



One Hundred Twelfth Congress
U.S. House of Representatives
Committee on Homeland Security
Washington, DC 20515

April 5, 2011

The Honorable Janet Napolitano
Secretary
Department of Homeland Security
Washington, D.C. 20528

Dear Secretary Napolitano:

We are writing to inquire about one of the Department's major acquisition programs – BioWatch Generation 3 (“Gen-3”). We recently learned that the Department will discontinue funding one of the two vendors participating in the Gen-3 procurement. As the steward of taxpayer dollars, Congress must ensure the Department's decisions on the Gen-3 procurement are the product of a sound acquisition process, based on valid science, which will provide the Department the best chance at successfully delivering the needed rapid biodetection capability. The Department's history demonstrates that pushing out technologies that lack sufficient maturity results in cost overruns and schedule delays. On the other hand, lack of competition may also allow for inefficiencies and higher costs. To avoid these pitfalls, it is essential for the Department to have a robust acquisition process where decisions are transparent, documented, and informed by independent, quantitative, science-based assessments that provide equitable opportunity for all businesses.

The criticality of environmental biodetection lies with its ability to detect a bioterrorism attack well in advance of the emergence of symptoms and hospitalizations, allowing for early medical intervention and greater opportunity to save lives. The BioWatch Gen-3 program could provide a major advancement in the Nation's biodefense posture by enabling faster life-saving responses. However, robust and realistic testing must be undertaken in order to justify the considerable expense of upgrading BioWatch.

Reportedly, the Department's decision to discontinue the first phase of testing of one vendor's technology is due to technical issues with the performance of that vendor's assay, despite the fact that the Science & Technology Directorate (S&T) has already invested over \$35 million to mature this vendor's technology as a Gen-3 candidate. Unfortunately, this decision may impact the vendor's ability to provide competing technology later in the Gen-3 acquisition life cycle and leave only one eligible Gen-3 candidate going into field and operational testing and evaluation. Downselects should only occur when technology is sufficiently understood and the risk of making the wrong choice is minimized. Therefore, it is imperative that the Department weigh its options based on a combination of performance, cost, schedule, and risk.

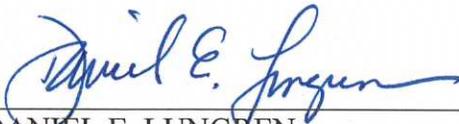
In order to evaluate whether the Department has taken full advantage of available contracting tools, technical expertise, and acquisition policies and procedures in arriving at its decision, we request a response to the following questions about the process and factors considered in making this decision:

- Did the Office of Health Affairs or another decision authority consider performance, cost, schedule, and risk in the downselect process? If not, why and what factors were considered?
- What alternative courses of action were explored in making this downselect decision?
- Is the Department allowing for spiral development efforts in the Gen-3 acquisition and deployment strategy?
- Did the Request for Proposals lay out for vendors the process and criteria that would be used for the downselect or critical decision points?
- What entities were involved in this decision?
 - Who made the determination not to continue funding the vendor through Phase 1 testing?
 - What entities, both internal and external to the Department, informed this decision?
 - Was the decision validated by all members on the BioWatch Gen 3 T&E working integrated product team (WIPT), including S&T? (Please indicate which organizations are members of the T&E WIPT). Has or does the Office of Health Affairs plan to share raw data and algorithms for interpretation with any of these entities and request their assessment, especially considering S&T's role in providing technology assessments, analysis and reviews and oversight of test and evaluation throughout an acquisition program's life and its statutory responsibility under Section 302 of the Homeland Security Act of 2002 for "coordinating and integrating all research, development, demonstration, testing, and evaluation activities of the Department"? Please provide any such assessment to the Committee.
- Did the assay test plan first call for determination of limits of detection to establish appropriate thresholds that could subsequently be applied in determining specificity of the assays? If not, how were the thresholds established?
- Which entities approved the assay evaluation test plan? Were those the same entities involved in the review of the assay test data?
- If the assay failed to meet the acceptance criteria, what is its currently assessed Technical Readiness Level and has this been validated by an independent entity or S&T?
- Was the assay validated prior to transition from S&T's biodetection program? If not, why? Will future biodetection assays undergo validation according to approved test plans prior to transition from S&T to the acquisition authority?
- Were vendors afforded the opportunity to review, comment, and resolve technical issues from any evaluation of their technology? Did OHA or S&T meet with vendors about these issues? Was an independent mechanism provided to resolve disagreements?
- If further research and development is necessary to re-engage the vendor, what contracting authorities would be available?
- Does OHA have rules and procedures governing the downselect process? Does the Department have rules and procedures to guide the downselect process? Are they consistent?
- Has the Department made similar downselect decisions for other technology programs and were similar processes followed?
- What is the Department's policy for maintaining competition throughout the life cycle of a program?
- How will OHA promote competition throughout the Gen-3 acquisition life cycle?

Thank you for your attention to this matter. We look forward to your response and urge you to use available tools and expertise, within the bounds of the rules governing federal acquisition and while maintaining the integrity of the Gen-3 procurement, to thoroughly examine and give due consideration to whether this decision was the right one for the defense of the Nation against potentially catastrophic bioterrorism events.

Should you have any questions, please do not hesitate to contact Drs. Diane Berry or Ellen Carlin of the Committee staff at (202) 226-8417.

Sincerely,



DANIEL E. LUNGREN
Chairman
Subcommittee on Cybersecurity,
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