during our audit work, we were unable to visit or meet with officials from HHS's third CIADM facility, which at the time was contracted to Novartis Aktiengesellschaft (AG) in Holly Springs, North Carolina. In lieu of a site visit to that facility, we met with senior officials in HHS's Office of the Assistant Secretary for Preparedness and Response to discuss the North Carolina CIADM facility. In December 2016, HHS informed us that bioCSL/Seqirus was now recognized by the U.S. government as the owner and operator of the HHS CIADM facility in Holly Springs, North Carolina. See appendix I for a more comprehensive description of our scope and methodology.

The performance audit upon which this report is based was conducted from June 2016 to May 2017 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. We subsequently worked with DOD and HHS in June 2017 to prepare this unclassified version of the original sensitive report for public release. This public version also was prepared in accordance with these standards.

[10] DOD, *Department of Defense Advanced Development and Manufacturing Capability Report* (Oct. 17, 2016) and Institute for Defense Analyses, *Cost Benefit Analysis of the DOD Advanced Development and Manufacturing Facility for Medical Countermeasures* (July 2016).

Background

Manufacturing Biologic Medical Countermeasures

DOD's ADM facility is to specialize in manufacturing biologics, with a focus on producing antibodies and vaccines.[11] Until recently, the manufacture of biologic medical countermeasures has required a single facility to produce a single product (e.g., a vaccine), and extensive cleaning and sterilization of equipment was required to switch from manufacturing one product to another. However, recent technological advancements have made "flexible manufacturing" possible. These technologies include the use of disposable equipment, such as equipment for growing cell cultures in disposable plastic material systems rather than in stainless steel tanks that require more time to clean and sterilize prior to the next use, and the use of modular sterile rooms to allow for the manufacture of multiple products simultaneously within a given facility. In the advanced research and development stage, potential medical countermeasures are further evaluated to demonstrate their safety and efficacy for preventing, diagnosing, or treating disease. Successful products are then available for final development and procurement.[12]

DOD and HHS Coordination in Producing Medical Countermeasures

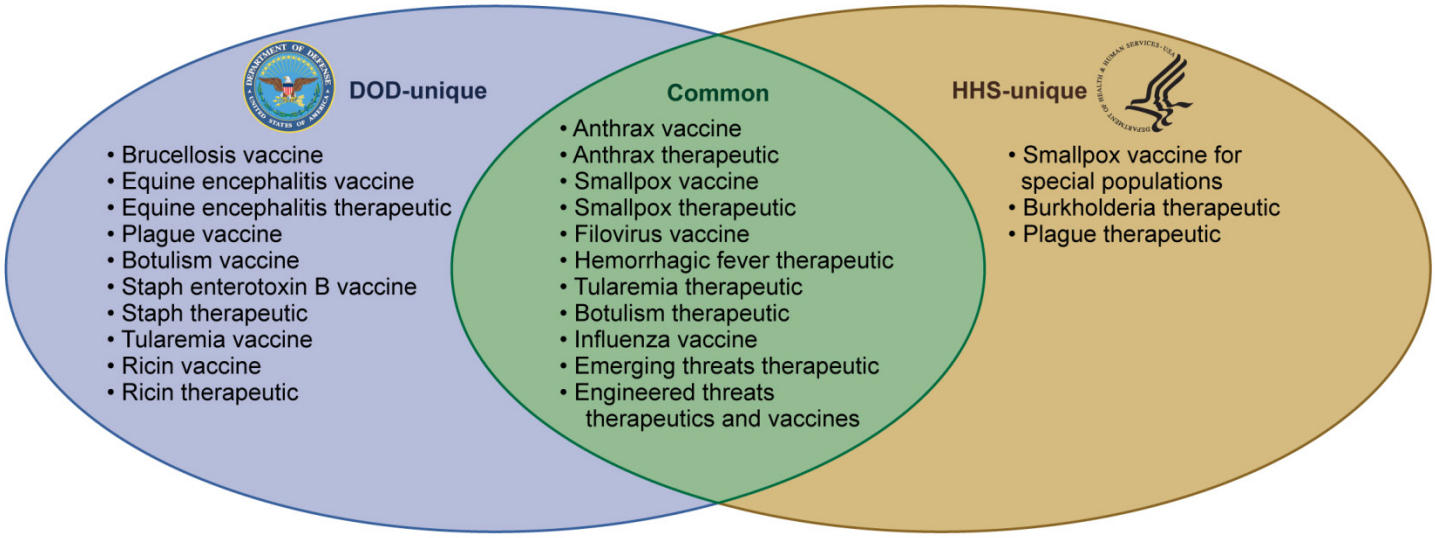
As we reported in 2014, DOD is one of several agencies, along with HHS, involved in addressing and countering biological threat agents.[13] As illustrated in figure 1, both DOD and HHS have specific biological medical countermeasure needs, some of which are shared.

[11] "Biologics" or large molecules (e.g., proteins or nucleic acids) are produced using cultures of living cells, such as bacteria; small-molecule drugs are low molecular weight chemical compounds that are produced by traditional organic synthesis.

[12] In addition to approving or licensing medical countermeasures, the Food and Drug Administration works with researchers throughout the development stages to review safety and effectiveness test results and provide technical assistance to help ensure that research meets the Food and Drug Administration's regulatory requirements. See GAO, *National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources*, GAO-12-121 (Washington, D.C.: Oct. 26, 2011).

[13] See GAO-14-442. While DOD is involved in researching and developing medical countermeasures against biological threat agents for military personnel, HHS leads the federal public health and medical response to potential chemical, biological, radiological, and nuclear threats and emerging infectious diseases. HHS is required to assess, on an ongoing basis, the potential public health consequences of any chemical, biological, radiological, and nuclear agents that the Department of Homeland Security determines pose a threat sufficient to affect national security. HHS also is required to determine the threat agents for which countermeasures are necessary to protect the public health.

Figure 1: DOD- and HHS-Unique and Common Biological Medical Countermeasure Needs as of March 2017



Source: GAO analysis of Department of Defense (DOD) and Health and Human Services (HHS) information. | GAO-17-701

According to officials with HHS's Office of the Assistant Secretary for Preparedness and Response and DOD's Joint Program Executive Office for Chemical Biological Defense (hereafter referred to as DOD's ADM program office), a driving factor for the establishment of the HHS CIADMs was the H1N1 influenza pandemic of 2009 and the difficulty HHS had ensuring that the United States had an adequate supply of pandemic influenza vaccine as well as other medical countermeasures for emerging infectious diseases that are necessary to protect the public's health. Driving factors for DOD's establishment of DOD's ADM facility were the difficulties experienced in attracting large, experienced pharmaceutical manufacturers to develop and manufacture needed biologic medical countermeasures to mitigate the health effects of biological agents and naturally occurring diseases on armed forces personnel.

DOD and HHS commissioned a joint analysis of alternatives for the development of emergency medical countermeasures that was published in June 2009 (hereinafter referred to as the 2009 analysis of alternatives).[14] This analysis was followed by the January 27, 2010, State

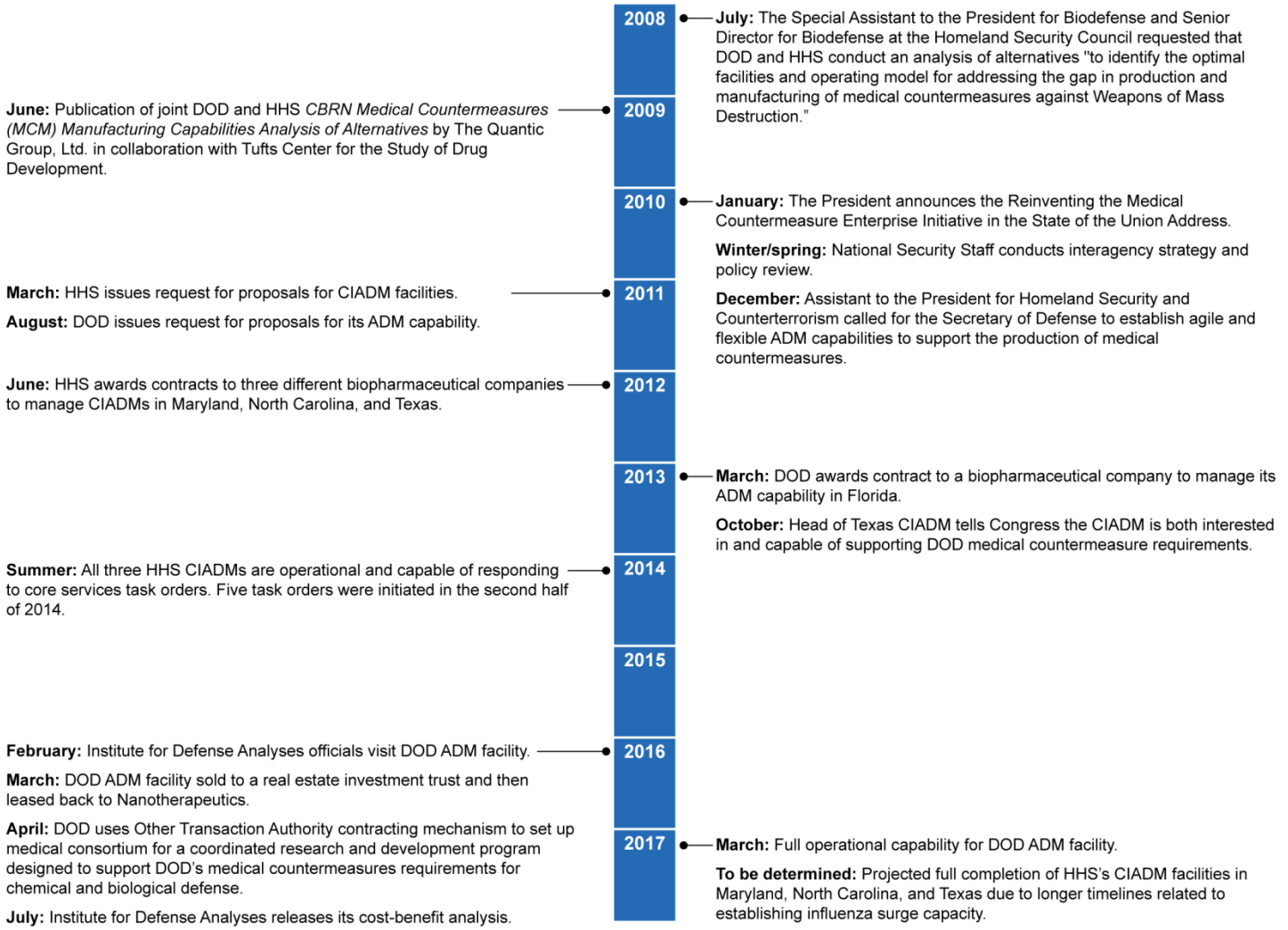
[14] See The Quantic Group, Ltd. in collaboration with Tufts Center for the Study of Drug Development, *CBRN Medical Countermeasures (MCM) Manufacturing Capabilities: Analysis of Alternatives* (June 15, 2009).

of the Union Address, in which the President announced the Reinventing the Medical Countermeasure Enterprise Initiative "that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease."[15] The National Security Staff then conducted an interagency strategy and policy review and, in December 2010, The White House called for the Secretary of Defense to, among other things, "establish agile and flexible advanced development and manufacturing capabilities to support the development, licensure, and production of medical countermeasures."[16] Part of DOD's strategy to address emerging and genetically modified biological threats was to establish a new capability for advanced development and manufacturing of DOD-unique medical countermeasures, which included the construction of an ADM facility in Alachua, Florida. At about the same time, HHS began to establish its three CIADM capabilities. In figure 2, we provide a timeline of efforts that led to the development of DOD's and HHS's respective ADM capabilities.

[15] See The White House Briefing Room, Barack Obama, "Remarks by the President in State of the Union Address." (Washington, D.C.: Jan. 27, 2010).

[16] Brennan, John O., *Memorandum for the Secretary of Defense: Medical Countermeasures against Biological and Other Public Health Threats*. (Washington, D.C.: The White House, Dec. 29, 2010).

Figure 2: Timeline of Efforts That Led to the Development of the Department of Defense's (DOD) and the Department of Health and Human Services' (HHS) Respective Advanced Development and Manufacturing Capabilities



Source: GAO analysis of DOD, HHS, White House, and Institute for Defense Analyses information. | GAO-17-701

According to officials with DOD's ADM program office and ADM contractor, the ADM capability comprises more than the physical facility in

Alachua, Florida—including, for example, other sites around the continental United States, such as fill and finish facilities, and the ADM contractor's network of 35 different partner companies that provide services in various areas such as testing and cell or virus banking.[17]

Officials from both DOD and HHS said that their departments have coordinated to develop their ADM and CIADM facilities, with agency officials serving on one another's contract evaluation panels and governance boards. For example, according to the advisory board charter for DOD's ADM capability, the board consists of officials from several DOD agencies as well as HHS's Biomedical Advanced Research and Development Authority. DOD officials also noted that they serve on the HHS CIADM steering committee and the Public Health Emergency Medical Countermeasures Enterprise, which have an oversight role for HHS's CIADMs.[18] DOD officials further noted that the two departments had considered the idea of a joint contract bid until HHS issued its solicitation about 6 months earlier than DOD, since HHS was concentrating on pandemic influenza requirements while DOD was looking for a capability to address a wider range of chemical and biological threats to members of the armed services.

[17] "Fill and finish" manufacturing is the filling and packaging of the formulated product (e.g., vaccine) into the final package. See GAO, *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).

[18] HHS and the Public Health Emergency Medical Countermeasures Enterprise have created a CIADM steering committee consisting of senior level officials from the Biomedical Advanced Research and Development Authority (BARDA), the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, and DOD. HHS has completed documents that provide governance for this process: a signed charter for the steering committee, preliminary criteria for selecting eligible contracts, and a signed governance document describing how the process will operate. Under the process, the steering committee issues a data call and, in response, medical countermeasure project managers from BARDA, the National Institutes of Health, and DOD are to submit proposals for current medical countermeasure contracts that would benefit from core services provided by the CIADMs to the CIADM steering committee. The steering committee is to then review the proposals and select the countermeasure projects and developers to which it will offer access to the CIADMs' core services. Next, HHS plans to issue task order requests for each selected project, and the CIADMs will be required to submit proposals in response to the task order requests. Finally, according to BARDA officials, BARDA plans to issue a task order to the CIADM contractor whose proposal best satisfies the selection factors for award under the task order. BARDA officials told us that the CIADM steering committee plans to meet at least semiannually. See GAO-14-329.

DOD Included Information in Its Report on the ADM Facility That Addressed the Six Required Elements Congress Requested

DOD addressed each of the required six elements in its October 2016 report to Congress on the department's ADM facility. Table 1 outlines the information DOD provided.

Table 1: Summary of Information That the Department of Defense (DOD) Provided to Congress on DOD's Advanced Development and Manufacturing (ADM) Facility

Element required by the National Defense Authorization Act for Fiscal Year 2016	Information DOD provided to address the required element
1. An overall description of the ADM facility, including validated DOD requirements	• Description of the ADM facility and its capacity and capabilities, as well as an explanation of the origin of the ADM capability requirement and reference to DOD's approach for validating medical countermeasure products
2. Program goals, proposed metrics of performance, and anticipated procurement and operations and maintenance costs (for the ADM facility) during the period covered by the current future years defense program	• Information on some of its program goals, medical countermeasures (e.g., vaccine) program performance measurements, and planned high-level performance metrics • Additionally, DOD provided estimated completion costs for the ADM facility in Florida, along with a statement that DOD is not requesting procurement or operations and maintenance funds in the future years defense program for the ADM facility and that sustainment costs for the capability will come from existing medical countermeasures programs
3. The results of any analysis of alternatives and efficiency reviews conducted by the Secretary (of Defense) that justifies the manufacturing and privately financed construction of an ADM facility rather than using other programs and facilities of the federal government or industry facilities for ADM of medical countermeasures	• A copy of a 2009 analysis of alternatives conducted by The Quantic Group, Ltd. and Tufts University for the Secretaries of Defense and the Department of Health and Human Services (HHS) contrasting different approaches for producing medical countermeasures for the U.S. government. DOD officials stated that this analysis justifies the ADM capability
4. An independent cost-benefit analysis that justifies the manufacturing and privately financed construction of an ADM facility described in (3)	• DOD contracted with the Institute for Defense Analyses to conduct an independent analysis of the cost and benefits, schedule, and performance of continued DOD investment in the DOD ADM facility. While this study did not identify any advantages to DOD inherent in maintaining DOD-unique capabilities with the ADM facility, it found that priority access to the facility could accelerate the availability of medical countermeasures, although additional costs might be incurred. However, DOD's report to Congress described the ADM facility's benefits compared with those of other contracted manufacturing organizations to justify the ADM capability • Additionally, the Institute for Defense Analyses reviewed and reported on the November 2015 Tufts University *Independent Assessment of the Direct and Indirect Costs to Build and Equip a Biologics Development and Manufacturing Facility*, which analyzed the sunk costs for the construction of the ADM facility
5. If no independent cost-benefit analysis makes the justification described in (4), an explanation for why such manufacturing and privately financed construction cannot be so justified[a]	

Element required by the National Defense Authorization Act for Fiscal Year 2016	Information DOD provided to address the required element
6. Any other matters the Secretary of Defense deems appropriate	• DOD's report laid out the department's medical countermeasures production plans for the DOD ADM facility • DOD also discussed its focus on platform technologies, which provide flexible systems that have the potential to produce medical countermeasures for multiple threats, like the Advanced Development and Manufacturing of Antibody Technologies Program • DOD's report provided a discussion of technology transfer from one contractor to another contractor

Source: GAO analysis of DOD, HHS, Tufts University, Quantic Group, Ltd., and Institute for Defense Analyses information. | GAO-17-701

[a]For reporting purposes, we consolidated elements 4 and 5 because element 5 was dependent on the answer to element 4.

Additional Information on DOD's ADM Capability That May Be Useful for Congressional Oversight

We identified additional information regarding DOD's ADM capability that may be useful to Congress in its oversight of the program. Moreover, this additional information may be particularly useful as DOD makes decisions on whether and how to renew its contract for 2-year option periods with the private-sector biopharmaceutical company that constructed the ADM facility.[19] DOD stated in its report that it will determine whether to exercise future contract option periods that extend the existing contract for the ADM capability by examining factors including, but not limited to, contractor performance, facility utilization, and urgent and/or emerging requirements. Table 2 summarizes the elements required in the National Defense Authorization Act for Fiscal Year 2016 and the additional information that we analyzed from DOD, HHS, and their contractors regarding information that may be useful to Congress.

Table 2: Summary of Additional Information on the Department of Defense's (DOD) Advanced Development and Manufacturing (ADM) Facility That May Be Useful for Congressional Oversight

Element required by the National Defense Authorization Act for Fiscal Year 2016	Additional information we identified that may be useful for congressional oversight

1. An overall description of the ADM facility, including validated DOD requirements	• Clarification about the
	  • potential for expanding the capabilities of the ADM facility
	  • source of and process for determining the ADM capability requirement

[19] This DOD contract has a base period that ended when the facility became fully operational—the "base period" being the time that elapses from the point at which DOD approved the contract to the point at which DOD accepted the completed facility. Once the base period ended, DOD can renew its contract up to four times, with the last contract option being available from 2022 through 2024.

Element required by the National Defense Authorization Act for Fiscal Year 2016	Additional information we identified that may be useful for congressional oversight
2. Program goals, proposed metrics of performance, and anticipated procurement and operations and maintenance costs (for the ADM facility) during the period covered by the current future years defense program	• Program objectives from the ADM contract • Detailed metrics used to evaluate contractor performance • The total cost to the ADM contractor for operating and maintaining the ADM facility • Clarification on the appropriateness of funding ADM infrastructure sustainment through program budgets for medical countermeasures
3. The results of any analysis of alternatives and efficiency reviews conducted by the Secretary (of Defense) that justifies the manufacturing and privately financed construction of an ADM facility rather than using other programs and facilities of the federal government or industry facilities for ADM of medical countermeasures	• An updated analysis of alternatives or other efficiency review that accounts for the availability of the Department of Health and Human Services' (HHS) three Centers for Innovation in Advanced Development and Manufacturing capabilities
4. An independent cost-benefit analysis that justifies the manufacturing and privately financed construction of an ADM facility described in (3)	• The cost-benefit analysis did not discuss the caveats, such as not assigning monetary value to the potential benefits of the ADM and using anecdotal evidence to justify time-savings benefits
5. If no independent cost-benefit analysis makes the justification described in (4), an explanation for why such manufacturing and privately financed construction cannot be so justified[a]	• Results from the November 2015 Tufts University *Independent Assessment*, which analyzed the sunk costs for the construction of the ADM facility and which was reviewed by, but not included in, the Institute for Defense Analyses' cost-benefit analysis
6. Any other matters the Secretary of Defense deems appropriate	• None for this element

Source: GAO analysis of DOD, HHS, Tufts University, Quantic Group, Ltd., and Institute for Defense Analyses information. | GAO-17-701

[a]For reporting purposes, we consolidated elements 4 and 5 because element 5 was dependent on the answer to element 4.

The following is information that we identified in addition to the information that DOD provided to address each required element.

Clarification about the Potential for Expanding the Capabilities of the ADM Facility and the Requirements for the ADM Capability

Supplementary Description of the ADM Capability

DOD's report noted, among other things, that the facility is 180,000 square feet and capable of producing up to 1.5 million doses of medical countermeasures within 3 months of a federal government request, with a surge capacity of up to 12 million doses. DOD's report also stated that the facility produces at a scale that is suitable for DOD's needs, is capable of complying with Current Good Manufacturing Practices manufacturing at

biological safety level (BSL) 3-capable containment, offers surge capability, and has additional room for expansion on site.[20] DOD reported that the ADM facility currently consists of two manufacturing suites with the capability to support up to four production lines, with options for adding up to three additional manufacturing suites. DOD also reported some information about the modular, single-use type of equipment found in the facility. Additionally, DOD's report stated that the ADM facility contractor, per its contract with DOD, provides additional capability and services through a network of industry partners and through contractor staff not located at the facility in Alachua, Florida.

During our review, we identified additional information that serves to clarify the potential for expanding the capabilities and capacity of DOD's ADM capability. For example, the DOD ADM facility is located on 29 acres of land within a secured perimeter and protected by motion-activated infrared cameras. In discussions with DOD program officials

[20] "Current Good Manufacturing Practices" refers to regulations enforced by the Food and Drug Administration. See, 21 Code of Federal Regulations Parts 210 and 211. According to the Food and Drug Administration, Current Good Manufacturing Practices provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the Current Good Manufacturing Practices regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards. Also, laboratories that handle pathogens are classified into four biological safety levels (BSL) based on the risk imposed by the pathogens. Laboratories classified as BSL-1 or -2 are suitable for work involving pathogens that pose minimal to moderate hazard to laboratory personnel and the environment, whereas high-containment laboratories such as BSL-3 and -4, are designed with additional safety measures to protect those working with dangerous pathogens that may cause serious and potentially lethal infection. Each level of containment describes the laboratory practices, safety equipment, and facility safeguards for the level of risk associated with handling particular pathogens. BSL-3 laboratories work with indigenous or exotic pathogens with known potential for airborne transmission or with those pathogens that may cause serious and potentially lethal infections. BSL-4 laboratories work with exotic pathogens that pose a high individual risk of life-threatening disease by airborne transmission and for which treatment may not be available. See GAO, *High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk*, GAO-16-642 (Washington, D.C.: Aug. 30, 2016). Further, according to the National Academy of Sciences, the BSL required for the production of certain medical countermeasures (i.e., vaccines) may not be the same BSL for working with the wild-type pathogen. See National Research Council of the National Academies, *Protecting the Frontline in Biodefense Research: The Special Immunizations Program*, (Washington, D.C.: 2011).

and with the ADM contractor, we learned that two of the additional three manufacturing suites (i.e., suites three and four) could be developed within the current structure of the building at the discretion of DOD, while a fifth manufacturing suite could eventually be built by expanding the building's perimeter, if needed. According to DOD officials, these additional suites, as well as the existing two manufacturing suites, are compliant with Current Good Manufacturing Practices. The facility currently uses DOD-purchased bioreactors with capacity for up to 500 liters each, although ADM contractor officials informed us that there is enough space in some manufacturing areas for bioreactors with capacity for up to 2,000 liters.[21] A more detailed description of the facility and its DOD-purchased equipment—including photographs of the equipment—can be found in appendix II.

Additional Information Regarding the ADM Requirements

Regarding DOD's inclusion of validated requirements in its report to Congress, DOD reported that the requirement for the ADM capability originated from a memorandum in December 2010 from The White House to the Secretary of Defense.[22] According to DOD officials with the Joint Requirements Office and the Chemical Biological Defense Program, although the requirement for the ADM capability was somewhat unique in its origins, infrastructure projects are normally not validated through the department's Joint Capabilities Integration and Development System.[23] According to DOD officials, the specific medical countermeasures (e.g., vaccines) produced by the ADM capability are to have a validated requirement through the department's Joint Capabilities Integration and Development System, while the means of production—such as an ADM

[21] Bioreactors are devices in which living cells synthesize useful substances.

[22] Brennan, John O., *Memorandum for the Secretary of Defense: Medical Countermeasures against Biological and Other Public Health Threats*. (Washington, D.C.: The White House, Dec. 29, 2010).

[23] DOD's Joint Capabilities Integration and Development System is the process used by DOD's Joint Requirements Oversight Council to fulfill its statutory responsibilities to the Chairman of the Joint Chiefs of Staff, including but not limited to identifying, assessing, validating, and prioritizing joint military capability requirements. Additionally, the system's outputs provide validated capability requirements to drive the Defense Acquisition System and inform DOD's planning, programming, budgeting, and execution processes. See Chairman of the Joint Chiefs of Staff Instruction 3170.01I, *Joint Capabilities Integration and Development System (JCIDS)* (Washington, D.C.; Jan. 23, 2015). DOD officials said that DOD has identified and created an Infrastructure Manager position and the department is evaluating its current Chemical and Biological Defense Program-related infrastructure policy, including validation of infrastructure projects as needed or able.

capability—will be determined by the program office that manages the acquisition of products to serve as medical countermeasures.

Throughout the course of our review, we identified additional information about the requirements process for the ADM capability. DOD officials with the ADM program office told us that the requirement for the ADM capability was validated by the direction of the Secretary of Defense to create such a capability, or was what a DOD official called a "directed requirement." Upon receipt of the memorandum from The White House, the Deputy Secretary of Defense responded that DOD would align its medical countermeasure efforts with The White House vision for strengthening protection against infections disease, in part by recommending funding starting in fiscal year 2012 to support rapid advanced development of medical countermeasures. According to ADM program officials, this direction was then disseminated through the Office of the Secretary of Defense until it reached DOD's ADM program office. Direction for creating the ADM capability also is captured in the following documents referring to DOD's Chemical and Biological Defense Program: *DOD Chemical and Biological Defense Program Fiscal Year 2012-2017 Program Strategy Guidance Implementation Plan* and the *Fiscal Year 2014-2018 Program Strategy Guidance Implementation Plan*.[24]

Program Goals, Metrics, and Costs

Additional Information Regarding DOD's Stated Goals and Metrics

DOD included in its report to Congress the program goals and performance metrics articulated in presidential memorandums to establish "agile and flexible advanced development and manufacturing capabilities to support the development, licensure, and production of Medical Countermeasures that address the needs of our military and the Nation."[25] With respect to performance metrics, DOD has established metrics in the contract for the ADM facility that it monitors periodically in conjunction with the contractor. DOD stated in its report that it will

[24] DOD, *DOD Chemical and Biological Defense Program Fiscal Year 2012-2017 Program Strategy Guidance Implementation Plan* (Washington, D.C.: Apr. 9, 2010) and the *DOD Chemical and Biological Defense Program Fiscal Year 2014-2018 Program Strategy Guidance Implementation Plan* (Washington, D.C.: May 10, 2012).

[25] DOD, *Department of Defense Advanced Development and Manufacturing Capability Report* (Oct. 17, 2016).

determine whether to exercise future contract option periods that extend the existing contract for the ADM capability by examining factors including, but not limited to, contractor performance, facility utilization, and urgent and/or emerging requirements. The report further states that the performance of the ADM contractor during the facility's operations will be measured based on its performance against the metrics of individual product (e.g., vaccine) contracts.

During our review, we identified additional information regarding DOD's goals and metrics. For example, in the *Acquisition Strategy and Plan for the Advanced Development and Manufacturing Prototype Capability for Medical Countermeasures* and the ADM contract's statement of objectives, we identified program objectives that collectively clarified DOD's overall program goal for the ADM facility:

- allowing third parties to mature and provide products to the government by leveraging the ADM capability while ensuring protection of intellectual property;
- providing streamlined capability that reduces cost and schedule risk;
- providing capabilities to rapidly respond to chemical, biological, radiological, and nuclear events, as well as emerging and genetically modified infectious diseases, by producing Food and Drug Administration-approved products or the expanded production of existing products;
- providing strategies for supporting and facilitating the transition of processes and technologies from DOD-affiliated science and technology organizations; and
- providing assistance and training in drug development and manufacturing.

Other information we reviewed addressed the evaluation of the contractor during the "base period" (i.e., the period in which the facility will be built by the contractor and accepted by DOD) and may be useful in demonstrating to Congress that oversight and accountability have been built into this public-private partnership contract. DOD's ADM contract and discussions with DOD's ADM program officials indicate that there are multiple metrics by which DOD assesses the performance of the contractor during the construction of the facility. For example, the contract requires the tracking of metrics such as technical performance, work product quality, contract management, and earned value management system data as part of a

quality assurance surveillance plan.[26] The ADM contract also requires the contractor to provide a number of reports to DOD on a monthly basis. For example, the contract data requirements list requires the ADM contractor to provide, among other things, a contract work breakdown structure that discusses the elements for which the contractor is responsible and a master government property list, which provides information on government property such as the cost of an item. Additionally, according to the contract, within 30 days following completion of facility validation, an *ADM Final Technical Closeout Report* must be completed to document the completion of the base period, including the achievement of all milestones and requirements. According to DOD officials, milestones for completion of the ADM facility include: (1) completion of construction activities; (2) installation of equipment in laboratory and clean room spaces; and (3) completion of all commissioning, qualification, and validation activities.[27]

Supplementary Information on ADM Costs

With respect to operations and maintenance costs, we identified additional information during our review that may be of use to Congress in its oversight of the program. DOD noted in its report to Congress that the ADM contract at completion is approximately $205 million and that there was neither dedicated funding in fiscal years 2015 and 2016, nor a request for fiscal year 2017 funding for the ADM capability. This contract completion cost includes an initial, fixed fee of approximately $18 million to the contractor, as well as costs associated with planning, architectural

[26] Earned value management is a project management tool that integrates the technical scope of work with schedule and cost elements for investment planning and control. It compares the value of work accomplished in a given period with the value of the work expected for that period. Differences in expectations are measured in both cost and schedule variances. The Office of Management and Budget requires agencies to use earned value management in their performance-based management systems for the parts of an investment in which development effort is required or system improvements are underway. See GAO, *GAO Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Capital Program Costs*, GAO-09-3SP (Washington, D.C.: March 2009).

[27] According to ADM program officials, the facility's commissioning, qualification, and validation activities include ensuring that the facility meets regulatory requirements established by the Food and Drug Administration as well as industry published guidelines, industry standard practices, and internal ADM policies and procedures. This also includes testing systems and equipment to ensure that they are capable, compliant with defined requirements, and fit for intended use. Among other things, the three documents that make up this report capture information such as the plans for addressing good manufacturing practices established by the Food and Drug Administration, regulatory compliance, and how the ADM contractor will operate the facility and address areas such as manufacturing, technology transfer, and quality control.

design, and the purchase of manufacturing equipment (for a more detailed discussion of items paid for by DOD, see app II). DOD's report to Congress noted that there are no procurement or operations and maintenance budget line item costs directly associated with the facility in upcoming DOD budget requests and included a discussion of future sustainment payments for the ADM capability. Specifically, DOD's report acknowledged that under contract options, should DOD exercise them, DOD would provide a sustainment payment to the ADM contractor to ensure that the contractor provides DOD with priority access to the ADM facility.[28] Each contract option is to be for 2 years, with the last contract option available from 2022 through 2024. The sustainment payment for the first contract option period, which began on April 1, 2017, was originally negotiated for approximately $18 million each year, but DOD said in its report to Congress that it was actively renegotiating the terms and amount of the sustainment option before awarding the option to the ADM contractor and anticipated that the payments would be less than the original amount. DOD's report said that the department will pay sustainment costs for the ADM capability from medical countermeasures programs requiring manufacturing and development activities in the year of budget execution.

Supplementary Information on the Appropriateness of DOD's Approach for Funding Sustainment Costs

We reviewed additional information that clarifies the relationship between the annual sustainment payment identified in the ADM contract options and the operations and maintenance costs of the ADM capability, as well as DOD's budgeting for the sustainment payments. DOD's sustainment payments for priority access to the ADM capability will be budgeted for as a cost of developing medical countermeasures (e.g., vaccines), according to officials from DOD's ADM program office, a funding structure similar to the model used with DOD-owned laboratories. For example, DOD's ADM program officials said that within the Chemical Biological Defense Program, of which they are a part, core DOD laboratories that provide critical infrastructure capabilities supporting the program sustain their capabilities by applying an indirect fee to Chemical Biological Defense Program-resourced projects. ADM program officials further stated that the annual sustainment payments will be used to retain trained personnel and maintain the equipment and systems in a ready state to support medical countermeasures development when program lines are ready to use the capabilities.

[28] Priority access allows the ADM contractor to use the capabilities for non-DOD purposes but must put DOD first if there are competing contracts.

Based on our discussions with DOD and ADM contractor officials, the total costs to ADM capability contractor Nanotherapeutics, Inc., hereinafter referred to as Nanotherapeutics, to operate and maintain the ADM facility—which are separate from and in addition to the costs in the initial contract with DOD for building the facility—were not fully known at the time of this report and were not fully covered by the DOD-provided sustainment payments. The contractor's executives told us that they were learning more about the costs of operating the facility as it becomes operational, and believe that overhead costs, such as personnel, may not be as significant as they first believed. According to the ADM contractor's executives, DOD's sustainment payments should represent approximately 25 percent of this overhead cost for operating the ADM facility. As noted earlier, DOD is working to renegotiate the amount of the sustainment payments based upon several changes, such as changes in facility size, the number of employees in the facility, and the sale of the contractor's building and the land for the ADM facility.[29] Further, as the cost-benefit analysis portion of the DOD report noted, the sustainment payments are not fixed at the amount negotiated by DOD and the contractor, but may be reduced through funded work. As the DOD report states, there is some uncertainty about the amount each dollar of funded work will offset a dollar of overhead cost (i.e., the costs covered in part by DOD's sustainment payments).[30] Nanotherapeutics executives noted, for example, that there can be great variations in the cost of labor and materials for some contracts, although other cost elements remain more fixed.

During our review, we learned that the contractor and DOD have taken some initial steps toward bringing additional funded work to support the DOD ADM capability, which may help to reduce DOD's sustainment payments under the contract options. First, executives from the ADM contractor stated that they were actively seeking additional work from both the federal government and the private sector, and had recently been awarded new contract work through HHS's National Institute of Allergy and Infectious Diseases. Second, included within the

[29] DOD and contractor officials stated that the property and building for the ADM facility was sold by the contractor to a real estate investment trust, which is leasing the facility back to the ADM contractor.

[30] As stated in the cost-benefit analysis portion of the DOD report to Congress, each dollar of funded work will offset less than one dollar of overhead costs due to the cost of consumables in the funded work, and factors that make operations more expensive than maintaining readiness, i.e., keeping the building open and staffed.

noncompetitive contracting mechanisms discussed in the cost-benefit analysis portion of the DOD report to Congress was Other Transaction Authority.[31] DOD's ADM program officials informed us that DOD used this authority in April 2016 to establish a consortium through which the department may be able to award some DOD medical countermeasures efforts to the ADM facility while retaining some of the benefits of competition, since the ADM contractor is a member of the consortium. DOD officials explained that because this consortium operates under Other Transaction Authority, it provides DOD with more flexibility to negotiate with contractors and to arrange for some subcontracted work to go through the ADM facility, as well as provide access to industry expertise and collaboration, among other things. DOD officials also expect the consortium to provide its members with a flexible contracting vehicle capable of multiple taskings with a single set of terms and conditions. DOD officials informed us that the ADM capability is likely to receive additional DOD work through the use of the Other Transaction Authority consortium. According to the cost-benefit analysis conducted by the Institute for Defense Analyses, additional DOD work would reduce annual sustainment payments, while increasing time saved by DOD.

DOD's Analysis of Alternatives and Additional Information on ADM Alternatives

In its report to Congress, DOD included results from the 2009 analysis of alternatives for the Secretaries of Defense and the Department of Health and Human Services, which informed the federal government's decision to create both DOD's ADM capability and HHS's CIADM capabilities.[32] As summarized in DOD's report, the 2009 analysis of alternatives attempted to address a gap in the production and manufacturing of medical countermeasures against weapons of mass destruction. In the analysis, The Quantic Group, Ltd., and Tufts Center for the Study of Drug

[31] Other Transaction Authority allows an agency to enter into agreements "other than" standard government contracts or other traditional mechanisms. Agreements under this authority generally are not subject to federal laws and regulations applicable to federal contracts or financial assistance, allowing agencies to customize their other transaction agreements to help meet project requirements and mission needs. Furthermore, because fewer requirements apply, other transaction agreements can be useful in attracting entities, such as companies that have traditionally not done business with federal agencies. However, we and others have previously reported that the use of other transaction agreements carries the risk of reduced accountability and transparency, in part because such agreements may not require compliance with federal requirements, such as government cost accounting standards.

[32] The Quantic Group, Ltd., in collaboration with Tufts Center for the Study of Drug Development, *CBRN Medical Countermeasures (MCM) Manufacturing Capabilities: Analysis of Alternatives* (June 15, 2009).

Development focused on three alternative methods of producing medical countermeasures: (1) continuing to contract with private-sector pharmaceutical companies for the production of medical countermeasures, (2) continuing existing methods while strengthening regulatory and sourcing capabilities and gaining enhanced access to development and manufacturing, and (3) building government facilities for the purpose of producing all medical countermeasures.

We identified additional information regarding HHS's CIADM capabilities as an alternative to the DOD ADM capability. As noted earlier, the 2009 analysis of alternatives jointly supported the DOD ADM and the HHS CIADM capabilities. However, since neither the DOD nor HHS capabilities existed at the time of the 2009 analysis (the contracts were signed in 2013 and 2012, respectively), the analysis did not consider HHS's CIADMs as alternatives for DOD or DOD's ADM capability as an alternative for HHS. HHS issued a request for contract proposals for the CIADMs in March 2011, 5 months before DOD issued its request for contract proposals for the DOD ADM. However, even though the HHS CIADMs were not analyzed as alternatives to the DOD ADM capability, HHS officials said that DOD could separately contract for medical countermeasures with any of HHS's CIADMs either independently or through existing HHS CIADM contracts. Additionally, a senior official with DOD's ADM program office informed us that the program office constantly assesses its portfolio, and maintains awareness of the HHS CIADMs through DOD's participation in HHS's Public Health Emergency Medical Countermeasures Enterprise—an interagency body—and the CIADM governing board.

Although officials from DOD's ADM program office stated that the HHS CIADMs are not appropriate for DOD's needs—with one official noting that they are large dedicated facilities designed primarily to address pandemic influenza threats—the cost-benefit analysis for DOD's ADM capability conducted by the Institute for Defense Analyses, as well as our own observations, suggest otherwise. Based on discussions with CIADM and HHS officials and some CIADM contractor documents, all three of the HHS CIADMs plan to use flexible manufacturing technologies in at least a portion of their facilities and may be capable of addressing DOD's flexible manufacturing needs. At least one CIADM official has testified about this capability at a CIADM facility upon completion, as at least 50 percent of

the CIADM capabilities will be available for non-HHS projects.[33] Officials from two of the CIADMs informed us that they could potentially address some of DOD's medical countermeasure manufacturing needs, to include potentially providing priority access to the CIADM capabilities under a contract. In addition, an official from one CIADM informed us that the CIADM's contractor currently is producing medical countermeasures for DOD. An official with the ADM program office said that DOD is represented on the governing board for the CIADMs and is aware of what HHS is doing there, so CIADM information can be taken into consideration along with ADM performance and utilization metrics as DOD considers future contract extensions for the ADM capability. See appendix III for more information on the HHS CIADM capabilities.

Additional Information to Clarify DOD's Cost-Benefit Analysis

In DOD's report to Congress, the department presented the results of a 2016 independent, DOD-commissioned cost-benefit analysis conducted by the Institute for Defense Analyses. During our review, we identified additional information that may add clarity to various aspects of the cost-benefit analysis. DOD's contracted analysis compared the cost and benefits, schedule, and performance of continued DOD investment in the DOD-dedicated ADM capability with a set of available alternatives.[34] The cost-benefit analysis also reviewed the results of a study conducted by Tufts University in 2015 to determine whether the "sunk" costs (i.e., costs incurred in the past that will not be affected by any present or future decision) of constructing the DOD ADM facility were of an appropriate magnitude.[35]

DOD reported that, per the results of the Institute for Defense Analyses-conducted cost-benefit analysis, with the exception of certain potential

[33] See Subcommittee on Intelligence, Emerging Threats and Capabilities, Committee on Armed Services, House of Representatives, *Biodefense: Worldwide Threats and Countermeasure Efforts for the Department of Defense,* 113th Cong., 1st sess., Oct. 11, 2013.

[34] Institute for Defense Analyses (July 2016).

[35] See Stella Stergiopoulos, Michael Wilkerson, James Hassenfeld, and Kenneth Getz, *Final Report Summarizing the Results of an Independent Assessment of the Direct and Indirect Costs to Build and Equip a Biologics Development and Manufacturing Facility* (Boston, MA: Tufts Center for the Study of Drug Development, Nov. 30, 2015). According to the Office of Management and Budget, sunk costs should be ignored in determining whether a new investment is worthwhile. See Office of Management and Budget, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs*, Circular A-94 (Oct. 29, 1992).

benefits that are hard to quantify, the benefit of having a DOD-dedicated ADM capability was largely focused on the priority access to the manufacture of biologic medical countermeasures guaranteed to DOD through the sustainment payments.[36] The cost-benefit analysis quantified this benefit as potentially saving 13 to 28 months of production time over the future years defense program—which captures and summarizes forces, resources, and programs associated with all DOD operations approved by the Secretary of Defense—and 23 to 50 months of production time over the course of current manufacturing production projections for medical countermeasures. The cost-benefit analysis also concluded that this priority access could come at a cost of between $55 million and $76 million over the future years defense program (and between $93 million and $136 million over the course of current manufacturing production projections). The cost-benefit analysis noted that DOD could offset some or all of this cost if the DOD-dedicated ADM facility received sufficient DOD and non-DOD funded work to offset DOD's annual sustainment payments to the contractor.

Our review of the cost-benefit analysis suggests that it can help inform decision makers about the potential economic effects of DOD's investment. We also identified additional information that would be useful for Congress in evaluating or interpreting the results of the DOD-commissioned cost-benefit analysis. Specifically, we reviewed the ADM cost-benefit analysis using selected key elements, based on economic guidance from the Office of Management and Budget and other sources, to determine whether the cost-benefit analysis provided evidence to decision makers of the potential economic effect of DOD's continued investment in the ADM capability.[37] Based on this review, we identified the following regarding the cost-benefit analysis:

- The cost-benefit analysis did not estimate the monetary value of the potential benefits of the DOD-dedicated ADM capability, such as

[36] The cost-benefit analysis also noted that there may be benefits that are difficult to quantify, such as the provision of advice. Further, it noted that non-competitive contracting, such as that provided under Other Transaction Authority, may provide additional benefits in terms of time savings as a result of the ADM capability.

[37] We reviewed the DOD-commissioned cost-benefit analysis in the context of economic guidance from the Office of Management and Budget. See Office of Management and Budget, *Regulatory Analysis*, Circular A-4 (Washington, D.C.: The White House, Sept. 17, 2003); Office of Management and Budget, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs*, Circular A-94 (Oct. 29, 1992); and Office of Information and Regulatory Affairs, *Regulatory Impact Analysis: A Primer* (Washington, D.C.: The White House, undated).

those associated with priority access, making it unclear whether DOD's continued investment in the ADM capability is economically justified (e.g., whether the benefits exceed the costs).[38]

- Future costs were not discounted.[39]
- The analysis did not clearly discuss the baseline that was used to estimate incremental costs and benefits (i.e., Institute for Defense Analyses officials explained to us that the ADM capability was evaluated against a baseline that was not a single facility, but rather a combination of the HHS CIADMs and other similar facilities owned by private contract manufacturing organizations).
- The analysis assumed that development and manufacturing costs of the DOD-dedicated ADM capability and the alternatives would be roughly comparable, but did not assess some plausible adjustments to this assumption in a sensitivity analysis.
- According to the Institute for Defense Analyses official overseeing the analysis, data used to develop the estimate of time savings—the primary benefit of having a DOD-dedicated ADM capability, according to the analysis—were anecdotal and were not assessed for reliability due to time constraints; additionally, industry changes limit the usefulness of retrospective studies.

In conducting the cost-benefit analysis, some of these limitations may not have been avoidable. Specifically, the Institute for Defense Analyses official leading the analysis told us that their analysis relied on anecdotal data for analyzing the benefits of the DOD-dedicated ADM capability because more objective data were not readily available and that conducting a more in-depth study, involving a study of wait times for access to the capability, would take longer than the time DOD had contracted to conduct the analysis. Moreover, the official noted that the flexible, single-use technology that the DOD ADM and alternatives would

[38] Institute for Defense Analyses officials explained that estimation of the value provided by priority access may be difficult, as it would depend upon highly uncertain operational and geopolitical factors, such as the extent to which DOD's reliance on the ADM capability might reduce the risk of U.S. troop casualties in combat in the event of a highly uncertain biological attack. The analysis also considered, but did not assign a monetary value to, other potential benefits of the ADM capability such as more expeditious contracting.

[39] A discount factor should be used to translate expected benefits or costs in any future year into present value terms. The discount factor is equal to $1/(1+i)^t$ where i is the interest rate and t is the number of years from the date of initiation for the program or policy until the given future year. See Office of Management and Budget, Circular A-94 (Oct. 29, 1992).

use has only recently become common place. As a result, these changes in the industry would limit the usefulness of retrospective studies because older data and practices are not comparable to current data and practices.

Additionally, the Institute for Defense Analyses' cost-benefit analysis reviewed a study previously conducted by Tufts University in 2015 to determine whether the ADM capability's sunk costs were of an appropriate magnitude. In its review, the Institute for Defense Analyses concluded that the Tufts University assessment was reasonable, and provided a brief explanation of the Tufts University sunk-cost analysis, stating that the 2015 Tufts University assessment demonstrated that the costs of building the facility were within the expected bounds for the project.[40] The 2015 Tufts University sunk-cost analysis may provide additional information in understanding the degree to which "the manufacturing and privately financed construction" of the DOD ADM facility is justified.[41]

Agency Comments

We are not making any recommendations in this report. DOD and HHS reviewed a draft of this report and provided us with technical comments, which we incorporated where appropriate.

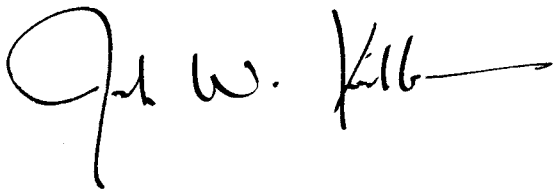
We are sending copies of this report to the appropriate congressional committees, Secretaries of Defense and Health and Human Services; the Under Secretary of Defense for Acquisition, Technology, and Logistics; the Assistant Secretary of Defense for Nuclear, Chemical, and Biological

[40] The 2015 Tufts sunk-cost analysis estimated that the cost of building a facility like the ADM facility would be between $144.1 million and $202.4 million for Nanotherapeutics, the ADM contractor. As DOD's report noted, the latest estimated cost to the government at completion is approximately $205 million. However, the Tufts analysis did not consider certain costs, such as property costs, that may be relevant to the cost of constructing the DOD ADM. According to a DOD briefing, among the costs not considered by Tufts was the $18 million fixed fee that was paid by DOD to the ADM contractor.

[41] According to Office of Management and Budget guidance, sunk costs should be ignored when evaluating the incremental benefits and cost of continuing with an investment. However, Congress required DOD to conduct a cost-benefit analysis to determine whether "the manufacturing and privately financed construction" of the ADM facility is justified. Further, the Institute for Defense Analyses noted that there was one major area of discrepancy in costs—in commissioning, qualification, and validation—but this represented less than 5 percent of total costs. See Office of Management and Budget, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs*, Circular A-94 (Oct. 29, 1992).

Defense Programs; the Deputy Assistant Secretary of Defense for Chemical and Biological Defense; the Chairman of the Joint Chiefs of Staff; the Secretary of the Army; and the Directors, Institute for Defense Analyses and Office of Management and Budget.

If you or your staff have any questions concerning this report, please contact Joseph W. Kirschbaum at (202) 512-9971 or KirschbaumJ@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.



Joseph W. Kirschbaum
Director
Defense Capabilities and Management

List of Committees

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Committee on Armed Services
House of Representatives

The Honorable Kay Granger
Chairwoman
The Honorable Pete Visclosky
Ranking Member
Subcommittee on Defense
Committee on Appropriations
House of Representatives

Appendix I: Objectives, Scope, and Methodology

This report is a public version of a sensitive report that we issued in May 2017.[1] The Departments of Defense (DOD) and Health and Human Services (HHS) deemed some of the information in our May report to be sensitive, which must be protected from public disclosure. Therefore, this report omits sensitive information about DOD's advanced development and manufacturing (ADM) facility and HHS's three Centers for Innovation in Advanced Development and Manufacturing (CIADM) facilities. Although the information provided in this report is more limited, the report addresses the same objectives as the sensitive report and uses the same methodology.

In this report, we (1) describe the information that DOD included in its report to address the six elements required by the National Defense Authorization Act for Fiscal Year 2016, and (2) present additional information related to each element that may be useful to Congress in its oversight role regarding DOD's ADM capability.

To address our objectives, we compared the six elements required by the National Defense Authorization Act for Fiscal Year 2016 with DOD's report to Congress to meet the congressional mandate and with the cost-benefit analysis included in the 2016 DOD-commissioned Institute for Defense Analyses report to DOD that was also submitted to Congress.[2] We reviewed DOD's report, the cost-benefit analysis conducted for DOD by the Institute for Defense Analyses and incorporated into DOD's report, and documents from the Institute for Defense Analyses that supported its study. Additionally, we interviewed and obtained documentation from officials from relevant organizations within both DOD and HHS as follows:

Department of Defense:

- Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics
    - Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs

[1] GAO, *Biological Defense: Additional Information That Congress May Find Useful as It Considers DOD's Report on Its Advanced Development and Manufacturing Capability*, GAO-17-297SU (Washington, D.C.: May 4, 2017).

[2] DOD, *Department of Defense Advanced Development and Manufacturing Capability Report* (Oct. 17, 2016) and Institute for Defense Analyses, *Cost Benefit Analysis of the DOD Advanced Development and Manufacturing Facility for Medical Countermeasures* (July 2016).

    - Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense/Chemical and Biological Defense Program
- Joint Science and Technology Office for Chemical and Biological Defense
- Joint Requirements Office for Chemical and Biological Defense
- U.S. Army
    - Office of the Assistant Secretary for Acquisition, Logistics, and Technology
    - Office of the Deputy Chief of Staff for Programming (G-8)
    - Joint Program Executive Office for Chemical and Biological Defense
        - Medical Countermeasure Systems Joint Project Manager Office

Federally Funded Research and Development Center:

- Institute for Defense Analyses

Department of Health and Human Services:

- Office of the Assistant Secretary for Preparedness and Response
    - Biomedical Advanced Research and Development Authority
    - Public Health Emergency Medical Countermeasures Enterprise

Additionally, we conducted site visits to compare the DOD ADM facility with the HHS CIADM facilities. Specifically, we visited the DOD ADM facility operated by Nanotherapeutics in Alachua, Florida, and two of HHS's three CIADM facilities—the CIADMs operated by Texas A&M University System in College Station, Texas, and by Emergent BioSolutions, Inc., in Baltimore, Maryland. We also obtained relevant documentation regarding all three contract organizations, about their facilities, relevant technologies, and their contracts with DOD and HHS. Due to the sensitive nature of the contract negotiations underway at the time of our audit work, we were unable to visit or otherwise meet with officials from HHS's third CIADM facility in Holly Springs, North Carolina, which at the time was contracted to Novartis Aktiengesellschaft. In lieu of this site visit, we met with senior officials from HHS's Office of the Assistant Secretary for Preparedness and Response to discuss the North

Carolina CIADM facility. In late December 2016, HHS informed us that bioCSL/Seqirus had become recognized by the federal government as the owner and operator of the HHS CIADM facility in Holly Springs, North Carolina. We compared the information we obtained through these visits with information from DOD's October 2016 report to Congress with the initial criteria laid out in the National Defense Authorization Act for Fiscal Year 2016.[3]

To further assess the extent to which DOD had conducted an independent cost-benefit analysis of the ADM facility, we reviewed the cost-benefit analysis conducted for DOD by the Institute for Defense Analyses using key characteristics of an economic analysis based on principles and guidance from the Office of Management and Budget (e.g., Circular A-94) and other sources.[4] Such key characteristics include: (1) objective and scope, (2) alternatives, (3) analysis of effects, (4) sensitivity analysis, and (5) documentation. For example, for the objective and scope element, we examined the extent to which the analysis clearly stated its objective and the question that it intended to address. For the alternatives characteristic, we examined the extent to which the analysis considered all relevant alternatives, including, that of no action. For the analysis of effects characteristic, we examined the extent to which analysis quantified and assigned a monetary value to the benefits and costs using the concept of opportunity cost. For the sensitivity analysis characteristic, we examined the extent to which the analysis explicitly addressed how plausible adjustments to each important analytical choice and assumption affected the estimates of benefits and costs. Finally, for the documentation characteristic, we examined the extent to which the analysis was clearly written, with a plain language summary and transparent tables that describe the data used and the results, and a conclusion that is consistent with the results. In addition, we interviewed DOD and Institute for Defense Analyses officials to obtain information about the analysis. Further, we interviewed officials from DOD, HHS, the DOD ADM facility, and two of the three HHS CIADMs to

[3] National Defense Authorization Act for Fiscal Year 2016, Pub. L. No. 114-92, §221 (2015).

[4] Office of Management and Budget, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs*, Circular A-94 (Oct. 29, 1992); and Office of Information and Regulatory Affairs, *Regulatory Impact Analysis: A Primer* (Washington, D.C.: The White House, undated) and other sources, which include Boardman, Anthony E., David H. Greenberg, Aidan R. Vining, and David L. Weimer, *Cost-Benefit Analysis: Concepts and Practice*, 3rd ed. (Boston, MA: Prentice Hall, 2006).

obtain information about medical countermeasures manufacturing facilities.

The performance audit upon which this report is based was conducted from June 2016 to May 2017 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 concluding observations based on our audit objectives. We subsequently worked with DOD and HHS in June 2017 to prepare this unclassified version of the original sensitive report for public release. This public version was also prepared in accordance with these standards.

Appendix II: The Department of Defense's Advanced Development and Manufacturing Facility, a Public-Private Partnership

The Department of Defense (DOD) advanced development and manufacturing (ADM) facility is a 180,000 square-foot biologics ADM facility located in Alachua, Florida. It was created in 2013 through a public-private partnership between DOD and Nanotherapeutics, Inc., a private-sector biopharmaceutical company hereinafter referred to as Nanotherapeutics. According to ADM program office and contractor officials, Nanotherapeutics, paid for the construction of the building and DOD paid for the design and equipment. Upon completion of the base period (i.e., the period in which the facility will be built by the contractor and accepted by DOD) for DOD's contract with Nanotherapeutics, DOD is to have priority access to the facility in exchange for an annual sustainment payment (paid monthly, according to ADM contractor officials) if the department chooses to exercise the optional contract periods. Figure 3 shows an external view of DOD's ADM facility.

Figure 3: The Department of Defense's Advanced Development and Manufacturing Facility in Alachua, Florida, a Public-Private Partnership with Nanotherapeutics.

Source: Nanotherapeutics, Inc. | GAO-17-701

The facility has two biological safety level (BSL)-3 manufacturing suites compliant with Current Good Manufacturing Practices, with a total of four

production lines.[1] It sits within a secured perimeter monitored by motion-activated infrared cameras. Some initial capabilities came online in August 2016, and DOD officials said that the facility became fully operational in March 2017.

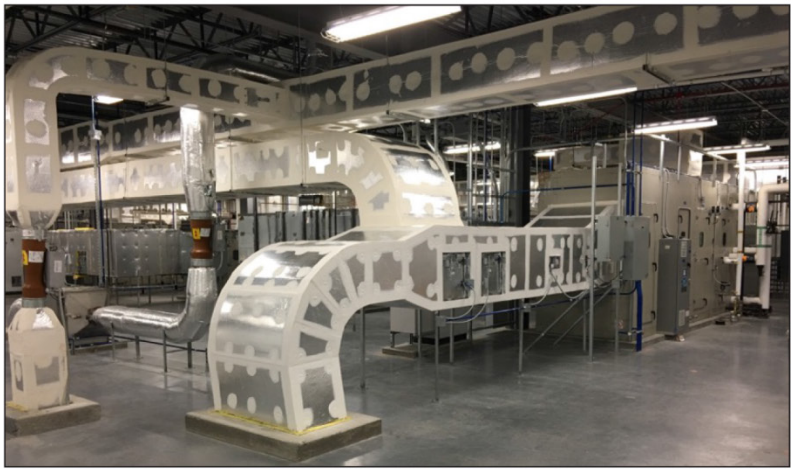
The facility was constructed with potential expansion in mind. The facility includes an unfinished space where—according to ADM program office and contractor officials—two additional manufacturing suites can be built with DOD's permission. Further, the facility sits on an approximately 29-acre site that provides room for the expansion of the building, a portion of which may be used for an additional manufacturing suite, according to an ADM program official. According to the contractor, expansion into the unfinished interior space is solely at the discretion of DOD, which owns the space, while Nanotherapeutics has the right to choose to expand the building at its own initiative, without DOD approval. Two images of DOD's

[1] Laboratories that handle pathogens are classified into four biological safety levels (BSL) based on the risk imposed by the pathogens. Laboratories classified as BSL-1 or -2 are suitable for work involving pathogens that pose minimal to moderate hazard to laboratory personnel and the environment whereas high-containment laboratories—BSL-3 and -4 for the purpose of this report—are designed with additional safety measures to protect those working with dangerous pathogens that may cause serious and potentially lethal infection. Each level of containment describes the laboratory practices, safety equipment, and facility safeguards for the level of risk associated with handling particular pathogens. BSL-3 laboratories work with indigenous or exotic pathogens with known potential for airborne transmission or with those pathogens that may cause serious and potentially lethal infections. BSL-4 laboratories work with exotic pathogens that pose a high individual risk of life-threatening disease by airborne transmission and for which treatment may not be available. See GAO, *High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk*, GAO-16-642 (Washington, D.C.: Aug. 30, 2016). Further, according to the National Academy of Sciences, the BSL required for the production of certain medical countermeasures (i.e., vaccines) may not be the same BSL level for working with the wild-type pathogen. See National Research Council of the National Academies, *Protecting the Frontline in Biodefense Research: The Special Immunizations Program*, (Washington, D.C.: 2011). Additionally, Current Good Manufacturing Practices refers to the Current Good Manufacturing Practice regulations enforced by the U.S. Food and Drug Administration. See 21 Code of Federal Regulations Parts 210 and 211. Current Good Manufacturing Practices provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the Current Good Manufacturing Practices regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards.

ADM facility were redacted because DOD deemed the images to be sensitive and for official use only.

According to representatives from Nanotherapeutics, the facility has two separate outside electricity feeds for redundancy, and has a backup generator that can meet the facility's electricity needs for up to 4 days (see fig. 4). The BSL-3 area has its own independent, high-efficiency particulate air-filtered, air-handling systems.

Figure 4: Department of Defense's Advanced Development and Manufacturing Facility Air Handler Unit and Backup Generator (and Generator Enclosure)



Air handler unit

Backup generator

Source: Nanotherapeutics, Inc. I GAO-17-701

The facility has a chilled water generator, as well as water purifying systems that include a system to provide purified water and another system to provide and dispense water for injection, used in the manufacturing of drug products and, according to Nanotherapeutics officials, DOD owns the manufacturing equipment (see fig. 5) as well as some building infrastructure, such as the facility's heating, ventilation, and air conditioning systems.[2]

[2] According to ADM contractor officials, the water purifying systems meet United States Pharmocopeia specifications. Furthermore, DOD's contract with Nanotherapeutics includes provisions for disposing of DOD-owned property at the end of the contract.

Figure 5: Portions of the Water for Injection Generation System at the Department of Defense's Advanced Development and Manufacturing Facility, Including the Dispensing Station

Dispensing station

Water for injection generation system

Source: Nanotherapeutics, Inc. | GAO-17-701

The facility employs single-use technology, in the form of the GE Healthcare LifeSciences' FlexFactory biomanufacturing platform, to provide more flexible manufacturing that reduces downtime between production runs. The facility can support manufacturing from 4.5 liters to multiple 1,000-liter production lines and uses 50- to 500-liter bioreactors. Nanotherapeutics officials told us that, although the facility is advertised to handle up to 1,000-liter bioreactors, the manufacturing space can handle 2,000-liter bioreactors in certain areas with taller ceiling spaces. Figure 6 shows a bioreactor (bottom right), a device in which living cells synthesize useful substances; a fermentor (left), used in the production of biologics to cultivate microorganisms, such as bacteria; and an autoclave (top right) for steam sterilization through the exposure of items to a certain temperature or pressure for a specified period of time. The

autoclave shown below is used to minimize cross-contamination in quality control testing.

Figure 6: Fermentor for the Production of Biologics, Autoclave in the Quality Control Area, and a Single-Use Bioreactor at the Department of Defense's Advanced Development and Manufacturing Facility

Fermentor

Autoclave

Single-use bioreactor

Source: Nanotherapeutics, Inc. I GAO-17-701

In March 2016, Nanotherapeutics sold the property associated with the ADM facility to a real estate investment trust, renting the property back from the trust under a 15-year lease. The sales agreement does not include DOD-owned property at the location, which—according to ADM contractor officials—includes the building's heating, ventilation, and air

conditioning systems.[3] According to Nanotherapeutics executives, this sale-and-leaseback was executed to reduce the financial costs to the contractor resulting from the debt associated with building the facility.

[3] DOD's contract with Nanotherapeutics includes provisions for disposing of DOD-owned property at the end of the contract.

Appendix III: Department of Health and Human Services' Center for Innovation in Advanced Development and Manufacturing Facilities, Public-Private Partnerships

The Department of Health and Human Services (HHS) has three Centers for Innovation in Advanced Development and Manufacturing (CIADM) facilities located in Texas, Maryland, and North Carolina. The CIADMs are intended to support HHS's flexible manufacturing of medical countermeasures by providing: (1) surge capacity for manufacturing the pandemic influenza vaccine; (2) core services for the development of chemical, biological, radiological, and nuclear medical countermeasures; and (3) workforce training.[1] The three HHS CIADMs are public-private partnerships between the federal government and contractors, with contracts that involve cost sharing between HHS and each contractor during each contract's initial phase, or "base period" (i.e., the period in which the facility will be built by the contractor and accepted by HHS). According to HHS officials, though there are commonalities, HHS negotiated each CIADM contract separately, and so each has different terms.

The HHS CIADMs may serve as alternatives for the Department of Defense (DOD) advanced development and manufacturing (ADM) capability once the CIADMs achieve readiness, according to DOD and HHS officials. The following is contractor and cost information for HHS's three CIADMs in Texas, Maryland, and North Carolina. Some details about the three CIADMs were redacted because HHS deemed the information to be sensitive and for official use only.

Texas CIADM:

Location:	College Station, Texas
Contractor:	Texas A&M University System
Cost to HHS:	$176.7 million
Cost to Contractor:	$108.9 million
Base period ends:	December 31, 2017[2]

See figure 7 for a photograph of the Texas A&M facilities.

[1] "Flexible" manufacturing is the use of disposable equipment and alternative technologies for product development and rapid manufacturing to aid in the development and production of medical countermeasures. See GAO-14-329.

[2] According to information from HHS officials, the time frame for ending the base period may be subject to possible extension depending on influenza vaccine development time frames.

Figure 7: Texas CIADM Facilities

Source: Texas A&M Health Science Center. | GAO-17-701

Maryland CIADM:

Location:	Baltimore, Maryland
Contractor	Emergent BioSolutions, Inc.
Cost to HHS:	$163.2 million
Cost to Contractor:	$58.6 million
Base period ends:	June 14, 2020

Figure 8 shows the Emergent CIADM as it should look upon its completion in 2017.

Figure 8: Planned Maryland Center for Innovation in Advanced Development and Manufacturing

Source: Emergent BioSolutions, Inc. | GAO-17-701

Emergent informed us that the company is interested in DOD medical countermeasures contracts. An Emergent official noted that the company already produces an auto-injector and several other products for DOD. Emergent also informed us that the company has interest in providing priority access to DOD, though Emergent officials told us that this interest would depend on the specifics of DOD's needs, and the compensation DOD is willing to provide in exchange for that priority access.

North Carolina CIADM:

Location:	Holly Springs, North Carolina
Contractor:	Originally Novartis AG, as of December 2016, bioCSL/Seqirus[3]
Cost to HHS:	$59.8 million[4]
Cost to Contractor:	$26.3 million
Base period ends:	December 31, 2016[5]

The North Carolina CIADM was created out of a partnership between HHS and Novartis AG (hereafter referred to as Novartis), an international pharmaceutical manufacturer headquartered in Switzerland. Costs and ownership were shared between HHS and Novartis; HHS officials informed us that the government has a 40-percent stake in the facility.[6] During our review, we were informed by HHS officials that HHS was involved in sensitive contract negotiations involving the CIADM following the sale of Novartis' influenza vaccine business to CSL Limited, an Australian pharmaceutical manufacturer. As such, we discussed this facility only with HHS officials rather than speaking with officials from—or visiting—the North Carolina CIADM facility. In December 2016, HHS

[3] HHS officials informed us of this change in December 2016.

[4] Previously, in fiscal year 2009, HHS's Biomedical Advanced Research and Development Authority awarded a separate contract worth approximately $487 million to Novartis for the construction of an influenza vaccine manufacturing facility in Holly Springs, North Carolina. This influenza facility is co-located with, and incorporated into, the North Carolina CIADM.

[5] At the time of our audit work, HHS was involved in sensitive contract negotiations involving the CIADM following the sale of Novartis' influenza vaccine business to CSL Limited, an Australian pharmaceutical manufacturer, so contract dates may be subject to change.

[6] According to Office of the Assistant Secretary for Preparedness and Response officials, HHS has a stake only in the North Carolina CIADM building; the land remains wholly owned by the contractor.

officials informed us that HHS had resolved its CIADM contract negotiations with Novartis AG and bioCSL/Seqirus. Seqirus is now recognized by the federal government as the owner and operator of the HHS CIADM facility in Holly Springs, North Carolina.

Appendix IV: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the contact named above, GAO staff who made key contributions on this report include Mark A. Pross, Assistant Director; Michele Fejfar; Ashley Grant; Timothy Guinane; Mae Jones; Amie Lesser; Bethann E. Ritter Snyder; Sabrina Streagle; Paola Tena; and Edwin Yuen.