

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

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BIOLOGICAL DEFENSE

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

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.