



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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**OFFICE OF INSPECTOR GENERAL**

WASHINGTON, DC 20201



September 15, 2015

The Honorable Tim Murphy  
Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations  
United States House of Representatives  
Washington, DC 20515

Dear Mr. Chairman:

I am writing in response to your September 1, 2015, letter regarding questions for the record from Representative Michael C. Burgess, Representative Susan Brooks, and Representative Richard Hudson. These questions relate to my testimony before the Subcommittee on Oversight and Investigations on Tuesday, July 28, 2015, at the hearing entitled "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax."

If you have any questions, please contact me or your staff may contact Christopher Seagle, Director of External Affairs, at (202) 260-7006 or [Christopher.Seagle@oig.hhs.gov](mailto:Christopher.Seagle@oig.hhs.gov).

Sincerely,

Gregory E. Demske  
Chief Counsel to the Inspector General

cc: Representative Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Enclosures:

Responses to questions for the record from Representatives Burgess, Brooks and Hudson

Gregory E. Demske, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services, responses to additional questions for the record (QFRs)<sup>1</sup> following the hearing on July 28, 2015, before the House Energy and Commerce Subcommittee on Oversight and Investigations entitled: “Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax.”

**Question from The Honorable Michael C. Burgess:**

**“The OIG reported to the committee that the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) had the third-most referrals from the CDC for potential FSAP enforcement, with three, and that Dugway also has three CDC referrals. According to that referral list, the CDC, the NIH, and USAMRIID had the most referrals in the FDAP.**

- a. What does it say to you that these leading federal agencies in handling select agents had the most referrals?”**

Response: OIG has not made any determinations about overall Federal laboratory compliance with the FSAP regulation based on the total number of CDC referrals. A referral, or the total number of referrals, does not itself establish that a particular laboratory is not in compliance with the FSAP regulations. OIG evaluates each FSAP referral through the same case-by-case fact-specific approach, regardless of whether a laboratory is Federal or non-Federal. OIG has found that some Federal entities have violated the FSAP regulations on multiple occasions. OIG has heightened concerns with any entity, including a Federal laboratory, that has multiple FSAP violations.

- b. “Do you think that this reflects well on the OIG enforcement discretion policy of not imposing civil monetary penalties on federal government entities?”**

Response: Many factors may affect FSAP compliance by a Federal or non-Federal entity. OIG has not established a causal link between CDC referrals and OIG’s practice to date of not imposing CMPs against Federal laboratories. OIG continues to believe there are significant policy arguments that weigh against penalizing Federal laboratories in violation of the FSAP regulations. Nevertheless, given the extent, severity, and repeated nature of FSAP violations by some Federal entities, OIG is reexamining how to best use its CMP authority to promote better compliance at such Federal laboratories.

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<sup>1</sup> Pursuant to Attachment 1 - Additional Questions for the Record

**Question from The Honorable Susan Brooks:**

**“This event shows us that we need to not only solve these problems from a managerial level, but be prepared to respond appropriately if these do fall into the wrong hands.**

- a. Absent a strong commitment from the federal government to partner with the private sector on MCM development and procurement, do you believe the federal government is capable of acquiring the MCMs needed to protect the United States against threats like anthrax, smallpox, or Ebola?”**

Response: OIG has not evaluated: (i) Whether and how the Federal government should partner with the private sector on MCM development and procurement, or (ii) The Federal government’s capability of acquiring the MCMs needed to protect the United States against threats like anthrax, smallpox, or Ebola. Therefore, OIG does not have information responsive to this inquiry.

Gregory E. Demske, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services, responses to Member Requests for the Record<sup>2</sup> following the hearing on July 28, 2015, before the House Energy and Commerce Subcommittee on Oversight and Investigations entitled: “Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax.”

**Question from The Honorable Michael C. Burgess:**

**“Please explain what OIG is doing to consider providing the same civil monetary penalties to federal labs or agencies that non-federal labs would face if they committed the same violations.”**

Response: OIG is committed to promoting efficient and effective government and using its CMP authority to promote FSAP compliance. Although OIG continues to believe there are significant policy arguments that weigh against penalizing Federal entities, OIG is considering whether these arguments can be overcome in some circumstances. Given the extent, severity, and repeated nature of FSAP violations by some Federal entities, OIG is considering how to best use its CMP authority to promote better compliance at such Federal entities.

OIG evaluates each FSAP referral through the same case-by-case, fact-specific approach, regardless of whether a laboratory is Federal or non-Federal. OIG does not employ a formula or test to determine whether a case is pursued for potential CMPs, requires additional investigating, or is closed. The status of the entity does not impact OIG’s determination of whether a FSAP violation occurred. Historically, OIG has addressed FSAP violations by Federal entities by issuing Notice of Violation letters to high-ranking officials with oversight responsibility for the entities. OIG has also issued Notice of Violation Letters to non-Federal entities, such as corporate and university laboratories.

While we believe OIG has the authority to impose a CMP on a Federal entity, we have not done so in prior cases on the basis of several considerations. Any money paid by a Federal entity would simply be moved from a Federal agency’s budget to the General Fund of the Treasury. Although there would be no net receipt of money for the Federal Government, the Government would incur the cost of negotiating or disputing the CMP. CMP payments from Federal agencies may not promote better future compliance and, in fact, may reduce resources for the Federal entity’s future compliance efforts.

Further, the enforcement and litigation process for Federal entities would differ from the process for non-Federal entities and may result in additional expenditure of Federal resources. OIG regularly imposes CMPs for many types of violations on non-Federal entities and individuals, whose administrative and judicial appeal rights are well established in regulation and practice.

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<sup>2</sup> Pursuant to Attachment 2 – Member Requests for the Record

If OIG imposes a CMP on a Federal agency, there is no clear process for resolving the matter, the process would differ for HHS and non-HHS Federal entities, and the matter may need to be submitted to the DOJ Office of Legal Counsel. These process issues do not preclude a CMP against a Federal entity, but they do add to the complexity, uncertainty of result, and commitment of resources that may be necessary to actually transfer money from the offending Federal agency to the General Fund of the Treasury.

While these considerations remain valid, OIG is evaluating how to apply the CMP to Federal entities going forward. We are particularly concerned with whether our past enforcement approach is sufficient for Federal entities that have engaged in repeated or severe FSAP violations. OIG is considering how to best promote FSAP compliance at such entities, including through means such as detailed reports to agency leadership, factual findings with respect to responsible individuals, and the imposition of CMPs. In short, OIG will consider imposing CMPs on Federal entities in pending and future cases.

**Question from The Honorable Richard Hudson:**

**“Please provide a summary of the existing tools that CDC has that would allow it to better oversee and take corrective actions against labs that commit violations.”**

Response: CDC’s Division of Select Agents and Toxins (DSAT) oversight includes: site inspections, denials, revocations, suspensions, and performance improvement plans. OIG has not performed an evaluation of CDC’s oversight tools. However, OIG has recognized several areas that present opportunities to improve the Government’s ability to administer FSAP and improve OIG’s ability to enforce violations of the regulations. These opportunities were outlined in my written testimony and include:

- requiring laboratories to document inactivation procedures, validation and safety/sterility testing procedures, and outcomes to ensure that a select agent or toxin is rendered nonvirulent;
- requiring registered entities to video entry/exit points and video specific laboratory select agent and toxin work;
- requiring registered entities to maintain additional records, including all documents created or maintained in the ordinary course of working with a select agent and toxin;
- expressly prohibiting the destruction or alteration of any document that is required to be maintained under the regulations; and
- expanding the document retention period for registered entities from three to six years to match the CMP statute of limitation period.

In addition, Federal inspectors’ ability to conduct effective and meaningful oversight should be strengthened by:

- requiring any registered entity to make available for interview upon reasonable request by inspectors any individual who has accessed, possessed, used, or transferred a select agent or toxin;
- allowing inspectors to physically inspect, handle, or test material that is believed to be a select agent or toxin, when appropriate (consideration should be given to DSAT’s ability to immediately transfer material, in accordance with the regulations, so that independent testing can be performed to determine whether particular material is covered by the regulations); and
- considering the viability of independent third-party testing of select agent or toxin material.