

September 9, 2008

Statement of Janet E. Stout, Ph.D.

Microbiologist

Members of the Committee, first I want to thank you for holding this hearing.

I am Dr. Janet Stout. I have a Ph.D. in infectious disease microbiology and I am a Research Associate Professor at the University of Pittsburgh Department of Civil and Environmental Engineering. I received both my Masters and Ph.D. degrees from the University of Pittsburgh, Graduate School of Public Health.

I am internationally-recognized as an authority on Legionnaires' disease. I have authored book chapters and more than 80 publications in peer-reviewed journals including the New England Journal of Medicine, the Journal of the American Medical Association (See Stout CV in Section 8 of written testimony).

I have lectured on Legionnaires' disease at national microbiology, infection control and engineering conferences, at the European Working Group on Legionella Infection and in 2009, I will speak at the International Legionella Symposium in Paris France.

I spent 25 years at the Pittsburgh VA Medical Center as a microbiologist in the Special Pathogens Laboratory.

My scientific achievements include identifying drinking water – not air conditioning – as the real source for hospital-acquired Legionnaires' disease. This finding was a major paradigm shift and unraveled the epidemiology of hospital-acquired Legionnaires' disease, and was published in the New England Journal of Medicine and in the Lancet.

I have worked with State and local public health agencies in developing guidelines for the prevention of hospital acquired Legionnaires' disease. This work provided the foundation for guidelines for the Health departments in the States of Maryland and New York, and the countries of Spain, Italy, Taiwan, the Netherlands, Denmark, and France, and the VA Healthcare System.

In 2005, I was asked by the VA Medical Inspector General to assist him in devising a new VA Legionella prevention Directive, which was issued nationwide in February 2008.

The Special Pathogens Laboratory

The VA Special Pathogens Laboratory was part of the VA microbiology laboratory and served as a national reference laboratory until its closure in 2006. As a microbiologist in this unit, I performed clinical and reference laboratory testing for VA and non-VA institutions (See Stout position description Section 5 of written testimony).

I was among the many students, physicians and scientists that worked in this "Center of Excellence" and whose accomplishments were highlighted in the VA "Vanguard" in 1996, on the occasion of the 20th anniversary of the discovery of Legionnaires' disease (See "Medical Advances May/June 1996).

The collection of isolates and specimens housed in this laboratory played a major role in those accomplishments and resulted in more than 200 publications on Legionnaires' disease.

The Collection

A scientifically valuable collection of microorganisms was destroyed. In order to fully understand the impact of this action, I will describe its scientific relevance and how we were the guardians of the collection until its destruction in 2006.

I was trained to catalogue isolates and specimens, place them in plastic freezer vials at -70°C and maintain a detailed record so others could retrieve the isolates for future study (See Section 4 of written testimony – Bacterial Stock Maintenance). I maintained the collection in the Special Pathogens Laboratory at the VA Medical Center in Pittsburgh, PA. Information about the isolates was recorded in a log book and typed into an electronic file on the lab computer.

From 1979 to 2006 , we banked over 8000 specimens from our studies on Legionnaires' disease and other infections. The specimens included isolates of *Legionella*, *Staphylococci*, *Pseudomonas*, *Klebsiella*, *Enterococci*, *Streptococci* and *Candida* species and thousands of serum, respiratory and urine samples. **They were all were destroyed.**

The role of this collection of microorganisms in our discoveries can be summarized as follows:

1. We showed that Legionnaires' disease was acquired from hospital drinking water systems. *Legionella* isolates in our collection proved this association for hospitals in Pittsburgh and across the U.S.
2. Our laboratory developed new and better ways to detect and treat this disease. Every antibiotic and *Legionella* diagnostic test in use today was tested in our laboratory. Our collection allowed new tests to fulfill FDA requirements for approval (See requests from scientist in Section 7 of written testimony). **These specimens were destroyed.**
3. We developed advanced environmental and clinical methods. Less experienced laboratories often gave incorrect results and advice, placing patients at risk. For example, in 2005 one laboratory failed to diagnose a large outbreak of Legionnaires' disease in a nursing home. Using our collection, we showed that the urine antigen test used by the laboratory

gave false negative results. **The specimens that allowed us to make this discovery were destroyed.**

4. Isolates from every hospital using our lab were stored in our freezer. Having these isolates available in the future would establish whether or not the hospital was the actual source or the patient acquired the disease elsewhere. **These isolates were destroyed.**
5. We demonstrated the development of resistance by Legionella to a commonly-used water disinfection method – copper-silver ionization. This observation was only made possible by comparison of historical (frozen) isolates to present day isolates. **The specimens that allowed us to make this discovery were destroyed.**
6. We showed that the risk of illness to patients could be predicted. Other scientists have requested our specimens for study in their laboratories to study disease-causing traits and evaluate new antibiotics. **These isolates are no longer available to the scientific community for study – they were destroyed.**
7. Our research was supported by the VA Merit Review System, the U.S. Environmental Protection Agency, and industry. The VA Merit Review study was an IRB approved study involving 20 VA institutions across the US. The results of that VA Merit Review-funded study were published in 2007 in the journal “Infection Control and Hospital Epidemiology.”
8. We also showed that patients get Legionnaires’ disease from the drinking water in their own homes. This was an EPA-funded IRB-approved study.

All of the isolates and specimens collected during the Merit Review and EPA studies were destroyed.

Did We Collect These Isolates For Research Purposes and Was the Research Approved?

Dr. Yu and the other VA infectious disease physicians participated in approved research activities that involved the collection and storage of microorganisms and specimens in the Special Pathogens Laboratory (See Section 5). When the lab closed in July 2006, we had an active R&D approved study that was in effect through December 2006 entitled “Various Studies Examining Treatment, Prevalence and Eradication of Legionella” ID: 00137.

What Did We Do to Save the Collection?

Initially, I was not concerned about the transfer of the collection from the VA. I knew that other VA investigators had left the VA and taken their collections of specimens with them. The VA Research office even told us that they had recently gone through this process with one of the VA physicians.

July 2006 – During a meeting in the Special Pathogens Laboratory in July, Sue Mietzner, a microbiologist in our lab, showed Dr. Melham the freezer where our collection was stored and told her of its importance. She also showed her the location of the computer file describing the isolates. The hand-written log book containing all the isolate identification information was also left in the laboratory. I was never asked to provide any information on the contents of our collection.

August 2006 - I first expressed my concern for the safety of the collection in an email to Dr. Yu on August 12, 2006. In response, Dr. Yu immediately sent an email to Steven Graham, the head of Research requesting his assistance in protecting the collection. In this email Dr. Yu stated “I fear the

vindictiveness of the administration....may imperil this irreplaceable collection.”

We were reassured by Dr. Graham when he responded:

“Of course I don’t want to see valuable specimens destroyed, but these specimens are biohazards so we must follow accepted procedures in order to transfer them. We recently went through this process in regard to Dr. VonKammens samples at Highland Drive”.

He told us that the collection “must be moved to an institution approved to handle biohazards. They must sign a materials transfer agreement and have an approved biosafety program”

In response, Dr. Yu and I obtained the assistance of Dr. Timothy Mietzner, Professor of Molecular Genetics and Molecular Biology at the University of Pittsburgh and on August 21st we requested the transfer of these materials to his laboratory at the University of Pittsburgh.

More assurances came from Dr. Sonel, who replaced Dr. Graham as head of Research in September of 2006. In an email to me on October 5th, he stated “We will work with you to facilitate the transfer.”

August and December 2006 - There were numerous emails between me and the Research office to affect the transfer of the collection, which included sending the Material Transfer form to the Research office. I actively engaged the Research office in my attempt to transfer the collection to the University of Pittsburgh. VA Administration was copied on these emails.

Throughout this time, there was never any indication that the disposition of the collection was in question or that the collection was in danger of being destroyed.

Dr. Sonel notified the Pittsburgh VA Administration on December 4th that I was to meet the Research Compliance Officer on December 5th in the Special Pathogens Laboratory to begin the process of transferring the collection to the University.

In response to this information, and less than 24 hours before I was to start the transfer of the collection they destroyed our collection on December 4th, 2006.

The Pittsburgh VA administration failed to preserve and protect this valuable scientific resource.

Were We Notified of this Action?

Dr. Sonel sent me an email on December 4th informing me that he “was asked by the front office to put this process on hold. I or someone from the front office will be updating you soon regarding this request. I apologize for any inconvenience that this may have caused.”

No one from the VA has ever contacted me regarding the destruction of our collection.

For me as a scientist, and for Veterans and the American public - The loss is incalculable.

A petition was published in the April 2008 issue of the medical journal “Clinical Infectious Diseases”(CID 2008;46:1053-9) and signed by over 250 scientists. They requested that an investigative committee review the actions of the Pittsburgh VA Healthcare System regarding the closure of the Special Pathogens Laboratory and the destruction of a scientifically valuable collection of microorganisms.

The petition signatories and I thank you for your time and effort today in fulfilling this request.

Sincerely,

Janet E. Stout, Ph.D.