UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
CASE NUMBER: 03-81110-CIV-HURLEY/HOPKINS

MAUREEN STEVENS, as Personal Representative of the Estate of ROBERT STEVENS, Deceased, and on behalf of MAUREEN STEVENS, Individually, NICHOLAS STEVENS, HEIDI HOGAN and CASEY STEVENS, Survivors,

Plaintiffs,

vs

UNITED STATES OF AMERICA,

Defendant.
_____/

DEFENDANT UNITED STATES' STATEMENT OF FACTS IN SUPPORT OF MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION UNDER 28 U.S.C. § 2680(a)

PRELIMINARY STATEMENT

Defendant, United States, submits this Statement of Facts in Support of its Motion to Dismiss under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction, based on the Federal Tort Claims Act's discretionary function exception, 28 U.S.C. § 2680(a), and alternatively as a Statement of Material Facts Not in Genuine Dispute for its Motion for Summary Judgment under Fed. R. Civ. P. 56(c).

Since the source of the anthrax that killed Robert Stevens is stipulated to be RMR-1029, the facts relevant to the discretionary function exception, as included herein, concern (1) whether any rules or regulations pertinent to RMR-1029 were specific and mandatory, and if so, were violated *and* germane to the harm done; and (2) if not, whether Plaintiffs can establish that the Government conduct allegedly causing the injury was not susceptible to policy analysis. Notwithstanding Plaintiffs' withdrawal of the stipulation that the evidence would establish, more likely than not, that Dr. Ivins was the perpetrator, Plaintiffs provide no evidence for an alternative perpetrator. While this Statement addresses matters regarding Ivins (and relevant to other hypothetical perpetrators), *this Statement and the Motion are not premised on identifying Ivins as the perpetrator*.

BACKGROUND

1. Robert Stevens was exposed to anthrax (*Bacillus anthracis*) sent to his workplace by a criminal assailant, and died as a result on October 5, 2001. Notice of Jt. Stip. of Facts, ECF No. 85 at ¶ 4.

2. The anthrax to which Mr. Stevens was exposed was produced by Dr. Bruce Ivins, a federal employee scientist who worked with, grew, harvested and stored anthrax in the course of his duties at the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID), Fort Detrick, Maryland. *Id*. at ¶ 2.

3. Genetic analysis traced the anthrax used to attack Mr. Stevens as derived from the flask RMR-1029 at USAMRIID. Ex. 1: Deposition of Russell Byrne at 79. The anthrax in RMR-1029 is genetically similar, but dissimilar in form, to the anthrax that caused Mr. Stevens' death. *Id*. No anthrax spores recovered from the anthrax attacks had the same physical form as spores kept at USAMRIID. Ex. 2: Deposition of Gerard Andrews at 89.

4. Dr. Ivins prepared the RMR-1029 material in 1997, by mixing spores from Dugway Proving Ground, an Army biological laboratory in Utah, with spores Ivins grew. Ex. 3:

Deposition of Patricia Worsham at 20-21; Ex. 4: Deposition of Arthur Friedlander at 57-58.

THE ROLE OF USAMRIID

5. Since renouncing development, production, stockpiling and use of biological weapons in 1969, the Department of Defense (DoD) invested in relevant biological defense. In 1969, USAMRIID was created to develop medical defensive countermeasures. Declaration of David Franz at ¶ 15 (quoting Ex. B: Defense Science Board, *Department of Defense Biological Safety and Security Program* (2009) (DSB report)[1] at 1, DOD-000081).

6. USAMRIID employs "cutting edge scientists" in bacteriology, infectious diseases, and virology. In 2001, USAMRIID and the Centers for Disease Control (CDC) employed the leading scientists in infectious disease research; USAMRIID was one of very few facilities worldwide with the ability to study particularly dangerous infectious diseases. Ex. 6: Deposition of Reynolds Salerno at 230.

7. As DoD's lead laboratory for medical aspects of biological warfare defense, USAMRIID plays a key role in national defense and infectious disease research – for developing vaccines, drugs, diagnostics for laboratory and field use, and other medical countermeasures against biological threats. USAMRIID is DoD's largest biological containment laboratory for studying hazardous diseases. USAMRIID investigates naturally occurring diseases requiring special containment, and operates a world-renowned reference laboratory for identifying biological threat agents and disease diagnoses. Ex. 6: Salerno Dep. at 228-29 (quoting Ex. 7: Sandia National Laboratories, *Security Review of the USAMRIID* (Sept. 2002) ("Sandia Report")[2] at 24, ARMY02-009966); *see* Ex. 5: Lynn Dep. at 74-75 (quoting Franz Ex. B: DSB Report at 51); Ex. 8: Deposition of Edward Eitzen at 190-91.

8. USAMRIID's research programs also critically benefit society as a whole by addressing extremely dangerous diseases unrelated to bioterrorism or biological weapons. Ex. 6: Salerno Dep. at 229-31. USAMRIID's contributions in defending against bioterrorism, and

[1] Dr. Franz was a member of the Task Force that authored the DSB report, Franz Decl. at ¶ 9, as was defense expert Larry Lynn. Ex. 5: Deposition of Larry Lynn at 34.

[2] Dr. Salerno headed the Sandia National Laboratories team that conducted this security review of USAMRIID in early 2002, to develop recommendations for enhancing biosecurity without impeding its vital operations and mission. Up to 2002, no laboratories were known to have better biosecurity than USAMRIID, and none had in place all that Sandia recommended. Even by 2002, the field of laboratory security did not yet exist, and Dr. Salerno authored the only book currently existing on the subject. Ex. 6: Salerno Dep. at 24, 35-37, 42-43, 198-206.

infectious diseases generally, have been immense. Ex. 8: Eitzen Dep. at 191.

RULES AND REGULATIONS AT USAMRIID BEFORE THE ANTHRAX ATTACKS

PHYSICAL SECURITY RULES AND COMPLIANCE

9. Army Regulation (AR) 190-13 (Sept. 30, 1993), establishes and implements the Army's Physical Security Program. It prescribes policy and assigns responsibility for developing and maintaining practical, economical, and effective physical security programs. Ex. 9: AR 190-13 at ¶ 1-1. The Regulation does not impose any specific, mandatory requirements that Plaintiffs claim were violated and would have averted Mr. Stevens' exposure, *e.g.*, mandatory searches of all personnel; video surveillance in all lab rooms; or stationing more guards, and arming them.

10. Prior to October 2001, there was no "formal program" or policy at USAMRIID to inspect people coming into or leaving the facility, or conduct personnel searches.[3] Ex. 10: Deposition of Jay Arrison at 20-21, 66. Rather, personnel were subject to inspection based on reasonable suspicion. *Id.* at 20-21. If there was a question of employee status and a concern about removal of property and management was involved, however, guards could and did conduct inspections. Ex. 10: Arrison Dep. at 66.

11. Prior to 2001, there were no Army requirements or policy to have a video system or maintain tapes from cameras. Ex. 10: Arrison Dep. at 23-24.

12. In 2001, Army Regulation (AR) 385-69, *Biological Defense Safety Program* (codified at 32 C.F.R. § 626 (1993)), set the requirements for limiting access to the Biological Defense Program containment laboratories. *See* Ex. 11: AR 385-69 at ¶ 2-9, ARMY02-001713.

13. Before the anthrax letter attacks, USAMRIID had a physical security system based on rules and regulations then in place, that restricted and controlled access to BSATs (biological select agents and toxins). Ex. 10: Arrison Dep. at 105-06. USAMRIID instituted physical security measures to ensure that only authorized personnel could obtain access to containment suites and pathogens there. USAMRIID had security guards stationed on premises at all times, 24 hours daily; personnel sign-in was required during off-hours. Ex. 8: Eitzen Dep. at 131; Ex. 10: Arrison Dep. at 18-19. Unguarded entrances were secured and locked during off-hours to prevent entry. Ex. 10: Arrison Dep. at 18-21, 89-90. During evenings, when guard staffing was

[3] Personnel searches were not required up to October 2001, in part because of privacy issues for civilians and the absence of a directive allowing searches. Ex. 8: Eitzen Dep. at 176-78.

reduced, a uniquely programmed badge was required for entry. Guards also regularly patrolled the facilities, inside and outside. *Id*. at 19-20.

14. If a scientist working in the Bacteriology Division needed access to the Biological Safety Level (BSL)-3 containment suite, the Chief of Bacteriology would obtain the required clearance and send the scientist's name to USAMRIID's Security office, which would obtain information from the Special Immunization Program (SIP) to ensure that the scientist had received all immunizations required to work in that containment suite. Ex. 10: Arrison Dep. at 40-43. The Security office only issued cards for accessing the various biosafety level laboratories after proper authorization, including a badge request signed by the Division Chief, and verifications that the person had undergone training and received all immunizations. *Id.* at 70-72.

15. Only after completing this process, USAMRIID Security issued a photo badge and PIN number granting access to a given area. Before the anthrax letter attacks, a person authorized to enter a containment suite had to use both credentials – a badge to gain access to the facility entrance – and a 4-digit PIN number that is entered into a keypad to enter and exit containment. Ex. 10: Arrison Dep. at 41-43; *accord* Ex. 2: Andrews Dep. at 177-80; Ex. 1: Byrne Dep. at 63-64; Ex. 12: Deposition of Susan Welkos at 44-45. Also, use of a pressure pad ensured that multiple persons did not enter a suite simultaneously. Ex. 2: Andrews Dep. at 180.

16. Since at least 1999, the RMR-1029 material was retained inside a BSL-3 containment suite with limited access. Ex. 3: Worsham Dep. at 20-22; *see also* Ex. 2: Andrews Dep. at 49-51; Ex. 13: Deposition of Jeffrey Adamovicz at 88 (RMR-1029 flask stored in freezer in BSL-3 cold room).

17. BSL-3 pathogens (*e.g.*, anthrax) were stored in refrigerators and freezers in a BSL-3 containment suite, physically secured to ensure only authorized personnel could enter. *See* Ex. 10: Arrison Dep. at 68; *accord* Ex. 14: Deposition of Peter Jahrling at 29, 71-72, 113-14; Ex. 2: Andrews Dep. at 178-180.

18. There are no instances known to USAMRIID's Security office in which persons gained unauthorized access to BSL-2, BSL-3 or BSL-4 containment. Ex. 10: Arrison Dep. at 64; *accord* Ex. 4: Friedlander Dep. at 58 (no unauthorized access to BSL-3).

19. Contractor personnel and non-scientist staff were subject to parallel requirements for obtaining access to containment suites, including obtaining advance authorization from the

division chief, filling out a badge request form, obtaining medical clearance from SIP, checking immunization listings, and obtaining clearance from the Safety Office. Ex. 10: Arrison Dep. at 40-41.

20. At times, authorization for containment suite access was granted to "trusted" foreign nationals working under green cards. Likewise, some enlisted soldiers in the Army were foreign nationals. Ex. 8: Eitzen Dep. at 110-13.

21. Before 2001, despite the absence of any Army requirement, video surveillance at USAMRIID included security cameras outside buildings, in interior hallways, and at a front door, with 13 monitoring screens covering about 54 CCTV areas. Ex. 10: Arrison Dep. at 22-24, 37, 90, 107-08.

22. Aside from any criminal misconduct Dr. Ivins is presumed to have committed, there is no evidence anyone at USAMRIID violated any statute, regulation, directive or policy and thereby allowed anthrax spores to be used in the letter attacks. Ex. 8: Eitzen Dep. at 192-93; *see also* Ex. 12: Welkos Dep. at 55.

PATHOGENS ACCOUNTABILITY RULES AND USAMRIID COMPLIANCE

Army Regulation 70-65 -- Inventorying and Two-Person Rule for Reference Stocks

23. Up to the time of the anthrax letter attacks, Army Regulation (AR) 70-65, *Research, Development and Acquisition – Management of Controlled Substances, Ethyl Alcohol, and Hazardous Substances in Army Research, Development, Test and Evaluation Facilities* (1979) ch. 3, was Army's policy governing accountability and security of anthrax and other controlled biological research materials – both for reference stocks and working stocks of agents. Ex. 15: AR 70-65; Ex. 8: Eitzen Dep. at 53-54, 169-70; *accord* Ex. 6: Salerno Dep. at 184, 215-17, 258-60.

24. AR 70-65 prescribed a two-person rule for pathogen access, and annual inventorying and reports, only for "reference stocks" held in USAMRIID's central repository, and not for "working stocks," which it defined as "Any passage of a strain of microorganisms or toxins in any quantity authorized by the commander to meet needs clearly identified in approved research protocols, test plans, and project/study directives." Declaration of Rita R. Colwell ¶¶ 103-04 (quoting Ex. 15: AR 70-65 at ¶ 3-1c, ARMY02-001731); Ex. 12: Welkos Dep. at 98 (Bacteriology Division stocks are "working stocks" under AR 70-65); Ex. 2: Andrews Dep. at 49 ("reference strains are sealed strains" – archival material).)

25. As scientists familiar with USAMRIID testified, RMR-1029 was "working stock" as defined by AR 70-65, and not subject to the AR 70-65 procedural requirements for "reference stocks," defined as the lowest passage/ earliest culture of a pathogen and held in a central repository. Ex. 14: Jahrling Dep. at 27-29, 71-73 ("clearly not reference stock"); Ex. 2: Andrews Dep. at 177-78 (flasks of anthrax material used by Ivins were working stock); Ex. 8: Eitzen Dep. at 68, 172-73; Ex. 3: Worsham Dep. at 73.

26. Under AR 70-65, the working stock requirements were left to the discretion of the commander. Ex. 6: Salerno Dep. at 258-60. AR 70-65 "left wide open how the facility could manage access and use of working materials." *Id*. at 215-17. There was no inventorying requirement for working stocks; stocks were decentralized, with each investigator free to keep an individual inventory. Ex. 12: Welkos Dep. at 98; Ex. 8: Eitzen Dep. at 182-83 (USAMRIID Commander would likely need commanding general's approval to require inventorying for working stocks).

27. USAMRIID complied with AR 70-65 requirements governing pathogens – both for "reference stocks" held in the central repository, and "working stocks." Ex. 14: Jahrling Dep. at 27-29, 71-72; Ex. 8: Eitzen Dep. at 55-56, 193; Ex. 12: Welkos Dep. at 47-48, 99-101; Ex. 10: Arrison Dep. at 56-58, 60-61; Ex. 6: Salerno Dep. at 215-17, 258.

28. Prior to the anthrax letter attacks, USAMRIID had closed-circuit television video surveillance of the central repository where "reference stocks" were held. Ex. 8: Eitzen Dep. at 123.

29. Because the anthrax used to attack Mr. Stevens was derived from flask RMR-1029, which was working stock, not reference stock, AR 70-65 was not violated.

30. Plaintiffs allege, erroneously, that the United States "failed to adequately secure" anthrax in that "as early as 1992, samples of this formidable, dangerous, and highly lethal [anthrax and other] organism[s] were known to be missing from the [USAMRIID] lab at Ft. Detrick." Compl., ECF No. 1 at ¶ 9. The supposedly "missing" samples were inactivated, killed pathogens that "were non-viable, non-infectious, and never a hazard to the public or environment." Each sample was, in essence, killed repeatedly, first killed with an overabundance of gamma radiation, and then "killed" with an "aldehyde fixative" or formaldehyde – a process that included "dehydration through ethanols, and finally embedded in resin, which would have killed it again.. There was no hazard to anyone from the dead

pathogens or blocks containing them. Ex. 16: Letter from Edward Eitzen to USA TODAY (Feb. 6, 2002), USAM-19803-04; Ex. 8: Eitzen Dep. at 164-67; Ex. 14: Jahrling Dep. at 56-59; Ex. 17: Information Paper: [USAMRIID] Response to Press Articles (Jan. 21, 2002) at USAM-19788. Also, the samples were not lost or "missing" from a lab at Ft. Detrick because the pertinent office, the Pathology Division, was located off-post in leased commercial space, where "[o]nly inactivated materials were taken." Ex. 17: Information Paper at USAM-19792. Subsequent investigation confirmed that no samples were missing. Ex. 8: Eitzen Letter at USAM-19804. Also, before the letter attacks, USAMRIID was not known to have any problem with accountability or inventory management for live anthrax stocks. Ex. 1: Byrne Dep. at 63 (former Chief of Bacteriology Division unaware of any problem with anthrax accountability or inventory management).

CDC/NIH Guidelines and USAMRIID Compliance

31. Pursuant to the non-mandatory CDC/NIH guidelines for Biosafety in Microbiological and Biomedical Laboratories (BMBL 4th ed. 1999) that USAMRIID used as guidance, BSL-2 or BSL-3 containment facilities were prescribed for laboratory operations involving anthrax, depending on the type of work. Work in BSL-3 containment suites – which is where USAMRIID conducted all work with live anthrax – is associated with greater biosecurity at BSL-2 level since there is more restricted access to containment and the pathogens there. *See* Ex. 4: Friedlander Dep. at 59-60; *accord* Ex. 18: Deposition of Richard Wade at 20.

CDC Select Agent Regulation and USAMRIID Compliance

32. Before late 2002, the only federal regulation for security of select agents – the term for dangerous pathogens and toxins – was limited to the security of *transfer* of select agents *from one facility to another*. In late 2002, prompted by the events of 2001, that regulation – the Select Agent Rule – was revised to include security of select agents at facilities. Ex. 6: Salerno Dep. at 199-203.

33. During and prior to 2002, USAMRIID's biosafety office ensured USAMRIID complied with the Select Agent Rule, 42 C.F.R. § 72 (2001). "All shipments of Select Agents from USAMRIID were documented, internally and with the CDC." Ex. 6: Salerno Dep. at 233-34.

34. The current Select Agent Regulations, which are substantially different than those in place in 2001, have been expanded to cover possession and use of select agents, and related

biosecurity measures. Franz Decl. at ¶ 46 (quoting Ex. C: National Science Advisory Board for Biosecurity, *Enhancing Personnel Reliability Among Individuals with Access to Select Agents* (2009) (NSABB report)[4] at ii-iii, NIH-000004).

35. Even the expanded Select Agent Program in place since 2002 provides only guidance on defining and interpreting minimum standards for physical security, leading to inspection and compliance challenges, without necessarily ensuring greater security. Colwell Decl. at ¶ 91 (citing Ex. B: National Research Council, *Responsible Research with Biological Select Agents and Toxins* (National Academies Press 2009) (NRC report)[5] at 123, NAS-000141).

PERSONNEL RULES REGARDING DR. IVINS AND USAMRIID COMPLIANCE

36. In and prior to 2001, civilian microbiologists at USAMRIID were required to be found eligible for Secret clearances as their positions were classed as "noncritical-sensitive." Several security investigations were conducted of Dr. Ivins well before the anthrax letter attacks. Before coming to USAMRIID, Ivins worked for DoD's Uniformed Services University of the Health Sciences from August 27, 1978, to December 1, 1980. Ex. 19: Employee Service Statement (Dec. 1, 1980) at ARMY-000996. On September 25, 1978, Defense Investigative Services (DIS) completed a National Agency Check (NAC) security investigation of Ivins for his position as a post-doctoral Teaching/Research Associate at USUHS, a position with "No Clearances Required," and none granted. Declaration of Andrea Upperman at Ex. H: Certificate of Clearance (Sept. 25, 1978), ARMY-001023.[6]

37. As part of his application for the "Noncritical-Sensitive" position of Microbiologist at USAMRIID, Ivins provided two certified statements on July 10, 1980, including required information on his birth, Social Security number, residential history, marriage, organizational affiliations, employment history, and identifying numbers; an August 12, 1980 stamped entry references the check of FBI files. Upperman Ex. A: Standard Form 85, at ARMY-000991-92;

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[4] Dr. Franz reviewed and supported the NSABB's release of the NSABB report as a board member of that organization. Franz Decl. at ¶ 9.

[5] Dr. Colwell, former Director of the National Science Foundation (1998-2004), chaired the Committee that issued the consensus report of the National Academy of Sciences/ National Research Council 2009, following the Government's request for the report on BSAT biosecurity. Colwell Decl. at ¶¶ 8-9.

[6] The report of the independent Expert Behavioral Analysis Panel, on which Plaintiffs and their experts rely, erroneously states that Dr. Ivins obtained a security clearance in 1978.

Upperman Ex. B: Personal Qualifications Statement, at ARMY-000997-1013.

38. Dr. Ivins began work as a civilian employee for the Army assigned to a noncritical-sensitive position as a Microbiologist with USAMRIID on December 2, 1980. Ex. 20: Disposition Form (Dec. 2, 1980) at ARMY-000809; Ex. 21: Notification of Personnel Action at ARMY 000987.

39. Prior to his USAMRIID employment, the Army required Dr. Ivins to undergo a security investigation for his assignment to a noncritical-sensitive position as a microbiologist. DoD regulation 5200.2-R, effective Dec. 20, 1979, the governing regulation in 1980, specified that a National Agency Check and Inquiry (NACI) be conducted for civilian employees in noncritical-sensitive positions. Upperman Decl. ¶ 8 (citing Ex. C: DoD 5200.2-R, *Personnel Security Program* (1979), §§ 3-202, 3-401(b)(1)(a), ARMY04-000704 - 000707). The NACI included checks of federal databases and written inquiries to former employers, supervisors, and schools, but no subject interview. Upperman Decl. at ¶ 8.

40. Army Regulation (AR) 604-5, which had not been updated since 1971, did not apply to the 1980 investigation because the newer DoD regulation outlined new security procedures and took precedence. Upperman Decl. at ¶ 24. DoD regulation 5200.2-R also prescribed different procedures governing requests for medical records and other documents concerning prospective employees. The 1980 NACI security investigation forms contained no questions about a subject's prior mental health treatment, and DoD 5200.2-R did not authorize or require Army or investigating agents to obtain medical records for NACI investigations. Upperman Decl. at ¶¶ 24-25.

41. The Office of Personnel Management (OPM) completed Ivins' security investigation on October 20, 1980, and the Army deemed him eligible for access to Secret information. The 1980 investigation complied with DoD 5200.2-R requirements. Upperman Decl. at ¶¶ 8-9.

42. In 1996, DoD regulation 5200.2-R was updated to require persons occupying noncritical-sensitive positions to undergo a periodic reinvestigation every 10 years. The 1996 update provided that Secret Periodic Reinvestigations (S-PR) include a National Agency Check (NAC), consisting of a search of DCII, FBI-HQ, FBI-ID, and OPM databases, and a credit bureau check. The S-PR did not include a subject interview. Upperman Decl. at ¶ 13 (citing Ex. E: DoD 5200.2-R (1996) § AP.1.1.1.4.2, ARMY02-010853). Army quickly complied with the new requirement, conducting a reinvestigation of Dr. Ivins in 1997. Army Regulation (AR) 380-

67, *Personnel Security Program* (effective Oct. 7, 1988), outlined Army's policies and procedures for access to classified information and assignment to a sensitive position, and prescribed the investigative scope, adjudicative standards, and criteria for access or employment. Upperman Ex. F: AR 380-67 at§ 1-200, ARMY02-000606.

43. In 1997, Defense Security Service (DSS) conducted an S-PR of Dr. Ivins, consistent with the DoD regulation; no derogatory information was found. Declaration of Les Blake at ¶¶ 6-8. At the time of the 1997 investigation, the security form (Standard Form 86) required subjects to identify mental health treatment only for the last seven years (during which Ivins had no such treatment). Neither DoD 5200.2-R nor AR 380-67 required Army or investigating agents to obtain a subject's medical records. Upperman Decl. at ¶ 16.

44. AR 380-67 required "Background Investigations (BI)" or "Special Background Investigations (SBI)" for certain categories of Army personnel, but not for U.S. national civilian employees assigned to a noncritical sensitive position, such as Dr. Ivins. *See* Upperman Ex. F: AR 380-67 at § 3-203, app. D, ARMY02-000614, ARMY02-000643. AR 380-67 imposed additional requirements for BIs and SBIs (personal interviews, periodic reinvestigations every five years, authorization to examine medical records in some circumstances) that were not required for NACIs, and that the Behavioral Analysis Panel report on which Plaintiffs rely incorrectly suggested were required for Ivins' S-PR security investigation. *See* Upperman Decl. at ¶¶ 14, 16, 17 n.6, 26-27.

45. Prior to the anthrax letter attacks, there was no formal personnel reliability program (PRP) for Army's biological materials and facilities; without direction from above and regulations, USAMRIID could not have initiated one. Ex. 8: Eitzen Dep. at 103, 176-77. Well after the anthrax letter attacks, Army adopted a Biological Personnel Reliability Program. *Id.* at 176-77.

46. Despite the absence of a requirement to establish a PRP, USAMRIID's personnel reliability practices included personnel security investigations, medical screening using annual physical examinations, questionnaires, mental health assessment, review of medications, immunizations against laboratory agents, assessment of immunity; mandatory biosafety training; and delayed entry to containment suites for many months pending completed immunization and security clearances. New personnel were cleared to work in a containment suite worked under a mentor, with close supervision, and not alone. In addition, USAMRIID's Safety Office

developed policies specific to USAMRIID's laboratory operations, and provided annual and other periodic training to personnel who worked in containment suites. All personnel were observed daily by their Division Chief or supervisor, and other investigators or technicians, including Safety Office personnel. Ex. 8: Eitzen Dep. at 71-79, 96-98, 177; Ex. 12: Welkos Dep. at 36-38; Ex. 1: Byrne Dep. at 35-48, 50-51; Ex. 3: Worsham Dep. at 50-51; Ex. 2: Andrews Dep. at 175-76; Ex. 22: Deposition of Kristie Friend at 20, 22-24; Ex. 23: Deposition of Alyce Bridges at 88-93.

47. With no PRP in place until after the letter attacks, Army physicians were restricted by patients' medical privacy rights. If a regulation prescribing a PRP had been in place, it would have given physicians the ability and authority to report concerns and information to a certifying medical official under the PRP. Ex. 8: Eitzen Dep. at 105-06.

SPECIAL IMMUNIZATION PROGRAM

48. The Special Immunizations Program (SIP), part of USAMRIID's Medical Division, is a program whereby USAMRIID physicians administer vaccines to scientists working with biological materials to provide immunity against pathogens and conduct investigative protocols. Protocols involve prospective vaccines (not FDA approved) tested to determine efficacy. Ex. 24: Deposition of [redacted] at 12, 17-18; Ex. 25: Deposition of [redacted] at 19-20.

49. In addition to the research mission, the SIP clinic provided health services to USAMRIID employees, in conjunction with Fort Detrick's occupational health unit. The occupational health clinic (later named Barquist) was a medical facility used by all civilian and military personnel at Fort Detrick. Though located within a USAMRIID building, the occupational health clinic was commanded by personnel from Army's Medical Command (MEDCOM), and not affiliated with USAMRIID's command structure. Ex. 26: Deposition of [redacted] at 18-20; Ex. 25: [redacted] Dep. at 19.

50. Before about 1999, employees requiring access to biological materials went to the SIP or occupational health clinics so physicians could evaluate their continuing ability to work in containment suites. Each year, USAMRIID employees completed a medical history form, which required them to place checks next to listed physical and mental problems they have had, and identify all current medications. The mental health section of the form required employees to indicate if they had suicidal thoughts, hallucinations, anxiety, depression, or nervous troubles. *See, e.g.*, Ex. 27: SIP Health Questionnaire and General History Review and Physical

Examination, ARMY-000051–58; Ex. 28: Report of Medical History, ARMY-000065–69; Ex. 29: Medical History Questionnaire for Personnel Assigned to Containment Areas, ARMY04-000230-32. Physicians then met with patient employees for examinations and to review histories and discuss information in more detail. Ex. 26: [redacted] Dep. at 33-34; Ex. 25: [redacted] Dep. at 61-63, 75; Ex. 24: [redacted] Dep. at 35, 52.

51. After about 1999, those requiring access to biological materials continued to use the physical form, but also had annual exams by SIP. Ex. 25: [redacted] Dep. at 20-21; Ex. 24: [redacted] Dep. at 41-42.

52. SIP physicians had employees sign their medical history forms, but did not consider the forms to authorize them to obtain the employees' non-Army medical records without separate and specific authorization. Ex. 24: [redacted] Dep. at 43-44; Ex. 26: [redacted] Dep. at 42-44.

53. Besides physical exams that SIP physicians administered, scientists were also required to undergo some health and fitness testing at the Occupational Health clinic, such as fitting for respiratory masks. Ex. 12: Welkos Dep. at 36-38; Ex. 26: [redacted] Dep. at 80; Ex. 25: [redacted] Dep. at 19-21.

54. SIP physicians understood that they shared a responsibility with the Occupational Health clinic to make sure containment suite employees were physically and mentally able to do their work. Ex. 26: [redacted] Dep. at 16; Ex. 25: [redacted] Dep. at 19-20; Ex. 23: Bridges Dep. at 58. When SIP physicians observed a health condition that caused them concern, they would report the concern to the employee's Division Chief. Ex. 25: [redacted] Dep. at 21-22; Ex. 1: Byrne Dep. at 45. SIP physicians would not necessarily notify the Division Chief of the employee's ailment, but would report that there was a health condition which might warrant a restriction. Ex. 1: Byrne Dep. at 46-48.

55. Division Chiefs had the authority to determine what action to take upon being notified of a problem. Division Chiefs could temporarily or permanently suspend suite access. Depending on the severity of the restriction, USAMRIID's Commander would need to approve a decision to suspend or terminate suite access. If a Division Chief suspended suite access, he would notify the Security Office to recode the employee's badge to disallow entry to the biological suites. Ex. 13: Adamovicz Dep. at 52-53, 102; *see* Ex. 24: [redacted] Dep. at 21-23.

56. Division Chiefs understood they were also responsible for making sure employees

were mentally and physically able to work in the biological suites. They relied on medical information from SIP and occupational health personnel, and their own observations of employees in the workplace. To determine if an employee was unfit for duty, Division Chiefs looked for unexpected behavioral changes, and medical conditions or changes that might warrant temporary or permanent revocation of suite access. Ex. 13: Adamovicz Dep. at 50-54; Ex. 1: Byrne Dep. at 43-48; *see, e.g.*, Ex. 30: Deposition of Stephen Little at 18-20 (removed from SIP because of medical condition).

57. For many years prior to the anthrax letter attacks, [redacted] Ex. 26: [redacted] Dep. at 40-41, 46, 71. In 2001, and even in a personnel reliability setting for BSAT biosecurity today, those are not red flags that trigger a need for full blown mental health exams. Many scientists have issues like this in their history, for which there is no reason to subject them to mental health exams. Setting the threshold so low for conducting mental health examination or psychological assessment would be counterproductive. More effective for promoting biosecurity and addressing potential insider threats is a culture of trust and responsibility. Colwell Decl. at ¶ 106; *see also* Ex. 26: [redacted] Dep. at 81 (depression not unusual among middle-aged researchers).

58. If during SIP annual examinations lab personnel disclosed psychiatric treatment for work-related stress or antidepressant medication, it would not necessarily warrant further investigation absent symptoms of instability. *See* Ex. 24: [redacted] Dep. at 36-37. Anti-depressants are among the most commonly prescribed drugs in our society; if used to address stress, or a situational depression that does not approach psychotic depression or involve delusional thinking, that will not necessarily require further investigation or obtaining medical records when one's ability to accomplish work is unaffected. Ex. 8: Eitzen Dep. at 88-89; Ex. 1: Byrne Dep. at 46-48; *accord* Ex. 26: [redacted] Dep. at 81-82 (SIP would not have necessarily asked for psychiatric records or contact a mental health care provider if a researcher self-reported treatment, and SIP detected no behavioral changes and had no complaints from supervisor concerned about safety). Whether further action should be taken for a person who has received psychiatric treatment "depends on the judgment of the treating physician as to the level of the disability." Ex. 8: Eitzen Dep. at 96.

59. Up to and after the anthrax letter attacks, USAMRIID's Commander, Dr. Ivins' supervisors at the Bacteriology Division, and colleagues – included those with whom he interacted daily – had no reason to suspect Ivins posed a threat, and did not believe he was unstable or would commit criminal, terrorist acts.[7] Up through the time of the letter attacks, none of USAMRIID's physicians ever believed that Ivins had a mental or emotional condition that warranted a suite restriction, or that posed a danger to himself or others. Ex. 24: [redacted] Dep. at 36-37. SIP physicians who examined Ivins and reviewed his medical history with him did not feel that his psychiatric status was compromised or that he was unstable prior to 2002. *Id.*; Ex. 26: [redacted] Dep. at 43.

60. Even after 2001, the psychiatrist who was [redacted] Kroop Decl. at ¶¶ 10-12 & Ex. A: Report of Investigation, at OPM-000097. [redacted] Ex. 18: Wade Dep. at 178-79.

61. In the years prior to and following the anthrax letter attacks, Dr. Ivins consistently received favorable performance appraisals at the top of the rating scale and awards; he was highly regarded for his professional contributions, expertise as an anthrax scientist, and "integrity." Ex. 4: Friedlander Dep. at 50-56; Ex. 23: Bridges Dep. at 93-96; *see, e.g.*, Ex. 33: Senior System Civilian Evaluations, ARMY02-11131-66. He enjoyed a good scientific reputation and was considered a very good scientist. Ex. 8: Eitzen Dep. at 175. A decade before the anthrax letter attacks, Ivins was already well-published in anthrax biology. Ex. 2: Andrews Dep. at 181-82.

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[7] Ex. 8: Eitzen Dep. at 175-76; Ex. 31: Deposition of [redacted] at 59,180-181, 185; Ex. 32: Deposition of [redacted] at 43, 94-95; Ex. 13: Adamovicz Dep. at 59-62; Ex 4: Friedlander Dep. at 53-56; Ex. 30: Little Dep. at 55-58; Ex. 12: Welkos Dep. at 99 (no concern re Ivins' mental stability); Ex. 10: Arrison Dep. at 75-76 (USAMRIID's security department had no problems with Ivins); Ex. 1: Byrne Dep. at 55 (no observation of erratic behavior by Ivins; never knew him to suffer depression); Ex. 2: Andrews Dep. at 176-77 (Bacteriology Division Chief never noticed odd behavior that made him question Ivins' trustworthiness or ability to work in lab); Ex. 26: [redacted] Dep. at 43, 82 (based on exams from 1999 to 2001, SIP did not view Ivins as psychiatrically compromised; [redacted].)

USAMRIID'S PHYSICAL SECURITY, ACCOUNTABILITY OF ANTHRAX, AND PERSONNEL PRACTICES ARE SUSCEPTIBLE TO POLICY CONSIDERATIONS

62. Identifying, developing and applying biosecurity measures at USAMRIID involved a complex mix of policy considerations – balancing relative effectiveness of alternative physical and personnel security measures and inventory standards against biomedical research operations, mission, financial resources, other cost considerations, and impact on scientific staff whose support is needed to execute the mission and promote biosecurity. Ex. 5: Lynn Dep. at 73, 81-84; Franz Ex. B: DSB report at DOD-000085; Colwell Decl. at ¶¶ 31-32, 96-98 & Ex. B: NRC report at ix-x, 28, NAS-000009–010, 046; Franz Decl. ¶¶ 44, 50, 64 & Ex. C: NSABB report at NIH-000004, 014.

63. Implementing changes to policies and practices involves tradeoffs between cost and mission performance and improvements in safety and security. Ex. 5: Lynn Dep. at 82-84 (quoting Franz Ex. B: DSB report at 5, DOD-000085). The impact on "mission performance" would include the biological research missions of USAMRIID and other laboratories. While undertaking improvements in security and safety, DoD would at the same time try to balance the costs, especially non-financial costs, such as impact on the mission. *Id*. at 83-84.

SECURITY EFFORTS MAY BACKFIRE, PARADOXICALLY UNDERMINING SECURITY

64. Future discoveries and successful research on select agents – and in the life sciences generally – depend on a healthy, vibrant and sustainable research environment. Scientific progress requires that the best and most creative researchers be encouraged to seek out and solve important problems. This requires minimizing unnecessary regulation and burdensome recordkeeping which serve as impediments, and providing clear justification for those adopted for legitimate reasons, such as enhancing security. Colwell Decl. at ¶ 32 (quoting Ex. B: NRC report at 28, NAS-000046).

65. Measures aimed at enhancing the biosecurity of select agent research could decrease national security if such measures diminished the capacity of the U.S. to prepare for, and respond to, emerging threats (including disease outbreaks and bioterrorism) by diminishing the ability to recruit top scientists and develop vaccines, treatments, and other countermeasures. Reliability measures that isolate select agent researchers from the mainstream scientific community could increase the risk of the insider threat. Franz Decl. at ¶ 50 (quoting Ex. C: NSABB report at 6, NIH-000014); *see* Colwell Decl. at ¶ 12 (quoting Ex. B: NRC report at ix-x, NAS-000009-10).

SECURITY EFFORTS CANNOT ASSURE PREVENTION OF BIOTERRORISM

66. Regardless of any physical security at a biological research facility, insiders have unique access authority and knowledge of operating procedures that enable them to transfer BSAT out of a facility, undiscovered. Ex. 5: Lynn Dep. at 90-91 (quoting Franz Ex. B: DSB report at 40-41, DOD-000120-21); *see also* Franz Ex. B: DSB report at xi, DOD-000077; Ex. 6: Salerno Dep. at 244 (quoting Ex. 7: Sandia report at 41, ARMY02-009983). A single organism can be amplified into millions of organisms. Ex. 6: Salerno Dep. at 220.

67. Physical security measures would at best only partially mitigate the overall risk of a harmful application of select agents, also available from nature. Franz Decl. at ¶¶ 48, 62 (citing Ex. C: NSABB report at iii, 5, NIH-000005, 000013). A determined adversary cannot be prevented from obtaining pathogens for nefarious purposes. Planning requires a realistic balance between prevention and consequence management. Ex. 5: Lynn Dep. at 88-89 (quoting Franz Ex. B: DSB report at x, 49, DOD-000076, 000129).

68. Post-2001 biosurety measures negatively impacted scientific research, by drawing scientific personnel away from research operations, rendering substitute personnel unavailable to support USAMRIID research projects, and requiring professional and technical staffs to interrupt normal activities to assist with implementing new procedures. Declaration of Kathleen Carr at ¶¶ 23, 39-40 (quoting Ex. B: Carr, *et al.*, *Implementation of Biosurety Systems in a Department of Defense Medical Research Laboratory*, 2 Biosecurity and Bioterrorism: Biodefense Strategy, Practice & Science no. 1, at 7, 14 (2004), NLM-000258).

ADDING INVENTORY REQUIREMENTS CANNOT PREVENT DIVERSION, AND COULD UNDERMINE SECURITY AND IMPEDE SCIENTIFIC RESEARCH

69. Pathogens at USAMRIID are found in multiple media, including Petri dishes, cell cultures, laboratory incubator environmental samples, clinical specimens, infected animal models, animal carcasses, animal excrement, refrigerator storage, or freeze-dried forms. The self-replicating nature of pathogens, the diverse places where located within a legitimate laboratory, the quantities required to do legitimate research, and their unquantifiable growth and decay rates (varying depending on genetic makeup, reagents or other materials used to supplement growth, and the environment where grown), indicate that the absolute amount of any given organism cannot be reliably quantified from day to day. Ex. 6: Salerno Dep. at 46, 49-50, 246, 250-51 (quoting Ex. 7: Sandia report at 46, ARMY02-009988). Even when the amount starting in a culture is known, it is very difficult to properly document amounts put onto plates,

remaining amounts going into tubes, and amounts going into autoclave. Ex. 3: Worsham Dep. at 79-80.

70. Even in a static repository, it is extremely difficult to measure the number of organisms. While vials might be counted, one vial might have only a few hundred organisms, while others have thousands to millions. The number of self-replicating organisms in a vial may fluctuate on their own and grow and die at unpredictable rates, making traditional inventory control mechanisms for securing material particularly challenging since the pathogen amounts cannot be quantified daily. Ex. 6: Salerno Dep. at 213-15; *see* Ex. 8: Eitzen Dep. at 69-70, 113-14, 181-82.

71. "Because a new culture can be grown from even a single microorganism, an individual would need only a miniscule—and undetectable—amount from a single vial to establish a new culture and grow large volumes in hours or a day. Determining that the number of vials is unchanged provides no guarantee that agents have not been removed." Colwell Decl. at ¶ 25 (quoting Ex. B: NRC report at 113, 115 NAS-000131, 133). "As convenient as it might be to count vials, volumes, or number of organisms, it is not a biologically relevant means of inventory."[8] *Id.* For these reasons, the NRC committee concluded that undue reliance on accounting practices leads to false security and is counter-productive. *Id.*

72. A rigorous biological inventory control system, monitored by regular and random audits and a compliance process may have more detrimental than positive outcomes. Keeping an accurate vial count for a facility like USAMRIID, with millions of vials of rapidly replicating pathogens, would be very costly and not contribute to security; instead, it would give a false sense of security and raise the level of cynicism among technical staff of biosecurity since minute quantities of pathogens can be stolen from a counted vial. Ex. 6: Salerno Dep. at 248-49. If an accounting system for pathogens were described as a required security measure, scientific staff will recognize it does not provide security, making it considerably more difficult to generate staff support for the overall security program. *Id*. at 251 (quoting Ex. 7: Sandia report at 47, ARMY02-009989).

73. Before the anthrax attacks, when considering whether to inventory working stocks, USAMRIID's commander followed the existing regulation requiring inventorying only for

[8] Dr. Ivins maintained an inventory for RMR-1029, Ex. 4: Friedlander Dep. at 56-58; Ex. 30: Little Dep. at 58-62 (referring to Ex. 34: RMR-1029 Reference Material Receipt Record, ARMY02-010387).

reference stocks, based on the concern that the mission of the laboratory would come to a screeching halt if they required inventorying also for working stocks. Ex. 8: Eitzen Dep. at 181-82.

74. Vial counting conducted pursuant to a rule that evolved since 2002 has cut into USAMRIID's mission, affected morale, and taken up a tremendous amount of time that could be invested in products for soldiers, forcing people to terminate experiments where it's too difficult to maintain that documentation. Ex. 3: Worsham Dep. at 72-74.

75. Counting and tracking vials has impacted USAMRIID's productivity and mission by taking up 20% to 30% of lab time. A single experiment requires preparation of numerous documents for chain of custody, and pulling people away from experiments to serve as monitors, and accounting for all movement of pathogenic material, and related animals, tissue, blood and cultures. *Id.* at 78.

EXIT SEARCHES FAIL TO ENHANCE SECURITY

76. Sandia's security review team, in its 2002 report to USAMRIID, did not recommend searching all lab personnel routinely on exiting USAMRIID's laboratories, because "even a strip search would not prevent a determined insider from removing biological agent from this laboratory." Biological scientists know the material they are working with, and how to remove material from the facility, if they want. Ex. 6: Salerno Dep. at 239-41. Imposing exit searches would have impacted USAMRIID's operations, created a risk that scientists quit working at USAMRIID, and involved privacy rights issues. *Id.*; Ex. 8: Eitzen Dep. at 179-80; Ex. 14: Jahrling Dep. at 97-98; Colwell Decl. at ¶ 100; Carr Decl. at ¶ 26; Franz Decl. at ¶ 50.

77. It would be simple for perpetrators to remove a pathogen from a lab because of the very small amount required to grow much larger amounts and the ability to conceal small amounts in clothing or an orifice, which cannot be detected. Ex. 8: Eitzen Dep. at 69-71, 178-81; *see* Ex. 14: Jahrling Dep. at 96-98.)

"TWO-PERSON RULE" FAILS TO ENHANCE SECURITY, AND IMPEDES SAFETY AND RESEARCH

78. Even with a two-person rule, it would be fairly easy for one scientist to divert a small amount of agent with the other scientist distracted. Ex. 8: Eitzen Dep. at 185. For that and other reasons, the Defense Science Board recommended against DoD imposing a two-person rule for security as counter-productive. Ex. 5: Lynn Dep. at 99-100 (quoting Franz Ex. B: DSB report at 42, DOD-000122).

79. A two-person rule is potentially dangerous as it requires someone other than the active scientist to be present in the lab. Ex. 5: Lynn Dep. at 94-95 (quoting Franz Ex. B: DSB report at 20, DOD-000100). Imposing a two-person rule would have conflicted with Army policy for minimizing exposure by using the minimum number of personnel for the minimum time. Ex. 11: AR 385-69 at ¶ 2-3a, ARMY02-001712.

80. After 2001, the short-lived attempt to employ a two-person rule detrimentally affected USAMRIID's operations, mission fulfillment, and staff morale. Ex. 3: Worsham Dep. at 55. For example, a two-person rule requires simultaneous scheduling for lab time on evenings or weekends when cultures have to be checked. Before October 2001, USAMRIID did not have the professional staff or budgetary resources needed to apply a two-person rule. Ex. 8: Eitzen Dep. at 184-86.

81. Adding an observer solely for achieving a two-person requirement would contribute to time pressures, stress, distractions, and interruptions – all factors identified by human performance management as error precursors. Colwell Decl. at ¶ 85 (quoting Ex. B: NRC report at 118 n.8, NAS-000136); *see* Ex. 5: Lynn Dep. at 96-97 (quoting Franz Ex. B: DSB report at 21, DOD-000101).

82. The two-person rule has been determined to be ineffective and counterproductive for the foregoing and other reasons, including: (1) it impractically requires two equally qualified scientists, equally familiar with the agent and work, (2) it would likely result in scientists feeling demoralized, which can promote increase turnover and also negatively impact security, and (3) employing two scientists to do the work of one is cost-prohibitive. Ex. 6: Salerno Dep. at 241-43; Ex. 8: Eitzen Dep. at 184-86; Ex. 5: Lynn Dep. at 97-100.

COMPLETE VIDEO SURVEILLANCE FAILS TO ENHANCE SECURITY AND IS INCREDIBLY COSTLY

83. Sandia proposed no video coverage inside containment suites because suites were compartmentalized to an extent precluding practical video design. Surveillance cameras would not be able to detect or distinguish a person's act of diversion. Ex. 6: Salerno Dep. at 252-54; Ex. 7: Sandia report at 73-74, ARMY02-010015 - 016; Ex. 8: Eitzen Dep. at 187-88.

84. Several years after the anthrax letter attacks, the Army expended about $50 million to install a new video surveillance system at USAMRIID, including cameras in all lab rooms and additional monitors, which exceeded USAMRIID's annual budget of "under $50 million" at the time of the installation. Carr Decl. at ¶ 39 (citing Ex. B, *supra* ¶ 68 at 14). *See also* Ex. 8:

Eitzen Dep. at 124-27.

85. Even if USAMRIID had video surveillance of all lab rooms before the letter attacks, it lacked qualified personnel to monitor surveillance. Monitoring requires sophisticated people because average security guards would not know what they were looking at. With well over 200 lab rooms to monitor – whether it was even possible to hire people to effectively monitor 200 camera areas 24 hours – USAMRIID did not have the resources. Ex. 8: Eitzen Dep. at 186-87.

ADDITIONAL PERSONNEL RELIABILITY MEASURES DO NOT ASSURE ENHANCED SECURITY AND RISK DRIVING OUT SCIENTISTS AND INCREASING INSIDER THREATS

86. Security clearance investigations, monitoring by using various databases during periods between investigations, and PRPs individually have limitations in their ability to identify potential threats from an insider. The most effective means of protecting against the insider threat is to create a culture of trust and responsibility among the professional staff. Security measures that are onerous and unreasonable interfere with the development of a culture of trust and responsibility. To develop that culture, it is important to have the active support of the professionals of the facility – which is achieved with their understanding, cooperation, and appreciating the need for biosecurity measures, and for them to be in place and followed. Colwell Decl. at ¶ 107.

87. Experts in personnel screening have long been concerned with the challenge that a system applicants find too intrusive or unfair could make even successful applicants feel the selection process is unjust, creating negative feelings or attitudes that could ironically contribute to someone's becoming disgruntled and potentially susceptible to the very behavior screening is intended to prevent. *Id*. at ¶ 64 (quoting Ex. B: NRC report at 76, NAS-000094).

88. Screening individuals for potential security concerns poses formidable challenges. The proportion of the population of job candidates who represent true security risks is unknown, but likely to be very small. This low base rate makes it difficult to detect true threats because "screening in populations with very low rates of the target transgressions (e.g., less than 1 in 1,000) requires diagnostics of extremely high accuracy" and these do not exist for the problems we are trying to address (or for many others). There is no way to escape the risk that good candidates will be screened out in order to detect a small number of people who pose genuine threats to security. *Id*. at ¶ 60 (quoting Ex. B: NRC report at 75, NAS-000093).

89. Identifying persons with malevolent intent by psychological testing and evaluation is extremely difficult, if not impossible. Franz Decl. at ¶ 28 (quoting Ex. B: DSB report at xi,

DOD-000120). Research suggests that however abhorrent their actions may be, the outstanding common characteristic of terrorists is their normality. Colwell Decl. at ¶ 77 (quoting Ex. B: NRC 2009 report at 87, NAS-000105). Psychological tests for mitigating insider threats are extremely resource-intensive, and lack known effectiveness or predictive value. Franz Decl. at ¶ 71 (quoting Ex. C: NSABB report at 10, NIH-000018).

90. Potential benefits of enhanced personnel reliability measures must be carefully weighed against the potential negative consequences such measures would likely have on the research community. A robust and agile research enterprise that has access to a diverse workforce and spans government, private, and academic sectors provides innumerable benefits to society. Promulgating additional reliability measures could serve as a powerful disincentive to those who would responsibly conduct research on select agents because the most talented young researchers, those with many options for research paths, may be far more likely to enter fields with less onerous regulatory requirements. A burdensome national PRP may not only drive scientists from important select agent research, but also drive select agent research out of academia and potentially out of the U.S. into countries with less stringent regulations. Furthermore, instituting onerous reliability measures could isolate select agent researchers from the mainstream scientific community, isolation that might inhibit research and paradoxically increase the risk of the insider threat. *Id*. at ¶ 50 (quoting Ex. C: NSABB report at iv, NIH-000006); *see* Ex. 5: Lynn Dep. at 107 (quoting Franz Ex. B, DSB report at 34, DOD-000114).

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 03-81110-CIV-HURLEY/HOPKINS

MAUREEN STEVENS, as Personal Representative of the Estate of ROBERT STEVENS, Deceased, and on behalf of MAUREEN STEVENS, Individually, NICHOLAS STEVENS, HEIDI HOGAN and CASEY STEVENS, Survivors,

Plaintiffs,

v.

UNITED STATES OF AMERICA,

Defendant.
_____/

Certificate of Service

I hereby certify that on July 15, 2011, I served the foregoing document, plus exhibits, on Plaintiffs' counsel of record identified on the attached Service List by Federal Express. I also served a redacted version on Plaintiffs' counsel electronically via the CM/ECF court filing system.

s/Jacqueline Brown
JACQUELINE BROWN

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Case No. 03-81110-CIV-HURLEY/HOPKINS
United States District Court, Southern District of Florida

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