**Written Statement**

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I was Chief of the Infectious Disease Section at the VA Medical Center, Pittsburgh, Pennsylvania for 30 years and received superior performance evaluations for each of these 30 years. I was also Chief of the Special Pathogens Laboratory (SPL) instituted under the aegis of VA Central Office during the Legionella outbreaks of the late 1970s. In the late 1970’s, outbreaks of hospital-acquired legionellosis occurred throughout the VA hospitals: 200 cases at Wadsworth VA (CA) in 4 years, 50 cases at Togus VA (ME) in 2 years, 100 cases at Pittsburgh VA (PA) over 3 years. In 1996, the SPL was established as a Special Clinical Resource Center by Thomas Cappello, previous director of the VA (see Appendix).

Our accomplishments are matter of record garnering honors from the VA, NIH, International societies and for me, the most treasured one, from the American Legion.

These are a few of many key discoveries

● Dr. Janet Stout’s discovery of the source in 1982 –the hospital drinking water. This was a controversial discovery not well-accepted by CDC for many years. They believed cooling towers were the source. This discovery suggested that prevention was possible.

● The SPL and the Department of Engineering at the University of Pittsburgh then instituted a systematic process of discovery and evaluation of possible disinfectants against Legionella in the drinking water. We were the first to either introduce and/or evaluate these methods in a controlled fashion:

 -Superheat and Flush (Lancet, 1983)

 -Chlorination (Lancet 1985)

 -Copper-Silver Ionization (Water Research 1996, Am J Infect Control 1997, Infect Control Hosp

 Epidemiol 2003)

-Chlorine dioxide (J Am Water Work Assoc 2004)

-Monochloramine (APIC abstract, 2012)

● The SPL developed and evaluated all the microbiologic methods in current use today. The culture media for isolation from water and from patients that is commercially available today was formulated by the Special Pathogens Laboratory. We performed the first comparative evaluation of the urinary antigen test for Legionella and found it to be accurate. This test is now the most common method used for diagnosis today.

● Most importantly, we formulated the strategy of using Legionella contamination of the hospital drinking water as the key parameter for assessing risk in the hospital – an approach opposed by CDC. However, several US states, most of Western Europe and Taiwan have adopted this approach.

● Our greatest discovery for the purpose of this Hearing was that the Special Pathogens Laboratory evaluated the antibiotics that could kill Legionella. The ones that were promising were commercialized by the pharmaceutical industry and we confirmed their effectiveness in FDA-approved patient studies of azithromycin, (Z-Mycin, Pfizer) and levofloxacin (Levaquin, Ortho McNeil). In a larger U.S. study for FDA approval, we found levofloxacin dropped the mortality of Legionnaires’ disease to 0%. This was confirmed by a large Spanish study of epidemic Legionnaires’ disease in which the mortality was again 0% (zero).

From 1991-2006: 21 consecutive years, not a single case of hospital-acquired Legionnaires’ disease occurred at the Pittsburgh VA. Compare this with subsequent numbers of cases seen at the Pittsburgh VA from 2007 to today (See Table in Appendix).

The Pittsburgh VA is an excellent medical facility with the superior physicians and capable healthcare staff. As the VA physicians well know, bureaucrats often dominate the VA system in ways not conducive to optimal care. This case is an unusually extreme and unfortunate example. I remain a loyal VA physician and feel dismayed that these bureaucrats have tarnished the reputation nationally and undermined its reputation for the veterans who obtain their care there.

With the closure of the Special Pathogens Laboratory, Senator Arlen Specter (R-PA) and the American Legion expressed concern about patient care. Mr. Moreland stated that the problem had been solved and we were no longer needed. Congressman Brad Miller (D-NC) from the 2008 Congressional Hearing decrying the destruction of our treasured scientific collection stated “We will never know how many patients will die because of the VA’s action”. He was wrong. Today, you know of at least 5 deaths at the Pittsburgh VA. Ironically, this was the hospital in which a zero percent mortality rate was first reported with antibiotic therapy. The most likely reason is that they did not receive the antibiotic at all or received the antibiotics too late.

We learned at this Hearing today that the fact that Legionella had re-entered the drinking water of the Pittsburgh VA in 2011 had been withheld from the physicians in the Emergency Room, the hospital ward, and most importantly, the nurses and physicians in the ICU. These veterans never had a chance.

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 **APPENDIX**

Special Pathogens Laboratory and Disinfection

VA Cases of hospital-acquired Legionnaires’ disease

Credentials of Dr. Yu

Reasons for Dr. Yu’s ouster from Pittsburgh VA

Publications of Legionnaires’ disease from Pittsburgh SPL

**Appendix: Special Pathogens Laboratory and Disinfection**

**Special Pathogen Laboratory - Position on Disinfection**

**Background**

Dr. Janet E. Stout and the Pittsburgh Special Pathogens Laboratory made the crucial discovery of finding the source of hospital-acquired Legionnaires’ disease in 1982. To everyone’s surprise, especially US CDC which had linked cooling towers to hospital-acquired Legionnaires’ disease, the actual source was found to be the drinking water of the hospital. Although controversial initially, scientific validation was soon forthcoming. Once this source was discovered, prevention became possible by disinfecting the drinking water such that Legionella would no longer grow and propagate.

 **Disinfection Modality-General Approach**

Over the next 30 years the Special Pathogens Laboratory, in conjunction with the University of Pittsburgh Department of Environmental Engineering, formulated and devised innovative approaches to disinfection and evaluated their efficacy in hospitals. All the methods in use today were first evaluated in controlled studies by SPL. These included heat and flush, hyperchlorination, ultraviolet (UV) light, copper-silver ionization, chlorine dioxide and monochloramine.

**Specific Disinfection**

**Super heat and flush** was the first modality tried. This method proved effective but it was tedious in that every faucet and showerhead needed to be flushed with hot water for at least 30 minutes (Best 1984). Patient care areas were flushed twice! This method is still used during emergencies and can be implemented immediately since no special equipment is needed.

**Chlorination or Hyperchlorination.**  The Special Pathogens group was the first to perform a controlled evaluation of chlorination in the world (Lancet 1985). This method became the predominant method as numerous hospital outbreaks were uncovered. Unfortunately, we found that this method had distinct disadvantages. Chlorine concentrations had to be monitored compulsively; if chlorine concentrations dropped below disinfection levels, Legionella quickly re-entered the water distribution system. This led to inconsistent efficacy. Corrosion of the water distribution system with pinholes leaks occurred in the piping such that flooding occurred behind the walls. Public health studies established that chlorine was a carcinogen.

**Ultraviolet (UV) Light.** While UV light is an effective method of disinfection, we were unsure of its efficacy if used on a water distribution system to control Legionella in downstream faucets. So we placed a UV unit on a hospital water system and tested for Legionella. UV was consistently effective only if used in combination with a systemic disinfectant and prefiltration (Liu- 95 Water Research)

**Copper-Silver Ionization:** This new modalitywas assessed by SPL in a laboratory model and a plumbing system. Copper-silver penetrated the biofilm of the pipes and eradication persisted for up to three months even if the copper silver was withdrawn thus providing a margin of safety (Liu 98 CID). Moreover, it had no odor and caused notably less corrosion than chlorination. It quickly emerged as the dominant disinfection modality worldwide. This system was installed at the Pittsburgh VA Medical Center in 1994 after experience in other hospitals showed efficacy. Legionella disappeared from the drinking water and the incidence of Legionnaires’ disease approached zero at the Pittsburgh VA (Stout 98). Independent evaluation at 16 medical centers proved it was highly effective (Stout ICHE 2003); 16 hospitals using copper-silver ionization over 5 to 11 years represented the final step in a proposed 4-step evaluation process of disinfection systems (see below for Stout Criteria).

**Chlorine Dioxide:** This modality was introduced in Europe where it proved disappointingly ineffective. Johns Hopkins instituted chlorine dioxide and found that Legionella could be adequately controlled; however, it took about one year before Legionella control could be sustained. We initiated the first controlled evaluation of chlorine dioxide in the United States and also found that efficacy required almost one year of disinfection (Sidari JAWWA 2004). We ultimately performed two more field evaluations with similar results (Zhang 2007, 2009). However, there were numerous advantages such as the ability to treat large volumes of cold water in multiple buildings. A study has not yet been done providing confirmatory reports from multiple hospitals during a prolonged time. Consequently, chlorine dioxide has fulfilled only 3 of the 4 Stout criteria (see below) and we have recommended its installation in selected facilities.

**Monochloramine:**  We have completed the first U.S. evaluation of a new system capable of on-site generation of monochloramine in a Pittsburgh hospital. Preliminary results are promising (Kandiah 2012).

**Stout Criteria**

In 2003 we proposed that all disinfection systems undergo objective evaluation that includes four steps:

* 1. demonstrated efficacy of Legionella eradication in vitro using laboratory assays
	2. anecdotal experiences in preventing Legionnaires’ disease in individual hospitals,
	3. controlled studies in individual hospitals
	4. validation in confirmatory reports from multiple hospitals during a prolonged time

To date, copper–silver ionization is the only disinfection modality to have fulfilled all four evaluation criteria.

**Conclusion**

In all of our consultations for disinfection with numerous medical centers in the U.S., we have never requested nor received a finder’s fee for recommending a specific disinfection modality. Evidence-based medicine is the criteria for our recommendations. Advantages and disadvantages exist for each individual modality. What works at one hospital may not be ideal for another. Water quality, pH, and the network design of each hospital will affect our recommendation. In addition, the susceptibility of the patients at that hospital (e.g. transplant patients are at higher risk than ambulatory patients) are also considered. All options are presented and every recommendation is transparent.

In summary, we have been leaders in the design and application of Legionella disinfection systems. We have acted mainly as researchers in academia. As consultants for hospitals requiring disinfection, we receive no financial incentive from any commercial manufacturers.

**Publications**

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**Appendix: VA Cases of hospital-acquired Legionnaires’ disease**

**Hospital-acquired cases**

**2012 5**

**2011 16**

**2010 0**

**2009 0**

**2008 0**

**2007 1**

**=====Victor Yu ousted and SPL closed===========**

**2006 0**

**2005 0**

**2004 0**

**2003 0**

**2002 0**

**2001 0**

**2000 0**

**1999 0**

**1998 0**

**1997 0**

**1996 0**

**Appendix: Credentials of Dr. Yu **

**Appendix: Reasons for Dr. Yu’s Ouster from the Pittsburgh VA**

The stated reason for Dr. Yu’s ouster by the VA was that he processed water specimens sent from hospitals or public health agencies concerned about Legionnaires’ disease after being ordered not to do so by the VA following the ill-advised order for closure of the SPL. Dr. Yu justified the processing by noting that the processing had already been initiated and these institutions relied on the Special Pathogens Laboratory (SPL) to assist them in solving an outbreak of a deadly disease. He noted the Hobson’s Choice in his reply to Mr. Moreland: follow his conscience as a physician vs. obey an order that he judged to be irrational and unjust. Ironically, one of the hospitals was a southwestern VA Medical Center. This VA Medical Center would subsequently express their gratitude to Dr. Yu and acknowledged that his firing was a result of his assistance in resolving their outbreak of Legionnaires’ disease.

After protests from the scientific community, his patients and members of Congress, Mr. Moreland asserted that:

1. Dr. Yu was conducting unapproved research on VA patients
2. Dr. Yu was providing laboratory testing to non-VA facilities and this was inappropriate.

Both of these assertions were false and documented to be false.

See website below for overview of closure of the SPL and ouster of Dr Victor Yu <http://www.legionella.org/vasplhome.asp>

1. Dr. Yu was conducting unapproved research on VA patients.

This claim was not only untrue but malicious. It is discussed at length in the 2008 Congressional Hearing before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, September 9, 2008. Serial no. 110-120. Biobanking: How the lack of a coherent policy allowed the VA to destroy an unreplaceable collection of Legionella samples, pages 416, 426-428.

The summary of the audited research claimed that “Dr. Yu had conducted human subjects research without prior IRB and R&D Committee approvals”. The auditor (Barbara Strelec) denied writing this summary. However, a sentence that she had written noted that Dr Yu’s studies were performed prior to HIPAA enactment and thus IRB and R&D approval were not required. This important sentence was removed from the document submitted to VACO without her knowledge. As the 2008 Congressional investigation noted, none of the VA administrators including Dr. A. Sonel, who signed the document, would admit to deleting this sentence.

2. Dr. Yu was providing laboratory testing to non-VA facilities and this was inappropriate.

See the Link below for a rebuttal of the untrue claims made by Michael Moreland in closing the SPL.

<http://www.legionella.org/vaspl/spl-FR.htm>

In 1996, the previous administration (Thomas Cappello, Director) and Chief, Laboratory Medicine and Pathology (Dr. Gurmukh Singh) established the Pittsburgh VA Special Pathogens Laboratory as a Special Clinical Resource Center Laboratory (M-2, Part VI, Chapter 11, March 1994) under VACO Guidelines. The Guidelines explicitly stated that work within the private sector was acceptable, since an objective was to obtain funds for VA use by exploiting the prestige of select laboratories within the VA system. Advertising to the community was proposed for this laboratory by the Pittsburgh VA administrators. We were instructed by the Pittsburgh VA financial officer (Ray Laughlin) that a Memorandum of Understanding or contracts was not required and we were instructed to use a fee-for-service system for billing

([http://www.legionella.org/vaspl/Attachment%208 %20SPLRef%20LabTestingServices1996Memos%20doc.pdf](http://www.legionella.org/vaspl/Attachment%208%20%20SPLRef%20LabTestingServices1996Memos%20doc.pdf))

Mr. Moreland testified under oath to my lawyer that had he known of this Guideline and approval by the prior Pittsburgh VA Director, he would not have closed the SPL. In fact, he was informed of this fact prior to closure and copy of the Special Clinical Resource Center Laboratory Guidelines had been submitted to an ABI initiated by him.

**Appendix: Publications of Legionnaires’ disease from Pittsburgh SPL**

**PUBLICATIONS ON LEGIONNAIRES’ DISEASE FROM INFECTIOUS DISEASE SECTION AND SPECIAL PATHOGENS LABORATORY, PITTSBURGH VA MEDICAL CENTER AND UNIVERSITY OF PITTSBURGH**

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