STATEMENT OF
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DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
OF THE
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

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Good morning Mr. Chairman and members of the Subcommittee. Thank you for the opportunity to discuss the events surrounding the closure of the Special Pathogens Laboratory (SP Lab) at the VA Pittsburgh Healthcare System (VAPHS). I am joined today by Dr. Ali Sonel, Assistant Chief of Research and Development, VAPHS; Dr. Mona Melham, Vice President Clinical Support Service Line, VAPHS; Ms. Cheryl Wanzie, Medical Technologist; and Dr. Steven Graham, Director, Geriatric Research and Education Center (GREC).

VAPHS is an integrated health care system serving a population of over 360,000 veterans throughout Western Pennsylvania, Ohio, and West Virginia. In Fiscal Year 2007, VAPHS served over 58,000 unique veterans and completed over 489,000 outpatient visits. Between 2000 and 2007, the VAPHS research program grew from $11 million to over $24 million in funded research including an initiative for a VA-led cooperative study; this growth is indicative of a healthy program that promotes a positive environment for researchers.

Today I will address the closure of the SP Lab, the disposition of equipment and specimens, and VA policies as they were in December 2006. Additionally, I will discuss some changes we have since instituted to these policies.

Closure of Special Pathogens Laboratory

Let me say at the outset that the Special Pathogens Lab operated within the VAPHS as a part of the regular clinical laboratory services. As such, the primary mission was to

support the clinical work of the organization. Its original focus was to perform clinical testing for legionella bacteria for the VA.

Further, it should be understood that research projects may be and, are indeed encouraged, to be undertaken by VAPHS clinicians in the scope of their VA employment if their protocols are presented and approved by the Research and Development Committee.

The Research Foundation, an incorporated not-for-profit organization, has the mission to support VA research operations. External funding resources are often secured and managed by this foundation for properly approved and sanctioned activities of VA researchers.

In January 2006, the Associate Chief of Staff (ACOS) for Clinical Support, who oversees all VAPHS' laboratory functions, reviewed the workload of the SP Lab. She determined the clinical workload could be managed more efficiently within the main clinical laboratory. She also discovered the SP Lab was acting beyond its intended scope.

Following a technical review by the ACOS for Clinical Support, we found it presented a potential biohazard to both employees and our veterans. The SP Lab also lacked a defined and approved research activity. The volume of clinical work being performed in the SP Lab was low. The ACOS for Clinical Support determined that this function could easily be absorbed by the main clinical laboratory at reduced cost. The supplies necessary to effect such a change were minimal and the conversion would free up the time of the full-time VA microbiologist to do other VA work. These concerns were the basis for the ACOS for Clinical Support's recommendation that the VA work of the SP Lab be moved into the main clinical lab and that there be an additional review of SP Lab research accounts.

On July 5, 2006, the Director of the SP Lab was notified via email and in person about the lab's closure and he and his staff were given two weeks to complete work currently in progress. This notification included instructions to stop accepting specimens from external consumers. The Lab's "closeout" plans were forwarded to the SP Lab staff on July 7, and formal letters of notification were delivered July 10. The SP Lab closed on July 21, 2006. The members of the lab received clear direction regarding labeling of existing and new specimens and stored samples, and the members of the lab were told to provide a map for storage. Although these instructions were specific, they were ignored.

Investigative Reports

As VAMC Director, I initiated an administrative board of investigation (ABI) on July 19, 2006, to review research and financial activities. In addition, I expanded the scope of the investigation on August 4, 2006, to include investigation of any breach of security and/or patient privacy surrounding activities in the SP Lab. The ABI determined the SP Lab was operating outside the scope of services for which it was established. It had evolved into an unauthorized commercial enterprise, which tested environmental water supplies for private companies (including hotels, restaurants, and gas station bathrooms), and was engaged in subcontracting for private environmental companies. The SP Lab had a commercial client list in the hundreds that included private hospitals, businesses, municipal water authorities and other institutions.

Funds were collected and deposited within the foundation accounts. As part of an internal financial review at the VA Pittsburgh, financial concerns were raised. Records indicated that their non-VA invoiced revenue for 2005 was $396,631.41 and for 2006 was $311,337.71. Since this was found, the Research Foundation has hired financial staff and enhanced financial oversight. Non-VA revenue remained unobligated. The Research Foundation has a procedure in place for left over funds from research accounts. These funds were pulled into the foundation and used for other projects.

In September 2006, the VA Associate Chief of Staff for Research, conducted a review of every publication generated in the SP Lab and concluded that human subject microbiological diagnostic and interventional human research studies were conducted at the VAPHS without required approval from the Institutional Review Board (IRB) and the Research and Development Committee. To our knowledge, no individuals were harmed as a result of this research.

We reported all of these findings to the VA Office of Research Oversight (ORO) on October 12, 2006. In October 2006, after reviewing these reports of investigations and the actions taken by VAPHS, ORO concluded the VAPHS had adequately addressed research non-compliance by suspending the SP Lab from embarking on any future research projects, eventually closing the lab, and establishing sufficient safeguards to prevent similar non-compliance from recurring.

Removal of Equipment and Environmental Specimens

Following the closure of the SP Lab, furnishings and equipment purchased with clinical lab's funds or with VA Research Foundation funds were moved to the main clinical lab. SP Lab staff were allowed to transfer equipment acquired by non-VA funds to a site off Federal premises. Properly labeled and cataloged clinical specimens from the SP Lab were also moved to the main lab. Research specimens associated with an approved research protocol, properly labeled and maintained by the principal researchers were transferred to the main clinical laboratory for proper storage. Those specimens that were not labeled, cataloged, or were in opened or damaged tubes were considered bio-hazardous material and were safely disposed of in accordance with hazardous materials procedures, safeguarding patient care and public health. VAPHS water samples were transferred to the clinical laboratory. For approximately two weeks, VAPHS sent water samples to an outside vendor for legionella testing. After this period, VA's clinical lab developed the ability to conduct legionella testing in-house and currently offers this service to several other VA Medical Centers.

Policy Governing Disposition of Research

In December 2006, VHA Directive 2000-043 (attached) governed the disposition of research collections. The Directive and a clarification memorandum from VHA's Chief Research and Development Officer (CRADO) addressed the collection and storage of clinical data that could be linked to the human biological specimens. Two additional policies discussed record retention. VHA Handbook 1200.05 (attached) states that "if an investigator leaves a VA facility, the original research records must be retained at the institution." VA Handbook 6300.1 (attached) states that "records and information collected and created by VA personnel in the conduct of official business belong to the Federal government and not to the employee(s) who initiated their collection or creation."

We determined in December 2006 that no VA-approved research protocol existed to cover the samples in question. The samples were not collected as part of any previously approved research efforts, nor were they collected, labeled, cataloged and properly stored to constitute a scientific collection. Even if the samples had been properly labeled and stored, the collection could not have been banked at a non-VA approved institution without a VA investigator.

In response to the investigations of the SP Lab and after the loss of research data in another VISN, VAPHS took steps to enhance awareness among staff of VA research and lab policies and procedures. In March of 2007, VAPHS held a two-week Research Stand Down to ensure staff understood laboratory policies and the importance of securing sensitive research data.

New Policy Governing Disposition of Research

On October 19, 2007, VAPHS issued Research Data Security and Privacy Policy. The new policy specifically outlines processes for disposition of research and clearly informs researchers that VA research is the property of VA and that investigators cannot take what they collect as part of VA-approved research when they leave the institution. Additionally, local policies and procedures will continue to be revised as needed, including policy related to tissue, specimen and data banking.

The VA Pittsburgh Healthcare System operates a robust research program committed to contributing to science and enhancing care to veterans and the broader community. We have added compliance staff to increase research oversight and leadership is continuing an ongoing, in-depth review to ensure all VA researchers adhere to the highest level of human subjects' protection.

This concludes my statement. I would be pleased to answer any questions the Subcommittee may have.