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House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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November 22, 2019

The Honorable Gene Dodaro
Comptroller General
U.S. Government Accountability Office
441 G Street, NW
Washington, D.C. 20584

Dear Mr. Dodaro:

We understand that Chairman Frank Pallone, Jr. and Ranking Member Greg Walden of the House Committee on Energy and Commerce, along with Chair Diana DeGette and Ranking Member Brett Guthrie of that Committee's Subcommittee on Oversight and Investigations, requested on August 7, 2019, that GAO "examine the Department of Homeland Security's (DHS) deployment of a new biodetection technology system called BioDetection 21 (BD21) to replace BioWatch."[1] The Energy and Commerce Committee asked GAO to consider the following questions pertaining to the BD21 program:

- "What are DHS's requirements for the acquisition of a technology and to what extent has BD21 followed those requirements?"

- "What is the technical maturity of the critical technology elements of BD21? How robust are the DHS test and evaluation plans to de-risk operational deployment of the critical technology elements of BD21 sufficiently, and what do the results, if any, show to date?"[2]

The House Committee on Science, Space, and Technology has a similar interest in scrutinizing BD21. The Committee has a long history of oversight regarding DHS's scientific and

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[1] House Committee on Energy and Commerce, Letter to the Honorable Gene Dodaro, August 7, 2019, https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/GAO.2019.08.06..pdf.
[2] *Id.*

technological enterprise. Since 2011, the Committee has conducted three oversight hearings focused on the DHS Science and Technology Directorate (S&T) and the Domestic Nuclear Detection Office (DNDO), which has now been merged into the Countering Weapons of Mass Destruction Office (CWMD) that oversees BD21.[3] The Committee is determined to ensure that DHS policymakers adhere to established processes and procedures in their efforts to develop new technologies and integrate those technologies into the Department's operational activities.

Request to Join GAO Review of BioDetection 21

We recognize that a strong and capable biodefense system remains as critical to America's national security as ever. The Trump Administration's *National Biodefense Strategy*, released in September 2018, characterizes biological threats as "among the most serious threats facing the United States and the international community," and the report emphasizes that the United States must be able to "stem infectious disease outbreaks at their source, wherever and however they occur."[4] We share the goal of a nationwide biodetection system that is accurate, reliable, and backed by a broad consensus among law enforcement officials, public health officials, and first responders in every jurisdiction. At the same time, the gravity of the threat compels us to subject any proposed biodetection system to vigorous examination. We must get biodetection right, because the stakes are too high to accept anything less.

Our Committee staff have discussed our interest in becoming co-requesters on this study with Chairman Pallone's staff, and there is agreement to allow us to join the request. Chairman Pallone's staff confirmed with Ranking Member Walden's staff that they are amenable to our joining the request.

We would like to become co-requesters on all ongoing GAO reviews associated with the agency's evaluation of BD21, pursuant to the House Committee on Energy and Commerce's request from August 7, 2019. Please contact Josh Schneider on the Majority Committee staff of the House Science Committee at 202-225-6375 or by email at Josh.Schneider@mail.house.gov, or Tom Connally on the Minority Committee staff of the House Science Committee at 202-225-6371 or by email at Tom.Connally@mail.house.gov, if you have any questions about this co-request.

Committee Findings on BioDetection 21

For the past several months the Committee has conducted its own bipartisan inquiry into BD21. While our oversight efforts will continue, we wish to share some of the information that we have gathered that may be pertinent to your review, including the aforementioned questions about BD21's acquisition requirements and technological maturity. We also wish to articulate some of our concerns about the program's implementation to date. We encourage you to incorporate these concerns into the scope of your examination as you proceed. Our primary concerns are as follows:

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[3] House Committee on Science, Space, and Technology, Hearings, accessed September 24, 2019, https://science.house.gov/hearings.

[4] White House, National Biodefense Strategy, 2018, https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf.

- CWMD may be moving too quickly through the BD21 requirements and acquisition processes, attempting to accelerate the pace of the program's implementation at the risk of cutting procedural corners and prioritizing speed over prudence.

- DHS waived the requirement for CWMD to complete a Capability Analysis Report for BD21, which could impair the Department's ability to ensure that the program is properly addressing capability gaps, two months after the DHS Office of Inspector General criticized the Department for taking similar actions with other programs.

- BD21's principal biodetection technologies appear to suffer from fundamental capability gaps in detecting some types of dangerous biological agents, including small-particle bacterial agents and viral agents, and in reliably identifying biological agents without further laboratory confirmation. CWMD appears to be disregarding these limitations as it develops a Concept of Operations (CONOPS) for the program.

- CWMD's plan to achieve operational feasibility with BD21 depends upon the successful use of "big data" to develop an algorithm that can compensate for technological shortcomings, but the algorithm does not currently exist and will itself be technically difficult to achieve.

We also ask that GAO incorporate the following questions about DHS's engagement with public health officials and first responders into the scope of your examination:

- Is CWMD conducting adequate outreach to the public health and first responder communities regarding the implementation of BD21?

- Has CWMD appropriately consulted with public health agencies, first responders and other key biodetection stakeholders regarding the operational role of confirmatory laboratory testing within BD21?

Adherence to DHS Requirements and Acquisition Rules and Guidelines

We are concerned that CWMD may not be properly adhering to DHS's requirements and acquisition processes for BD21. The Committee has reviewed internal DHS documents pertaining to BD21 that reveal deviations from established DHS procedures.

Federal acquisition procedures exist for a purpose: to maintain the integrity of an acquisition program; to ensure that acquisition decisions are properly conceived and promote the agency's broader objectives; and to guarantee that all programmatic possibilities are duly considered before final decisions are made on the use of taxpayer dollars. In October 2016, GAO reviewed the DHS joint requirements process and its role within the Department's acquisition life cycle.[5] The DHS Office of Inspector General (OIG) evaluated the implementation of the Department's

[5] Government Accountability Office, *Homeland Security Acquisitions*, October 2016, https://www.gao.gov/assets/690/680600.pdf.

procedures for the requirements process in January 2019.[6] Both assessments confirmed the importance of adhering to DHS's acquisition and requirements processes in order to promote successful outcomes for major acquisition programs.

CWMD has publicly stated that it intends to fully implement BD21 by 2025, with a projected operating budget of $80 million annually.[7] If achieved, this operating budget would be the same as BioWatch, which has cost the federal government roughly $1.6 billion since its rollout in 2003.[8] The program's long-term costs are likely to be substantial, which increases the importance of a sound acquisition process to ensure the judicious use of taxpayer dollars.

CWMD has deviated from the established DHS requirements process by failing to complete a Capability Analysis Report (CAR) for BD21. The CAR is a key early document in the DHS joint requirements (JRIMS) process that is to be prepared at the beginning of the formal acquisition life cycle.[9] According to the OIG, the CAR "documents the results of a sponsor-conducted capability assessment" and establishes a formal linkage between strategic guidance, operational factors, relevant threats, and requirements.[10] The CAR also identifies any capability gaps that can be addressed through the acquisition process. The DHS Joint Requirements Council (JRC), which oversees the JRIMS process, is required to validate a CAR in order to ensure that a component has performed an adequate evaluation of capabilities to inform subsequent requirements planning.[11] But rather than follow that established procedure for BD21, the JRC formally waived the requirement for a CAR altogether in March 2019.[12] As a result, CWMD never completed a CAR for BD21 and the elements of the CAR have been either delayed or neglected entirely.

DHS's formal rationale for waiving the CAR requirement for BD21 is inadequate. CWMD asserted that it was not required to complete a CAR "due to the JRIMS process not being fully codified at the time of submission."[13] But the JRIMS process has been functional for years. GAO's own analysis found that as early as August 2016, the JRC had already reviewed or validated 30 documents for 28 distinct programs.[14] It therefore appears that CWMD would have been required to complete a CAR if the requirement had not been waived by the JRC. The waiver is troubling in light of an OIG report that was published in January 2019, two months prior to the waiver, which criticized the JRC for failing to strictly uphold the JRIMS process. The OIG specifically noted that the JRC "does not hold components accountable for failing to follow guidance," and argued that as a consequence, "the Department cannot be assured that capability

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[6] DHS Office of Inspector General, *DHS Needs to Improve the Process for Identifying Acquisition Planning Capability Needs*, January 2019, https://www.oig.dhs.gov/sites/default/files/assets/2019-02/OIG-19-19-Jan19.pdf.
[7] David Willman, Homeland Security replacing troubled biodefense system with another flawed approach, LOS ANGELES TIMES (Feb. 15, 2019), https://www.latimes.com/politics/la-na-pol-biowatch-replacement-20190215-story.html.
[8] *Id.*
[9] GAO, *supra* note 5. (JRIMS formally stands for the Joint Requirements Integration and Management System).
[10] DHS OIG, *supra* note 6.
[11] GAO, *supra* note 5.
[12] US Department of Homeland Security, Countering Weapons of Mass Destruction (CWMD) Office, *Mission Need Statement for Biological Detection*, May 2019 [hereinafter *Mission Need Statement*].
[13] *Id.*
[14] GAO, *supra* note 5.

needs are properly identified."[15] We are concerned that the absence of a CAR could similarly impair DHS's ability to assess BD21 program requirements in the context of the Department's capability needs.

Other steps CWMD has taken to expedite BD21 may not support deliberative acquisition and requirements processes. For example, the JRC permitted CWMD to delay the development of "mission outcome metrics" for BD21. According to the established JRIMS process, mission outcome metrics are normally documented in either the CAR or a subsequent Mission Need Statement (MNS). But in the case of BD21, CWMD did not detail the mission outcome metrics in either document because the JRC allowed CWMD to defer that task to a later phase of the acquisition process.[16] As a result, CWMD was unable to utilize mission outcome metrics to inform the program's early steps. In an October 2015 report, GAO asserted that to "define mission need" at an early stage – before the design and development of program capabilities – represents a best practice for federal acquisition programs.[17] CWMD's delay in developing mission outcome metrics for BD21 appears to deviate from this best practice.

Further questions arise from the timing of the BD21 technology demonstration in relation to the JRIMS process. The technology demonstration, which is ongoing and features the deployment of sample biodetection equipment to different sites around the country, began at the end of 2018. This was several months before the JRC waived the requirement for a BD21 CAR and even longer before the completion and validation of the MNS, the next major document in the JRIMS process. The analytical steps of the JRIMS process are meant to guide and inform all subsequent analyses of program capability needs and operational requirements. By starting the technology demonstration before the validation of the MNS and without a CAR entirely, CWMD increased the risk that the technology demonstration could be structured in a manner that diminishes the value of its data to the program.

Finally, we have questions about how the BD21 Analysis of Alternatives (AoA) will be executed. The purpose of an AoA study is to assess the range of possible solutions to an identified DHS need and weigh the advantages and drawbacks of each one, thereby providing program officials with a comprehensive evaluation of the available options before they proceed to the later stages of the acquisition life cycle.[18] AoAs are a key element of the DHS acquisition process because the results of their systematic analyses can offer critical support to the eventual selection of a particular acquisition approach by program officials.

In June 2019, DHS approved Acquisition Decision Event-1 for BD21, which formally initiated the program's Phase 2 of the acquisition life cycle. CWMD hopes to complete this phase – which includes the AoA – within 12 months, despite an independent study's finding on behalf of DHS that AoA timelines for major acquisition programs "typically range from 12 months to 2½

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[15] DHS OIG, *supra* note 6.
[16] *Mission Need Statement*, *supra* note 12.
[17] Government Accountability Office, *Amphibious Combat Vehicle*, October 2015, https://www.gao.gov/assets/680/673405.pdf.
[18] Homeland Security Studies and Analysis Institute, *Analysis of Alternatives (AoA) Methodologies: Considerations for DHS Acquisition Analysis*, Version 3.0, January 2014, https://www.anser.org/docs/reports/AOA%20Methodologies%20Considerations%20for%20DHS%20Acq%20Analysis.pdf.

years."[19] Given this accelerated timetable, we hope that CWMD officials will not seek to restrict or influence the AoA in order to avoid any disruption to their desired program timeline. The stakes are high: the JRC has formally warned CWMD that the BD21 AoA will "determine solution readiness to meet capabilities outlined in the MNS" and will establish whether "advances in technology and changes in concept of operations (CONOPS) can provide significant cost and capability advantages" over the existing BioWatch system.[20] In other words, the AoA will weigh heavily on DHS's final decision regarding the feasibility and practicality of BD21. We believe that DHS must maintain a robust commitment to the AoA process in the months ahead and that this issue warrants GAO's attention.

We are troubled by the prospect that CWMD may be prioritizing speed over methodical and diligent planning. We urge you to consider these issues and their potential consequences in your review.

Technological Viability

We are concerned that CWMD may not be adequately addressing questions regarding BD21's technological viability.

CWMD's vision for BD21 calls for the deployment of two core technologies in civilian environments across the country:

- Trigger devices, which would use anomaly detection to distinguish the presence of biological agents in the air; and

- Portable Biological Identifiers (PBIs), which would be used by first responders in response to positive alerts from trigger devices to perform localized field-screening tests on airborne samples and verify the presence of biological agents.

BD21's primary goal with the coordinated use of these technologies is to facilitate near real-time detection and allow a much shorter timeline for making operational decisions. Unlike the current BioWatch system, which requires a filter sample to be transported to a laboratory for testing each day, the combination of trigger devices and PBIs could theoretically provide near-instantaneous detection of an airborne release and rapid verification testing on the scene within hours. The aim is to reduce BioWatch's current 36-hour testing process to a timeframe under BD21 of less than three hours before an operational response can be initiated to protect public health.

According to CWMD, BD21 will be able to issue a near real-time alert of a biological incident within 20-30 minutes of a release. The program will be capable of surveilling the environment for an unlimited spectrum of anomalous biological agents that can be continuously updated to account for new and emerging threats. It will be able to successfully operate in all climates, all seasons and all environments, including indoor, partially indoor and outdoor locations. It will provide reliable, near real-time data that public health officials and first responders can utilize to make rapid operational decisions without waiting for laboratory confirmation. It will allow

[19] *Id.*

[20] *Mission Need Statement, supra* note 12.

authorities to move beyond simply deploying medical countermeasures and facilitate actions to minimize the actual impact of biological releases. And it will accomplish these goals on the same annual budget as BioWatch.[21]

Johns Hopkins University Applied Physics Laboratory Review of Biodetection Technologies

In the spring and summer of 2018, the Johns Hopkins University Applied Physics Laboratory (JHU/APL) served as the Independent Assessor for a technology demonstration that was organized by DHS S&T under the BioDetection Technology Enhancements (BTE) program. The BTE technology demonstration evaluated the capabilities of several types of trigger devices and PBIs. JHU/APL produced an independent analysis of the test performance of each technology. The Committee has reviewed the test results and JHU/APL's accompanying analysis.

JHU/APL found that some trigger devices did prove to be effective at detecting certain specific categories of biological agents, such as larger vegetative bacteria and larger bacterial spores (in this case, an Anthrax simulant) at a high aerosol concentration level.[22] But all of the trigger devices struggled to detect those same agents at a smaller particle size, and all of the devices failed entirely to detect the Anthrax simulant at the smaller particle size (0 for 100 or 0%).[23] The trigger devices also failed to reliably detect a viral agent at any particle size or aerosol concentration level (8 for 168 or 5%).[24] The JHU/APL analysts overseeing the tests noted that similar flaws with trigger device technology have long existed, detailing that "previous testing has indicated that several of the triggers being evaluated in this test have good detection performance for larger particles but may miss detections for smaller particles."[25] The analysts concluded after testing that the situation remained largely unchanged, asserting that there were "still clear limitations" to even the most mature trigger device technology "for detection of smaller particles and some biological threat categories like viruses."[26]

JHU/APL found that the PBIs performed well in sensitivity testing, as the devices proved largely capable of detecting the biological test agent at a comparable level to the existing BioWatch process.[27] However, the PBIs struggled in specificity testing due to their inability to distinguish between the test agent and two "near-neighbor" agents, which possessed similar genetic elements to the test agent and therefore presented a risk of a false positive.[28] While the JHU/APL analysts overseeing the tests concluded that the near-neighbor alerts should not be considered false positives due to the presence of "similar or exact genetic elements," the tests did reveal that the PBIs would face great difficulty in differentiating between similar biological agents without the assistance of additional confirmatory laboratory testing.[29] Since dangerous biological agents are

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[21] *Id.*
[22] Biodetection Technology Enhancement (BTE) Program – Independent Assessor Report, Prepared by The Johns Hopkins University Applied Physics Laboratory (JHU/APL) for the Department of Homeland Security, September 2018.
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*

often genetically similar to harmless and naturally-occurring near-neighbors, the analysts recommended against the use of PBIs, concluding that "laboratory based confirmatory testing would be required for high regret actions resulting in very little time savings for high regret responses" from a PBI positive.[30]

We believe that the capability gaps revealed by the BTE technology demonstration raise serious questions about BD21. While the trigger devices were unable to detect a small-particle spore-based bacterial agent, biodefense experts told the Committee that spore-based bacteria such as Anthrax represent one of the most dangerous biological threats, and that these types of bacterial agents often occur naturally at precisely the smaller particle size the trigger devices failed to detect. Moreover, the smaller particle size also happens to be the perfect size for spore-based bacteria to enter the human lungs and penetrate the respiratory tract, allowing it to inflict harm on an exposed person. One expert called small-particle spore-based bacteria such as Anthrax "just the right size to get into the lungs and stick there," as well as "very common and very easy to grow." Viral agents pose a comparable dilemma, as most virus particles are smaller than bacteria by an order of magnitude and therefore too small for existing trigger device technology to detect. Biodefense experts informed us that both small-particle spore-based bacterial agents and viral agents represent plausible biosecurity threats. The fact that existing trigger device technology cannot reliably detect them would thus create a major gap in any biodetection system reliant upon that technology, including BD21.

The BTE technology demonstration revealed capability gaps for the PBIs as well, reinforcing concerns that PBIs may not be reliable enough on their own to produce data that can be confidently used by public health officials to justify major operational decisions, such as evacuating a building or shutting down a transportation system. As noted above, PBIs may lack the technological maturity to provide a sound basis for decision-making without further laboratory confirmation. CWMD, however, has embraced PBIs as the sole necessary source of confirmatory testing for major operational decisions. CWMD officials have expressed, both publicly and in a staff briefing to the Committee, that major operational actions under BD21 – such as evacuating a major rail hub like Pennsylvania Station in New York City – would be based upon trigger device alerts and PBI analysis, with confirmatory laboratory testing assigned a secondary role in support of additional medical countermeasures.[31] CWMD believes that this concept of operations (CONOPS) will accelerate the timeline for operational response to any biological attack. Our concern is that greater speed may come at the expense of reliable data.

Questions surrounding the technological maturity of PBIs risk confronting public health officials and first responders with difficult decisions in real-time under BD21. Would they be willing to authorize high-regret operational actions without confirmatory laboratory testing? If so, the resulting social disruption could weaken public confidence in public health warnings; if not, the program itself could come into question. We are concerned that PBI technological shortcomings could thus undermine the BD21 program by threatening the confidence of key stakeholders and the public.

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[30] *Id.*

[31] Willman, *supra* note 7.

"Big Data"

CWMD suggested to the Committee that the application of an algorithm derived from "big data" will be pivotal in supporting BD21's technological feasibility, notwithstanding any limitations in existing biodetection technologies. CWMD officials told the Committee that the algorithm was "central" and "crucial" to BD21. But we are concerned that the algorithm may represent a more difficult endeavor than CWMD is prepared to acknowledge.

CWMD intends to develop an algorithm that can bolster BD21's technological viability by improving the ability of the core technologies to more reliably interpret their data. The algorithm would incorporate data on a vast range of factors impacting biodetection and use that data to help BD21's trigger devices and PBIs become more accurate in their ability to distinguish between genuine biological agents and harmless airborne biological materials.[32] CWMD officials have publicly highlighted the importance of utilizing "big data" in BD21 on several occasions, including at a panel hosted by the Blue Ribbon Study Panel on Biodefense in November 2018.[33] They were similarly emphatic in a briefing with the Committee, during which they repeatedly highlighted the importance of the algorithm for the program.

CWMD officials also acknowledged to the Committee that the algorithm does not yet exist. In fact, the algorithm has not advanced beyond the conceptual phase, and CWMD's hope that it will be able to do so may not be well-founded. Multiple biodefense experts told the Committee that "big data" should be regarded skeptically as a near-term asset for biodetection technology. One expert informed us that the time horizon for the development of an algorithm of this type was likely to be longer than 3-5 years. Another expert noted that many claims are currently being made in the biodetection sector about "data analytics," but that those claims should be received with great caution until any algorithm has been extensively tested. A third expert disclosed that current initiatives to develop comparable biodetection algorithms are struggling in the face of biodetection's enormous complexity and the diverse range of factors that must be successfully incorporated for any algorithm to work.

BD21 is proceeding on an ambitious timetable that leaves little margin for error, but the program's viability is predicated on the creation of an algorithm that represents a daunting technical challenge in its own right. CWMD informed the Committee that it has taken preliminary steps for the development of an initial version of the algorithm, but even that goal is largely conceptual in nature rather than a product that can be deployed operationally. We are concerned that CWMD's assumptions about the algorithm are not supported by the available evidence and may be overly optimistic. This is a matter that requires further scrutiny, because the development of the algorithm and the capabilities of the program's core technologies are closely linked.

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[32] According to CWMD officials, some examples of the factors that will be incorporated into the BD21 algorithm include seasonal temperatures, wind patterns, levels of pollen and dust, and human activities such as smoking.
[33] Kim Riley, *End of BioWatch Looms Near, Blue Ribbon Study Panel Members Learn*, HOMELAND PREPAREDNESS NEWS (Nov. 20, 2018), https://homelandprepnews.com/stories/31415-end-of-biowatch-looms-near-blue-ribbon-study-panel-members-learn/.

We believe that CWMD must directly confront these concerns about technological viability if the office hopes to maintain stakeholder confidence in BD21. CWMD should not deploy technologies that do not work within the structure of the program. In validating BD21 to advance to the next phase of the acquisition life cycle, the JRC noted that "it is unclear if a reliable detection system is technologically mature enough to support the near real-time and presumptive identification capabilities" proposed for the program.[34] We urge you to carefully examine BD21's technological capabilities as a part of your review in order to provide further clarity to that question.

Additional Questions: Consultation with Public Health Officials and First Responders

Many of our concerns relate to issues that already fall within the scope of the Energy & Commerce Committee's August 7 request, which we have detailed above. Based upon our Committee's inquiry into the program thus far, we are also requesting that you incorporate additional questions into the scope of your examination. We are concerned that CWMD may be failing to engage in proper consultation with the public health and first responder communities regarding BD21. We have questions about whether CWMD's outreach to public health agencies and first responders is adequate, both in terms of the frequency of communication and the degree of transparency regarding the program's implementation.

Collaboration with the public health and first responder communities is essential for biodetection. Public health officials and first responders are the on-the-ground decisionmakers who will be forced to confront the immediate aftermath of the release of a biological agent. They are responsible for assessing the information produced by biodetection technologies, determining whether that information is reliable enough to act upon, carrying out high-stakes operational actions and deploying public health countermeasures. Since BD21 proposes a dramatic shift in the technological and operational foundation of U.S. biodetection, it is essential for DHS to consult with these communities about the program, incorporate their perspectives, and win their trust. Public health officials and first responders are among the core institutional stakeholders of biodetection.

CWMD initiated the BD21 program in 2018, and the program's technology demonstration had already been deployed in multiple cities by February 2019.[35] Yet CWMD's first apparent attempt to truly solicit feedback from public health officials and first responders did not occur until June 12, 2019, when CWMD hosted a national workshop for representatives from those communities. Before the workshop, it is unclear whether CWMD had conveyed even basic details about the program to public health officials and first responders, including the operational responsibilities that would fall to them, the program's technological foundation, and logistical details surrounding the deployment of the technology demonstration in some cities. Even after the workshop, the level of transparency being offered by CWMD is uncertain. The full implementation of BD21 could carry enormous implications for public health agencies in particular, in terms of costs, training needs, operational requirements, and new communication processes. But as we understand it, CWMD's outreach strategy for BD21 thus far has consisted of the single in-person workshop on June 12, a single virtual workshop in which the public

[34] *Mission Need Statement*, *supra* note 12.
[35] Willman, *supra* note 7.

health and first responder communities were engaged separately, and a handful of phone updates. We are concerned that CWMD has not established a sufficiently robust process for continuous information-sharing and consultation with stakeholders in the public health and first responder communities, which risks generating anxiety among those groups.

Extensive outreach is particularly important regarding CWMD's proposed minimization of the role of laboratory testing within BD21. This concept has the potential to be contentious among stakeholders. According to the program's own requirements documents, BD21 envisions a reduced operational role for traditional laboratory testing and confirmation. CWMD believes that the program concept of operations (CONOPS) will allow for the "elimination of redundant laboratory operations," and the JRC affirmed that "BD21 also aims to eliminate expensive and redundant laboratory testing in favor of a timelier field presumptive identification capability."[36] CWMD officials presented a similar argument to the Committee in the form of a proposed scope for BD21 that derives core operational response decisions from the data gathered by trigger devices and PBIs while relegating the existing Laboratory Response Network (LRN) to a secondary partner, whose confirmation would primarily be required for additional public health measures such as the distribution of antibiotics and vaccines.

Public health agencies have traditionally emphasized the need for laboratory confirmation of a biological event to ensure that operational decisions are based upon the most reliable information.[37] Given BD21's technological limitations, we are concerned that local officials could be reluctant to make high-regret operational decisions on BD21's expedited timeline without laboratory confirmation. The divergence between the culture of the public health community and CWMD's proposed framework for BD21 could undermine broader support for the program if left unaddressed.

The public health community has previously expressed its own concerns regarding BD21. In a March 2019 letter to CWMD[38], the Association of Public Health Laboratories (APHL) wrote that it "would like to express concerns regarding the deployment of Biodetection (BD)-21 sensors and the lack of information provided to our member laboratories." APHL noted specific concerns with "the use of handheld devices, risk assessment and mitigation strategies, subsequent laboratory testing and epidemiological follow-up." The organization suggested that the Centers for Disease Control (CDC) might not be "fully engaged and aware of DHS's plans," while emphasizing that its member laboratories must possess "the scientific knowledge of the performance of the BD-21 sensors and any handheld devices used for field screening." APHL expressed that it "remains concerned that the continued lack of communication, planning and coordination among federal, state and local partners will negatively impact the ability of BioWatch laboratories to function at their current capabilities" and admonished DHS for a "lack of transparency." It is unclear whether CWMD has taken the appropriate steps to address APHL's concerns.

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[36] *Mission Need Statement, supra* note 12.

[37] National Academies of Sciences, Engineering and Medicine, *Strategies for Effective Improvements to the BioWatch System: Proceedings of a Workshop*, 2018.

[38] *See* Appendix 1.

Procedurally and culturally, public health officials and first responders are critical stakeholders that must be taken into consideration for the successful implementation of BD21. We urge GAO to broaden the scope of its review to incorporate the additional questions pertaining to CWMD's outreach to the public health and first responder communities that we detailed on Page 3 of this letter.

Thank you for your attention to these matters.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space, and Technology

Frank Lucas
Ranking Member
Committee on Science, Space, and Technology

Mikie Sherrill
Chairwoman
Subcommittee on Investigations and Oversight

Ralph Norman
Ranking Member
Subcommittee on Investigations and Oversight