ANALYZING VA'S ACTIONS TO PREVENT LEGIONNAIRES' DISEASE IN PITTSBURGH

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON VETERANS' AFFAIRS
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ANALYZING VA'S ACTIONS TO PREVENT LEGIONNAIRES' DISEASE IN PITTSBURGH

Tuesday, February 5, 2013

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, D.C.

The Subcommittee met, pursuant to notice, at 9:59 a.m., in Room 334, Cannon House Office Building, Hon. Mike Coffman [Chairman of the Subcommittee] presiding.

Present: Representatives Coffman, Roe, Huelskamp, Benishek, Walorski, Kirkpatrick, Kuster, and Walz.

Also Present: Representatives Miller, Rothfus, Murphy, and Doyle.

OPENING STATEMENT OF CHAIRMAN COFFMAN

Mr. COFFMAN. Good morning. This hearing will come to order.

I want to welcome everyone to today's hearing titled Analyzing VA's Actions to Prevent Legionnaires' Disease in Pittsburgh.

I would also like to ask unanimous consent that several of our Pennsylvania colleagues be allowed to join us here on the dais to hear about an issue very specific to their constituents. Hearing no objection, so ordered.

Today's hearing is based on a recent outbreak of Legionnaires' Disease in the Pittsburgh VA Medical Center. At least 26 recent cases of Legionnaires' Disease have been associated with the Pittsburgh VAMC.

While VA has stated that eight of these cases were definitely not contracted at their hospital, it has also stated that it cannot determine whether 16 of these cases were contracted at the hospital.

VA contacted the CDC last fall to investigate the issue. The CDC's report just released on Friday not only determines that many veterans likely contracted Legionnaires' Disease through the Pittsburgh VA Healthcare System, but that tragically five veterans have died over the past two years from Legionnaires' Disease acquired at the hospital.

The CDC report paints a more complete picture and it turns out that problems originated much earlier than the VA has stated and are much more widespread.

While VA's public acknowledgment of Legionella bacteria in the water at Pittsburgh VAMC did not occur until November 2012, the Subcommittee in the course of its investigation uncovered a great deal of evidence that officials at the Pittsburgh VAMC were aware of the serious problems with their water sterilization system well before this time.

What is more, this outbreak was more than likely preventable. This event is rooted to the history of the special pathogens lab that at one time was a hallmark of the Pittsburgh VAMC and the flagship of Legionella research across the globe.

Its abrupt closure in 2006 under questionable circumstances was followed by a congressional hearing in 2008 that led to the exoneration of Dr. Stout and Dr. Yu, the lab's directors, and the admonition of VA.

But the loss of the special pathogens lab and the experts within it directly impacted VA on both a local and as well as on a national scale.

According to VA's own documents, the Legionella protocol in place at Pittsburgh from 1997 to 2006 resulted in no hospital acquired Legionnaires' Disease. This protocol mandated testing copper and silver levels and Legionella testing every other month. How is it that a successful system is now blamed for the problems in Pittsburgh?

VA also tells us that Legionella is a national problem. I agree that there should be a more comprehensive program with a single focal point.

However, VA provided documents to the Subcommittee stating that as of December 17, 2012, there have been only five Legionella cases across the entire VA health care system and all five cases were community acquired.

Even basic news reports tell us that these numbers are far from accurate. Does VA even know how many cases of Legionnaires' Disease exist in its patients and where they could have originated?

The recent CDC report indicates VA either has no idea or is deliberately downplaying what actually happened. The deaths of five veterans and the many other cases of Legionnaires' Disease are nothing to be downplayed.

I understand that different agencies have different protocols for preventing and responding to Legionella bacteria. It is my wish that today's discussion and the recent outbreak in Pittsburgh can provide an opportunity for appropriate agencies to put forth a unified effort to establish a national framework on addressing Legionella.

From that framework, local protocols can be put in place so that a local facility can respond appropriately. The Subcommittee is not advocating for any one method of Legionella treatment, just that whatever proven system is put in place be used correctly regardless of the method.

What happened in Pittsburgh could have been prevented and veterans have unnecessarily paid the price.

I look forward to a thoughtful discussion today on what VA officials knew about Legionella in the water at Pittsburgh VAMC, when they knew it, and what actions they took to address this serious problem in a responsible and timely manner.

However, I am disappointed that, despite several requests to VA from the Subcommittee, no one from the Pittsburgh VAMC who was there during the incident is here to deliver firsthand knowledge of events.

Hopefully the witnesses that are here today can at the very least recommit to the Department following its own protocols and holding accountable those employees who fail to do so.

I now yield to the Ranking Member for her opening statement.

[THE PREPARED STATEMENT OF CHAIRMAN COFFMAN APPEARS IN THE APPENDIX]

OPENING STATEMENT OF HON. ANN KIRKPATRICK

Ms. KIRKPATRICK. Thank you, Mr. Chairman.

Because they have already paid the price, we must fight for our veterans with all our might. Today this Subcommittee will examine the sufficiency and efficacy of the Veterans Health Administration's policies and protocols on the prevention of Legionnaires' Disease.

We will also scrutinize the actions and follow-up measures that the Department of Veterans Affairs took once it learned of the outbreak.

In December 2012, we were informed by the VA that there had been an outbreak of Legionnaires' Disease at the VA Pittsburgh Healthcare System. VA had identified a total of 29 cases of veterans with Legionella pneumonia with five of those cases having originated in the hospital. I am sad to say that five patients have since died.

Legionnaires' is a deadly disease. I am sure everyone here would agree that we must ensure every precaution is taken to mitigate the risk of exposure both for the veteran patients and employees.

It is my understanding that the VA Office of Inspector General is not only reviewing the VA Pittsburgh Healthcare System, but they have also begun a national review of Legionnaires' Disease at Veterans Health Administration facilities. I look forward to reading both reports.

Because of this unfortunate outbreak, our attention has been drawn to really focus on the sufficiency of the policies, protocols, and guidelines that are available to the VA medical facilities about the prevention of Legionella.

In a recently released trip report on the Pittsburgh facilities, the Centers for Disease Control reported that Pittsburgh had a large number of health care associated Legionnaires' Disease cases during 2011 and 2012 and widespread Legionella in the hospital's potable water system.

I understand that Pittsburgh VA was recognized as the leader in Legionella research and was considered a model for control and prevention, even providing Legionella services for VA facilities nationwide. Indeed, they had no hospital acquired cases from 1997 to 2006.

In testimony, Dr. Stout, who established the program at Pittsburgh, attributes the recent outbreaks to inadequate Legionella testing of the water and inadequate monitoring for ionization levels.

I am troubled by this. If it turns out to be true, that means that the current outbreak could have been avoided had someone done their job properly.

Further, it begs the question when did Pittsburgh actually learn of Legionella in the water, what steps did they take to mitigate it,

did Pittsburgh alert the National Office of the Legionella in the water, why were patients and VA employees not notified earlier that a problem may have existed? Looking back, were the decisions that were made rational responses to a developing crisis?

Finally, I would hope by the end of this hearing to come to a better understanding of what actually happened, when it happened, where failures occurred, and how we can fix it.

With that, Mr. Chairman, I yield back.

Mr. COFFMAN. Thank you, Ranking Member Kirkpatrick.

I ask that all Members waive their opening remarks as per Committee's custom. However, I understand that one of our visiting colleagues, Congressman Doyle, is going to have to depart early, and since his constituents are directly impacted, I will yield five minutes to him for opening remarks.

Mr. Doyle.

OPENING STATEMENT OF HON. MIKE DOYLE

Mr. DOYLE. Thank you, Mr. Chairman.

And I want to thank you and Ranking Member Kirkpatrick for allowing me to address the Subcommittee and today's witnesses.

I served on this Committee for six years. The Veterans' Affairs Committee is a great Committee.

As many of you know, I represent the city of Pittsburgh and the events in the last several months have been of great concern to our community, myself included.

As disturbing reports about the Legionella outbreak at the Pittsburgh VA began to break in the local media late last year, I, along with my colleague and friend, Tim Murphy, contacted the Veterans' Affairs Committee to request a hearing. And I am extremely thankful to the Committee's swift action on this issue.

I want to start off by saying that in the 18 years that I have represented Pittsburgh in Congress, the Pittsburgh VA has been an asset to my community and my constituents. The VA, its doctors, its nurses, its volunteers serve our veterans with top-of-the-line care.

I frequently speak to veterans in my district and I constantly hear great stories from them about the care they receive at Pittsburgh VA. And as our soldiers return from tours abroad, providing the best care to those who have served our country has never been more critical.

My father was a hundred percent service-connected disabled vet who received excellent care at Pittsburgh VA in the 1950s and 1960s, so we know firsthand as a family about the good care that comes from Pittsburgh VA. And I am proud to represent the facility.

But having said that, we are all here today with the same goal, to get to the bottom of a very clear failure of water testing and treatment at Pittsburgh VA. This tragic incident resulted in the death of at least one veteran and possibly four more at VA. This is simply unacceptable.

It is my hope that today we can start getting some of the much needed answers. It is critical that Pittsburgh VA clarify both for this Committee and the victims' families, some of whom are here, exactly what happened.

The questions must be answered. When did the VA know that there were unacceptable levels of Legionella bacteria in the water? What did they do about it once they knew? And was that response appropriate? And perhaps more importantly, was this an isolated incident or does VA need to develop and mandate better standards for testing and treatment of water at its facilities across the country?

I think these are relatively simple questions that we need answers to. It is my hope that not only do we leave here today with a greater understanding of the events as they occurred, but also with a plan to move forward.

This tragic series of events makes clear that we need a better set of best practices when dealing with Legionella. Clearly this is a regionally significant issue for southwestern Pennsylvania, and I hope that this Committee and the testimony of these witnesses will help us move forward with a protocol to prevent future outbreaks in my region and across the country if it turns out that this is not an isolated incident.

Mr. Chairman, I apologize that my duties on Energy and Commerce require me to be at a hearing which has started also at ten o'clock, but I know that my colleague, Tim Murphy, is here to ask questions on both of our behalf. My staff will be staying here for the entire hearing. I look forward to finding out what we learn here today and reviewing what the Subcommittee learns.

And I want to just close by once again, Mr. Chairman, thank you and the Ranking Member for agreeing to hold this critical oversight and investigation hearing and allowing me the privilege to once again address the Veterans' Affairs Committee.

Thank you very much.

Mr. COFFMAN. Thank you, Congressman Doyle.

With that, I invite the first panel to the witness table. On this panel, we will hear from Dr. Robert Jesse, Principal Deputy Under Secretary for Health at the Department of Veterans Affairs.

Dr. Jesse is accompanied by Mr. Mike Moreland, Network Director for VISN 4, and Dr. Gary Roselle, Chief of Medical Service and Program Director for Infectious Diseases at the Department of Veterans Affairs.

We will also hear from Dr. Lauri Hicks, Medical Epidemiologist at the National Center for Immunization and Respiratory Diseases with the Centers for Disease Control and Prevention.

Both of your complete written statements will be made part of the hearing record.

Dr. Jesse, you are now recognized for five minutes.

STATEMENTS OF ROBERT JESSE, PRINCIPAL DEPUTY UNDER SECRETARY FOR HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS ACCOMPANIED BY MIKE MORELAND, NETWORK DIRECTOR, VISN 4, U.S. DEPARTMENT OF VETERANS AFFAIRS, AND GARY ROSELLE, CHIEF, MEDICAL SERVICE PROGRAM DIRECTOR, INFECTIOUS DISEASES, U.S. DEPARTMENT OF VETERANS AFFAIRS; LAURI HICKS, MEDICAL EPIDEMIOLOGIST, NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION

STATEMENT OF ROBERT JESSE

Dr. JESSE. Thank you, sir.

Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Subcommittee, and I would add Members representing constituents in the Pittsburgh area, thank you for the opportunity to speak to you today about the causes of Legionnaires' Disease identified at the Department of Veterans Affairs Pittsburgh Healthcare System.

I am accompanied, as mentioned, by Mr. Michael Moreland, who is the Director of the VISN Integrated Service Network 4, and Dr. Gary Roselle, the National Director for VA's Infectious Disease Program.

VA takes the prevention of Legionella serious and has partnered nationally and locally to understand and control Legionella related illnesses.

The current situation in Pittsburgh is complex and not fully understood. But regardless, we express our deepest regrets to the affected patients and we pledge that we will do whatever is necessary to implement corrective actions that might prevent this from happening again.

Legionnaires' Disease is a form of pneumonia caused by the bacteria Legionella commonly found in water sources. It is typically associated with the water supply building since warm water is most conductive to bacterial growth.

Individuals become ill after inhalation of water droplets containing Legionella usually within two to 14 days after exposure. It is important to note that Legionella is not contagious. The bacteria is not transmitted from person to person.

Controlling Legionella in water distribution systems requires active surveillance of both the environment and of clinical infections and is balancing the risk of bacterial growth with the potential for scalding by hot water.

To mitigate the latter, VA Pittsburgh has a copper- silver-ion system to further suppress Legionella growth to maintain a lower hot water temperature and prevent scalding.

Pittsburgh routinely tests water for the presence of Legionella, and over the spring and summer of 2012 performed remediation protocols to the water systems because of positive findings.

Despite this remediation from August of 2012 through September, they identified patients with pneumonia who tested positive for Legionella who might have become infected while receiving care.

Pittsburgh retested its water system again and the presence of Legionella was again confirmed and the system was again remediated.

Additionally, Pittsburgh worked through the local and state public health authorities to engage the Centers for Disease Control and Prevention, CDC, and request gene typing to compare the Legionella from these patients with the environmental samples. The testing results that showed a relationship became available October 31st and Pittsburgh requested assistance from the CDC.

A team comprised of staff from Pennsylvania Department of Health, the Allegheny Health Department, and CDC arrived at Pittsburgh on November 7th, 2012. Based on their findings, CDC recommended immediate remediation of the potable water system and Pittsburgh promptly implemented an aggressive multi-phase remediation effort including again super heating the water supply to 167 to 170 degrees followed by hyper-chlorination of the hot water distribution system.

For safety reasons, Pittsburgh restricted patients' exposure to potable water until testing results indicated that Legionella mitigation was completed. These restrictions were lifted at the University Drive campus on November 30th and the Heinz campus on December the 7th.

Pittsburgh will continue to test the water at various locations in the distribution system every two weeks per CDC recommendations.

Pittsburgh also took its existing copper-silver ionization system off-line and to assure that patient care remained uninterrupted temporarily installed a continuous chlorine drip to maintain control of Legionella levels until a long-term definitive plan is implemented.

VA recognized the need for transparency and an incident command and call center was activated to communicate news and updates to veterans, staff, and family members.

Additionally, Pittsburgh attempted to contact all known veterans diagnosed with Legionella but whose sources of infection was unknown to offer those individuals testing of their home water systems.

In response to Legionella cases, the Pittsburgh VA has implemented a number of system-wide control strategies including the reemphasizing with all networks and medical center directors the requirements regarding Legionella prevention.

The under secretary for Health has directed site visits by VA's medical inspector starting with those having transplant programs being the centers at highest risk.

Currently, VA is updating its directives regarding Legionella which will incorporate the lessons learned from the activities going on in Pittsburgh now, new scientific evidence, recommendations from the CDC, and current industry standards.

This is a very complex issue and we greatly appreciate the support of the CDC, Allegheny County, the State of Pennsylvania, the Joint Commission, and others who have visited with us.

The assistance helped us validate that we have taken the necessary steps to effectively reduce Legionella to ensure safety and protection of our patients at all facilities.

We are committed to the prevention of Legionella infection and we will continue to update our practices as well as seek expert consultation and analysis to provide the best care for veterans.

I thank the Committee for the opportunity to appear before you today to discuss this important issue, and my colleagues and I are ready to address your questions. Thank you.

[THE PREPARED STATEMENT OF ROBERT JESSE APPEARS IN THE APPENDIX]

Mr. COFFMAN. Dr. Hicks, you are now recognized for five minutes.

STATEMENT OF LAURI HICKS

Dr. HICKS. Good morning, Mr. Chairman and other distinguished Members of the Committee.

My name is Lauri Hicks and I am a medical officer at the Centers for Disease Control and Prevention within the Department of Health and Human Services.

Thank you for this opportunity to speak to you today about CDC's investigation into the Legionnaires' Disease outbreak at the VA Pittsburgh Healthcare System or VAPHS.

I want to extend my deepest sympathies to the patients and their families affected by this outbreak.

I will provide background on Legionnaires' Disease, CDC's role in responding to outbreaks, details regarding the findings of the investigation, and our recommendations.

Legionella bacteria are often implicated in outbreaks associated with building water systems. Exposure to Legionella occurs when a person inhales water droplets containing the bacteria. Most people who are exposed do not get sick. Persons with underlying lung disease, a history of smoking, and immune suppression are at higher risk.

Legionella causes a severe form of pneumonia called Legionnaires' Disease. While treatable with antibiotics, five to 15 percent of patients die.

The CDC's Legionnaires' Disease Program supports public health partners and hospitals by providing assistance through consultations and field investigations or Epi-Aids. And these are conducted with the goal of controlling and preventing outbreaks.

On October 12th, CDC received two isolates from the Pennsylvania Bureau of Laboratories obtained from VAPHS patients who had Legionnaires' Disease and one environmental isolate from the hospital.

On October 29th, CDC reported preliminary results indicating a link between the two patients and the hospital. The Pennsylvania Department of Health requested an Epi-Aid.

With the agreement of VAPHS on November 6th, CDC sent a team to Pittsburgh. The field investigation began on November 7th and the last member of our field team left on November 16th.

The objectives of our investigation were to identify and characterize cases of Legionnaires' Disease, complete an environmental investigation, and recommendation interventions to prevent ongoing disease transmission.

We conducted case finding by searching medical and public health records for cases of Legionnaires' Disease at VAPHS in 2011 and 2012. We identified five definitely and 16 probably health care associated cases for a total of 21 cases. Five patients died.

The 16 probable cases were among patients who were only in the hospital for part of their exposure period which means they could have been exposed somewhere else.

Our environmental investigation revealed that 29 of 44 samples collected from the hospital water system grew Legionella. The outbreak strain was widespread.

VAPHS used copper-silver ionization to disinfect its water system. We measured copper and silver ions in 11 samples and found that mean copper and silver levels were within the manufacturer's recommended ranges. All 11 samples showed growth of Legionella and nine were positive for the outbreak strain indicating that the copper-silver ionization system was not controlling Legionella growth at the time of our investigation.

In summary, the CDC investigation identified an outbreak of health care associated Legionnaires' Disease during 2011 and 2012. The outbreak occurred in the setting of a Legionella risk reduction program consistent with the national Veterans Health Administration and the local health department guidelines.

Factors contributing to this outbreak included, one, persistence of a dangerous strain of Legionella in the water despite copper-silver ionization.

Two, reliance upon the VHA directive action thresholds. Cases occurred despite Legionella levels in the water system that were below the action threshold. CDC guidelines recommend eradication of Legionella from the water as there is no known safe level.

Three, construction on hospital campus likely reduced incoming chlorine in the water, thus promoting Legionella growth.

And, four, the hospital believed that their Legionnaires' Disease cases were not health care associated.

CDC made recommendations to VAPHS to stop disease transmission including super-heating and hyper-chlorinating the building water system. They also recommended limiting patient exposure to the water and enhancing their Legionella risk reduction program.

The hospital was very cooperative and immediately implemented our recommendations to protect patients. The steps taken by the hospital were successful and no further cases of health care associated Legionnaires' Disease have been detected.

CDC will continue to provide support to VAPHS on an as-needed basis.

Thank you, and I am happy to answer your questions.

[THE PREPARED STATEMENT OF LAURI HICKS APPEARS IN THE APPENDIX]

Mr. COFFMAN. Mr. Moreland, were you aware that Legionella was identified in the facility over the Labor Day weekend in September 2012?

Mr. MORELAND. Yes, sir. When I look at the data for the water sample testing over multiple years, it is not uncommon to find Legionella in the water.

What is required then is that immediate response to that occurrence of the Legionella in the water which includes heat and flushing and also going to the areas where you find it and chlorine washing and cleaning it.

And over the years, we have had samples that have positive, we have taken that action.

Mr. COFFMAN. Mr. Moreland, did you know that your employees were caught falsifying copper level data in December 2011?

Mr. MORELAND. I am not aware of anyone falsifying data about the copper-silver levels.

Mr. COFFMAN. Mr. Moreland, between June 2011 and September 2011, VA Pittsburgh had at least two Legionella incidents.

Did VA issue any written alerts to physicians, staff, or patients so that they could protect themselves and the patients?

Mr. MORELAND. Over the course of many years, we have had situations where we had Legionella identified in the water and took remediation action.

We have had anywhere between two and eight diagnosed Legionella cases pretty much every year going back as far as I can find the data back to 2000——

Mr. COFFMAN. Please answer the question.

Mr. MORELAND. And——

Mr. COFFMAN. Would you like me to repeat the question?

Mr. MORELAND. Yes, please.

Mr. COFFMAN. Okay. Between June 2011 and September 2011, VA Pittsburgh had at least two Legionella incidents.

Did VA issue any written alerts to physicians, staff, or patients so that they could protect themselves and the patients?

Mr. MORELAND. There was no written alert at that time.

Mr. COFFMAN. Dr. Hicks, the Pittsburgh VA microbiology laboratory is CDC certified for Legionella environmental testing, yet it failed to detect Legionella during routine testing and used out-of-date methods.

How is it possible that a lab with a CDC ELITE certification could fail so miserably and yet retain CDC certification? If this can happen, what is the value of the ELITE certification?

Dr. HICKS. Thank you, Mr. Chairman.

Actually, during our investigation when we reviewed reports of the laboratory testing that had been done on the environment, we actually found that the lab was quite capable of detecting Legionella in the environment. And they repeatedly detected Legionella in the environment.

So I am not sure why there is a perception that Legionellae were not being detected. They were. They routinely tested their water for Legionella and they routinely found Legionella.

And it is my impression that the volumes they were collecting were somewhat smaller than what CDC recommends. So CDC recommends collecting a liter volume sample as opposed to a 100 milliliter sample which was what the VA was using at the time.

What we did when we arrived on-site is we actually compared our results. We sampled in tandem. We had the infection prevention folks sample along with us. And they used a liter water sample and we used a liter water sample. And their lab was quite capable of detecting Legionella throughout the system.

So they have always been able to detect Legionella. And I am a little perplexed as to why there is a perception that they were not detecting Legionella. They were finding Legionella. It was just below the action threshold that they usually use for taking action.

Mr. COFFMAN. But is it correct that no amount of Legionella is positive?

Dr. HICKS. So CDC recommends that when you find Legionella in a water system that you do everything possible to eradicate it because we know of no known safe level of Legionella.

However, in the VHA directive and in several published reports recommend using a 30 percent threshold. That means a threshold of 30 percent of sites positive in order to initiate action.

And so I think what happened here is that folks on the ground felt like they had a false sense of security because they were receiving test results back. They knew they had Legionella, but their levels of Legionella were typically below 30 percent and below that action threshold recommended to take widespread action to remove Legionella from the system.

I think it is really important to note that we compared an old strain from 1982, actually a couple of old strains from 1982 to strains from this outbreak in 2012 and what we found is that old strain was almost the same strain from 1982 all the way to 2012.

So it indicates that in the system, there has been a persistent outbreak strain that has never been eradicated.

Mr. COFFMAN. Ranking Member Kirkpatrick.

Ms. KIRKPATRICK. Thank you, Mr. Chairman.

Thank you for your testimony today.

Many of you know that I have a background as a hospital attorney and so this is, a very serious concern of mine.

Dr. Jesse, I want to start with you. In your written testimony, you say there has been a 217 percent increase in Legionella from 2000 to 2009.

To what do you attribute that?

Dr. JESSE. That actually is data from the CDC. It is national data about the incidence of Legionella in this country.

Now, it is important to note that over that time, the sensitivity, the capability to test for Legionella has improved and, frankly, the sensitivity, the awareness of the need for testing, I think, has become more common.

Ms. KIRKPATRICK. So you just attribute that not to more cases but increased surveillance?

Dr. JESSE. Well, it may be more cases, but Legionella historically is, at least the perception is that it is under reported because if you do not test for it, you do not see it. It is particularly difficult to grow.

As was mentioned, there is a certification for labs that actually do culture it. There is a urine test that one can look for a urinary antigen for Legionella. But in many instances, patients show up with respiratory symptoms and they are simply put on antibiotics. And it is not necessarily followed through.

And it has been a practice at Pittsburgh to pretty aggressively test patients for Legionella because we know that is a problem there.

Ms. KIRKPATRICK. Dr. Jesse again, would you explain the hierarchy of the personnel who are responsible at the facility level for maintaining the system to keep the growth of Legionella under control? So can you just explain from the bottom up how that is reported and who is responsible?

Dr. JESSE. If it is okay with you, I would defer that to Mr. Moreland.

Ms. KIRKPATRICK. That is fine.

Dr. JESSE. Okay.

Ms. KIRKPATRICK. Mr. Moreland.

Mr. MORELAND. Yes, ma'am. The system of control for Legionella, as the CDC said, at Pittsburgh is very comprehensive. And so you have the engineering department who is looking at the water and managing the water.

Then you have a group of infectious disease professionals who are reviewing the copper-silver ionization levels. They are reviewing the water samples and they are looking at that. So that is their surveillance of the environment.

And then you also have the infectious disease docs looking at the incidence of Legionella diagnosed pneumonia.

So it starts with there is an engineering group and the infectious disease group. They meet as a committee in a group.

So the next level is a committee of infectious disease. And on that committee you have clinical professionals and the engineering group and they talk about this at every meeting every other month all through the year.

They feed that information to the clinical administrative group which is chaired by our chief medical officer at the hospital and they review that data at the Executive Clinical Leadership Board. And ultimately that is passed to the hospital director who oversees the entire operation.

And then finally, it comes to me as the VISN director who is overseeing the system across the ten VA hospitals in VISN 4.

Ms. KIRKPATRICK. How often do you get those reports?

Mr. MORELAND. I generally do not see the reports unless there is an issue. And so when the medical center director identifies that there is a concern, then they inform me. And I get those kind of reports when there is an issue of concern.

Ms. KIRKPATRICK. When did you first receive the report on this facility?

Mr. MORELAND. Yeah. The first time that I heard about a concern at VA Pittsburgh was in the fall of 2011. And in that fall of 2011, there were several diagnosed cases not confirmed as hospital acquired but several diagnosed cases.

And at that time, the VA Pittsburgh sat down and did a very structured situational review, what was going on, what happened. They made some changes to the system. And rather than rely on the 30 percent rule, for example, they decided if we find Legionella anywhere, we will do a heat and flush. So they made some changes to that.

They made some changes to their preventative maintenance of the copper-silver ionization system stepping up and above and beyond what the manufacturer guidelines were. They called in the manufacturers to say let's talk about this and how does this work

and make sure that they knew what was happening. And they made some changes to that.

And the clinical group on the infectious disease stepped up their work. For five months after that, we had no cases. The assumption was the actions that we took care of the issue.

And so it was not then until months later that we again saw some cases and this time when it happened, the infectious disease professionals came to the chief of staff, that next level, came to the hospital director, came to me and said we see this happening again, we are surprised. We think we need some help.

And that is when we initiated our actions to go to the CDC and say come help us, we want to make sure we are on top of this.

Ms. KIRKPATRICK. Would it have been possible at any time just to change your water system, for instance, bring in bottled water or something just to make sure that it was not spreading to the patients?

Mr. MORELAND. And this is where, you know, when you look at data in a 12-month window, you only see 12 months. This is pretty typical what happens over going back to at least 2003 when I have looked at the data. And so it is not unusual to have water in the—have Legionella in the water and then you remediate and you move forward and you do not see cases.

That is kind of what happened. We did have a hospital acquired case in 2005. We did have a hospital acquired case in 2007. The difference in this episode is that we had three cases in the fall. And that is why I think the hospital director called me and I said absolutely call the CDC because it was something different and unusual. And so a different response was required and that is why we called the help chain.

Ms. KIRKPATRICK. I appreciate your answer, but I do not think you completely answered my question which is, why not use an alternate water source? Why not bring in bottled water or something else during that investigation stage?

Mr. MORELAND. Yeah. You know, when you look back, that might have been something to consider. But, you know, at the time, the professionals that we were dealing with, the infectious disease docs, we did not think that it was at a level of danger to be worried.

Remember, it is not the drinking of the water. It is the inhalation of the fumes, of the droplets. And so you can drink the water and it is not an issue. The problem is when you breathe it and inhale the droplets. So that is why that.

But the reason we used bottled water was actually because we were hyper-chlorinating the water. It was not about the Legionella. It was about the hyper-chlorination.

Ms. KIRKPATRICK. What efforts were made to notify the providers that this was an issue?

Mr. MORELAND. Well, when we finally confirmed that there was hospital acquired cases, not only did we inform the providers, but we went on the Internet and put it on the hospital's Web page. We issued a fact sheet. The hospital director called each of the union presidents to talk to them to make sure they knew what was going on. We sent out an all employee news blast.

You know, it happened once we had confirmed and knew that we had a real problem and that was November the 14th, I think, when CDC gave us the final report that confirmed that there was really a problem.

Ms. KIRKPATRICK. Thank you.

I may have additional questions, but I will submit those in writing. Thank you.

Thank you, Mr. Chairman.

Mr. COFFMAN. Dr. Roe.

Mr. ROE. Thank you, Mr. Chairman.

First, I want to complain a little bit about getting written testimony on a Monday night. I have seen this happen over and over again and it is very frustrating for me. I actually read these things. And I cannot read them if I do not get them.

So I almost did not come to this hearing because there is no point in me being here and wasting my time if I have not had a chance to prepare. So that is just a bit of frustration.

Number two, Saturday I went to a basketball game in Johnson City, Tennessee where we have a VA. And I presented basketballs to five wounded warriors there at halftime. And a soldier expects to be at risk when they are on the battlefield. They do not expect to be at risk when at a VA hospital. We expect to be at risk for our lives then, but we are there to help them at the VA.

And I see some real shortcomings here and I have several questions I would like to ask.

And, Dr. Hicks, you said that the VA was complacent. And I know you have had a system. When you said that same strain of Legionella had been there since 1982, they obviously had a system from many years where no cases of Legionella were detected.

So I think in just listening to this testimony, I do not know, it sounds like that you may have had a sampling error. I did not realize you used a 30 percent, 30 percent of the disks had to be positive for you to consider there to be a problem.

And when you only test this much volume versus that much volume, when there is not much bacteria in there to start with, that may have—do you think that is the reason why or why did they become complacent? Was it the ten years or so of no cases? And whatever they were doing, they obviously were doing it correctly.

Dr. HICKS. Yeah. It is my perception that they had a false sense of security. They were under the impression that they had Legionella control in the environment because they had a copper-silver ionization system in place.

And when we were on-site, we measured those levels. Those levels were adequate. And we looked at the maintenance of the system while we were on-site and at the——

Mr. ROE. Let me stop you there. And obviously you are the expert here.

Dr. HICKS. Uh-huh.

Mr. ROE. Is that a bad system? I mean, it worked for ten years——

Dr. HICKS. Yeah. I——

Mr. ROE.—with no cases. And so now you say the levels are all fine. That gives me a very bad feeling because then what metric do I use?

Dr. HICKS. I think that is a question that we would like to look into more. We have not had many opportunities to really evaluate the system. This was actually our first field investigation into an outbreak where there was a copper-silver system.

But we do receive over 200 consultations each year related to Legionella. Many of them are related to troubles controlling Legionella in the environment and many of those are related to concerns about copper-silver——

Mr. ROE. Here is where I think the antenna should have been up. And when you are in a big system seeing a lot of people and incidence of something is so small, I understand that, but an outbreak is defined as two or more cases.

Dr. HICKS. Uh-huh.

Mr. ROE. That is all. And the same bug and the same environment, that happened and that was the antennas apparently did not go up.

Dr. HICKS. Uh-huh.

Mr. ROE. So why do you think that was?

Dr. HICKS. It goes back to the perception that they were doing everything they could to control Legionella in the environment. And when they were testing their water, they found levels that were below the 30 percent threshold that calls for action.

Mr. ROE. And I do not want to delve on this too long, but have other VAs, have you seen this elsewhere because if it is, then you have got a system that does not work?

Dr. HICKS. In terms of the copper-silver system?

Mr. ROE. Yeah.

Dr. HICKS. I have not personally done a field investigation into copper-silver system ionization, but we have received anecdotal reports from other facilities that have also had trouble with it, yes.

Mr. ROE. Well, then I think that is a metric that needs to be looked at certainly if that is the case.

I think one of the things that also, and this is not in any of the testimony because I did not get it, but I was reading a news report, and Dr. Murphy may have some more information on this, but one of the family members was asked to go home and test their water.

Dr. HICKS. Uh-huh.

Mr. ROE. And I think that that family member felt like that they may have caused the—and that was very wrong to do that when you knew you had an outbreak right there in your own shop. I do not understand that. And, I mean, that is now putting the blame on me that I did something to my dad to cause his death. And that is not the case at all it turned out.

Dr. HICKS. Yeah. I mean, I think it is very——

Mr. ROE. You mentioned that early.

Dr. HICKS. Yeah.

Mr. ROE. And I think we do owe these families an apology. And I know that people were trying. I mean, I understand that. I am not here—people—I mean, good, smart people were out there trying to do that.

Dr. Jesse, why aren't the people who were involved in actually doing that here? Why are you here? I mean, because if I had a problem in the operating room, I would want to talk to the surgeon who did the surgery.

Dr. JESSE. Well, sir, I am here in my role as a principal deputy under secretary having oversight over——

Mr. ROE. I think that is fine.

Dr. JESSE.—the system. There was——

Mr. ROE. And I appreciate you being here, but my question is, where are the people who actually were involved in doing this? They should be the ones who are here.

Dr. JESSE. Well, there is a huge team of people that are involved in this. It is the building engineers, as you have heard. It is the——

Mr. ROE. You can—you can——

Dr. JESSE.—infection control folks. It is the hospital staff.

Mr. ROE. Dr. Jesse, when I go to the operating room, there are huge numbers of people there, too, but I know who is responsible, me.

Dr. JESSE. Right.

Mr. ROE. It is not the scrub nurse, the anesthesiologist, and all those other people. There is somebody that is responsible at the top. That is who should be sitting here.

I yield back.

Mr. COFFMAN. Mr. Walz.

Mr. WALZ. Well, thank you, Mr. Chairman.

And, first of all, congratulations to you and your Chairmanship, and to the Ranking Member. I appreciate the work you do.

Mr. COFFMAN. Thank you, Sergeant Major.

Mr. WALZ. I would also like to comment on the very proud work and I think from institutional knowledge of this Committee several years ago, Dr. Roe under his leadership initiated a very similar hearing on contamination of medical instruments, of colonoscopy scopes, for example, which led to not only best practices and changes in that, but it went systemwide throughout the country as a best practice.

So I appreciate the spirit that this is being held and trying to figure that part of it out.

Dr. Hicks, could you explain to me how the protocols at the VA compare to their civilian counterparts in the region and maybe nationally? I understand this is more of a geographic issue to a certain degree, but could you explain to me, is there a difference there or is there a uniform protocol?

Dr. HICKS. Okay. There is a VHA directive that has been in place since 2008, I believe, and we also have a CDC guideline for prevention of health care associated Legionnaires' Disease. And there are some differences.

One thing I would mention before I get into the differences is that most health systems in this country do not have a prevention plan at all. And so I think it is important to recognize that the VA is ahead of the game because they do have a prevention plan. They do require that hospitals have a written prevention plan and all their hospitals have to comply with this.

This hospital had a plan, but it goes to show you that policies are not necessarily full proof. And so in this situation, we looked at the VHA directive and we compared the directive to our policies. And there are some areas where we would recommend some

changes and we are going to be looking forward to working with the VHA colleagues to make those changes.

The one area that I think is probably most critical is this threshold, action threshold level. So throughout the directive, there is mention of an action threshold. And it implies that if your testing reveals that you are below 30 percent, then you will not have health care associated cases or you will not be at risk for health care associated cases.

And in our experience, that has not been the truth or not the case. We have actually investigated several outbreaks where we found fewer than 30 percent of sites colonized.

And, in fact, this situation perfectly illustrates why that policy does not work because the VA repeatedly detected fewer than 30 percent of sites colonized over and over again. So they thought that they had their Legionella problem under control.

So that was a big issue that I think we really need to work on together. The other issue has to do with the volume of sampling. And CDC typically uses a liter volume when we sample and that increases our ability to detect Legionella when we are doing an investigation.

Mr. WALZ. Was this an issue here that the sample size was too small?

Dr. HICKS. From what I can tell you, I do not think it made a big difference in the ability to detect Legionella in the long run. I do not think it plays a huge role in this particular outbreak because they were detecting Legionella even with the smaller volume.

Mr. WALZ. Then the question I was going to ask on this, I understand it is this issue of should we test for everything. You can do an X-ray for every single thing or whatever, but at some point the cost benefit analysis is reduced.

Is there a point where you have these areas especially in the northeast or whatever? About how much does it cost to test? What does it cost to test?

Dr. HICKS. Yeah. I cannot speak to the exact amount. I would be happy to get back to you on that. But it is expensive. And, of course, the larger volume you use, the more money it costs because it takes more money to ship the sample, so——

Mr. WALZ. Would it be just not wise to test all the time at these places? Would that be an unwise use of resources that would not detect or would not prevent?

Dr. HICKS. Yeah. I think that in a setting where you have decided to use testing as your measure for your effectiveness of your Legionella prevention plan, I mean, you do have to routinely test.

But I think it is important to note that testing is one parameter to measure, but there are many others that you can evaluate in addition to actually evaluating Legionella in the environment.

So things like temperature and your disinfection levels and pH and chlorine, so there are——

Mr. WALZ. This issue of hospital acquired infections and illnesses is far broader than this issue, right——

Dr. HICKS. It is very——

Mr. WALZ.—and all these come together?

Dr. HICKS. Right.

Mr. WALZ. Okay. Very good.

Dr. HICKS. This is very complex.

Mr. WALZ. My time is up. I would like to end by thanking all of you.

And the question was, why are you here, Dr. Jesse. I am glad you are here and I know it is public health. You are a public health expert and I think this gets into the broader question obviously, I think.

And I appreciate, Dr. Hicks, your concern. One patient infected that could have been prevented is one too many and it is very difficult to get to zero, but we have to strive for that. So I appreciate the spirit that you are taking that.

I yield back.

Mr. COFFMAN. Mr. Huelskamp.

Mr. HUELSKAMP. Thank you, Mr. Chairman. I appreciate the opportunity to ask a few questions this morning.

First, I had a follow-up with Dr. Hicks.

You mentioned 30 years of Legionella in this facility?

Dr. HICKS. Yes.

Mr. HUELSKAMP. Are there other cases CDC is aware of where you have 30 years of the same strain of Legionella?

Dr. HICKS. Well, we only conducted the investigation going back to 2011, so I cannot comment on cases prior to 2011. But I believe earlier in the testimony some folks mentioned that there had been other cases. So perhaps my VA colleagues can comment on that.

Mr. HUELSKAMP. And I will follow-up with them. I am just curious of what you knew elsewhere given your regimen.

Do you have a different standard or certification regimen if you have 30 years of persistent cases of the same strain or do you just treat them all the same across the board?

Dr. HICKS. Our approach to Legionella's prevention is if you find Legionella in the environment, especially in a place where there are vulnerable patients, you must try to get rid of it.

The policies that have been in place for very many years allowed for about 30 percent of sites to remain colonized. And these policies were carried forward over many decades.

And so what I think is really important here is to understand that there was a perception that if you have low levels of Legionella in your system that you will not see cases of Legionnaires' Disease. And that is just not true.

And when we tested——

Mr. HUELSKAMP. Yeah. Well, it is certainly not true in this case——

Dr. HICKS. Right.

Mr. HUELSKAMP.—after 30 years on and on.

Dr. HICKS. Right.

Mr. HUELSKAMP. And that would be a question if I could for Mr. Moreland.

How long have you been in your particular position?

Mr. MORELAND. I have been the network director since 2006.

Mr. HUELSKAMP. And so this whole time you knew there had been at that time 24 straight years of this persistent strain of Legionella in this particular facility?

Mr. MORELAND. When they are talking about that particular strain, they are talking about the genotyping for that specific

strain. And so not every case is necessarily from that specific genotype strain. But the strain that they found now, I think, matches six out of eight——

Dr. HICKS. Yeah.

Mr. MORELAND.—of the chromosomes, I guess it is, for that strain. So it is kind of a grand daddy of a grand daddy to that strain. So it is a very closely related strain, but that does not mean that there were not different strains of pathogenic Legionella that occurred on occasion across the years.

Mr. HUELSKAMP. And my question is, are you doing the same testing regimen in other facilities that do not have this 30-year case history? Did you treat this facility any differently?

It is my understanding elsewhere in VA, you—there is a facility, and I am not sure which one it is, actually does testing three times a week.

How often did you do testing in this particular facility?

Mr. MORELAND. The testing at the VA Pittsburgh historically has been every other month and that has been not just one test every other month but multiple tests of multiple distal sites in the water system during those months.

Now, since we have had this outbreak, we are doing it every two weeks and we will continue that until we have got a system where we believe it is stable.

There is a lot of activity if you would like to ask about, you know, what are we going to do, the way forward, and how are we going to change because, you know, we have looked at what we have done and the effectiveness of what and we have decided to move in a different direction and use a different system for control.

Mr. HUELSKAMP. And I appreciate that, Mr. Moreland. My concern, though, we have got the testing, one can argue that probably not enough testing, improper sample size. Also the question I have is remediation.

Mr. MORELAND. Right.

Mr. HUELSKAMP. And can you describe very briefly the remediation efforts since you arrived there in 2006, how often they were done and clearly they were insufficient? What would you have done differently and did it meet the CDC standards for necessary remediation?

Mr. MORELAND. Yeah. The testing was done and when we found positive samples, we did remediation. The remediation included——

Mr. HUELSKAMP. Only if it was over 30 percent?

Mr. MORELAND. Not necessarily. While that is the VA policy to, you know, to look at what level do you think, and it is not directed that you use the percent, but that is kind of what we had in your policy. However, we still did the remediation at lower levels.

And as I mentioned earlier, in 2011, they decided let's do remediation no matter what the level. And so for at least a year, we have been doing remediation every time we found some Legionella. The remediation——

Mr. HUELSKAMP. And you found Legionella every time you tested?

Mr. MORELAND. Not every time we tested.

Mr. HUELSKAMP. No, that is not what you said earlier. Every test you found some level of Legionella. Is that——

Mr. MORELAND. No.

Mr. HUELSKAMP.—incorrect——

Mr. MORELAND. No.

Mr. HUELSKAMP.—the earlier statement?

Mr. MORELAND. Not every test was positive. We did multiple tests. So we may have done 15 or 20 tests and maybe three or four of them showed positive or——

Mr. HUELSKAMP. Positive at the 30 percent level when you say a positive test?

Mr. MORELAND. There would be ten sites. You go out and you test all ten. And if there are one or two, that is less than 30 percent. However, we would remediate those two sites anyway.

Mr. HUELSKAMP. Even though it is in the same system, you mean?

Mr. MORELAND. Even though it is in the same system, yeah, because it is interesting. The Legionella can be in a dead leg of a pipe. It can be in the faucet. It does not have to be in the entire system.

Mr. HUELSKAMP. And I do not know where it is. All I know is we have deceased veterans and their families asking for answers here.

And my question is, you are now saying you have remediated every single time you found a sample with Legionella in it?

Dr. JESSE. If I may give a concrete example, following——

Mr. HUELSKAMP. No. I want a concrete answer. If you can provide it back to the Committee every time you did a remediation.

And has there been independent review of all the sampling? Who did the sampling for you?

Mr. MORELAND. The sampling of the Legionella water samples?

Mr. HUELSKAMP. Well, yeah. That is what we are talking about.

Mr. MORELAND. Yeah. Well——

Mr. HUELSKAMP. I do not know what else we would be talking about. Go ahead.

Mr. MORELAND.—there is a silver test as well. But for the Legionella test of the water, it was done by our lab in VA Pittsburgh which is a certified lab. And that lab continues to do testing for multiple hospitals across the VA.

Mr. HUELSKAMP. And they recommend the 30 percent level?

Mr. MORELAND. That recommendation of the 30 percent level is in the policy by the infectious disease group that is in our local VA policy. But despite that policy set, and it is also at the national policy level, despite that number, in 2011 when they wanted to make sure that they were doing above and beyond, they started doing heat and flushes and chlorine washing of the faucets every time at the site where they found a positive test.

Mr. HUELSKAMP. Okay. I appreciate that.

And I yield back my time. Look forward to a list of the remediation efforts tied to the testing results. Thank you.

Mr. COFFMAN. Thank you, Mr. Huelskamp.

Ms. Kuster.

Ms. KUSTER. Yes. Thank you very much, Chairman, and Ranking Minority, thank you.

I have a question to follow-up on this 30 percent because it seems as though that is where our attention is getting focused.

And I wanted to ask Dr. Jesse whether the VA has a plan to re-evaluate the existing guidelines and policies that might not have been adequate when it comes to preventing Legionella or the outbreak of Legionnaires' and would you consider a change in recommendations to lower that to a zero threshold or some number less than the 30 percent to address what Dr. Hicks has described as a false sense of security?

Dr. JESSE. Yeah. So the Legionella directive, the national Legionella directive is under revision now. They are completing their evidence review which will review all the published literature particularly that has been out since the last directive was put in place.

And as I said earlier, that directive will be informed by the lessons learned from Pittsburgh as well as the emerging scientific evidence, consultation with CDC and others. So I can assure you that there will be a change in that 30 percent threshold.

That directive was written in 2008 and it was informed by prior experience. And the experience across many years was that that appeared to be a safe level.

As Mr. Moreland said, in 2011, they changed, despite the national policy, it does not restrict you, but they said because of the issues here, we're going to remediate and at one point even finding one of 27 samples positive they did a remediation process.

Ms. KUSTER. Yeah. It just seems as though this is a much more persistent bug than had been earlier predicted.

And, Dr. Hicks, do you think that would be an appropriate change in policy that could hopefully—I mean, the purpose of this hearing is to protect future veterans and to spare their families.

And I want to agree with my colleague on the other side of the aisle that we understand our troops are going to be in harm's way, but when we get them home safely, our goal is obviously to keep them safe going forward.

Dr. HICKS. So I absolutely agree the VHA directive is wonderful because there is a policy in place intended to prevent Legionellosis. And this is a policy that has had great uptake, from what I understand, across the VA.

But I do think this is an opportunity to identify where we can make improvements so that we can protect this very vulnerable population.

Ms. KUSTER. And I just have one other question and that is with regard to the people that are working in this facility.

Have you had any instances of employees that have been stricken with Legionella or Legionella leading to Legionnaires' Disease? And also, what are the precautions that are being taken going forward because I could imagine this would be a stressful work environment?

Mr. MORELAND. When we sent out the notice on November the 14th or 15th to tell everybody that we had a concern, we advised every employee if you have any kind of respiratory concern, please come to employee health. We will provide tests and assistance with you.

We have had people come with respiratory concerns, but we have had no diagnosed Legionella of employees. The challenge is you have to get, you know, a clinical test to make sure it is diagnosed. And so there are concerns of a couple employees that had pneumonia, but they do not have a diagnosed Legionella diagnosis and that is a concern.

My understanding is that they filed a claim with the Department of Labor for workmen's comp and we certainly support their opportunity to file that claim and doing that.

In terms of the way forward in the water system, was that what you asked me?

Ms. KUSTER. Well, I am just thinking about precautions both for incoming patients but also particularly the people who are working there day in and day out, their exposure to an obviously very dangerous bug.

Mr. MORELAND. Yes, ma'am. I think the most important thing is to clear the system of the Legionella. And what we are in the process of doing now, in fact, just a week ago because since they started in November, we have been sitting down with experts, what do you do, how do you make things better, what we do in the way forward, and one of the main suggestions we have had is to raise the temperature in the pipes.

And as we talked earlier, one of the challenges is when you raise the temperature, you have got to be careful of scalding patients because I do not want to be back here talking about scalding patients.

Ms. KUSTER. Yes.

Mr. MORELAND. And so what we have done is we have purchased some scald protection faucets and showerheads that we have just let a contract on. They will start the installation of those.

Once those get into place, we can raise the temperature in the pipes to a much higher level and we believe that will add a higher level of suppression of Legionella. And then we will move forward with some consideration of other supplemental systems.

Ms. KUSTER. Thank you.

Mr. MORELAND. Thank you.

Mr. COFFMAN. Thank you, Ms. Kuster.

Chairman Miller.

Mr. MILLER. Thank you very much.

I want to thank Dr. Murphy and Mr. Doyle for bringing this personally to my attention.

But, Mr. Moreland, I have got a couple quick questions. Is it your testimony you say that this all started in November?

Mr. MORELAND. I said in November of 2011 that we had some concern and took remediation and then had five or six months of no concern. And then it returned again in the fall of this year and that is when we are in this current outbreak.

Mr. MILLER. And you allowed employees immediately once you found out that it was an issue again, that is when you told the employees to go ahead and report to you if they had any respiratory concerns?

Mr. MORELAND. Once we confirmed that there was a substantial outbreak in the water, yes, sir.

Mr. MILLER. How long did that take for you to confirm there was a substantial outbreak in the water?

Mr. MORELAND. When we got the final report from the CDC November the 14th of this year.

Mr. MILLER. Did you know any earlier than that before the final report?

Mr. MORELAND. Over the course of, and this is, I am sorry you missed, but over the course of years, we have had Legionella positive water testing.

Mr. MILLER. Oh, no. I have been here.

Mr. MORELAND. Oh.

Mr. MILLER. I apologize. I have been monitoring on the television as well.

Mr. MORELAND. Okay.

Mr. MILLER. Yeah. I am very well aware it has been in the system for a very, very long time.

Mr. MORELAND. Right. And then we have done remediation and cleared it and then done samples. And we have done that for years. So it was not really until we got the confirmed report from the CDC in November that we recognized that we had a very significant issue and took aggressive action for remediation.

Mr. MILLER. Did you suspect before you got the final report from CDC that you had a serious problem?

Mr. MORELAND. I think that what happened was in early September and into October, we had concern, but no confirmation.

Mr. MILLER. What did you do when you have had that concern? What action did you take?

Mr. MORELAND. We collected samples from the patient's clinical samples. We collected water samples, talked to Allegheny Health Department, got the information to them so we could get it to CDC, asked them to help us look at the situation. We did——

Mr. MILLER. And once that occurred——

Mr. MORELAND.—heat and flush of the water system.

Mr. MILLER. Once that occurred, who did you notify within the physician groups or the staff? I mean, did anybody know that this was happening?

Mr. MORELAND. The infectious disease group knew because they were the ones that were working with the local clinical people at the hospital.

Mr. MILLER. But the staff did not at the hospital——

Mr. MORELAND. We did not do a general——

Mr. MILLER.—the physicians did not——

Mr. MORELAND.—announcement to the staff, no.

Mr. MILLER. Because you just did not think that it was warranted until you had the final report from CDC or——

Mr. MORELAND. We had had these kind of concerns multiple times over years and done heat and flushes and had things resolve effectively. This time we were concerned and called CDC. And once we confirmed it——

Mr. MILLER. But wouldn't you want a physician to know? I mean, wouldn't physicians want to know that you had a concern that was so serious that you were bringing the Allegheny County Health Department? I just——

Mr. MORELAND. Well, certainly the chief of staff, the medical director of the hospital, the infectious disease community, we were working in an open environment talking about how to work——

Mr. MILLER. But, again, open environment to who? I guess my concern is——

Mr. MORELAND. Right.

Mr. MILLER.—if I had a suspicion that there was a—if I had had this for 20 years and I thought that there was a very large suspicion that it was more than what I had been coping with, I would have thought that I would have—but where did the 30 percent number come from? I mean, I know you were saying the group, the clinical group. But, I mean, is that a written policy? I am interested in knowing where the 30 percent comes from.

Dr. ROSELLE. Okay. I have heard a lot about 30 percent so far this morning and I think the 30 percent—first, let's talk about the directive because that is where the hospitals get their information from the VA.

And what it says specifically is the directive specifies that each facility set its own threshold and that is directive 2008–010, page 85. The directive then goes on to recommend 30 percent and that is because in the literature, 30 percent is noted as a risk level. It is consistent with Allegheny County and many other places. So——

Mr. MILLER. I mean, is the problem any less virulent in Florida than in—why would you give hospitals the ability to set their own levels?

Dr. ROSELLE. Oh, this was discussed at great length when this directive was written by the consensus group because there is no absolute data on the—while the CDC I agree with, it is impossible to know what a safe level is. Legionella is ubiquitous and it is very, very, very hard to eradicate.

So the literature is inconsistent now, even now about what those numbers mean which is why we gave enough flexibility to the facility to set their own threshold because they know their pipes, they know their system.

And, in fact, Pittsburgh did just that. When they considered that they had some issues, they remediated not with no regard to the 30 percent and did heat and flushes and all the things that we have been talking about.

So the flexibility is designed for the stations because there are a lot of hospitals with a lot of plumbing and yet the 30 percent is in the literature. So I think that everything that they did was consistent with the directive.

Now, should there be more rigor——

Dr. JESSE. To answer your question directly, yes, there is a difference between Pittsburgh, Florida, Arizona, California both in terms of the prevalence of the disease—the CDC will say that it is the mid-Atlantic, Pennsylvania, New York, New Jersey where it is the highest and other areas of the country it is significantly lower.

And the other issue is that I think the number is 25, but many of our facilities get their water from municipalities who treat their water with monochloramine which seems to be a way to get it to the tap without having to do anything intervening.

So it would not make sense to have a national policy that has a one-size-fits-all. The important thing is that every facility needs

to assess its risk of Legionella. It does that through surveillance of both the water supply and clinical cases and based on that builds its strategy.

Mr. MILLER. Thank you.

And thank you, Dr. Murphy, for allowing me to speak out of order.

Mr. COFFMAN. Dr. Murphy.

Mr. MURPHY. Thank you, Mr. Chairman, and thank you for holding this hearing.

So how often is the VA Pittsburgh required to test its water systems?

Mr. MORELAND. So the requirement is based on——

Mr. MURPHY. Just how often?

Mr. MORELAND. It would be absolutely required twice a year.

Mr. MURPHY. Twice a year.

Mr. MORELAND. And that would be——

Mr. MURPHY. Is every VA the same?

Mr. MORELAND. No.

Mr. MURPHY. Okay. So Pittsburgh is twice a year. Other VAs may be how often?

Mr. MORELAND. Other VAs may be not at all.

Mr. MURPHY. Okay. So this is based on——

Mr. MORELAND. But it is——

Mr. MURPHY. How about the CDC, how often does the CDC recommend hospitals test their systems?

Dr. HICKS. So in the setting where there are transplant patients, we recommend that a testing protocol——

Mr. MURPHY. Just number.

Dr. HICKS.—but there is no——

Mr. MURPHY. Once or twice a year? You do not have a protocol?

Dr. HICKS. No.

Mr. MURPHY. Now, for those who are not aware, the VA system in Pittsburgh is in the midst of the University of Pittsburgh campus across the street from the huge Peterson Event Center where we have our basketball games, a block away or across the street from Western Psychiatric Institute and clinic, a block away from Presbyterian Hospital, a lot of transplants are done there, Montefiori Hospital, several hospitals nearby.

When the CDC was looking at Legionella levels, did you check any other hospitals nearby?

Dr. HICKS. No, we did not check any other hospitals nearby.

Mr. MURPHY. Do we know if they have Legionella levels that are a problem?

Dr. HICKS. I know that other hospitals in the area have struggled with Legionellosis and it is a very common problem in hospitals across the country.

Mr. MURPHY. I understand that. But I am saying here we have one hospital here and we have several hospitals across the street and nobody checked for their Legionella levels. Am I correct?

Dr. HICKS. Yes. Well, I do not know what their current policies are.

Mr. MURPHY. That is important too.

Dr. HICKS. Yes.

Mr. MURPHY. I am just trying to find out if CDC checked and I would hope we would find that out because if you are going to do an epidemiological study, you have to find out why at one building and not others.

When did Pittsburgh VA first learn they had some problem levels outside the normal reading levels with their copper-silver ionization system? Do you know that, Mr. Moreland?

Mr. MORELAND. For as many years as I know, there has always been issues of maintaining the copper-silver level. And that is why they have a valve that you adjust the levels. And so if you look at the levels over several years, there is low levels and high levels and then a group of levels in the middle.

Mr. MURPHY. And to your knowledge, no one has ever caught any staff putting false numbers down for copper-silver ionization levels?

Mr. MORELAND. I have seen no such evidence.

Mr. MURPHY. Whenever there is abnormal or outside the normal limits of copper-silver ionization levels, does this increase the risk that Legionella could be surviving in the water systems?

Mr. MORELAND. I really do not know that. I mean——

Mr. MURPHY. Well, perhaps we will have some testimony later on in that. If you do not know, we will just have someone ask that.

And it was first detected in the system when? What was the date of that when you first detected Legionella in the water system?

Dr. JESSE. Legionella has been in——

Mr. MORELAND. Nineteen eighties.

Mr. MURPHY. But, I mean, during this recent outbreak because you had several years without Legionella cases.

Mr. MORELAND. Looking at the date from 2003 until 2012, there were two to seven diagnosed cases every year of Legionella but not hospital acquired. We had a hospital acquired case in 2005 and a hospital acquired case in 2007.

Mr. MURPHY. Mr. Moreland, you know I have the highest respect for you and the VA. And you have received national awards in the Veterans Administration for your work to stop hospital acquired infections. Something broke down here.

And one of my concerns also is here you have some cases showing up and the medical staff was not notified. This is a serious problem.

So you have Legionella above the 30 percent threshold. Am I correct in that? So the medical staff was not notified that it was showing above that level. But even then, we are not sure if this 30—you could have one percent and it could still be dangerous.

Dr. HICKS. That is the point I was making. Actually most of the cases that occurred here were when levels were well below 30 percent.

Mr. MURPHY. It almost sounds like in some ways it is people washing their hands and saying, you know what, I did not set the standards, there are no national standards. Everybody gets to make up their own standards. Thirty percent is some number that people pulled out, but one percent could be enough.

And we have some people dead here and I do not hear anybody saying, you know what, this was wrong. The CDC and the VA and hospital associations nationwide are going to set some other standards here.

Dr. HICKS. Uh-huh.

Mr. MURPHY. Is that going to happen?

Dr. HICKS. One thing I would like to mention is that there is a new standard about to be released and the CDC has been working on that standard——

Mr. MURPHY. Thank you.

Dr. HICKS.—with a number of other experts related to Legionella. And this standard is called prevention of Legionellosis associated——

Mr. MURPHY. Can I just ask something?

Dr. HICKS. Yes.

Mr. MURPHY. Mr. Chairman, could I just be given another minute here because there are a couple more critical things I just want to ask? Would that be all right, Mr. Chairman?

Mr. COFFMAN. Go ahead, Mr. Murphy.

Mr. MURPHY. When you tested the water systems at the Pittsburgh VA, how many different water systems are there within the Pittsburgh VA system?

Dr. HICKS. It is a very complex water system.

Mr. MURPHY. Just how many?

Dr. HICKS. Oh, I could not tell you off the top of my head. I would have to get back to you on that.

Mr. MURPHY. Three, four, five, six maybe, self-enclosed, does that sound about right?

Dr. JESSE. I think there is four.

Mr. MURPHY. Four? There is four different systems. Did you test all the systems?

Dr. HICKS. Yes.

Mr. MURPHY. And when the systems were flushed, were all the systems flushed thoroughly?

Dr. HICKS. Uh-huh.

Mr. MURPHY. Every faucet, every showerhead?

Dr. HICKS. Right.

Mr. MURPHY. Every one was tested?

Dr. HICKS. Yes. Well, not every single one was tested, but many of them were tested.

Mr. MURPHY. What does that mean?

Dr. HICKS. So when we went in, we had to collect a representative sample——

Mr. MURPHY. But I also heard someone say that, you know, you could have some dead-end pipes and things which could still be remaining in there.

Dr. HICKS. Correct.

Mr. MURPHY. And so a representative sample?

Dr. HICKS. Right.

Mr. MURPHY. At least five people died. One other thing I wanted to point out here, when people are saying that there was some testing done, what I have here is some information that says that is not true.

Some testing was done on urine antigen levels, but Legionella cultures were not done on several people. We do not have names. But patients number one, two, four, six, seven, 11, 12, 13, 19, 21, 22, 23, 25, 26, and 28, there was no Legionella cultures done.

Why was that?

Dr. JESSE. So these are individual patients. I cannot answer the specifics of why as for each. But I would say as a generalization it is often difficult to get sputum and the cultures have to come from sputum from those patients. Often when you get a urinary antigen test, and the patients may already have been put on antibiotics which would suppress the growth in——

Mr. MURPHY. And if we had——

Dr. JESSE. I cannot answer——

Mr. MURPHY. If we had the information, though, could we also compare the sources of that if we looked back on some of the things from the old lab, the pathogen labs that would have had some of that old data in terms of sources?

Dr. HICKS. So I just want you to know that we were able to compare what we had from the patients to what we found in the environment. And we had isolates from both patients.

Mr. MURPHY. But you did not have the old data from the old lab. I understand that was destroyed.

Dr. HICKS. We had some isolates from the old——

Mr. MURPHY. But the old lab——

Dr. HICKS.—from the 1980s.

Mr. MURPHY.—all that old was—a lot of that was destroyed, though, right?

Dr. HICKS. I do not know, but I know that we had three isolates from the 1980s for testing.

Mr. MURPHY. Mr. Chairman, I hope that someone could answer this question because it is critical because I understand a lot of that data had been destroyed. And I understand my time is up, but I hope you or someone else will follow-up and ask that question why was all of that data destroyed and who ordered that.

Thank you, Mr. Chairman.

Mr. COFFMAN. Thank you, Mr. Murphy.

Dr. Benishek.

Mr. BENISHEK. Thank you, Mr. Chairman.

Were all of you at the VA in Pennsylvania? Doctor, have you ever been there, Dr. Hicks? Dr. Jesse——

Dr. JESSE. I have been there. I have not——

Mr. BENISHEK. Have you been there since this happened and interviewed people?

Dr. JESSE. No. Dr. Roselle.

Mr. BENISHEK. Mr. Moreland, have you been to the——

Mr. MORELAND. Yes, I have.

Mr. BENISHEK. You were there since this happened and interviewed people?

Mr. MORELAND. I have been there and I have talked to numerous people involved in the process, yes.

Mr. BENISHEK. Well, you know, that is one of the questions that I am concerned about whenever we have this sort of hearing is that we just do not get to talk to the people that are directly involved. And that is very frustrating to me because it seems to be filtered through people like you.

And I do not understand why we can't get to talk to the people that are actually involved to try to get a better answer. It always comes through, you know, congressional liaison people.

So is there a better answer? Can anyone tell me why that some of the people from the Pittsburgh VA are not here specifically? Dr. Jesse?

Dr. JESSE. Well, it was our feeling that this is a broad issue, that Mr. Moreland could, you know, represent the events that occurred at the VA.

Dr. Roselle had a team that went in and did a thorough investigation, spoke to everybody there, not everybody, but the appropriate——

Mr. BENISHEK. I know, but only Mr. Moreland has actually spoken to people at that VA. None of you——

Dr. JESSE. No. Dr. Roselle has. Dr. Roselle took a team in of infectious disease——

Mr. BENISHEK. Dr. Roselle, you were there? I did not get that.

Dr. ROSELLE. Yes.

Mr. BENISHEK. So who exactly did you talk to, Mr. Moreland, at that VA?

Mr. MORELAND. I have talked to the hospital director, the chief medical officer, the chief of infectious disease, the chief of engineering, the water maintenance supervisors, and other people as well.

Mr. BENISHEK. So there is not a really good answer to the question as why we could not hear those people ourselves? No, I guess not.

Let me ask another question about this 30 percent. This is 30 percent of the samples that are taken, that is the threshold where something has to be done? So are these the same places that are being sampled every time? I mean, is it the same place that is positive consistently and there is only 20 percent of the places that are positive? I mean, is that what happens? I mean, are you aware if the 20 percent that is positive are the same sampling sites?

Mr. MORELAND. They do a random sample across the entire system and if there is a positive, they do a heat and flush and then retest to make sure that it is a negative. And then they rotate around.

Mr. BENISHEK. Are they aware then which sample site is positive?

Mr. MORELAND. Absolutely.

Mr. BENISHEK. And was it the same sample sites that were repeatedly positive?

Mr. MORELAND. I have not looked at that closely.

Mr. BENISHEK. That would be sort of like an important thing, wouldn't it? I mean, if the same site is consistently positive, that 20 percent, that does not really mean anything then because——

Mr. MORELAND. They tested——

Mr. BENISHEK.—it is the same site that is positive all the time.

Mr. MORELAND. They tested the site. Then they heat and flushed and they retested to make sure it was negative. And then they went around and picked other sites.

Mr. BENISHEK. Can you explain to me a little bit further about why there is a discrepancy between the CDC and the no tolerance and this 30 percent? Who made that decision?

Dr. ROSELLE. When that policy was written, because the science is not very good, I brought together a consensus group of experts including people from Pittsburgh and others——

Mr. BENISHEK. Who made that decision; do you know?

Dr. ROSELLE. When we wrote it, it was a group decision. We wrote the directive. And then it goes through a standard concurrence process.

Mr. BENISHEK. So that was your decision then or is there a panel?

Dr. ROSELLE. I do not make decisions alone. It was a consensus group in the VA.

Mr. BENISHEK. What group is that? What is the name of that group?

Dr. ROSELLE. It was a group formed just for this purpose.

Mr. BENISHEK. So do you ever talk to the CDC about this because obviously their standard is different than yours?

Dr. ROSELLE. Yes and no. The CDC, yes, we have talked to the CDC multiple times over the years. Remember the CDC does not even make a firm recommendation that water should be tested at all. For transplant centers, it says periodic testing can be done. For non-transplant centers, it is an unresolved issue. So when we——

Mr. BENISHEK. Well, I guess I do not understand. When she is telling us that there is no percentage of Legionella is acceptable and then you are saying that up to, you know, 30 percent of the samples can be positive, so I cannot understand the difference between that.

Dr. ROSELLE. The difference between that is there has been and still is differences of opinion on action levels, water culturing at all, and Legionella remediation. The science is imprecise. So we end up making decisions that are reasonable. And, again, Allegheny County has made the same decision. So I——

Mr. BENISHEK. Do you think that this decision is reasonable at this time?

Dr. ROSELLE. The group is going to reconvene. In fact, it was supposed to convene today—it has been postponed—to start looking at this again going back to the science, talk to the CDC——

Mr. BENISHEK. But you think it is unreasonable? Today you would say it was unreasonable?

Dr. ROSELLE. Pardon me?

Mr. BENISHEK. Today you would say that was an unreasonable decision that you guys made——

Dr. ROSELLE. We are going to look at that.

Mr. BENISHEK.—in retrospect?

Dr. ROSELLE. We are going to look at——

Mr. BENISHEK. All right.

Dr. ROSELLE. We try to go in retrospect.

Mr. BENISHEK. My time is up.

Mr. COFFMAN. Thank you, Dr. Benishek.

Mr. Rothfus.

Mr. ROTHFUS. Thank you, Mr. Chairman.

My apologies for not being here for the earlier testimony. We have multiple hearings going on.

Just a couple quick questions. As I understand it, there was an issue spotted back in November of 2011; is that correct?

Dr. JESSE. In 2011, there was one hospital acquired and then a group of other diagnosed cases of Legionella.

Mr. ROTHFUS. But did testing reveal that there was Legionella in the system at the time in November of 2011?

Dr. JESSE. Yes, it did. And there were actually three rounds of remediation that occurred at that time.

Mr. ROTHFUS. And did that, in fact——

Dr. JESSE. And the final was where a single sample of 27 was positive and they did another heat remediation.

Mr. ROTHFUS. And that was over a period of how many months from November 2011?

Dr. JESSE. Well, that was September, October, November when the cases were identified. There actually was a remediation in August and November and December and in January. From December through April of 2012, there were no cases.

Mr. ROTHFUS. And so between January 2012 then and November 2012, there were not——

Dr. JESSE. No. Actually, through April of 2012, there were no cases. There were three cases of Legionella diagnosed at the facility, one in May, two in June. None in July. And then in August, this seemed to come out where two were hospital acquired.

This is where the epidemiologists, infectious disease folk at the hospital became concerned because they needed to link them back. In fact, one of those patients was never hospitalized, had only been there, I believe, on two occasions for outpatient visits.

But involving the CDC through local and county health authorities and doing genotyping which takes time because you have to culture and grow the Legionella and then do the genotyping. So those results came back to the VA on October 31st.

November 2nd I think the letter from the director went out through the county and state authorities to request inter-session of the CDC. That team was on-site on the 7th, was there through the 16th.

Mr. ROTHFUS. Following the remediation that followed the 2011 finding, what would the standard procedure have been for testing again?

Dr. JESSE. Well, again, the standard is one that is set by the local system. I think the minimum mandate would have been twice a year because they have a transplant center. The practice was they actually did it more like six to ten times per year. And, in fact, testing was done in March and April and in June.

Mr. ROTHFUS. And the results of those tests?

Dr. JESSE. I shall put my glasses on and tell you. Zero in March, zero in April, five of 26 in June. Remediation followed that.

Mr. ROTHFUS. Okay. Thank you.

Thank you, Mr. Chairman.

Mr. COFFMAN. Thank you, Mr. Rothfus. All right. We are going to begin a second round of questions with the same panel. Dr. Jesse, was the outbreak of Legionnaires' Disease in Pittsburgh preventable?

Dr. JESSE. So I am going to answer that cautiously.

Mr. COFFMAN. Just answer it please. Thank you.

Dr. JESSE. It would be preventable by maintaining a water temperature at the tap of 130 degrees. There is a risk in the risk of scalding of patients, and that is an unacceptable risk——

Mr. COFFMAN. Versus a patient dying?

Dr. JESSE. Patients die from scalds. So what we are dealing with is an area between a water temperature between about 110 and 130 degrees, where one has to balance the risk of scalding patients——

Mr. COFFMAN. Was it preventable?

Dr. JESSE. Was it preventable? As I said if you put the water temperature high enough——

Mr. COFFMAN. Can you just answer the question?

Dr. JESSE. I have answered the question. If we had turned the water temperature——

Mr. COFFMAN. You are saying that it is preventable?

Okay. Please put up a slide.

[Slide]

Mr. COFFMAN. According to information provided to this Subcommittee by the VA as of December 17, 2012, can we get that up? Okay, you are bringing it up? There were only two Legionnella cases in 2012 and neither were hospital acquired. Okay, I will wait until that is up. Okay. In speaking to just one of the county health departments that VA would typically report Legionella cases to, VA reported seven Legionella cases in 2007, six in 2008, one in 2009, five in 2010, ten in 2011, and seven in 2012. These numbers do not necessarily represent hospital acquired Legionella. But CDC's investigation that covers only two years shows 14 Legionella cases definitely or probably acquired at the VA facility in 2011, and 17 Legionella cases definitely or probably acquired at the VA facility in 2012. There is a glaring disparity between what VA accepts responsibility for and what CDC and others attribute to the VA. Would any of you care to comment on that?

Dr. JESSE. Sure, let me make a couple of comments. I think you started off talking about two cases, and let me make very clear what that refers to. When we had seen the issues in Pittsburgh at a national level, we went to every VA facility and said, "Do you have any cases of Legionella now?" A point in time survey. There were five cases, two in Pittsburgh, I think one in New England, one in the Intermountain West, one in the South. That was a point in time survey. It was in no way intended to, it was point prevalence, not incidence.

In terms of the number of cases being reported, be very cautious. Because CDC often reports county data. And so in Allegheny County in 2012 there were 50-plus or minus one or two because of late December, we are not sure, cases of Legionella. Five of those were VA patients. But that is only patients who were in the county. It is not from the hospital, it is county residents. So it is a different reporting structure.

My understanding in looking at CDC, we fully agree with the number of cases reported by the CDC. We fully agree with the attribution of hospital acquired.

Mr. COFFMAN. Mr. Moreland, why was the lab data destroyed in 2006?

Mr. MORELAND. When the Special Pathogens Lab was closed, there were multiple sets of data and specimens in the Lab. All lab specimens that were categorized, labeled, and had a catalog were moved intact to the other laboratory at the VA Pittsburgh. Those things still reside there. The only thing destroyed at the VA Pitts-

burgh, at Pittsburgh when the Special Pathogens Lab closed were uncategorized, unlabeled samples that did not have a catalog of what the samples were. So they were unknown samples left in the lab. That's the only thing that was destroyed. Because uncatalogued samples left in a laboratory are considered biohazards and need to be destroyed.

Mr. COFFMAN. Ranking Member Kirkpatrick?

Mrs. KIRKPATRICK. Thank you, Mr. Chairman, and thank you panel. I have many questions about this and I will submit most of them in writing in the interest of time for this Committee. But in my briefing materials I want to take the conversation in a little bit different direction. There is a note that there was a sprinkler system interruption due to a water line break in November of 2012. And then I also want to reference for the record the CDC report of January 25th of this year. And here is what it says. "Extensive construction at the hospital, the timing of construction work at the hospital coincides with the outbreak. Construction likely introduced organic matter to the potable water system, increasing consumption of chlorine in the municipal water supply leading to amplification of Legionella. Residual chlorine in the water system, although at adequate levels in the incoming municipal water supply, was at an insufficient concentration for microbicidal activity at all distill sites measured within the hospital."

That is extremely concerning to me. Dr. Hicks, could you talk with me about that? And I would like to know, what the circumstances were, but also what remedial efforts have been put into place?

Dr. HICKS. Okay. So I think it is important to note that this hospital was not paying particular attention to the chlorine levels because they had a copper-silver ionization system in place. And the claim is that copper-silver ionization in and of itself is effective for disinfecting water. What we found here is that obviously during our investigation when we measured copper and silver levels, we found Legionnella in all of those samples despite adequate levels. So we were trying to hypothesize as to why this happened when it did. Because this copper-silver system has been in place for so many years.

So we looked back and the construction work that had been done and the construction work actually was, it was right before this big increase in cases. And so we hypothesized that the construction introduced material into the water supply that consumed chlorine. And it may have been that quite a bit of chlorine was getting through to the distill parts of the building and lowering levels of Legionella prior to the construction work. And that may have kind of produced a synergistic effect with the copper-silver system.

But once that chlorine was out of the picture, one there was no chlorine in the system to knock back Legionella levels, then Legionella just grew rampantly.

Mrs. KIRKPATRICK. Dr. Jesse, can you address in terms of a systemwide effort or policy to be more vigilant during times of construction? It looks like there is definitely a clear link.

Dr. JESSE. Well it may not be so clear. There has been construction on that campus going back many, many years. I think the issue here is that this is indeed complex. What we are trying to an-

swer is, why did a system that was apparently effective for many years all of a sudden start having problems? And despite having adequate levels of copper and silver ions in the system could still grow Legionella? And so as Dr. Hicks said, you have to start looking beyond the obvious, and what are other things that might have contributed? And the construction would be one. So——

Mrs. KIRKPATRICK. Excuse me for interrupting, but not to quibble with you but my reading material says that Legionella has been at this campus since 1981.

Dr. JESSE. Legionella has been everywhere since, you know, time immemorial. So——

Mrs. KIRKPATRICK. Right. My question, and I understand systemwide, but my question is have you looked at construction, you say that happens all the time on the campus, to be more vigilant? And maybe Mr. Moreland——

Dr. JESSE. Absolutely, I think we need to be. And as we are rewriting the national directives, I think this is something that has to come into play. It clearly is one of the things that explains the difference. But it is, at this point it is a hypothesis. But I think we need to take it seriously.

Mrs. KIRKPATRICK. Thank you, Mr. Chairman. I yield back.

Mr. COFFMAN. Thank you, Ranking Member Kirkpatrick. Dr. Roe?

Mr. ROE. Thank you. Thank you, Mr. Chairman. And I think we have to go back and say why is this a serious issue? And the reason it is a serious issue, as Dr. Hicks brought up, is that Legionella pneumonia carries a five to 15, some as high as a 30 percent, mortality rate. That is higher than open heart surgery. So that is why it is a serious issue, because it has such a high mortality rate. And that is why we have to be vigilant and try to prevent this. Because we know, and these are either immunocompromised patients, or patients over 65, or patients with chronic lung disease, or any of the debilitating diseases that we get as we age. So that is why it is important.

And the Chairman asked a minute ago, was this preventable? And I think you can say that yeah, the easy answer is a lot of things were tried but the answer is yes because it is prevented in a lot of other places. And there are I think 37 other systems that use a copper-silver system that has not had this problem. So it is clearly working somewhere. Something happened. And Dr. Jesse, you may be right. It could be the factor, the construction, or whatever that was another factor in there if the levels were normal. But some of the analytics that we have got here, and this is a very cumbersome book, I obviously did not read that all last night, that suggests that these levels were not adequate. Is that right?

Dr. JESSE. So I do not know and I cannot speak to the necessity to constantly maintain these levels at all times. We do know that these systems require a lot of manipulation to keep them line. The testimony submitted from Pittsburgh Presbyterian describes a process very much like what VA was doing, measuring, readjusting, readjusting constantly. But we also know there has been another hospital in Pittsburgh that despite having good silver ion levels over a long period of time also was no longer handling the

Legionella burden and put in place a monochloramine system. That was reported in an abstract.

Mr. ROE. It says, these analytics right here say that for more than a year that the silver levels were not adequate.

Dr. JESSE. I do not know if they were not adequate. There were probably points in that year when they were not on, I do not think that there was time——

Mr. ROE. Yeah, these are yours. These are not, I mean, these are reports from the VA here. So we need to get that answer because we need to know that.

Dr. JESSE. But we——

Mr. ROE. And obviously those patients in that hospital and their families need to know that. I think that is, we will get a written after this is over. We will put that in writing for you. And Dr. Hicks, have you seen this? I know you do not just look at VA's, you look at hospitals across the country.

Dr. HICKS. Mm-hmm.

Mr. ROE. Have you seen this? I have been in a medical center with 600 beds, and a VA hospital right next door to it that is a large VA, and I have not seen this problem at either one of those facilities in over 30 years I have been in Johnson City, Tennessee. Have you seen this in other hospitals where outbreaks? And again, when you are seeing thousands of patients, I realize that it is hard to identify two which would be an outbreak.

Dr. HICKS. Mm-hmm.

Mr. ROE. I have got that. I understand that. Have you seen that?

Dr. HICKS. Yes, I would say that it is a very unfortunate occurrence. But health care associated Legionnaires' Disease is quite common. And in the U.S. we believe there are somewhere between 8,000 and 18,000 cases of hospitalized Legionnaires' Disease every year and a good portion of those are health care associated. So this is not an uncommon occurrence in hospitals. And I would say that I suspect, and this may, this will be very disturbing to many of you, I suspect that many of these outbreaks go undetected. I think this is a situation where this outbreak was detected because they have a very aggressive testing policy, both for testing patients——

Mr. ROE. I would think though that, I mean we are pretty, when you look at an x-ray, and you have many times and I have too, of pneumonia, you are going to pretty aggressively try to diagnose because you have to know what antibiotic to treat it with.

Dr. HICKS. Sure. Yes.

Mr. ROE. Not just a, "Here is a pneumonia and let me just take a shotgun and fire it at the x-ray."

Dr. HICKS. Mm-hmm.

Mr. ROE. You want to know exactly what bug it is because you can lose that patient by not doing that, and certainly in patients that are debilitated to begin with.

Dr. HICKS. Yes.

Mr. ROE. Who typically get pneumonia. So I think we need some answers to this right here. It is important because this seems to be an outlier.

Dr. HICKS. Right.

Mr. ROE. As opposed to what happened. And I think the reason it would give me some comfort is if those levels were normal then

maybe those standards need to be changed. And I think the other thing, I was a little, I did not know how 30 percent, you know, a lot of times things are arbitrary. How many liters of fluid went on the space shuttle? Somebody said four, and that's how many there are. So this 30 percent, was there any basic science in that that said, "This was a threshold," or any studies that document——

Dr. JESSE. Yeah, there has been a study that talks about this and documents it. But I will reiterate what I said before. The science for almost everything we have talked about today is weak. Most recommendations are not strong for any of these because the science just is not there. So, which is again why we are going to, we are reviewing the literature again. And I am sure that new guidelines coming from the CDC will have also reviewed all of the literature——

Mr. ROE. Just one more question for you all and Dr. Hicks, is the CDC's recommendation zero tolerance?

Dr. HICKS. Yes, that is correct.

Mr. ROE. Okay, that is the standard. That would be easy. I could make that vote this afternoon. I yield back.

Mr. COFFMAN. Thank you, Dr. Roe. Mr. Walz?

Mr. WALZ. Thank you. I'm going to kind of piggyback onto what Dr. Roe said. I think that is really the bigger issue here. This is a much broader issue. Dr. Jesse, I appreciate your point on that.

Obviously, we come back again to this issue of zero sum. I do not know if there has ever been a congressional hearing on private sector hospitals and their infection rates, but we heard on this. We are going to hear from some experts next that I think is going to help clarify some of this and go through it.

But can someone tell me is it kind of just personal choice? Or is it cost involved? Why chlorine dioxide over copper-silver ionization? The research I looked at, and some of the people who wrote the research are sitting behind you, seems to indicate it is up in the air. Is there a reason? And what do the other local hospitals, you just mentioned it a little bit, Dr. Hicks, they used the chlorine, or excuse me, the copper-silver ionization.

Dr. HICKS. So I think it is a really important question because there really is no one size fits all solution to controlling this problem. And it is a very difficult problem to solve. And as someone mentioned recently that it is like trying to get rid of house flies. But obviously a much more dangerous type of situation here.

Mr. WALZ. Yes. Okay.

Dr. HICKS. So it obviously needs to be taken very seriously. But there are, there are different disinfection methods to try to address it in the environment. The two that are currently EPA approved are chlorine and chlorine dioxide. And so those are the two EPA approved methods for disinfection of water systems. And it would be nice, ideally, if we can build the capacity within our program and work with EPA, we would really like to take the opportunity to evaluate all of these different approaches to Legionellosis prevention and do head to head studies.

Mr. WALZ. Because I am interested. And from a CDC perspective, I understand. And it is, we all want to reach zero. We want to do this. But there are considerations based on cost, what you have the capacity to put in place and things like that.

Dr. HICKS. Right.

Mr. WALZ. And I would get back at this issue of preventability. I mean, I think it is important. But this is a tough one with medicine. And maybe it is because of the successes that we have had that folks want to see that and we should strive for zero on this. But from a preventability case. The only way to prevent that they would have gotten this there is for them not to enter the facility. The same way to prevent automobile accidents, if no one drives. That is the only certain way you can do that. But the cost of not doing that, the cost of a veteran not going to the Pittsburgh hospital with chronic chest pains because of this, I think we have to be very careful. On we want to strive for a zero preventability. But I think there is always a squeezing of the balloon, if you will, that something happens somewhere else. And the same thing on are we putting our money in the right place? Are we testing accordingly? Are we mitigating circumstances where they should be?

Because I think, and I was just mentioning this, I would have to think if there were any test at all that showed anything at the Minneapolis VA, all kinds of red flags would go up. Because if I am understanding it right, that is very unusual, that I do not think they would get a test. Am I right on this, where we are going?

Dr. JESSE. So as I said, there are some VAs whose municipal water is treated with monochloramine that do not have a problem. It is almost pointless for them to test. And if they did, and something popped up, it would really raise a red flag. There are certain parts of the country, likewise, never had a case, never tested positive in the water. So to continue testing would not make sense.

But again, the management of Legionella is not a single thing. It is surveillance of both the clinical cases, and this is the only thing I know of where we also monitor environmental cases. You know, we monitor pertussis, we monitor TB from the clinical incidents. But in this case, we are also monitoring the environment. And we do that most rigorously in cases, in areas, in hospitals where we have historically had a problem or we have ever identified cases. And the strategy then is built on, you know, the individual hospital and their history.

Mr. WALZ. Dr. Hicks, would you happen to know if CDC's budget is cut under sequestration or not?

Dr. HICKS. I do not know anything about the budget——

Mr. WALZ. I am just curious, as we as a Nation have these conversations, I am guessing and I am seeing this, this monitoring and this remediation is a very expensive process. Am I right to say that?

Dr. HICKS. Yes.

Mr. WALZ. Now my question is, is that it is worth it, because I agree that no veteran should go there, or no patient should go to a U.S. hospital. But I think this broader issue, and if there are specific issues of, that we missed at a high chance hospital, or high rate hospital, we should work with that. But I think this gives us an opportunity, Mr. Chairman, to take this to a broader level about what is CDC's role, what are those standards. Because I am baffled, too, by the 30 percent thing. And I understand that at some point you have to set a number. But I kind of agree with Dr. Roe, that if it is causing it, that is where it should be.

But I yield back. Thank you, Mr. Chairman.

Mr. COFFMAN. Thank you, Mr. Walz. Dr. Benishek? Mr. Rothfus?

Mr. ROTHFUS. A question on the copper-silver ionization. Do you have confidence today that that process, is it still being used at the VA in Pittsburgh?

Dr. JESSE. VA Pittsburgh took the copper-silver offline. Again the major sway point was that at the time the CDC looked at their samples, the copper and silver ion levels were within range and they could still grow Legionella. And again, this was a system that had worked for many years of suppressing Legionella. It does not eradicate it completely, but it suppresses it. And clearly at this point in time something different, something had changed. So now it is offline and they are using what is called a chlorine drop to increase the chlorine level running to the tap heads to control that.

And again, that is pending the, a more long-term and permanent solution, as Mr. Moreland mentioned, that is going to include putting a scald free taps in place for all the taps and showers. And that allows us to raise the water temperature up, which also mitigates growth. And a more permanent solution, whether it is monochloramine, whether it is chlorine dioxide, we do not know. We have to look into that. We will make that decision based on the best advice of both internal and external experts and advisors.

Mr. ROTHFUS. How recently was the chlorine drip initiated?

Dr. JESSE. It was initiated in November? Yeah.

Mr. ROTHFUS. Have we done testing since that time?

Dr. JESSE. So they did, the CDC recommendation was, they did the heat remediation, they followed that with a hyperchlorination. So that is like chlorine to pool level. You cannot drink it. And now a chlorine drip that maintains a lower but, you know, drinkable level of chlorine in that system.

Mr. ROTHFUS. When was the last time we tested for the presence of Legionella?

Dr. JESSE. We've been testing, they have been testing every two weeks and the system has been clear. The plan is to continue that testing for at least 90 days. And then in consultation with CDC, we will change whatever that testing strategy might be.

Mr. ROTHFUS. Thank you. Thank you for that.

Mr. COFFMAN. Thank you so much, panel. And I just want to note again for the record that the individuals that were requested to be here and testify, that were directly involved in this particular incident, are not here today. Oh, Mr. Murphy? Okay. Let us bring the next panel. I now invite the second panel to the witness table.

On our second panel, we will hear from Dr. Victor Yu, Professor of Medicine at the University of Pittsburgh; Dr. Janet Stout, Director of the Special Pathogens Laboratory; Mr. Aaron Marshal, Operations Manager for Enrich Products, Inc.; Mr. Steve Schira, Chairman and Chief Executive Officer of Liquitech, Inc.; and Ms. Kathleen Dahl, President of AFGE, Local 228 at the Pittsburgh Veterans Affairs Medical Center. All of your complete written statements will be made part of the hearing record. Dr. Yu, you are now recognized for five minutes.

STATEMENTS OF DR. VICTOR L. YU, PROFESSOR OF MEDICINE, UNIVERSITY OF PITTSBURGH; DR. JANET STOUT, DIRECTOR SPECIAL PATHOGENS LABORATORY; MR. AARON MARSHALL, OPERATIONS MANAGER, ENRICH PRODUCTS, INC.; MR. STEVE SCHIRA, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, LIQUITECH, INC.; AND MS. KATHLEEN DAHL, PRESIDENT, AFGE LOCAL 2028, PITTSBURGH VETERANS AFFAIRS MEDICAL CENTER

STATEMENT OF DR. VICTOR YU

Dr. YU. Mr. Chairman, I was Chief of Infectious Disease at the VA Medical Center for almost 30 years and received superior performance evaluations for each of those 30 years. And I also want to say that the Pittsburgh VA is a great medical center. Healthcare givers and the services there are extraordinary.

However, the upper layer of bureaucrats causes, and this I think is true for many hospitals, the bureaucrats cause us some problem. But as I was listening to today, where you say, "Hey, it is not 30 percent so you do not have to do anything." They had 16 cases with five deaths. And maybe if there is a patient who dies of Legionnaires' Disease, maybe you should pay attention to that one and not whether or not it is 30 percent. So that is just a parenthetical statement.

I was also Chief of the Special Pathogens Lab. And the Special Pathogens was established under the aegis of VA's central office in the early 1980's because of the massive number of outbreaks. Not only the American Legion outbreak, but outbreaks at Wadsworth VA Medical Center, 200 cases, four years; VA Medical Center, 100 cases, three years; Togus VA Medical Center, 50 cases, possibly in one to two years. And based on that, our lab was designated as a special reference lab. And then it was formalized under the previous director, before Mr. Moreland came, as a special clinical resource center for the VA. And one of the things that we were supposed to do was because of the prominence of our lab, we were doing not only cultures for the entire VA Medical Center, but for all academic medical centers in the United States, and in public health agencies that would send specimens just because we were the only lab that was doing that. And therefore the VA thought, "We can charge money for it." And three special clinical resource centers were set up. Yale, for virology; Florida, for fungi, but the most famous one of them all became the Pittsburgh VA Special Pathogens Clinical Resource Center. And we did the cultures for the entire VA.

Now our accomplishments I think are a matter of record. And we received many honors, not only from NIH, but most of them have come from the VA, from international societies. And the one that I treasure the most is from the American Legion. Here are a few of the key things that were done.

Janet Stout discovered the source of Legionella in the hospitals was not in the cooling towers. It came right from the drinking water of the hospital, published in the New England Journal of Medicine in 1982. But 1976 was when the outbreak was occurring. So these outbreaks are occurring all over the world, actually, at

this time. And they started to look for cooling towers and it was right in the drinking water.

But that discovery also meant another thing. If we know where it is, and it is right in the hospital, we can prevent it by going after it in the hospital. And this is a sore point between we and CDC because we endorsed the drinking water concept and CDC endorsed the cooling tower concept. And it now turns out that we have a pretty good record now. And so now we are able to prevent it. And so we and the University of Pittsburgh Department of Engineering instituted a systemic process where we would try innovative ideas, trying to figure out how could we get this organism out of the water distribution system? Dr. Hicks was so shocked that this was, this organism was in there since 1982. And she is relatively new to Legionella. Every hospital, this is be it Barcelona, Spain, or Palo Alta VA, or all of the VAs, that organism stays in the hospital for the rest of the lifetime of the hospital. And Columbia Presbyterian wondered maybe they should tear out all their pipes? They did that accidentally by using chlorination and then would later switch over to copper-silver.

So the organism, it gets into the biofilm, which is a thick film and detritus, the calcium deposit, and it stays there. And so you can suppress it pretty easily. But if you do not maintain the system, that organism will come out. And so every hospital, be it Barcelona, Spain, the United Kingdom, when it comes out it is the same organism by genotyping that was there 30 to 40 years ago. That is an actual fact that almost all Legionella experts know about.

Now this is what we and the Department of Engineering did. And these were engineers that were graduate students and professionals in engineering. We were the first to evaluate all of these innovative technologies. The first one we tried was super heat and flush. There are some problems with that because it is tedious. The second one we tried was chlorination. And so many, many hospitals institute chlorination and we did the first controlled study published in the Lancet in 1985. So we know chlorination. And there are some problems with chlorination. But by the early 1990's, we decided to try another modality called copper-silver. That modality is now, and you have a list, all the great medical centers in the United States, almost all of them have copper-silver today. And that can be discussed later.

We were the first to introduce chlorine dioxide in the United States. The second, but the first one to evaluate it in the controlled studies. The chlorine dioxide had failed in the United Kingdom. But we found out that it could work if you did some certain things and that will come out.

Monochloramine, which Dr. Jesse mentioned. We are the first in the United States to institute monochloramine. That is our study and it is undergoing evaluation.

Now we also developed all of the microbiology methods. You do not need to use a liter, or 100 liters. And I will not go into that. Every one of the culture media used for isolation from patients or from the drinking water, we developed that media. That media is commercialized. We gave out no patent. So all of the culture media

that all of the hospitals use in the United States today, almost all of them are based on——

Mr. COFFMAN. All right. I think, I am sorry, but we are running out of time. I wonder if you could just conclude with your testimony? And we will get to the rest of the panel and then we will get to questions, and you will certainly have an opportunity to amplify things in questions.

Dr. YU. Okay. Well the most important that we did, we came up with the antibiotic that resulted in over a 95 percent cure. And we tested all the antibiotics for the pharmaceutical industry. And based on that, we recommended that certain antibiotics come out two one. One is called Azithromycin, which is the Z-pack. What is used in the hospital is a more powerful IV form. Then the second one that we came out was Levaquin, or Levofloxacin. And that one led to almost no mortality.

So that is the one point that we want to make. You can not only prevent it from occurring in the hospital. If it occurs, you can save their life by giving them the antibiotics. And so from 1996 to, 21 consecutive years where there was not a single case of Legionella. But if there was, they would have lived.

And Arlen Specter and the American Legion, because when they closed the Special Pathogens Lab, they warned the VA that maybe this is not a good idea for the patient. And Brad Miller, Congressman Brad Miller in the 2008 hearings, made this prophetic statement. He said, "Dr. Yu, we will never know how many patients died because of what the VA did." But it turned out Congressman Miller was wrong. We did know. There were five at the Pittsburgh VA Medical Center. Preventable disease by prevention, and preventable with antibiotics.

[THE PREPARED STATEMENT OF DR. VICTOR YU APPEARS IN THE APPENDIX]

Mr. COFFMAN. We will come back to you with questions. Dr. Stout, you are now recognized for five minutes.

Dr. YU. It says only four minutes on my clock, sir. 4:50. I only have one sentence to make, if I could just make it? Because I do have ten seconds on my clock. Oh, okay.

STATEMENT OF JANET STOUT

Ms. STOUT. Okay. I want to thank the House Veterans' Affairs Subcommittee on Oversight and Investigation for holding the hearing; Senator Casey, Congressmen Doyle and Murphy for requesting investigations into the Legionnaires' Disease outbreak that occurred at the VISN 4 health care facility in Pittsburgh. The affected veterans and their families deserve full disclosure from the administrators at the University Drive and Heinz facilities in Pittsburgh.

I am a microbiologist trained in environmental and clinical microbiology, and hold a masters and Ph.D. degree from the University of Pittsburgh Graduate School of Public Health. I am testifying today as a subject matter expert on Legionnaires' Disease. My 30 years of research in the field of Legionnaires' Disease provides me with special knowledge about Legionella bacteria, the methods to control it in hospital water systems, and the methods to inves-

tigate possible cases of hospital acquired Legionnaires' Disease. I also have intimate knowledge of the procedures and practices that were established at the Pittsburgh VA facilities in response to previous outbreaks at those facilities. And this includes methods and scheduling for monitoring or testing Legionella and the copper and silver ions, maintenance of the ionization system, and the microbiological methods for detecting Legionnaires' Disease both in patients and the environment.

The approach to prevention of Legionnaires' Disease developed at the Pittsburgh VA stopped an epidemic and resulted in groundbreaking discoveries in case detection and water system disinfection. These procedures were followed by other facilities to prevent the disease, including guidelines in Pennsylvania, Maryland, New York, and the Veterans Healthcare System. Through our efforts, Legionnaires' Disease was controlled at the Pittsburgh VA. In fact, as we heard earlier, there were no cases of hospital acquired Legionnaires' Disease for over ten years.

So the question is, how did this happen? You will hear excused and diversions trying to shift responsibility to methodology, policies, public health authorities, and even blaming the disinfection technology that protected the VA patients from 1994 to 2006. Do not be distracted.

The failures to be investigated include, one, failure of the Pittsburgh VA to recognize they had an outbreak and take preventative actions. The delay may have contributed to additional cases and deaths. Two, failure of the VA lab to detect Legionella in the water at the VA University Drive. This has likely contributed to delay in detecting the outbreak. And this failure was due to lack of knowledge and experience, a problem that was brought to the VA Inspector General's attention in 2009. Three, failure of the VA to operate and manage the copper-silver ionization disinfection system. And finally, failure to communicate with physicians, staff, patients, and families regarding the increase in cases. The delay in alerting physicians may have contributed to additional morbidity and mortality.

The only way an outbreak of this magnitude could have occurred is if the water system at the Pittsburgh VA had become heavily contaminated with Legionella. The environmental testing performed by the VA microbiology laboratory should have detected this increase.

At the time of the 2012 outbreak reports from the ionization manufacturers indicated that the copper-silver system monitoring, when performed, did not meet the suggested target levels and that documentation of this condition began as early as the spring of 2012. We really need to know what were those results of testing for copper-silver in 2011 and 2012?

Based on my experience, and after review of the CDC report, I offer the following comments and recommendations. The Pittsburgh VA microbiology laboratory failed to detect Legionella in environmental samples due to inexperience, lack of knowledge, and use of outdated methods. A problem that, as I said, was brought to the attention of the Inspector General in 2009. However, they continue to perform testing for other VA facilities. The Pittsburgh VA microbiology laboratory should discontinue this process of offering test-

ing to other VAs and they should notify those facilities that the results of that testing may be inaccurate.

The CDC is invited to assist with facilities in dealing with outbreaks. As their guest, their recommendations will not assign responsibility, but will merely suggest changes in policy, which we have heard today. It will be the role of this Committee to hold people and the administration accountable for the failures that led to this outbreak. And accountability needs to come from the top down, not the bottom up.

The VA Legionella directive and public health policies should not be rewritten due to the management failures of this facility. It was the responsibility of the Pittsburgh VA to be current in knowledge and vigilant in following the policies and procedures that were already in place. The system is not broken, so do not fix it.

Finally the VA management does owe an apology to the physicians, staff, patients, and families regarding the delay in informing them that there was an increase in cases and that an outbreak of Legionnaires' Disease was suspected.

Thank you for your attention. I am happy to answer any of your questions.

[THE PREPARED STATEMENT OF DR. JANET STOUT APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you, Dr. Stout. Mr. Marshall, you are now recognized for five minutes.

STATEMENT OF AARON MARSHALL

Mr. MARSHALL. Mr. Chairman, Committee Members, thank you for inviting me to testify today. My name is Aaron Marshall and I am the operations manager for Enrich Products. Enrich supplies copper-silver ionization systems for the control of Legionella in potable water systems. I am also a veteran of the U.S. Army, having served honorably for over four years. And my father was also a veteran who received exception medical care from the VA Health System for many years and currently receives that same exception care in West Virginia VA Health System.

The intent of my testimony is to provide information that will contribute to a better understanding of what transpired at the VA University Drive Campus in Pittsburgh, and to provide supporting evidence that copper-silver ionization, when applied properly, is an effective method for controlling Legionella in potable water systems.

There are two ways copper-silver ionization systems can be implemented. The first is a proactive course, and the second is a reactive course. In a proactive course a copper-silver ionization system is installed as a preventative measure. In these facilities, there is no confirmed cases of Legionnaires' Disease or Legionellosis. The facility may not even test for Legionella. In a reactive course, a facility has either confirmed the presence of Legionella in the water through testing, or the facility's potable water system is suspected or implicated as the source of Legionnaires' Disease or Legionellosis cases. In response, a copper-silver ionization system is installed temporarily or permanently. Once the desired results are achieved through the reactive course, the equipment is either

removed or continues to operate in the course as transition to the proactive regimen.

The difference between the two rests in the courses of action recommended, and they are quite significant. In the proactive course, lab monitoring for copper and silver ions is recommended monthly. Flushing of non-used fixtures is recommended monthly also, and Legionella testing may or may not happen.

In the reactive course, lab monitoring for copper and silver ions is performed weekly. The facility institutes a controlled flushing program such that all fixtures are flushed weekly and Legionella testing at day 15 and day 30 is conducted to determine the course's effectiveness. This reactive course has been successfully implemented at numerous facilities, including the Cleveland VA Medical Center, as well as facilities in Pennsylvania, Florida, New York State, North Carolina, and Illinois.

I am here today because in June of 2012, at the request of the Pittsburgh VA, I personally was called in to perform a review of the copper-silver ionization system and its operation at their facility located on University Drive in the Pittsburgh neighborhood of Oakland. I was asked to make recommendations that would help to improve the functioning of their existing equipment, their existing equipment provided by Liquitech. And they are just another supplier of copper-silver ionization equipment.

Before submitting my general recommendation report on July 6, 2012, I visited the VA University Drive campus facility three times. The dates were June 4, June 24, and July 2. There was no charge to the VA for these visits, or for my report. During my visits, I personally viewed the four different locations where the Liquitech copper-silver systems were installed. I was provided access to the site records from January, 2012 until the end of June, 2012, and the lab copper-silver data from June, 2011 through July, 2012. I requested but was denied access to view the Legionella test results.

During two of the three visits, I had separate visits with infection control and engineering and maintenance personnel. The two meetings covered similar topics. Those major topics were system maintenance, frequency for monitoring of copper and silver ion levels, and criteria to determine site tests and lab testing locations. In each of the two meetings I covered the Enrich recommendations for the routine and reactive course of actions, as described earlier. Had Enrich Products been aware of the presence of Legionella or Legionellosis cases at the VA University Drive campus, we would have definitely recommended implementing the reactive course immediately.

Sometime in November, 2012 Enrich learned through the media that in fact there were reported cases of Legionnaires' Disease at the VA University Drive campus and that there were deaths as a result. In addition to the reporting of the outbreak the media, through quotes from the CDC and others, offered data on the efficacy of copper-silver ionization.

Copper-silver ionization is an effective method of controlling Legionella bacteria. However, in order to maintain its efficacy, the installed system needs to be properly maintained and regularly monitored. Another important point to note is that in order to definitely know where the source of Legionella, or Legionnaires' Dis-

ease cases came from, testing must be conducted. Often it is assumed automatically that the source must be the hot water system in a facility. We have found a number of times, that sources were other than hot water, and more recently they have been identified from water features and ice machines.

In conclusion, during the short time that Enrich worked with the VA University Drive campus through today, the VA has not shared its Legionella testing data or results with Enrich. If the investigation concludes a potable hot water system was the source of the outbreak, there is no question that regular testing could have detected the presence of the bacteria and that the reactive course of actions would have been implemented, at least we would have recommended it immediately, likely minimizing the risk of the outbreak.

We hope to have the opportunity to work with the Department of Veterans Affairs in the future in an effort to reduce this risk at all of their facilities. We also hope to establish a dialogue with the CDC where we can share data and information demonstrating the real world experiences and successes of copper-silver ionization.

Thank you, Chairman. And I would yield the remainder of my time.

[THE PREPARED STATEMENT OF AARON MARSHALL APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you. Mr. Schira, you are now recognized for five minutes.

STATEMENT OF STEVE SCHIRA

Mr. SCHIRA. Thank you. I would like to thank the Subcommittee to allow us to try to assist in devising, learning, and understanding what goes on in an environmental of care in dealing with pathogenic bacterias such as Legionella.

I am going to somewhat drop my offered statement here a little bit, because I was so shocked at some of the things I heard. First of all, much of what I have to say, which I will try to state where we physically were at the VA in two courtesy visits. But basically what Aaron has stated is in fact the gold standard, if you will, for how to maintain and operate a copper-silver system. It just requires, okay, a partnership between you and your client, your customer. We have more than 1,400 systems installed for over 20 years. We know how to collaborate and work on the issues as Aaron has just analyzed, as well as what we were. We never got a call from the VA to come in and help. We had not heard from them for years. We collect a history datalogue sheet on every system that we try to have communications that logs their copper-silver, logs their Legionella, logs their ICPs, logs the cleaning cycle. We had zero on the four sheets for the four systems at the Oakland VA. We prompted a courtesy call back in December of 2011, where we went unsolicited to simply see if we could regenerate some dialogue with the facility. During that visit we were actually informed that there was potential problems with Legionella, they had sporadic shows, low levels. But we also were able to see in the walk through, that the systems were not being maintained, clearly the issue of maintenance of the flow cells and also the settings.

The systems that are installed at the VA have what is called proportional control. They increase and decrease. There is no valves. There is no switching around, as was indicated. It is a computer that actually reacts instantaneously to the water demands on that hot water loop. So we are giving you more ions or less ions according to that water demand. We are also able to remote monitor that system and collect data minute by minute of what those systems, every one of those four systems at the Oakland VA, were capable of having such remote monitoring. They chose not to do it.

Copper-silver as a disinfection technology has been, I would venture to say, more popular, more successful than chlorine or chlorine dioxide. We would be happy to contribute as much data and information to what those site visits we learned. One was, frankly, in April where three of our people were visiting with a Dr. Mutter, a Patty Harris, a Rodney Gutz, all of whom admitted that the systems were not being maintained as they should. One of the reasons for that was there was a gentleman who was in charge was out on disability and therefore the few people left did not really know what to be doing. We offered that we would jump in and do whatever we could possibly do, give them advice, give them the ability to remote, we told them we would clean the cells if necessary. We never got a response. Nobody ever came back to us.

So what has occurred here is clearly, clearly a lack of true concern for the veterans that are being treated at that facility. Because since 1993, where a research study was done by Dr. Yu and Dr. Stout, and were able to control the Legionella after trying chlorine, chlorine dioxide, heat and flush, they were able to utilize the system we gave them in 1993 and affect the right results.

One last point as a matter of more chemistry than technology. If you are going to heat and flush, if you are going to hyper-chlorinate while you are trying to use a copper-silver system, you might as well turn the copper-silver system off. Because you are throwing out all the ions when you are doing those flushes and operations. So, which we were never told. We had no idea they were doing these things. There are steps and actions you can take that could potentially work, and you want to do heat and flush that is okay. But we should know what you are going to do and collaborate how you are going to get the ions back up to where they are at. Thank you.

[THE PREPARED STATEMENT OF STEVE SCHIRA APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you for your testimony, Mr. Schira. Ms. Dahl, you have five minutes for your testimony.

STATEMENT OF KATHLEEN DAHL

Ms. DAHL. Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Committee, thank you for the opportunity to testify today. My responsibility as an AFGE local president is to present the safety concerns surrounding the current Legionella outbreak.

Notification on November 16, 2012 that the hospital was going to water conservation due to elevated water samples for Legionella really was not heart stopping at that moment. As a nursing assist-

ant that started in 1994, became an RN in 1995, I was often told, "Do not drink the water," because Legionella had been in the pipes for a very long times. Hospital employees are surrounded by exposure risks everyday, be it TB, tuberculosis, the flu, Hepatitis, MRSA, C. Diff. But hospitals used isolation precautions, immunizations, masks, and other preventative measures everyday to reduce these risks. Why would Legionella be any different?

It became heart stopping when I began to piece together media reports, employee reports, emails, and previous notices of emergency heat and flushes and problems with the pipes. I began to question exactly how long did the VA know about this and why were not preventative measures put in place? I grew concerned and requested to meet with Director Terry Wolf. She was not on campus at that time but promptly arranged a meeting with her leadership designees.

Following that meeting, I really began to feel that employees were simply collateral damage, not even considered to be harmed or at risk. They were not provided protective gear. They were not provided notification to take precautions. I had employees that stopped me in the halls, coming to our office, and calling on the phone with concerns that they had assisted with the flushing and did not, they were not provided masks. Could they get it? How do I get it? Should the hospital be shutting down? They were in the hospital with pneumonia only four weeks prior to the notification. Was it related? Reports started coming in back in July and August of being hospitalized for five to six weeks. We instructed them to report to Employee Health, only to be turned away.

AFGE immediately notified VA leadership that Employee Health had been turning the employees away, and they immediately corrected the problem. But the employees when they did go, they were told that they did not need a urine antigen test to see if respiratory illness was related to Legionella. After all, it was flu season. Legionella can be contracted in your homes. Or they were told it was too late to get tested because it was only good for 30 days and that they were not at risk. It only happens to immunocompromised people, people that are sick.

Do not forget our employees. They are an aging population that are over 50. Some of them smoke, ex-smokers, some of them have diabetes, some of them are on chemotherapy and they come to work. They are immunocompromised. So they were at risk.

OSHA guidelines are clear and AFGE shared them with leadership. When you have two or more positive cases of Legionella within 30 days, this is considered an in progress outbreak. The VA should be screening employees who are absent three or more days in a six-week timeframe in relation to these positive cases. This would have allowed early identification and information to employees that they were potentially exposed and provide the opportunity for a voluntary response. This would have allowed for timely testing and linking, or even better, ruling out Legionella exposure.

Please do not forget the employees. Many of them are veterans themselves. They worked day and night to flush these pipes to reduce the Legionella without personal protective equipment and were not even instructed that they needed to. They were not screened or timely tested for Legionella as they should. They took

care of our veterans during this time. They have a tough job, toileting and bathing patients that may or may not have control of their bodily functions. Imagine doing that without running water. They cleaned patients with hand wipes and small bottles of drinking water. There is pressure to not only hygiene the patients, but to prevent cross contamination of other infectious diseases.

It is the law and VA policy to maintain safe environment at all times. We can do this by developing stronger policies that deal specifically with water interruption related to the existence of Legionella in our pipes and the construction. We can do this by better training those in the plumbing shop. Not all of them are plumbers. We can do this by having awareness and implementation of OSHA guidelines when sometimes occurs and protect the employees that provide to our veterans.

Our Director Terry Wolf is genuinely concerned about the well being of the patients and the staff. I am confident that she is going to find solutions that prevent something like this from happening again. But the union needs to be part of this process in educating the employees and providing safe environments. It is the law and it is common sense. Thank you.

[THE PREPARED STATEMENT OF KATHLEEN DAHL APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you, Ms. Dahl. Dr. Stout or Dr. Yu, in your professional opinions were the deaths of the five veterans preventable?

DR. YU. Yes, absolutely. I write the chapters in Harrison's Textbook of Medicine, the most widely used textbook, up-to-date, and all of the infections disease texts. And one of the points I make to physicians and medical students, that the mortality from Legionnaires' Disease with these new antibiotics that we have brought drops the mortality close to zero. So it does not have to be that we have knocked out the 40 mortality that we saw in hospitalized patients.

So how did these patients die? First of all, we showed you could prevent it. Twenty-one consecutive years. The only way that they could have died was they did not get the antibiotic or they got it way too late, as they were dying. And the 30 percent has been characterized. It is not that you ignore everything with 30 percent. As soon as it hits that danger point of 30 percent you go into red zone. Essentially what you do, and this was done and we monitored this at the Pittsburgh VA, infection control nurse looked at all the chest x-rays just to see if somebody with congestive heart failure may actually have Legionnaires' Disease and to see if they received the Legionella test. The culture is actually the best test. That disappeared after we left. The urinary antigen picks up 80 percent. So another 20 percent were missed. Everybody in the ICU has to get a culture.

So as soon as Legionella reentered the water supply, probably as early as 2007, because that was the first case after we left, and certainly after 2011 where you now have 16 cases, you go into red zone alert. And this is what was done. The fact that Legionella had recontaminated the system, was not communicated to the emer-

gency room physician, the hospitalist, or the intensive case physician.

Mr. COFFMAN. Dr. Yu, thank you. So it was preventable. Dr. Stout?

Ms. STOUT. Well I would have to completely agree with that. And all you have to do is look at the history at the Pittsburgh VA to know that it was preventable. And I really do not know how much more evidence you need. We were using the same system. We were vigilant about monitoring for the ions in the cases. In fact, one of the things that is noted in the CDC report was the absence of the culture respiratory specimens of patients that were diagnosed by the urinary antigen test. Well when we were there, even if the physician did not order a Legionella culture of the sputum, we made sure that that sputum that he ordered for staph streptococcus was in the refrigerator and held for seven days. And we could go back to that sputum and recover Legionella and do the matching. And you know, these are things that should have been done there, should have been continued in our absence. And clearly they were not.

Mr. COFFMAN. Okay. Mr. Marshall, was the Pittsburgh VA forthcoming with information that helped your company work with it better to detect and prevent Legionella in its water system?

Mr. MARSHALL. Mr. Chairman, no. In fact, as I mentioned in my earlier testimony, Enrich never received an indication either verbally or written that there was a Legionella issue, or Legionella positivity in the water at their hospital. So the way that I perceive it is that we were not able, as an outside source, to do our job as effectively as we possibly could.

Mr. COFFMAN. Thank you. Mr. Schira, did your company brief the VA in December of 2011 about poor results related to the Pittsburgh facility's water?

Mr. SCHIRA. Well first of all, we did not have any results as to what was going on. The only thing that actually was shared during that visit was that they were experiencing problems and had some issues. We never, either previously or even during the visit, had the opportunity to actually do copper test, or copper-silver tests. Or the ultimate test, of course, is the Legionella validation. So we were just operating from what we were told as to what was going on in their environment of care, which it now sounds like there was a lot more going on than we realized.

Mr. COFFMAN. Thank you. Ranking Member Kirkpatrick?

Mrs. KIRKPATRICK. Thank you, Mr. Chairman. Let me just say this is an excellent hearing. I thank you very much for putting together these panels.

Ms. Dahl, do you feel that you are being treated differently by the VA since you have assisted this Committee?

Ms. DAHL. I probably would not know that until I return to my place of duty.

Mrs. KIRKPATRICK. Were you told that your reference to four employees who had respiratory illness to the media could be a HIPAA violation?

Ms. DAHL. I was advised that I was close to a HIPAA violation. I have quite a bit of awareness, as my profession is a nurse, to know that I did not provide any identifiers. But I was told by lead-

ership that was close to it, and cautioned me when I speak with the press.

Mrs. KIRKPATRICK. Thank you for your testimony today.

Ms. DAHL. Thank you.

Mrs. KIRKPATRICK. Mr. Schira, you indicated that the copper-silver system was not being properly maintained. What signs pointed you to this conclusion?

Mr. SCHIRA. Well the systems that we had provided to them, first of all, were to have attachments of flow meters so that the automatic computer can react to the water demand and those were not properly installed or in most cases not functioning. We were able to see that the ionization chambers when sitting or removed from the system were heavily caked with scale, which will prevent the amount of appropriate number of ions to be admitted. Also the systems were being run in a continuous mode as opposed to what would be a proportional control mode.

Mrs. KIRKPATRICK. Can you describe for us, what should be in place to have the proper maintenance for these copper-silver systems? What would be the proper way that they should have been handling this?

Mr. SCHIRA. Well basically what we do is, first of all, we do a start-up and training, which typically will take about three hours. We provide the facility with an education binder, a three-ring binder, which literally walks you through what the whole start-up and training is about. Then we work with infections control to find out how many distill sites they and the facility would like to test for the Legionella, the frequency of that testing. Also, we recommend, because the data can come up and we move it around, that you stay at, for one quarter, the same sites. So we can track to see exactly if there are any anomalies in what is going on. One of the key factors in paying attention to your environment of care on any system, but a copper-silver system of course in our particular, is knowing whether there are situations where rooms and distill sites are not being used. They actually start to create a dead link and are capable of generating Legionella, even though our system is installed and operating. That is why we have a three-page protocol for flushing of inactive sites in the operation.

And then the most important thing is share the data. Tell us what is going on so that we can contribute. And if it is remote monitoring, we can actually adjust the system remotely. So we will know exactly what your water demand was, what your amps, your volts, and how the system may be adjusted to be either more aggressive or potentially turned down. But it is data collection and consolidation of that data to be able to have a true environment of care view.

Mrs. KIRKPATRICK. And so it is constant maintenance? And that is something that you thought was missing at this particular hospital?

Mr. SCHIRA. That is correct.

Mrs. KIRKPATRICK. Thank you. I yield back the remainder of my time.

Mr. COFFMAN. Thank you, Ranking Member Kirkpatrick. Dr. Murphy?

Mr. MURPHY. You said you tested some of the systems within the hospital? Am I correct in that?

Mr. MARSHALL. We did not, Enrich did not test any of the systems. But what we did receive from the Pittsburgh VA was site records and lab copper-silver data, which is what——

Mr. MURPHY. Did you receive lab copper-silver data that said the readings were outside of their acceptable ranges?

Mr. MARSHALL. Yes. In fact as I look at them now, the one, it is why I also like to know exactly where the cases happen.

Mr. MURPHY. Okay.

Mr. MARSHALL. Because then we can, but in one system in particular, AA114, the levels for both copper and silver were below from June, 2011 until April, 2012.

Mr. MURPHY. Did you make a recommendation to the hospital that they should take some action?

Mr. MARSHALL. Yes, of course.

Mr. MURPHY. Did they take any action?

Mr. MARSHALL. Well the recommendations I made in my report was more or less based on a routine monitoring. And again, if I would have known more——

Mr. MURPHY. If you would have known there was Legionella cases you would have done something differently?

Mr. MARSHALL. But even at that, I still requested increasing the frequency of their lab copper-silver testing. Simply because with a history of low levels that would have given us a better opportunity to make more timely adjustments.

Mr. MURPHY. Okay. Now Ms. Dahl, it has been stated that whoever was supposed to more or less manage, maintain, monitor this was out on disability. Were there sufficient staff within the VA system who had expert knowledge of how to manage and monitor this system available consistently throughout time?

Ms. DAHL. I can only speak of my first, this year is my first year as local president. I have learned things that I did not know before, you know, regarding boiler plants and the plumbing and things of that nature. So I am not an expert to state. But I do know that there has been consolidation of, to build efficiencies in staffing. So we have combined duties to make, fit into the——

Mr. MURPHY. But I would, something like this, is this something that requires, for someone to work on these systems, requires some level of experience or training? Or can they simply walk on the job and look at the chart and do it?

Ms. DAHL. They would need some form of training to know what to do with the information.

Mr. MURPHY. But we understand that the person who normally does this was out on disability, and so were other sufficiently trained staff available to your knowledge? If you do not know——

Ms. DAHL. To my knowledge they had 15 minutes of training, what they reported to me.

Mr. MURPHY. All right. Thank you.

Ms. STOUT. Can I comment on the backside of that?

Mr. MURPHY. Yes.

Ms. STOUT. Just to point out that the VA's own policy indicates that there should be two fully trained individuals on how to operate this system at all times.

Mr. MURPHY. Are there two fully trained individuals on how to operate this system at the VA? Do any of you know that? If you do not know——

Ms. DAHL. I do not know.

Mr. MURPHY. Mr. Schira, I want to read you something from a timeline the Committee has here. It says, "Liquitech reports," and this is April 16, 2012, "that they completed a site visit with contractor regarding new system as well as facilities and infection prevention regarding existing systems. The contractor, Tomco, and VMS people were having issues connecting the systems up. Nika and John resolved these issues. The LTI team visited each system and met with IP and facility management. We were told that the gentleman who normally takes care of our systems was out on leave or disability and the remaining maintenance staff did not know how to maintain the systems. Furthermore, they had not been doing weekly testing or regular maintenance. When the LTI team went into the maintenance shop, LTI personnel encountered Oakland VA staff fabricating," as in falsifying, "handheld copper records. Upon visiting the systems, there was obvious evidence that the systems had not been regularly maintained and flow meters were not working. Infection prevention said they had some dark water issues."

Sir, to your knowledge is it true that someone was fabricating this data?

Mr. SCHIRA. I believe so, yes. We queried the three people who are on site. Two were very experienced, knowledgeable engineers. And the term of whipping copper levels is where you simply, to respond quickly——

Mr. MURPHY. How did you query the people? And please put your microphone right in front of you, if you would?

Mr. SCHIRA. Oh, I am sorry.

Mr. MURPHY. That is okay. How did you query these staff who, someone physically observed someone writing down false information?

Mr. SCHIRA. Correct. These were three of my employees.

Mr. MURPHY. And your employees saw someone else writing down information?

Mr. SCHIRA. Correct.

Mr. MURPHY. Was it from lack of training? They didn't know what to do? They just, they didn't understand how to write down the data? Did you query to find out?

Mr. SCHIRA. No. It was somewhat embarrassing so they did not even comment.

Mr. MURPHY. Was that brought to the attention of the VA, or to anybody else to find out what——

Mr. SCHIRA. Unfortunately, no.

Mr. MURPHY. And because of this information was registered, did it come out then that the copper ionization levels were acceptable?

Mr. SCHIRA. I believe that is what was being documented on the sheet, yes.

Mr. MURPHY. You know, I have got to tell you. A few years ago when I joined the Navy, I did it to try and help a lot of our wounded soldiers when they were coming back and coming in the hospital. And what I am hearing here is deeply disturbing. That either

we have weak or absent standards of what we should be doing, weak adherence to standards, or some incredible negligence that led to the death of five people. I yield back.

Mr. COFFMAN. Thank you, Dr. Murphy. Mr. Walz?

Mr. WALZ. Well, thank you. First of all, my comments here is that some of the accusations that were made here, I am going to put in for the record, Mr. Chairman, that I think these witnesses should have been sworn in, or still should be. Because the accusation of knowledge of a crime of this magnitude is a pretty serious accusation. My question now is are we going to get names? Are those people involved in this going to have recourse? So for the record, I would counsel that. With that in mind, witnesses, we all here want to get the best care for our veterans the best way possible and find out what's going on. But there have been some pretty serious accusations. If they prove true, someone should be prosecuted, someone should go to jail. But I hope all our witnesses understand to make such a statement in this setting holds very serious consequences. So with that, and not to further the stereotype of passive-aggressive Minnesotans, I just do have a couple of questions.

I did dovetail on that, Ms. Dahl, I am concerned for your workers. The government, a government entity should always set the standard in terms of workplace safety, workplace protocols that are in place. I myself do not know, that is why I think Dr. Murphy's questions were correct. Were we following protocol? Were we putting your people in a position? I think that is something this Committee needs to follow up on. And I pledge to you, that is what we will do.

Mr. Marshall, do other companies share their data with you, that you have this installed with?

Mr. MARSHALL. Well first of all, this is not our equipment.

Mr. WALZ. Okay.

Mr. MARSHALL. So but yes——

Mr. WALZ. Are you on contract to the VA to maintain the equipment?

Mr. MARSHALL. No.

Mr. WALZ. Okay.

Mr. MARSHALL. We service equipment all over North America, and we also sell equipment all over North America. This was not our equipment, but they were familiar with us helping them or other facilities in the Pittsburgh area, and asked us to come in and just put a new set of eyes on it.

Mr. WALZ. Okay. Mr. Schira, you said that no one told you or whatever. Are you under contract to the VA to provide that type of counsel? So were you prepared to do that pro bono? Are you prepared to do that today, to go in there pro bono?

Mr. SCHIRA. We did two site visits at no charge trying to learn what was going on.

Mr. WALZ. So if they choose to use you, though, they are going to have to pay you. And we are going to have to go through the contracting procedures that are put in place. So it would not be unusual for them to not share that data with someone who is looking for a contract? Would you say that is fair?

Mr. SCHIRA. Yeah. I would say if you interpret sharing the data is simply a financial motivation for technologies like us. That is not the purpose. The purpose is to validate the efficacy of the system. And the only way we know what that validation is, is by you sharing it.

Mr. WALZ. I agree. And there are protocols to do this. I thought it was getting intimate, at that folks were ignoring you and had they listened to you things could have been better. I think there might be some data that would need to be first before they entered into such a contract to prove that. Is that true?

Mr. SCHIRA. Well I think we have the data and the track record that actually does provide that and prove it. We are installed in more than 15 VA hospitals that we are able to work with. So we have history that can——

Mr. WALZ. Did this VA hospital handle it different than your other ones?

Mr. SCHIRA. Mostly from lack of communications.

Mr. WALZ. Okay. All right. Doctor, you and Dr. Stout, you again, some pretty strong statements. You said knowing the history of this VA. Could you tell me your history with that VA center?

Ms. STOUT. I started to work at the Pittsburgh VA as a graduate student in 1980. And then I went on to be employed at the Pittsburgh VA starting in 1983. And my work there with Dr. Yu was to basically understand Legionnaires' Disease transmission, prevention, not only at the Pittsburgh VA but for health care facilities nationwide.

Mr. WALZ. And I want to be clear that the research you have done is greatly appreciated. When you look up Legionella.org it is you, and it is the two of you. So I want to be very clear on that and the work you have done there. I also want to be very clear, it is the 800-pound gorilla in the room. Is it safe to say there is some history between the two of you and the Pittsburgh VA?

Ms. STOUT. Well as was actually brought up by the Chair, I believe, in 2006, and people probably do not know this, the chapter that then had sued happened because I had worked for the VA since 1983 and this is 2006, and never asked for a raise. When I asked for a raise, after getting a masters degree, a Ph.D., and national prestige for the VA, the administrator said, "Give her a raise? And why do we even need the Special Pathogens Laboratory? I think I will close it and make Dr. Stout,"——

Mr. WALZ. Is that on official record?

Ms. STOUT. Yes, it is part of the testimony——

Mr. WALZ. From 2008?

Ms. STOUT.—from 2008. And I also, just because Mr. Moreland brought it up, I want to share with the Committee, you know, this is the result of the 2008 investigation. Which showed clearly that our collection of isolates was a well catalogued, very well maintained——

Mr. WALZ. So you dispute the comments that it was——

Ms. STOUT.—not a bunch of broken glass and——

Mr. WALZ. So you do dispute that point on the——

Ms. STOUT. Absolutely. And I do not dispute it. The hearing proved that it was untrue. And I am astonished that it was as-

serted here today. Amazing. It really calls into question the testimony of Mr. Moreland.

Mr. WALZ. Doctor, how did you end your employment with the VA?

Dr. YU. I was fired. And I was fired because they closed the Special Pathogens Lab. But we had specimens that had to be processed and they came from some of the most famous hospitals in the United States and public health agencies if they suspected an outbreak. And I said, "You are closing it? But we have got all of these that we are processing." So they said, "Stop processing them." And I wrote a letter to Specter and to Mr. Moreland. I had a choice between my conscience as a physician to process these samples that were being sent to look at outbreaks, or I could stop. So I processed them and that was the reason I was fired.

Mr. WALZ. Did you go through due process? Did you go to court over your firing?

DR. YU. It turns out that I am a University of Pittsburgh professor with tenure, as many, many of the VA deans hospitals are. And they said that I had no recourse.

There is one anecdote that you would be interested in. One of the specimens that we processed turned out to have Legionella. And we, and it turned out they were having an outbreak. So we informed them that, "You have an outbreak. Your cultures are all positive for Legionella." And then because I was fired, because I processed those cultures, the health care facility's manager emailed me because this had become national news. And thanked me for doing them this service because they now recognized that the Legionella in their patients had come from that in the water and that they recognized that they——

Mr. WALZ. You know as a layman, I have to tell you on this, and I say this not because I have any expertise on that, but because of the nature of it, I represent the Mayo Clinic area and have had numerous encounters with this. Biobanking is very complex. I had a critical access hospital that was nearly closed and went through six years of fights because a lab had a broken centrifuge and they carried it to another lab. The two of you know this is serious business. This is serious, the slightest breaks in protocol on biobanking are certainly reasons for recourse. Is that an untrue statement? And that biobanking——

Ms. STOUT. I do not really follow your logic there. What are you talking about, breaks in, what are you——

Mr. WALZ. The protocol. This issue of saying that you processed them afterwards. From a layman's perspective, I think there is great frustration. If we had samples here, and said that they could have helped on this, how those samples are collected, and the chain of custody of them, and how they are done is so critically important. One lab test carried in a hospital from one lab to another broke the protocol of that and almost closed down the entire hospital because of contamination and all of those issues. So my question here is, is no one is denying the value of the research but how the research is conducted is critically important. Is that correct? Am I wrong on that, Dr. Stout?

Ms. STOUT. Well all I have to say is that after months of investigation what the Committee found, which is the Committee on

Oversight and Investigation in Science and Technology is that there was absolutely nothing wrong with the protocols that were being followed at the Pittsburgh VA in the Special Pathogens Laboratory.

Mr. WALZ. So in recourse then I would have assumed that you would have gone to court to right your wrong, your grievances.

Ms. STOUT. One of the things that I always say is that as an employee in the laboratory service, I was able to be represented by the union. Without representation by the union, I would have been fired without the ability to defend myself. With the union's help, I successfully defended myself against various accusations which were patently false.

DR. YU. Let me answer your question directly. Because I think you are implying that maybe if we mislabeled something, left a tube out, hey, that is good enough reason to destroy the whole collection. Is that what you are saying?

Mr. WALZ. I am not saying it is good enough reason. But I am saying that those protocols are into effect.

Dr. YU. Right. And so——

Mr. WALZ. And you both know that. If you——

Dr. YU. Yes, I agree with you.

Mr. WALZ. That is a serious violation.

Dr. YU. It is a serious violation. Dr. Melham said that that is the reason she destroyed it and she mentioned that in the televised hearing. But when she was deposed in a lawsuit she said she never, she never gave that order. It was done by four employees without her knowledge.

Mr. WALZ. Okay. Well I just, Mr. Chairman, and I apologize for going down the road. The question I always have is trying to find this. I think myself a sense of frustration that maybe a third person in this field maybe should have been here too, because there is a history. And that does not invalidate your testimony. It certainly does not invalidate the work that you have done. I think it brings into question, especially when strong accusations are made of criminal behavior, it brings into question the validity of that. And I think that undermines our ability to get at the heart of this. So thank you for your patience on that.

Mr. COFFMAN. Let me just remind the witnesses and read from a little section that was sent to you. And it says, "Please be reminded that testimony requested or pursuant to this is governed by the applicable provisions of Section 1001, 1505, and 1621 of Title 18, United States Code, which dictate penalties pertaining to submitting intentionally false statements to the Committee, or knowingly falsifying or concealing pertinent facts related to inquiries made by the Committee."

With that, I have got a few questions. Oh, I am sorry, Mr. Rothfus?

Mr. ROTHFUS. I yield back.

Mr. COFFMAN. Okay. Mr. Schira, what is the remote monitoring system, or RMS, and why is it important?

Mr. SCHIRA. The remote monitoring system allows, if they are willing to tie it in, allows us to see minute by minute the activity of the individual computer and controller as to how much amperage, voltage, and GPM is, oh I am sorry, I keep doing that, how

much amperage is required to maintain the targeted levels of copper and silver ionization. This is recorded. It is graphed and documented all automatically with no intervention on the customer's part or our part, and it all goes to a Web site that collects the data which is accessible to the individual customer, their infectious control personnel, their engineering staff, etcetera. So it just gives us another insight to really seeing what is going on in that environment of care.

Mr. COFFMAN. Did the Pittsburgh VA have the remote monitoring system?

Mr. SCHIRA. They had the capabilities. We had provided them with systems with the computer boards that was capable. But they chose not to connect them to a modem that would have allowed that remote monitoring access.

Mr. COFFMAN. Ms. Dahl, have you experienced any retaliation related to your scheduled appearance here, or in any other role at the Pittsburgh VAMC?

Ms. DAHL. I have not been retaliated for my testimony here today. Like I said, I will not know how people will respond until I return to my duty station.

Mr. COFFMAN. Any intimidation?

Ms. DAHL. I have been advised that I did not have to come. I do not think I was, in a mean way. It was just——

Mr. COFFMAN. Were you encouraged not to come?

Ms. DAHL. I was told I could be sick.

Mr. COFFMAN. Really?

Ms. DAHL. Yes, sir.

Mr. COFFMAN. And who told you that?

Ms. DAHL. The associate director.

Mr. COFFMAN. Okay. When did they tell you that?

Ms. DAHL. The Friday before I left.

Mr. COFFMAN. Okay. Mr. Schira, did your company provide training and written documentation to Pittsburgh VA personnel?

Mr. SCHIRA. Yes, we did. Over probably easily three or four years with the institution of the newer model systems, and on-site training was provided to the various facilities people.

Mr. COFFMAN. Okay. Ranking Member Kirkpatrick?

Mrs. KIRKPATRICK. I yield back. Thank you, Mr. Chairman.

Mr. COFFMAN. Thank you, Ranking Member. Mr. Murphy?

Mr. MURPHY. Thank you, Mr. Chairman. I am curious for everyone who has worked at the VA hospital, and I go back to, I remember once being at a ceremony at VA Pittsburgh receiving some national recognition for its superb record of dealing with hospital acquired infections. And I have talked to many people over the years and that has helped me with learning and push forth some legislative issues in terms of how to handle hospital acquired infections and reduce them. It is a serious concern. I think it causes about 50,000 lives a year and maybe $100 billion or so. Or maybe I have those numbers reversed. But let me ask this. Dr. Yu to start, when you were at the VA system in Pittsburgh and what was the protocol when there was some infectious disease outbreak? MRSA or something else? Were staff generally notified when there was an infectious disease that was——

Dr. YU. Sure. The 30 percent rule was not that you just ignore everything.

Mr. MURPHY. I mean, with any infectious disease.

Dr. YU. Yes. It is standard to certainly notify the staff because they are at the front lines.

Mr. MURPHY. But do you think that helped the VA develop a stellar record in terms of handling infections, because staff were notified fairly quickly?

Dr. YU. Yes.

Mr. MURPHY. And so, like I say, anything like Methicillin-resistant Staphylococcus aureus, or central line infections, or pneumonia, any communicable disease. How were staff usually notified when there was an outbreak?

Dr. YU. Well, I was in charge of all of that when I was there. And we did it through a combination. I met with all the interns and residents, because it is a teaching hospital. An infection control practitioner met with all the nurses. And then we gave conferences. And then I rounded with the intensive care unit physicians, because they handle the sickest patients. And we notified them of, "You have to wash your hands. Legionella has come back into the water system. And so forth."

Mr. MURPHY. And other——

Dr. YU.—very strong contact.

Mr. MURPHY. Would this have been done within a week, a day, an hour, I mean, immediately?

Dr. YU. Immediately.

Mr. MURPHY. Okay. And Ms. Dahl, for employees of the VA hospital system, are there standards also set in terms of notification timing of employees when there is an infectious disease outbreak that you might be aware of?

Dr. YU. Yes. When we are, we have protocols in place for things like the MRSA, and things that you, there are screening tools that identify a person, that they need isolation precautions. So the staff use gowns and things of that sort. With the Legionella, you know, again, I learned all my information from googling OSHA guidelines as far as Legionella goes. And one of the things that they first said was that we should screen the employees that had been out for six weeks as soon as they noticed that there was an outbreak, which was two or more positive cases. So I immediately brought that to the attention of leadership because I was concerned that we were not going to do that. And I was told that that would be a HIPAA violation to screen for that and send out letters. And I had argued that it was a Legionella outbreak and not a HIPAA violation.

Dr. YU. We also notified the patients and if they had Legionnaires' Disease, all of them lived, so it was no big deal that you have Legionnaires' Disease, we are treating you for this. And we did that with MRSA patients as well.

Mr. MURPHY. Dr. Yu, I just wanted to clarify something too. You said there was zero Legionnaires' Disease between 1997 and 2006?

Dr. YU. 1996 to 2001.

Mr. MURPHY. 1996 to 2001.

Dr. YU. It was in 2005, they have one there. But we have a memo from the hospital director that says exactly the same years. Ten years, there were none.

Mr. MURPHY. So with regard to my questioning regarding following protocol if there was an infectious disease outbreak. We have already heard testimony that when Legionella was discovered in the water system, medical staff were not immediately notified. Is that your experience, Ms. Dahl? That people were not notified?

Ms. DAHL. Yes, sir.

Mr. MURPHY. And do you have any, what was that lapse of time between an official notification, not what you may have found on the Internet but an official notification, and the others?

Ms. DAHL. The first notification that I had as the local president was on the 16th of November, 2012. That there was a problem, we were going to water conservation. I received a call from the director.

Mr. MURPHY. And what was the date, do you recall what the date was that they actually detective Legionella in the system then?

Ms. DAHL. When I met with them on the 20th, leadership at the VA, to inquire about the situation with Legionella, I had asked, "When did you first know that there were patients that were positive Legionella?" And they had generally stated at least a couple of weeks prior, earlier in the month.

Mr. MURPHY. Okay. I am just trying to establish how much time between when the hospital knew and you were notified. We will have to check that in the record, too. Ms. Dahl, you mentioned that the associate director said to you that you could be sick today. Who is that associate director?

Ms. DAHL. Her name is Lavita Ford.

Mr. MURPHY. Was that a private meeting?

Ms. DAHL. It was.

Mr. MURPHY. So no one else was present?

Ms. DAHL. No, sir.

Mr. MURPHY. Any notes taken of that meeting? Any emails? Anything else?

Ms. DAHL. No.

Mr. MURPHY. All right. Thank you. I yield back.

Mr. COFFMAN. I want to thank the panel for your testimony today, and thank you very much. And this panel is concluded now, excused.

The Chair would now like to call Mr. Michael Moreland back to the witness table. Thank you, Mr. Moreland. Mr. Moreland, what is the training for Pittsburgh VA employees in running the sterilization system and how much training was provided?

Mr. MORELAND. I really do not have the details on that. I know that they met with the vendor. I am sorry, but I do not know the details of the exact minutes and time. I know that they met with the contractor to have an orientation to the system. But I do not have that at the tip of my tongue.

Mr. COFFMAN. Are there supposed to be two FTE, or full-time equivalent employees, assigned at all times to run the system as was stated? And how many were at Pittsburgh VAMC?

Mr. MORELAND. I know that the policy prior to its more recent talked about recommending two people. But the most recent policy, which I will have to pull out and reference, requires two people to be there at all times.

Mr. COFFMAN. And were there two people there at all times?

Mr. MORELAND. I do not know that for a fact.

Mr. COFFMAN. It would really help to have the people that we asked to be here to testify that would in fact have that information, would it not?

Mr. MORELAND. I can find that information for you, sir.

Mr. COFFMAN. For the record? What was the reason for removing Dr. Stout?

Mr. MORELAND. Dr. Stout was not removed. She resigned.

Mr. COFFMAN. And Dr. Yu?

Mr. MORELAND. Dr. Yu was, his services were not longer required because as mentioned he was doing work that was not authorized and not needed at the VA.

Mr. COFFMAN. What is the VA's response to the fabrication of results?

Mr. MORELAND. I am not aware and I do not recall ever having seen any information about that. If there was concern that that occurred, it would have been my expectation that that would have been communicated to the VA Pittsburgh so that we could have taken action to address that concern.

Mr. COFFMAN. Ranking Member Kirkpatrick?

Mrs. KIRKPATRICK. I yield back my time.

Mr. COFFMAN. You are dismissed. Thank you.

Mr. MORELAND. Thanks.

Mr. COFFMAN. My thanks to the panel. VA Pittsburgh has been caught manipulating their own data to cover poor maintenance of the copper-silver system. VA has been caught intimidating its own employees, both those who wanted to convey information to their fellow employees about potential unsafe working conditions, as well as those testifying today. Make no mistake, the VA will be closely scrutinized for its actions towards those who have testified here today and towards employees who do the right things. Furthermore, there has been a serious breakdown in how the VA assessed its responsibility in diagnosing and reporting Legionella. There was a dismal failure in the VA following its own policy and CDC guidance in addressing Legionella. There was a tragic failure in leadership at the local level, the VISN level, and at the VA central office level. And in the end, five veterans died. Five veterans died that we know of. And others, both veterans and employees, became very ill.

This hearing was necessary in order to accomplish a number of items. One, there must be an accounting for the failures that have been identified through hard evidence. Two, the VA central office needs to strengthen the inherent weakness of the infection control program office, thoroughly reviewing the reports and plans from well performing facilities and applying those practices elsewhere. Three, there needs to be a unified focus from CDC, the VA, and other organizations to ensure everyone knows what to do, everyone can be held accountable, and that this travesty never happens again. Four, within 30 days, I expect the VA to contact my Subcommittee staff and in a bipartisan fashion we will chart out a road ahead. With that, this hearing is adjourned.

[Whereupon, at 1:08 p.m., the Subcommittee was adjourned.]

A P P E N D I X

Prepared Statement of Hon. Mike Coffman, Chairman

Good morning. This hearing will come to order.

I want to welcome everyone to today's hearing titled "Analyzing VA's Actions to Prevent Legionnaire's Disease in Pittsburgh." I would also like to ask unanimous consent that several of our Pennsylvania colleagues be allowed to join us here on the dais today to hear about an issue very specific to their constituents. Hearing no objection, so ordered.

Today's hearing is based on a recent outbreak of Legionnaire's Disease at the Pittsburgh VA Medical Center. At least 29 recent cases of Legionnaire's Disease have been associated with the Pittsburgh VAMC. While VA has stated that eight of these cases were definitely *not* contracted at their hospital, it has also stated that it cannot determine whether 16 of these cases were contracted at the hospital.

VA contacted the CDC last fall to investigate the issue. The CDC's report, just released on Friday, not only determined that many veterans likely contracted Legionnaire's Disease through the Pittsburgh VA health care system but that, tragically, five veterans have died over the past two years from Legionnaire's Disease acquired at the hospital. The CDC report paints a more complete picture, and it turns out that problems originated much earlier than what VA has stated and are much more widespread. While VA's public acknowledgment of *Legionella* bacteria in the water at Pittsburgh VAMC did not occur until November 2012, the Subcommittee in the course of its investigation uncovered a great deal of evidence that officials at the Pittsburgh VAMC were aware of serious problems with their water sterilization system well before this time.

What's more—this outbreak was more than likely preventable.

This event is rooted to the history of the Special Pathogens Lab that at one time was the hallmark of the Pittsburgh VAMC and the flagship of *Legionella* research across the globe. Its abrupt closure in 2006, under questionable circumstances, was followed by a congressional hearing in 2008 that led to the exoneration of Dr. Stout and Dr. Yu, the Lab's directors, and the admonition of VA. But the loss of the Special Pathogens Lab and the experts within it directly impacted VA on both a local as well as a national scale.

According to VA's own documents, the *Legionella* protocol in place at Pittsburgh from 1997 to 2006 resulted in no hospital acquired Legionnaire's Disease. This protocol mandated testing copper-silver levels and *Legionella* testing every other month. How is it that a successful system is now blamed for the problems in Pittsburgh?

VA also tells us that *Legionella* is a national problem. I agree that there should be a more comprehensive program with a single focal point. However, VA provided documents to this Subcommittee stating that, as of December 17, 2012, there have been only five *Legionella* cases across the entire VA health care system, and all five cases were community acquired. Even basic news reports tell us that these numbers are far from accurate. Does VA even know how many cases of Legionnaire's Disease exist in its patients and where they could have originated?

The recent CDC report indicates VA either has no idea or is deliberately downplaying what actually happened. The deaths of five veterans- and the many other cases of Legionnaire's Disease- are nothing to be downplayed.

I understand that different agencies have different protocols for preventing and responding to *Legionella* bacteria. It is my wish that today's discussion and the recent outbreak in Pittsburgh can provide an opportunity for appropriate agencies put forth a unified effort to establish a national framework on addressing *Legionella*. From that framework, local protocols can be put in place so that a local facility can respond appropriately. This Subcommittee is not advocating for any one method of *Legionella* treatment - just that whatever proven system is put in place be used correctly. Regardless of the method, what happened in Pittsburgh could have been prevented, and veterans have unnecessarily paid the price.

I look forward to a thoughtful discussion today on what VA officials knew about *Legionella* in the water at the Pittsburgh VAMC, when they knew it, and what actions they took to address this serious problem in a responsible and timely manner. However, I am disappointed that, despite several requests to VA from the Subcommittee, no one from the Pittsburgh VAMC who was there during the incident is here to deliver first-hand knowledge of events. Hopefully the witnesses that are here today can, at the very least, recommit to the Department following its own protocols and holding accountable those employees who fail to do so.

Prepared Statement of Hon. Robert L. Jesse, M.D., Ph.D.

Good morning, Chairman Coffman, Ranking Member Kirkpatrick and Members of the Subcommittee. Thank you for the opportunity to discuss the cases of Legionnaires' disease identified at the Department of Veterans Affairs' (VA) Pittsburgh Healthcare System (VAPHS). I am accompanied today by Mr. Michael E. Moreland, Director, Veterans Integrated Service Network 4, and Dr. Gary Roselle, National Director, VHA Infectious Diseases Service.

VA is committed to providing quality care to our Veterans and has partnered nationally and locally in an ongoing effort to understand and control Legionella. Legionnaires' disease is a form of pneumonia caused by a bacterium known as Legionella, discovered and named following an outbreak of pneumonia among attendees of a July 1976 American Legion convention at the Bellevue Stratford Hotel in Philadelphia. Legionnaires' disease is contracted by breathing in an aerosol (mist or vapor) of water containing the Legionella bacteria. The disease is not contagious and cannot be transmitted from one person to another. Most people exposed to the bacteria do not become ill, though patients who are immune-suppressed are most at risk.

According to the Centers for Disease Control and Prevention (CDC) website, between 8,000 and 18,000 people are hospitalized with Legionnaires' disease or Legionellosis in the United States each year. However, it is likely that many Legionella infections are not diagnosed or reported, so this number may be higher. In a recent publication, CDC reported that Legionellosis is increasing in the United States with an increase of 217 percent reported through surveillance between 2000 and 2009. This publication reports the highest age-adjusted incidence rate is found in the Middle Atlantic region (New York, New Jersey, and Pennsylvania).

As a national health care system, the Veterans Health Administration (VHA) recognizes that there are two critical components to the management of Legionella in its facilities. The first consists of surveillance of both clinical infection of patients and the presence of Legionella in the environment. The second is preventing the growth of Legionella in the facilities' water systems. VHA has one of the most comprehensive Legionella prevention policies in the United States, including very specific algorithms for annual evaluation of risk at the facility level. The VHA Policy requires an annual evaluation of facility risk. For example, in transplant centers, VHA specifically directs twice-yearly testing of water samples, consistent with CDC guidance. VA Pittsburgh is a transplant center and performs water sampling at a rate more frequent than the VHA Policy or CDC require. Of note, the CDC makes no recommendations regarding long-term, supplemental systemic treatment of hospital water systems to prevent Legionella growth. Several supplemental treatment systems exist including copper-silver ionization and several methods of chlorination. These are in addition to the primary prevention strategy which is control of water temperature limits for the hot water distribution system. While these practices will not entirely eliminate the possibility of hospital acquired Legionella, the risk of it can be substantially reduced.

Background on Legionella Prevention at VA Pittsburgh Health Care System (VAPHS)

Legionella is naturally present in water and is particularly prevalent in the area around Pittsburgh, and is most problematic in late summer through the fall. Legionella prefers warm water, and can grow at temperatures as high as 115 degrees Fahrenheit. As a result, there is a need to maintain the hot water supply at a temperature that can balance the risk of Legionella growth versus the risk of scalding individuals. Generally, this is done by maintaining a temperature gradient that is high at the source but reduced at the taps.

It is expected that Legionella would be sporadically detected in some VAPHS water samples, and this has been the case over the years. Regardless of whether the levels detected met VAPHS thresholds for action, the facility would typically

perform remediation when detection levels rose. When Legionella is confirmed in a facility's water system, two methods of remediation are most commonly used in this country; super-heating or hyper-chlorination of the water. For VAPHS, remediation included super-heating of water systems where feasible as well as manual disinfection of water outlets. Remediation is not always successful and successive remediation efforts may be required to reduce Legionella contamination.

Additionally, VAPHS has used a supplemental, continuous copper-silver ionization system to maintain long-term suppression of Legionella bacteria in the water supply. Ion levels may be affected by water pH or other elements present in municipal water systems. The protocol for the routine examination of the water system and copper-silver Legionella control consisted of visual checks of the amperage and voltage of the copper-silver ionization system, monthly rotation and cleaning of the flow cell units of the copper-silver ionization system and periodic water sampling to evaluate ion levels. The copper-silver ionization system requires frequent monitoring and ion levels may vary based on fluctuations in the character of the incoming municipal water source. More recently, continuous chlorine infusion into the water supply has been introduced as a method of Legionella suppression. The long-term solution is a plumbing project which will add instantaneous water heaters and mixing valves in order to maintain consistently high hot water temperatures while preventing the risk of scald injuries. This will be coupled with a chlorine dioxide water treatment system, which will provide Legionella suppression to all water entering the facility.

Recent Cases of Legionella

On October 5, 2012 a Legionella specimen from two patients and one from an environmental culture were transmitted to the CDC via a protocol that involved the state and local public health authorities. The purpose was to determine if the patients might have a hospital-acquired infection even though they had limited contact with VAPHS. Following this, a third patient was diagnosed and a specimen was sent to CDC on October 23, 2012. A positive relationship, i.e., DNA sub-type similarity between the patient and environmental strains of Legionella, for the first two patients was communicated to VAPHS on October 30, 2012, at which time these two were counted among the hospital-acquired Legionnaires' disease group. Working again through Allegheny County Health Department (ACHD) and the Pennsylvania Department of Health (PDoH), VAPHS requested assistance from CDC, and on Nov 7, 2012 a team representing CDC, ACHD, and PDoH arrived at VAPHS to initiate their case review and environmental assessment.

The CDC used its water sample collection technique, which results in a more sensitive screening process. For the patient case review, they expanded the definition of the incubation period for Legionella pneumonia in order to capture the widest possible number of Veterans who may have been infected. When the first 44 water sample tests were complete, more than half of them demonstrated Legionella growth.

During the course of the collaborative review by VAPHS and the CDC, a total of 29 cases of Veterans with Legionella pneumonia were identified from January 1, 2011 through November 2012. Five of those cases were confirmed to have originated at VAPHS. Of the five cases confirmed as hospital-acquired, four patients recovered and one died within 30 days of the Legionnaires' disease diagnosis. The Veteran who died suffered primarily from congestive heart failure, but Legionella pneumonia was listed as a contributing cause of his death. Sixteen cases were identified to have had contact with VAPHS, which means that they may have contracted the disease at the VAPHS but a definitive determination cannot be made. CDC refers to these cases as "probable hospital-acquired". Eight cases were determined to be community-acquired, meaning that they contracted the infection outside of the hospital. It is important to note that none of the probable or confirmed cases was in a transplant patient.

CDC confirmed the linkage of Legionella in the water supply with pneumonia patients in a communication that VAPHS received on October 30, 2012, and on November 15, 2012, after performing its environmental assessment, CDC recommended remediation. VAPHS promptly instituted an aggressive, multiphase water remediation effort. Phase one of this effort involved superheating the potable water system from 160 to 170 degrees Fahrenheit and then flushing this system with a goal of eliminating any existing Legionella bacteria. Due to the complexity of the water systems, the heat and flush procedure was successfully implemented at some, but not all, parts of the water system. As an added measure, VAPHS then hyper-chlorinated its water system per CDC guidelines and instituted water-use restrictions. Water restrictions at University Drive and H.J. Heinz campuses were initiated on November 16, 2012. The restrictions were lifted on November 30, 2012 at

the University Drive campus after water cultures, which require two weeks to process, confirmed successful remediation. On December 7, 2012, the restriction was lifted at the H.J. Heinz campus. VAPHS continues to conduct water testing at various locations in the water distribution system, every 2 weeks as per CDC recommendations and protocol. Bimonthly water testing will continue until CDC recommends lower frequency of testing and any areas testing positive are immediately remediated.

VAPHS had concerns about Legionella growing in water samples with sufficient copper-silver ion levels, and there had been numerous past adjustments to the copper-silver ion levels in response to both low and high levels of one or the other ions. As a result, VAPHS took the copper-silver ionization system off-line. VAPHS also instituted a continuous chlorine drip to help maintain control of Legionella levels in the water system until a permanent supplemental treatment strategy is formalized.

VAPHS had been balancing the need for maintenance of high hot water temperatures with the need for preventing scald injuries, which resulted in water temperatures that were low enough to permit the growth of Legionella. The decision regarding the circulating hot water temperature was made with the belief that copper-silver ionization provided sufficient supplemental protection. However, as previously noted, the performance of this system, its maintenance and monitoring, is complex and may have failed to consistently prevent Legionella growth.

VAPHS has also chartered a water safety committee, which will be charged with the oversight of efforts to maintain effective communication about water safety and oversight of monitoring and remediation efforts throughout the facility. The chairperson is the associate director and the group will have representation from facilities management, infection prevention, and laboratory service. The committee will report to the medical center's executive leadership board.

Outreach Efforts

VAPHS proactively contacted local media and provided a brief summary of the findings, the status of remediation efforts, the number of confirmed hospital-acquired cases of Legionella at VAPHS to date (5), and the number of probable cases to date (16). On November 16, 2012, VAPHS leadership activated an incident command center and tasked this center with clarifying facts and communicating news and updates to Veterans and employees. A call center was established to answer questions from Veterans, staff, and family members. All inquiries were addressed by the call center staff or referred to the Director of Infectious Disease for resolution. In addition, VAPHS leadership held Town Hall meetings with employees at all three VAPHS campuses. VAPHS public affairs department also notified local congressional offices, union partners, and the media about the presence of Legionella in the VAPHS water system and the identification of patients with Legionella pneumonia. VAPHS has identified and attempted to contact all known Veterans diagnosed with Legionella pneumonia, but whose source of infection is unknown. For patients where community acquired Legionnaires' disease was suspected, VAPHS proactively offered to test the water systems in the homes of these individuals and access to our medical experts in order to determine if the source of infection was in their home. To date, in response to this request, no samples were received. Finally, the VAPHS public affairs department has been posting pertinent updates and information in various places on VAPHS' internal and external Web sites, *http://www.pittsburgh.va.gov.* The designated call center remains open and Veterans can contact the call center at (412) 360–1199. Any employees with questions relating to Legionella have access to an e-mail group that will address their questions and concerns. Legionella updates were provided at recent employee town hall meetings and a Veteran roundtable event.

Summary

VAPHS is following the recommendations of the numerous external and internal review teams, such as superheating and hyper-chlorinating the water system among other remediation efforts. These efforts have successfully reduced Legionella in the water supply. Our ability to provide the best care to our Veteran patients improves through this expert consultation and analysis. VHA is committed to the prevention of Legionella and is continually looking to update best practices for prevention.

Chairman Coffman and Ranking Member Kirkpatrick, VA is committed to providing the highest quality of care that our Veterans have earned and deserve and continues to take appropriate actions to ensure the safety and protection of our patients. We deeply regret that any Veteran was exposed to Legionella bacterium at VAPHS.

We appreciate the opportunity to appear before you today. My colleagues and I are now prepared to answer your questions.

Prepared Statement of Dr. Lauri Hicks

Good morning Mr. Chairman and other distinguished Members of the Committee. My name is Lauri Hicks, and I am a medical officer at the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services. Thank you for the opportunity to speak to you today about CDC's epidemic assistance investigation (Epi-Aid) into a Legionnaires' disease outbreak at the Veterans Affairs (VA) Pittsburgh Healthcare System in Pittsburgh, Pennsylvania. I also want to extend my deepest sympathies to the patients and their families affected by this outbreak.

Today, I will provide some background on Legionnaires' disease and CDC's role in these types of investigations. I will then provide specific details on CDC's epidemic-assistance investigation (Epi-Aid) at the Pittsburgh VA Medical Center, a description of our findings, and our proposed recommendations.

Legionnaires' disease

In 1976, CDC in cooperation with other Federal, State, and local authorities launched one of the largest joint disease investigations in history following an outbreak of severe pneumonia among the participants of the American Legion Convention in Philadelphia. This investigation led to the identification of the previously unrecognized bacterium, Legionella, and the establishment of Legionnaires' disease (LD). *Legionella* is a type of bacteria found in fresh water. Outbreaks of legionellosis have occurred after persons have breathed mists that come from a manmade water source, such as building potable water systems (*i.e.,* through exposure to faucets and showers), air conditioning cooling towers, whirlpool spas, or decorative fountains contaminated with *Legionella* bacteria. Most people who are exposed to *Legionella* do not get sick, but *Legionella* can cause a severe form of pneumonia, referred to as LD. The illness most often affects the elderly, those who smoke cigarettes or have chronic lung disease, and persons whose immune system are suppressed by diseases such as cancer, kidney failure requiring dialysis, or diabetes.

Legionella does not spread from person-to-person. LD can usually be successfully treated with antibiotics, but it does lead to death in 5–15 percent of cases. CDC estimates that between 8,000 and 18,000 people are hospitalized with LD in the United States each year.

Even though *Legionella* may be present in fresh water systems, finding it there does not necessarily mean it is the source of someone's illness. There is not a clear relationship between the amount of *Legionella* in the water and risk for disease, and therefore there is no safe level of *Legionella* in a water system. When *Legionella* is identified in a water system, CDC recommends that measures be taken to remove the bacteria from the water, known as remediation. The most frequently used initial remediation measures include superheating or hyper-chlorinating the water system. These methods do not usually lead to permanent removal, so a long term plan for prevention of *Legionella* growth is almost always necessary.

The CDC role in epidemic assistance investigations (Epi-Aids)

CDC provides rapid assistance to States and Federal agencies, as well as international organizations and ministries of health, through formal requests for epidemic-assistance investigations (Epi-Aids). Since 1946, CDC has conducted more than 5,000 investigations. Epi-Aids always are performed collaboratively with the requesting partners and with the goal of controlling an epidemic and preventing future epidemics attributable to the same or related causes. The specific objectives of an investigation are to define the parameters of the epidemic (i.e., time of illness onset and conclusion of the epidemic, number of cases, and morbidity and mortality), to identify control or prevention measures, and possibly to identify new data relevant to the epidemiology of the health problem.

When CDC is invited to conduct an Epi-Aid, the general role of its investigators is to assist with: verifying the diagnosis and developing a list of hypotheses for the cause of the outbreak; establishing a case definition; collecting and analyzing data; categorizing cases as possible, probable, or confirmed on the basis of available data and knowledge; evaluating the hypotheses as to the outbreak's cause based on the data collected; determining and implementing control measures; using surveillance to assess the control strategy; and writing and disseminating the final report. The report provides the requesting public health officials with an explanation of the extent of the outbreak and potential causes, which enables timely and effective public

health action. The report identifies the risk factors that resulted in the epidemic, and it is disseminated to the health authorities and persons who requested assistance with the investigation.

CDC's epidemic-assistance investigation (Epi-Aid) at the VA Pittsburgh Healthcare System

CDC works 24–7 to save lives and protect people from harm, and this investigation illustrates the power of public health in action both to identify serious health problems and to coordinate a targeted response that protects our nation and its citizens from infectious disease threats.

On October 5, 2012, the Pennsylvania Bureau of Laboratories contacted CDC *Legionella* laboratory to request subtyping of some *Legionella* isolates at the VA Pittsburgh Healthcare System (VAPHS).

On October 12, 2012, CDC received two clinical isolates and one environmental isolate for sequence-based typing (SBT). On October 29, 2012, CDC reported preliminary results indicating a link between these two cases of LD with onsets of illness on August 25 and August 27, 2012 and an environmental *Legionella* isolate collected from the VAPHS University Drive Campus on October 3, 2012. CDC notified the Pennsylvania Department of Health (PA DOH), which notified the Allegheny County Health Department (ACHD) for further investigation. A conference call was held on November 5, 2012 with CDC, VAPHS and others and, upon learning of the results, the VAPHS Director promptly requested a visit from the CDC.

PA DOH requested an Epi-Aid on November 2, 2012. After discussion and with the agreement of VAPHS on November 6, 2012, CDC sent two Epidemic Intelligence Service (EIS) Officers and one microbiologist to Pittsburgh to join the ACHD and PA DOH EIS Officers and epidemiologists in the investigation. The field investigation began on November 7, 2012 and the last member of the field team left Pittsburgh on November 16, 2012. The objectives of this Epi-Aid were to: 1) Identify additional cases of LD among patients at VAPHS; 2) Complete an environmental assessment of LD risk and environmental sampling for *Legionella* at the hospital; and 3) Recommend interventions to prevent ongoing disease transmission.

For background purposes, I would like to provide a brief description of the VAPHS. The VAPHS serves the veteran population throughout the tri-state area of Pennsylvania, Ohio, and West Virginia, and has three campuses in Pittsburgh. The University Drive campus, "the hospital", is a 150 bed acute-care hospital that opened in 1954 and provides inpatient and outpatient services. The H.J. Heinz campus houses primary care clinics, a long-term care facility, substance abuse program, and dental rehabilitation. The Highland Drive campus serves only administrative functions. Since 2007, electronic medical records have allowed computerized linkage of patient care information across all campuses.

In May 2004, VAPHS was approved for an almost $200 million major construction project and underwent extensive construction work on all campuses, beginning at the University Drive campus in January 2009.

VAPHS uses copper-silver ionization to control *Legionella* in its water distribution system. The process of copper-silver ionization releases positively-charged copper and silver ions into the water, which form electrostatic bonds with negatively charged bacteria cell walls. This bond is thought to disrupt bacterial cell walls and lead to cell death.

Case-finding

To identify additional cases, CDC queried two databases for LD cases occurring between January 1, 2011 and October 31, 2012. We searched the Pennsylvania National Electronic Disease Surveillance System (PA–NEDSS) for Legionnaires' disease cases for which VAPHS was mentioned in the case entry. We also searched the VAPHS's electronic medical records for positive laboratory results for Legionella-specific respiratory culture and *Legionella* urine antigen testing.

Using a medical chart abstraction form developed for this Epi-Aid, and with the help of the infection prevention team at the hospital, we classified cases into definitely healthcare-associated, probably healthcare-associated, and not healthcare-associated and collected epidemiologic, clinical, and exposure data on cases. A probable case had exposure to VAPHS, including but not limited to: overnight stay, outpatient visit, visitor, employee, and volunteer, during a portion of the 2–14 days prior to onset, and a clinical respiratory isolate was not available for molecular testing to confirm whether the clinical and environmental isolate were the same. We requested all available patient isolates for subtyping at CDC's *Legionella* laboratory. VAPHS reported all new-onset cases directly to the Epi-Aid team following their departure from Pittsburgh.

We identified five definitely and 16 probably healthcare-associated cases of LD, for a total of 21 cases. All cases were patients who had been exposed to VAPHS before the CDC-recommended interventions were implemented. The median age of the 21 healthcare-associated case-patients was 64 years. All case-patients were male. All case-patients were Pennsylvania residents except for one from West Virginia. All cases were in patients at VAPHS; none were staff or visitors. Five case-patients or 24 percent died within 30 days of a positive diagnostic test for LD. All 21 cases had *Legionella* urinary antigen testing performed and nine of these also had *Legionella*-specific culture performed. In 13 cases, the exposure was only to the University Drive campus, in two cases only to the Heinz campus, and in six cases to both.

Environmental Assessment and Evaluation

The environmental investigation, which was conducted on the University Drive campus, began on November 7, 2012 with a visual inspection of the healthcare facility to determine possible sources of aerosolized water. This included patient care areas, waiting areas, decorative fountains, and cooling towers. We reviewed the potable water system, including visual inspection of the instantaneous hot water heaters and distribution system as well as three copper-silver ionization flow cells and controllers. Additionally, we reviewed blueprints and process flow diagrams of the potable water system with the facility manager.

We discussed the hospital's layout, equipment, and maintenance practices with the hospital facilities and infection prevention staff. The staff provided verbal information and written records regarding construction work on campus and associated water outages; measured copper and silver levels, maintenance logs, and a consultative report; pH measurements; *Legionella*-specific culture results; date and site of emergency remediation measures; and their written protocol for *Legionella* risk-reduction.

Results of Environmental Sampling

For our environmental sampling for *Legionella,* CDC collected specimens in tandem with the hospital infection preventionists at their routine sampling locations. We also collected additional samples later that same day from patient care areas, central distribution points, and the decorative water fountain according to standard CDC sample collection protocol. We measured total chlorine, pH, and temperature and collected samples for copper and silver concentrations at representative locations throughout the potable water system.

Twenty-nine of 44 environmental samples collected by our field team in November showed growth of *Legionella*. *Legionella* grew from samples collected from various locations throughout the potable water system, including from all samples collected from sites immediately after the copper-silver systems, indicating widespread *Legionella* colonization throughout the hospital. Distal sites testing positive included patient care areas, the sink of the intensive care unit room of one probably healthcare-associated case, and a shower in a room used for liver transplant patients.

Clinical *Legionella* isolates from three cases were identical and matched environmental isolates collected from multiple locations in the hospital's potable water system. This strain of *Legionella* was the outbreak strain. There were several other types of *Legionella* found in addition to the outbreak strain. Also, a sample from the sand filter of the decorative fountain at the entrance showed growth of the outbreak strain; therefore the fountain cannot be ruled out as a potential source of exposure for some cases.

Copper and silver levels were measured in 11 water samples in tandem with *Legionella* testing at routine sampling locations; seven samples were from distal sites, and four were collected from sites immediately before or after copper-silver flow cells. For copper, the mean concentration was 0.33 parts per million (ppm) at central sites, and 0.24 ppm at distal sites.

For silver, these mean concentrations were 0.04 and 0.02 ppm, respectively. Seven of 11 samples were within the manufacturer's recommended range for *Legionella* control for both copper and silver. However, all 11 samples showed growth of *Legionella*, and nine were positive for the outbreak strain.

Our environmental assessment and evaluation identified the following factors and policies that contributed to the outbreak:

- There was persistence of a highly pathogenic strain of Legionella in the potable water system despite copper-silver ionization and intermittent superheating during the past two years. At the time of our investigation, the copper and silver levels in the water were appropriate for controlling Legionella according to the manufacturer's recommendations and the hospital's protocol. However,

these same samples still tested positive for Legionella, indicating that the copper-silver ionization system was not controlling Legionella growth. The diversity of species, serogroups, and serotypes among Legionella isolates makes resistance to copper-silver ionization an unlikely explanation for amplification within the system, and points to an environment adequate for Legionella growth, indicating a systemic problem that was not being controlled by the copper-silver ionization system at the time of sample collection. The hospital collected small volumes (100 ml) of water for routine culture-based monitoring of the potable water system for Legionella. Compared to the 1 L volumes recommended by CDC, this smaller volume likely resulted in decreased sensitivity to detect widespread colonization of the potable water system.

- The hospital relied upon an action threshold (30 percent of distal sites positive) to prompt remediation. Cases occurred when sampling indicated that less than 30 percent of sites were colonized. A recent review determined that the 30 percent threshold provides both low specificity (74 percent) and sensitivity (59 percent) for legionellosis risk assessment. CDC's records on known outbreaks from 2011 revealed two outbreaks where Legionnaires' disease cases occurred after exposure to building water systems with Legionella positivity at less than 30 percent of distal sites.
- The hospital has been undergoing extensive construction. The timing of construction work at the hospital coincides with the outbreak. Construction likely introduced organic matter to the potable water system, increasing consumption of chlorine in the municipal water supply leading to amplification of Legionella. Residual chlorine in the water system, although at adequate levels in the incoming municipal water supply, was at an insufficient concentration for microbicidal activity at all distal sites measured within the hospital.

In addition, the following epidemiologic and surveillance factors were found to contribute to the outbreak:

- The hospital did not recognize healthcare-associated cases of LD for an extended period of time. A low index of suspicion that lab-confirmed cases were healthcare-acquired can be partially attributed to a perception of Legionella control in the hospital water systems.
- The cases reported to county and state public health offices were not recognized to be healthcare-associated and part of an outbreak. This may be due to a high baseline prevalence of Legionnaires' disease in Pittsburgh.

CDC's Findings and Recommendations

CDC findings and recommended interventions to prevent ongoing transmission of LD at the VAPHS have been detailed in a report provided to the VAPHS and the PA DOH.

The CDC investigation revealed a large number of healthcare-associated LD cases during 2011–2012 and widespread colonization of Legionella in the hospital's potable water system. These cases occurred in the setting of a comprehensive Legionella risk-reduction program consistent with national Veterans Affairs and county health department guidelines. This program included disease surveillance, environmental testing, and a long-term disinfection system for control of Legionella in the potable water.

CDC made some initial recommendations to stop disease transmission, which included:

- Minimize patient exposure to potable water sources. There are several ways to do this, including restricting patient showering, restricting drinking from potable water sources, installing point-of-use filters for faucets and showerheads, and turning off all decorative water features and whirlpool spas until remediation strategies have been shown to be effective.
- Implement short-term systematic potable water system remediation as referenced in American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. ASHRAE Guideline 12–2000: Minimizing the risk of legionellosis associated with building water systems, 2000:
  - Hyperchlorination to greater than or equal to 2 ppm at all distal sites and flushing at all points of use , and/or
  - Superheating and flushing of the potable water system to 160–170 degrees.

CDC also recommended enhanced testing and surveillance for LD to identify any new cases.

Additionally, CDC made recommendations for long-term Legionella control measures, including:

- The long-term disinfection system for prevention of Legionella growth in the hospital's potable water system should be reevaluated in consultation with experts.
- The facility should strive for eradication of Legionella from the potable water system, as there is no known safe level of Legionella.
- The hospital should continue testing for Legionella every two weeks for three months, and then every month for three months to ensure remediation has been effective. If any Legionella is detected during this time frame, remediation throughout the facility will need to be adjusted and the testing cycle must start over.
- LD surveillance should be conducted at the hospital according to CDC recommendations, with a strict case definition and action upon identifying one definite or two possible healthcare-associated cases.
- Close communication among hospital staff and between the hospital and public health would improve surveillance.
- The Legionella control protocols of the hospital, the Veterans Health Administration, and the Allegheny County Health Department should be carefully reevaluated to include changes in surveillance methodology, including action thresholds and sampling methods.
- The hospital should modify their Legionella sample collection procedures. Both swabs and 1L water bottles should be collected at various sampling sites, with samples processed as soon after collection as possible and results communicated to infection preventionists, building facilities manager, hospital administrators, and CDC. Chlorine, pH, and maximum temperature should be measured at the water heaters and at least a couple of distal sites.
- A standard operating procedure for appropriate maintenance, including regular cleaning, of decorative fountains should be drafted and followed. Facility managers should consult with the manufacturer of the decorative fountain to determine an acceptable biocide for Legionella control.

Conclusion

The VAPHS has rapidly implemented CDC's recommendations and has taken several steps to protect patient safety. The hospital shut down their potable water system on November 15, 2012 to initiate remediation. Meanwhile, a combination of bottled water and point-of-use filters were used for patient care needs. Superheating and hyperchlorination were performed, followed by installation of a chlorine drip to maintain the chlorine level at approximately 1–2 ppm throughout the system. Repeat sampling two weeks later showed that remediation was successful, and water usage restrictions were lifted on November 30, and the VAPHS declared the water system clear of Legionella. To date, no further LD cases have been detected.

I would be happy to answer any questions the Committee may have.

Prepared Statement of Victor L. Yu, M.D.

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.

APPENDIX

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 modality was 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:

a. demonstrated efficacy of Legionella eradication in vitro using laboratory assays

b. anecdotal experiences in preventing Legionnaires' disease in individual hospitals,

c. controlled studies in individual hospitals

d. 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.

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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: 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*)

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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Executive Summary

Victor L. Yu, M.D., Professor of Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania

I was the former Chief of the Infectious Disease Section at the Pittsburgh VA Medical CenterI. I received Superior evaluations for 29 consecutive years. I was also the Chief of the Pathogens Laboratory (SPL) – a laboratory initiated under the aegis of VACO during the Legionella outbreaks in VA hospitals in the late 1970s. Discoveries were made by the VA Special Pathogens Laboratory that brought honor and renown to the Pittsburgh VA Medical Center.

- Discovery of the source of hospital-acquired Legionnaires' disease was the drinking water of the hospital. In 1982, this historic discovery was published in the New England Journal of Medicine. It was a controversial article that was not accepted by authorities at that time, notably the CDC who favored cooling towers as the source.
- Formulation and application of disinfection strategies which included : Superheat and Flush, Chlorination, Copper-Silver Ionization, Chlorine dioxide, Monochloramine (see Appendix).
- Testing and patient evaluation of new antibiotics effective for treating Legionnaires' disease. Azithromycin and Levofloxacin decreased the mortality to < 5%.
- Development and testing of the current laboratory methodologies including the culture media for patients and water plus the evaluation of the urinary antigen test in pneumonia patients.
- Creation of the strategy for prevention of hospital-acquired Legionnaires' disease that has been adopted by the VA and worldwide. Ironically, CDC opposes this strategy which uses contamination of drinking water as the key parameter for prevention.

In 2006, our SPL was abruptly closed. I was fired because I had disobeyed an order not to process specimens during my appeal to VACO. One set of cultures un-

covered an outbreak of Legionnaires' disease. This VA later thanked me for processing the cultures knowing that I had been fired because I assisted them in their time of need (See Appendix). After protests from my patients, the American Legion and members of Congress , Mr. Michael Moreland, Hospital Director, informed the press and others was that I had conducted unapproved research and operated a rogue laboratory for profit. Both of these accusations were proven false. (See Appendix)

The primary issue before you is the deaths of the 5 veteran patients. From 1996 to 2006, we saw no cases of hospital-acquired Legionnaires' disease. After closure of the SPL, patients began contracting Legionnaires' disease after entering the VA. Physicians were not warned that Legionella had re-entered the drinking water. Attempts to disinfect the re-contaminated water supply were unsuccessful for more than one year.

In Congressional investigations, you have uncovered deficiencies and mismanagement by senior VA bureaucrats and you have been frustrated by a culture in which maximum effort is given to protecting the bureaucrats rather than the veteran patients. Despite a 2008 congressional investigation and the adverse media publicity, all of the bureaucrats s involved in closing the SPL and destroying a valued scientific collection were promoted. The VA is an excellent healthcare care system but it is tragic that its reputation has been so tarnished.

APPENDIX

Special Pathogens Laboratory and Disinfection
VA Cases and hospital-acquired Legionnaires' disease
First two pages of CV
Special Clinical Resource Center
Publications of Legionnaires' disease

Prepared Statement of Janet E. Stout, PhD

PURPOSE AND BACKGROUND

I am testifying today before the House Veterans Affairs Subcommittee on Oversight and Investigation to assist in gathering information about an outbreak of Legionnaires' disease that occurred at the VISN 4 Veterans Health Administration facility at University Drive, Pittsburgh, PA. The affected veterans and their families deserve full disclosure from the administrators at the University Drive and Heinz facilities in Pittsburgh.

I have been invited to testify today as a subject matter expert on Legionnaires' disease. My 30+ years of research in the field of Legionnaires' disease provides me with specialized knowledge about Legionella bacteria, the methods used to control it in hospital water systems and the methods used to investigate possible cases of hospital-acquired Legionnaires' disease.

I also have intimate knowledge of the procedures and practices that were established at the Pittsburgh VA facilities in response to previous outbreaks. I was among the group of scientists that were funded by VA Central Office to investigate and study the occurrence of Legionnaires' disease at the Pittsburgh VA – the VA facility that is the subject of this investigation. I started my studies with the group in 1980, the year after the first cases of Legionnaires' disease were diagnosed at the Pittsburgh VA. I became part of the VA Special Pathogens Laboratory, which was created to study Legionnaires' disease and ultimately became a Legionella special reference laboratory.

Over 100 cases of hospital acquired Legionnaires' disease were diagnosed at the Pittsburgh VA in the first years of the outbreak. These veterans had come to the VA for routine procedures, but were infected with Legionella bacteria from the hospital water system and developed a severe form of pneumonia called Legionnaires' disease. The mortality rate for hospital-acquired Legionnaires' disease can be as high as 30–40%.

We were the first to definitively demonstrate the link between Legionnaires' disease and the presence of Legionella in hospital water systems This seminal discovery in 1982 shifted the focus from cooling towers to water distributions systems as the primary source for Legionnaires' disease.

I participated in many studies on Legionnaires' disease which were conducted in collaboration and under the direction of Dr. Victor Yu, Chief of Infectious Diseases and Microbiology at the Pittsburgh VA. These studies resulted in seminal findings on identification of the source of the bacteria, the treatment of the disease and prevention of the disease through disinfection of the hospital hot water system.

Through these efforts, Legionnaires' disease was controlled at the Pittsburgh VA and our findings translated into hundreds of peer-reviewed papers which helped countless other healthcare and non-healthcare facilities prevent Legionnaires' disease.

My work at the Pittsburgh VA Medical Center from the early 1980's through 2007 provided me with specific relevant information of the processes and procedure we put in place at the Pittsburgh VA to prevent hospital-acquired Legionnaires' disease. This includes the methods and schedule for monitoring (testing) Legionella and copper and silver ions, maintenance of the ionization system, diagnostic and microbiological methods used for detecting Legionnaires' disease in patients at the Pittsburgh VA, and procedures used to investigate possible cases of hospital-acquired Legionnaires' disease.

In 1981, while at the Pittsburgh VA Medical Center, I was part of the team that first demonstrated the link between the presence of Legionella bacteria in hospital water systems and the occurrence of hospital-acquired Legionnaires' disease. This seminal discovery was published in the New England Journal of Medicine in 1982. We went on to develop the prevention strategy for hospital-acquired Legionnaires' disease which now serves as the model for national guidelines.

We also developed the diagnostic and microbiological approaches and methods used for detecting Legionnaires' disease in patients at the Pittsburgh VA, and the procedures used to investigate possible cases of hospital-acquired Legionnaires' disease.

QUALIFICATIONS (CV Attached)

I am a microbiologist trained in clinical and environmental microbiology. I received a BS in Biology from Clarion State College, Clarion, Pennsylvania; and a Masters and PhD degree in Microbiology from the University of Pittsburgh Graduate School of Public Health. I am the Director of the Special Pathogens Laboratory in Pittsburgh, PA and concurrently a Research Associate Professor in the Department of Civil and Environmental Engineering University of Pittsburgh.

My research and academic studies on Legionella–the bacteria the causes Legionnaires' disease have received international recognition. As an invited speaker to international and national scientific and professional organizations, including the International Symposium on Legionella and Legionnaires ' disease, I lecture worldwide on the subject of Legionnaires' disease. I serve as a subject matter expert in legal cases dealing with Legionnaires' disease, and am a member of national societies such as the American Society for Microbiology, the Association for Professionals in Infection Control, the Cooling Technology Institute, and the America Society of Heating, Refrigerating and Air-conditioning Engineers (ASHRAE), in which I a member of the ASHRAE Legionella Standards and guideline committees. My expertise includes disinfection and control strategies for the prevention of Legionnaires' disease and other waterborne pathogens.

My research on Legionnaires' disease in water systems of homes, buildings, hospitals, hotels and utility water systems has been reported in over 100 articles published in medical and scientific peer-reviewed journals. I co-authored the "Legionella" chapter published in Hospital Epidemiology and Infection Control and the Manual of Clinical Microbiology. Currently, I serve as a reviewer on the editorial board of Infection Control and Hospital Epidemiology, the International Journal of Environmental Health, the Journal of Clinical Microbiology, and Water Research.

OUTBREAK OF HOSPITAL- ACQUIRED LEGIONNAIRES' DISEASE AT THE PITTSBURGH VETERANS HEALTHCARE SYSTEM UNIVERSITY DRIVE (VAHS–UD)

The focus of this investigation should be:

1.The failure of the Pittsburgh VA to recognize they had an outbreak and take preventive actions. We now know there were 16 cases and 5 deaths. The delay in recognizing the outbreak may have contributed to additional cases and deaths.

2.The failure of the VA lab to detect Legionella in the water system of the VA University Drive. This likely contributed to the delay in detecting the outbreak. This failure was due to lack of knowledge and experience - a problem brought to the attention of the VA Inspector General in 2009.

3.Failure of the VA to operate and manage the copper-silver ionization disinfection system.

4.Failure to communicate with physicians, staff, patients and families regarding the increase in cases of hospital-acquired Legionnaires' disease. The delay in alerting physicians may have contributed to additional morbidity and mortality.

Legionnaires' disease Reported: On November 16, 2012, the Pittsburgh VAHS–UD reported that it had an outbreak of Legionnaires' disease and would ultimately report that 5 cases of hospital-acquired Legionnaires' disease had been diagnosed at the University Drive facility. One of these five patients died. In a latter report the VA disclosed that 16 cases of Legionnaires' disease had been diagnosed at the facility in 2011, but these cases were described as having been acquired prior to admission to the UD facility, i.e. were community acquired.

In setting the bar for prevention of Legionnaires' disease, the Pittsburgh VA cannot be compared to what is done at other facilities, but should be judged only by whether they followed their own policies and procedures.

MONITORING FOR LEGIONELLA

Methods: We established the methods used to test for Legionella in water systems, including developing the culture media used to isolate Legionella. For many years I collected the samples (swabs and water) and processed them in the Special Pathogens Laboratory. This task was ultimately taken over by other members of the Special Pathogens Laboratory. A minimum of 10 outlets and water from the hot water tanks were regularly tested as part of the infection control policy for Legionnaires' disease prevention.

When a case of Legionnaires' disease was diagnosed at the Pittsburgh VA, we tested the water outlets that the patient may have been exposed to, including the faucets and showers in their immediate environment.

Frequency of Testing: When we began testing for Legionella in the water supply at the Pittsburgh VA in 1981, the frequency of testing was monthly. After the ionization system was installed in 1994, the frequency of testing was reduced to every other month. This frequency was derived from studies that showed that an interruption in ion generation would result in growth of Legionella within 8- 12 weeks (Liu-98). Therefore we were uncomfortable with extending the frequency of testing beyond the every other month schedule. When I left the Pittsburgh VA in 2007, testing for Legionella was conducted every other month.

The Pittsburgh VA microbiology laboratory failed to detect Legionella during routine testing and were using out of date methods. However, the Pittsburgh VA microbiology laboratory is listed as a CDC certified laboratory for Legionella environmental testing – successfully participating in the CDC Environmental Legionella Isolation Techniques Evaluation (ELITE). Obviously a CDC ELITE certification does not guarantee that a laboratory is knowledgeable and experienced enough to give reliable results. This failure was due to lack of knowledge and experience of the technicians doing the testing - a problem brought to the attention of the VA Inspector General in 2009 (case number 2000–01219–HL–0293).

UNANSWERED QUESTIONS:

1. How was it determined that the 16 cases of Legionnaires' disease diagnosed in were not hospital-acquired and who made this determination?

2. Following the diagnosis of Legionnaires' disease in all of these patients, was Legionella testing performed on water outlets (faucets and showers) in the immediate vicinity of each of these patients – a practice that was instituted during my tenure at the Pittsburgh VA?

3. What was the schedule for Legionella testing at the University Drive VA?

4. What were the results of routine Legionella testing for 2011 and 2012 at the University Drive and Heinz campuses?

5. Were these results discussed at the Infection Control Committee and are the minutes of the committee meetings for 2011 and 2012 available for review?

6. Why does the current (2011) Pittsburgh VA Infection Control Policy (MCM IC–001) stipulate retention of Legionella testing for a minimum of 1 year?

THE COPPER–SILVER IONIZATION SYSTEM

Water System Disinfection: The press release from the Pittsburgh VA stated that the disinfection system copper-silver ionization system "may not be as effective as previously thought". This statement seems to attempt to shift the responsibility for the outbreak to the technology. Subsequent statements from VA Healthcare officials have also suggested that the original installation of the ionizations system in 1994 was not scientifically based.

Heat & flush thermal disinfection was used at the Pittsburgh VA from 1981 to 1994. The difficulty in performing heat & flush eradication procedures, as well as the propensity for Legionella to recolonize months after the procedure, led us to seek alternative disinfection approaches. Starting the early 1980's, 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, chlorine dioxide and monochloramine.

Efficacy of Copper-silver Ionization:

This disinfection system was installed at the Pittsburgh VA Medical Center in 1994 after results from laboratory studies and field studies in other hospitals showed efficacy in controlling (killing) Legionella bacteria. The first hospital to install ionization in Pittsburgh Mercy Hospital, not the Pittsburgh VA. It was 1994 when an ionization system was installed at the Pittsburgh VA .

Compared to thermal heat & flush, ionization was found to be more effective in controlling Legionella environmental positivity and occurrence of cases. Following the use of heat & flush (from 1981 to 1994) and after 4 years of use of copper silver ionization (from 1994 to 1998) there was a significant reduction in environmental Legionella positivity (Stout 98). Our prospective studies showed ionization was more effective than thermal methods (Heat & Flush) in reducing both environmental positivity and the incidence of Legionnaires' disease at the Pittsburgh VA.

By 2005, among 48 healthcare facilities in Western Pennsylvania, 85% of hospitals with Legionella in their water systems had initiated disinfection and 29% had used a copper-silver ionization system (Squier 2005). Nationally, by 2001 nearly 300 healthcare facilities had installed ionization.

Not relying solely on our own experience, we conducted a survey of 16 hospitals also using ionization located in cities across the U.S. These 16 hospitals were surveyed twice, once in 1995 and again in 2000. The results showed that ionization was also highly effective in preventing hospital-acquired Legionnaires' disease in these 16 hospitals (Stout ICHE 2003). These hospitals had had ionization in place for 5 to 11 years. This study represented the final step in a proposed 4-step evaluation process of disinfection systems. At the time of this publication (2003), a further reduction in Legionella environmental positivity and hospital-acquired cases was seen at the Pittsburgh VA Medical Center. It was noted in this publication that zero (0) cases of hospital acquired Legionnaires' disease occurred at the Pittsburgh VA Medical Center from 1999 to 2002 (the date of the report submission). This trend continued until the cluster (outbreak) of Legionnaires' disease which seems to have occurred at the Pittsburgh VA Healthcare system (University Drive and Heinze) in 2011 and 2012.

MONITORING AND MAINTENANCE OF THE COPPER - SILVER SYSTEM AT THE PITTSBURGH VA HEALTHCARE SYSTEM – UNIVERSITY DRIVE

Methods and Schedule: I established the program for monitoring the ionization system at the Pittsburgh VA. In the September 1999 Pittsburgh VA policy (Memorandum IC–1 entitled "Copper-silver Ionization System Maintenance and Monitoring") copper testing by a kit was to be performed by engineering weekly and silver (+ copper) monitored by an analytical test laboratory monthly. Sometime later, water samples for laboratory-based testing for copper and silver ions was performed on water samples collected on the same schedule as the routine Legionella testing – every other month. This testing was performed in the Special Pathogens Laboratory by atomic absorption spectroscopy (AA). Weekly testing for copper was done by the VA plumbers (Facilities Management Service) using a hand held device colorimetric test. In the 1999, 2007 and 2011Infection Control policies, the suggested target levels for copper was 0.2 – 0.8 mg/L (ppm) and for silver 0.02 – 0.08 mg/L (ppm).

Maintenance of the ionization system was performed by the plumbers on a routine basis, generally monthly to quarterly depending on the condition of the electrodes.

At the time of the 2012 outbreak, reports from the ionization manufacturers (LiquiTech and Enrich Tarn-Pure) indicated that the copper and silver monitoring, when performed, did not meet the suggested frequency for testing or the target levels. Documentation of this condition began as early as the spring of 2012. In addition, at the request of CDC, the Pittsburgh Water and Sewer Authority performed copper and silver testing on 11 samples in mid-November and found the levels to be "low".

UNANSWERED QUESTIONS

1. Can the VA Healthcare System (University Drive and Heinz) produce the records of regular documentation of the amperage and voltage of the ionization systems in 2011 and 2012?

2. What was the schedule for copper and silver ion monitoring, both in-house and by the external analytical laboratory in 2011 and 2012?

3. When was that schedule established?

4. What were the results of this testing for all tests performed in 2011 and 2012?

5. If results were not adequate (meeting their own internal standards), what corrective actions were taken to remedy the situation?

6. As stipulated in the Pittsburgh policy, were problems reported to Infection Control in a timely fashion?

CASES OF LEGIONNAIRES' DISEASE AT THE PITTSBURGH VA HEALTHCARE SYSTEM UNIVERSITY DRIVE AND HEINZ FACILITY

As stated above and reported in peer-reviewed publications, the use of copper-silver ionization for controlling Legionella in the water system of the Pittsburgh VA facilities had been effective in reducing/eliminating hospital-acquired Legionnaires' disease. The Pittsburgh VA Healthcare System administration reported 5 confirmed cases of hospital-acquired Legionnaires' disease acquired from exposure to Legionella from the hospital water system in 2012. They later reported that 16 cases were diagnosed in 2011, but whether they were hospital-acquired or had the disease on admission could not be determined.

The Pittsburgh VA Healthcare System administration appears to have been aware of a problem with Legionnaires' disease at their facilities well before the November 16th media release reporting the outbreak. There were meetings with the Allegheny County Health Department. Strains of Legionella recovered from sick veterans seen at the University Drive facility were sent to the Centers for Disease Control and Prevention for analysis before November 1st.

The CDC guidelines state that an investigation is required if 2 cases of probable hospital-acquired Legionnaires' disease are identified within a 6 month period? Did the Pittsburgh VA conduct such an investigation in 2011 after identifying 2 cases?

UNANSWERED QUESTIONS

1. What was the date of admission, date of onset of symptoms and date of diagnosis for all cases of Legionnaires' disease diagnosed at the Pittsburgh VA Healthcare System (University Drive and Heinz) for 2011 and 2012?

2. Who made the determination and what were the criteria used to conclude that the 16 cases of Legionnaires' disease diagnosed in 2011 were acquired prior to admission in the community and were not acquired at the Pittsburgh VA University Drive or Heinz facilities?

3. What was the result of analysis by CDC of the Legionella strains taken from VA patients and compared to the Legionella from the water systems of the University Drive VA and Heinz facility?

4. Were these strains compared to historical strains from other cases of hospital-acquired Legionnaires' disease diagnosed at the Pittsburgh VA Healthcare System (University Drive and Heinz) and historical water system strains?

5. The Special Pathogens Laboratory had a collection of thousands of Legionella strains from the patients and water at Pittsburgh VA Healthcare System dating back to 1979. Unfortunately, administrators at the Pittsburgh VA Healthcare System destroyed this collection in 2006 without approval from the Research Compliance Office and on the day that I was to meet with a representative of the Research office to transfer the collection to the University of Pittsburgh.

From 1981 to 2006 the Pittsburgh VA had a Legionella special reference laboratory – the Special Pathogens Laboratory that successfully controlled Legionella. The microbiologists in this laboratory had more than 50 years of experience in Legionnaires' disease. As part of our Legionella management program, we coordinated and communicated effectively with infection control and engineering to insure patient safety. This laboratory also housed a collection of thousands of Legionella strains from the patients and water at Pittsburgh VA Healthcare System dating back to 1979. Unfortunately, administrators at the Pittsburgh VA Healthcare System closed the laboratory and destroyed this collection in 2006 without approval from the Research Compliance Office and on the day that I was to transfer the collection to the University of Pittsburgh.

A congressional hearing on the matter was conducted in 2008 by the Subcommittee on Investigations and Oversight, Committee on Science and Technology. The proceedings were published and entitled "Biobanking: How the Lack of a Coherent Policy Allowed the Veterans Administration to Destroy an Irreplacable Collec-

tion of Legionlla Samples". The committee found no credible rationale for the destruction of this collection and closure of the Special Pathogens Laboratory. The Chairman of the Subcommittee, Congressman Brad Miller warned that "there was something terribly wrong with the management at the Pittsburgh VA" . I expressed concern about the VA microbiology and their lack of knowledge and experience - a problem brought to the attention of the VA Inspector General in 2009 (case number 2000–01219–HL–0293). Dr. Yu forecasted in 2008 when he said "By doing this, they've hurt the entire VA system and its patients," Incredibly no one was held accountable and there were no consequences for closing the lab and destroying the microbes.

Here we are again 5 years later; unfortunately, people died this time, not just microbes.

Recommendations:

1.The Pittsburgh VA microbiology laboratory failed to detect Legionella in environmental samples due to inexperience, lack of knowledge and use of outdated methods. They perform testing for other VA facilities across the U.S. **The Pittsburgh VA microbiology laboratory should discontinue offering Legionella testing services to other VA medical centers and should notify those facilities that the results of that testing may be inaccurate.**

2.The Pittsburgh VA microbiology laboratory is listed as a CDC certified laboratory for Legionella environmental testing – successfully participating in the CDC Environmental Legionella Isolation Techniques Evaluation (ELITE). Obviously a CDC ELITE certification does not guarantee that a laboratory is knowledgeable and experienced enough to give reliable results. **The CDC should revisit their certification qualifications to address this weakness in the program. They should require laboratories to participate in another external proficiency program such as the European Health Protection Agency Legionella External Quality Assessment for Legionella Isolation from Water Samples.**

3.The CDC is invited to assist facilities in dealing with outbreaks. As a guest, their recommendations will not assign responsibility, but will merely suggest changes in policy. It will be the role of this committee to hold people in administration accountable for the failures that led to this outbreak – both past and present. They are management failures, not the failures of the front line worker. **Accountability needs to be from the top down, not the bottom up.**

4.**The VA Legionella Directive and public health policies should not be rewritten due to the management failures at this facility.** It was the responsibility of the Pittsburgh VA to be current in knowledge and vigilant in following the policies and procedures that were already in place. The system is not broken, so don't fix it.

5.**The VA management owes an apology to the physicians, staff, patients and families** regarding the delay in informing them in a timely manner about the concerns that there was an increase in cases and that an outbreak of Legionnaires' disease was suspected.

Disclosure: I am the Director of the new Special Pathogens Laboratory, Pittsburgh, PA. We provide Legionella testing services to VA hospitals across the U.S.

Executive Summary

When it comes to Legionnaires' disease, the Pittsburgh VA is unique. From 1980–2006, the Pittsburgh VA was recognized as the leader in Legionella research, a model for control and prevention, and provided Legionella services for VAs nationwide. Unfortunately, in 2012, veterans have now died from a wholly preventable disease.

The Pittsburgh VA identified the cause of the outbreak on November 16 stating that the disinfection system copper-silver ionization system, "may not be as effective as previously thought." However, this explanation is inadequate and raises more questions regarding monitoring and maintenance required for efficacy.

As a microbiologist and former director of the Special Pathogens Laboratory housed at the Pittsburgh VA from the 1980s through 2007, I established the program for monitoring the ionization system at the Pittsburgh VA. From 1997 – 2006, no cases of hospital-acquired occurred at the facility using this same technology. It is my understanding that this trend continued until the cluster (outbreak) of Legionnaires' disease, which seems to have occurred at the Pittsburgh VA Healthcare system (University Drive and Heinz) in 2011 and 2012.

Based on 30 years of expertise in Legionnaires' disease and intimate knowledge of Legionella control and prevention at the Pittsburgh VA, it is my suspicion that

adequate Legionella testing of the water and adequate monitoring for ionization levels weren't conducted. At the time of the 2012 outbreak, reports from the ionization manufacturers indicated that the copper and silver monitoring, when performed, did not meet the suggested frequency for testing or target levels and that documentation of this condition began as early as the spring of 2012.

My research at the Pittsburgh VA Medical Center from the early 1980s through 2007 provides me with specific relevant information of the processes and procedures in place at the Pittsburgh VA to prevent hospital-acquired Legionnaires' disease. This includes the methods and schedule for monitoring (testing) Legionella and copper and silver ions, maintenance of the ionization system, diagnostic and microbiological methods used for detecting Legionnaires' disease in patients at the Pittsburgh VA, and procedures used to investigate possible cases of hospital-acquired Legionnaires' disease.

Through these efforts, Legionnaires' disease was essentially eliminated at the Pittsburgh VA and our findings translated into hundreds of peer-reviewed papers which helped countless other healthcare and non-healthcare facilities prevent Legionnaires' disease. The Pittsburgh VA had the expertise that others went to for help and set the highest standard for prevention. Unfortunately, in 2006, VA officials determined that Legionnaires' disease was no longer a priority and closed the lab suddenly ending the nation's most prestigious program and research for Legionnaires' disease.

The focus of this investigation should be:

1.The failure of the Pittsburgh VA to recognize they had an outbreak and take preventive actions. We now know there were 16 cases and 5 deaths. The delay in recognizing the outbreak may have contributed to additional cases and deaths.

2.The failure of the VA lab to detect Legionella in the water system of the VA University Drive. This likely contributed to the delay in detecting the outbreak. This failure was due to lack of knowledge and experience - a problem brought to the attention of the VA Inspector General in 2009.

3.Failure of the VA to operate and manage the copper-silver ionization disinfection system.

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concerns that there was an increase in cases and that an outbreak of Legionnaires' disease was suspected.

Disclosure: I am the Director of the new Special Pathogens Laboratory, Pittsburgh, PA. We provide Legionella testing services to VA hospitals across the U.S.

It is my hope that these hearings will underscore the need for a stronger commitment by the VA to protect veterans from a disease that should have never happened, especially at the Pittsburgh VA.

Prepared Statement of Aaron Marshall

Mr. Chairman and Committee Members, thank you for inviting me to testify at this hearing today. My name is Aaron Marshall and I am Operations Manager for Enrich Products. Enrich supplies copper-silver ionization systems for the control of Legionella in potable water systems. I am also a veteran of the US Army having served honorably for just over four years. My father, also a veteran, received exceptional medical care from the Pittsburgh VA Health System for many years. Currently he receives the same exceptional care in the West Virginia VA Health System.

The intent of my testimony is to provide information that will contribute to a better understanding of what transpired at the VA University Drive Campus in Pittsburgh and to provide supporting evidence that copper silver ionization, when applied properly, is an effective method for controlling Legionella in potable hot water systems.

There are two ways copper-silver ionization systems can be implemented. The first is a **proactive course** and the second is a **reactive course**.

In a **proactive course,** a copper-silver ionization system is installed as a preventative measure. In these facilities there is no confirmed case(s) of Legionnaires' disease or Legionellosis. The facility may not even test for Legionella.

In a **reactive course,** a facility either has confirmed the presence of Legionella in the water through testing, or the facility's potable water system is suspected or implicated as the source of Legionnaires' disease or Legionellosis cases; in response, a copper silver ionization system is installed (temporarily or permanently). Once the desired results are achieved through the **reactive course**, the equipment is either removed or continues to operate and the course is transitioned to the **proactive** regimen.

The differences between the two rest in the course of actions recommended and they are significant:

In the **proactive course,** lab monitoring for copper and silver ions is recommended monthly, flushing of non-used fixtures is recommended monthly and Legionella testing may or may not happen.

In the **reactive course,** lab monitoring for copper and silver ions is performed weekly, the facility institutes a controlled flushing program such that all fixtures are flushed weekly, and Legionella testing at day 15 and day 30 is conducted to determine the course's effectiveness.

This **reactive course** has been successfully implemented at numerous facilities including The Cleveland VA Medical Center, as well as facilities in Pennsylvania, Florida, New York State, North Carolina, and Illinois.

I am here today because in June of 2012, at the request of the Pittsburgh VA, I was called in to perform a review of the copper-silver ionization system (and its operation) at their facility located on University Drive in the Pittsburgh neighborhood of Oakland (sometimes referred to as the VA Oakland facility). I was asked to make recommendations that would help to improve the functioning of their existing LiquiTech equipment. LiquiTech is another supplier of copper-silver ionization equipment.

Before submitting my general recommendation report on July 6, 2012, I visited the VA University Drive Campus facility three times. The dates were June 4th, June 21st and July 2nd. There was no charge to the VA for these visits or my report.

During my visits I personally viewed the four different locations where the LiquiTech copper-silver systems were installed. I was provided access to the site records from January 2012 until the end of June 2012, and the lab copper-silver data from June 2011 through July 2012. I requested but was denied access to view the Legionella test results.

During two of the three visits, I had separate meetings with Infection Control and Engineering / Maintenance personnel.

The two meetings covered similar topics. The major topics were: system maintenance, frequency for monitoring copper-silver ion levels, and criteria to determine site test locations. In each of the two meetings I covered Enrich recommendations for the **routine course** and **reactive course** as described earlier.

Had Enrich Products been aware of the presence of Legionella or Legionellosis cases at the VA University Drive Campus, we would have recommended implementing the **reactive course** immediately.

Sometime in November of 2012, Enrich learned through the media that in fact, there were reported cases of Legionnaires Disease at the VA University Drive Campus and that there were deaths as a result. In addition to the reporting of the outbreak, the media, through quotes from the CDC and others, offered doubt on the efficacy of copper silver ionization.

Copper silver ionization is an effective method of controlling Legionella bacteria. However, in order to maintain its efficacy, **the installed system needs to be properly maintained and regularly monitored.**

Another important note is that in order to definitively know where the source is, testing must be conducted. Often it is assumed (automatically) that the source must be the hot water system in a facility; we have found a number of times that sources were ice machines or decorative water features in the facility.

Conclusion:

During the short time that Enrich worked with the VA University Drive Campus, through today, the VA has not shared its Legionella testing data or results.

If the investigation concludes that the potable hot water system was the source of the outbreak , there is no question that regular testing could have detected the presence of the bacteria and that the reactive course of actions would have been implemented immediately minimizing the risk of outbreak.

We hope to have the opportunity to work with the Department of Veterans Affairs in the future in an effort to reduce this risk at all of their facilities.

We also hope to establish a dialogue with the CDC where we can share data and information demonstrating the "real world experiences" of copper silver ionization's effectiveness in treating Legionella in facilities throughout the country.

Thank you for your attention.

Prepared Statement of Steve Schira

I would like to thank the Subcommittee; we appreciate the opportunity to share what we know, to ensure the truth gets told and most importantly to work together to see that preventable outbreaks of Legionella do not occur in the future.

I think it is important to state that we consider Veterans Administration a proactive organization in regard to its efforts to prevent Legionnaires Disease. In 2008, the VA issued a directive to assess and address Legionella in their facilities water system.

Unfortunately, during our interaction with the Oakland VA Pittsburgh, it was obvious the VA was not performing the maintenance essential to keeping the copper silver ionization systems effective. The lack of regulation and oversight also plays an important role here. Without anyone checking to make sure they are maintaining a safe water environment, this important area of patient safety is the proverbial, "out of sight, out of mind" and all too often gets set aside for seemingly higher priority issues.

In December of 2011, LiquiTech provided a courtesy site visit to the Pittsburgh Oakland VA in an effort to reengage the hospital. Prior to this visit LiquiTech did not have any performance data, the VA was not sharing any copper silver levels, or legionella results. This lack of communication, partnership and most importantly validating data, is a big red flag and cause of concern.

While a walkthrough of the facility found obvious evidence that there were maintenance shortcomings, multiple people at the VA acknowledged and understood that adequate maintenance was not being performed. This also resulted in the first disclosure that the VA was experiencing low levels of Legionella. Additionally, Mr. Goetz brought up that there was an area of the hospital that was left untreated, seemingly because of plumbing renovations that needed to be corrected. The VA staff in attendance, Mr. Rodney Goetz, Patty Harris and Dr. Muder was supportive of the need for maintenance improvements. They requested proposals for service and support what would help solve the issues they were having. The sentiment we took away from this meeting was that the VA was going to take action to correct the maintenance problems.

LiquiTech provided a second courtesy site visit in April of 2012. During this visit LiquiTech service engineers found that no maintenance activities were being performed. The explanation given was that the gentleman put in charge of the systems was out on disability leave. Three LiquiTech representatives also encountered a VA staff member falsifying copper levels.

After these visits, a LiquiTech account manager made multiple attempts to follow up on the proposals provided and follow through on the issues encountered to no avail.

While LiquiTech has improved its technology and services to include remote monitoring and control, in an effort to prevent occurrences such as this, clearly the VA could have prevented the Legionella problem itself with simple maintenance. Had routine maintenance been preformed, had more decisive action been taken by the VA and had the VA communicated or requested help this outbreak could have been avoided.

In our opinion, there needs to be better measures in place to ensure that any disinfection method is being maintained with sufficient third party CDC elite validation that Legionella is not present.

Prepared Statement of Kathleen Dahl

Chairman Coffman, Ranking Member Kirkpatrick and Members of the Subcommittee.

Thank you for the opportunity to testify before the Subcommittee on the critical issues surrounding the Legionnaire's Disease outbreak at my facility, the Pittsburgh VA Healthcare System. I hope my testimony will assist the Subcommittee in its efforts to ensure that patients and workers are adequately protected from Legionnaires going forward.

As President of AFGE Local 2028, I represent approximately 2,500 non-management employees at the University Drive (UD) and Heinz facilities representing a wide range of positions. These include plumbers, engineers, physicians and nurses, and support personnel making patient appointments and working in medical labs among other functions.

As a union President, it is my duty and privilege to ensure that all of our employees are provided a safe working environment and preventions to maintain this environment at all times. Therefore, when an incident such as the current outbreak occurs, it is my job to ensure that employees receive adequate personal protective equipment, timely notices of exposures, and timely testing to ensure proper treatment.

Management is required by statute and regulation to contact me regarding all changes in working conditions, information that needs to be disseminated to employees, and to request input and suggestions from the union. Equally important, I am the person who employees talk to when they have concerns, especially when they are afraid to voice those concerns to management on their own.

As indicated in my timeline (Appendix A), I was not aware of any potential Legionella outbreak at my facility until the morning of November 16th, when Director Terry Wolf called the union Vice President Antoine Boyd. In that call, Director Wolf informed him that the water supply at UD was being tested for Legionella bacteria because some patients had reported feeling ill, similar testing would begin at Heinz as soon as possible, the water supply would be flushed with chlorine over the weekend (Nov. 17–18) and water conservation would be in effect for approximately two weeks until test results on the water came back.

On November 16th at 12:36PM, management put out its first all-employee notice at both UD and Heinz. We were informed that there would be no tap water for hand washing, drinking or bathing. Employees were instructed to use bottled water for hand washing for visibly soiled hands or following care of patients with Clostridium Difficile. Later on the 16th, UD and Heinz held town hall meetings for staff but none of the union officers could attend given the short notice.

The news about water conservation did not alarm me initially. Back in 1994, when I started at the VA, I was advised not to drink the water because it had problems with Legionella, and I knew that Legionella had been in the pipes since at least 1981. However, over the next few weeks, through various emails from staff, union local officers and the media I began to realize that management may have learned about this outbreak much earlier than they represented to us. This demonstrates VA's failure to comply with OSHA requirements about notification and precautions. For example, I first assumed that flushing of the water system on November 13th and 14th was related to a steam line break earlier that month.

Similarly, in early November (November 5th-9th), I was one of several employees notified of pertussis exposure. We were sent to Employee Health, where we were screened and given the antibiotic azithromycin. Later, the pertussis incident raised two red flags in my mind: first, if management followed OSHA rules about notice and screening for a pertussis outbreak, why didn't they follow these rules for a Legionella outbreak after receiving two confirmed cases in early November? Second, was it a coincidence that management provided the same antibiotic for pertussis exposure that would also be prescribed for Legionella exposure?

Other events prior to November 16th suggested to me that confirmation of the outbreak occurred earlier. For example, on November 15th, I learned through an email forwarded to AFGE Local President Colleen Evans at the Highland Drive (HD) facility that Executive Leader Mona Melham had contacted supervisors in her service line. Dr. Melham told the supervisors to wear masks when washing their hands and to drink bottled water because water had tested positive at UD for the same Legionella bacteria recovered 20 years ago. Dr. Melham attributed this recurrence to the failure of an old copper silver system that had been installed to eliminate the organisms, and she stated that efforts were underway at UD to hyperchlorinate water and conduct additional surveys at Heinz and HD.

After I learned that plumbing staff was already flushing the water system as early as November 13th, I questioned whether employees were instructed to wear masks and provided with other necessary personal protective equipment (PPE). In my discussions with the employees involved with Legionella remediation, I learned that they were not provided with any PPEs and there were no communications from management regarding PPEs. I also inquired about PPEs at a January 2013 meeting with Director Wolf, Chief of Staff Sonel, and national AFGE leadership. I was disturbed when COS Sonel responded that he did not know that plumbing staff should be provided PPEs to flush the water systems and had not made any effort to determine if they were needed under OSHA guidelines or VA's own policy.

Based on my growing concerns about the events unfolding around November 16th, I requested a meeting with management to ensure that employees received more accurate information. The meeting took place on November 20th and included union officials and executive leadership from the facility. During the meeting, AFGE representatives raised the issue of delayed notification to the union and employees as well as management's failure to link Legionella with employees diagnosed with pneumonia or exhibiting other respiratory symptoms.

I also asked COS Sonel why management had not surveyed employees over recent absences and illnesses as required by OSHA. His reply was troubling and dismissive. He stated that employees were more likely to be exposed to Legionella in their own homes. Deputy Director Cord said that the symptoms could be related to the flu since it was flu season. I reminded them that many of our employees are over 50, smokers, ex-smokers, diabetics, on corticosteroids and chemo which could place them at risk. At that point, management agreed to evaluate employees if they reported to Employee (occupational)Health. When I asked how employees would be treated, the response from management was if they had symptoms and reported to Employee Health, they would obtain a chest x-ray and if necessary, treated with azithromycin.

I requested that they do an employee survey as required by OSHA and referred management to a sample OSHA letter on its website. COS Sonel replied that they could not conduct this OSHA survey because it would violate HIPAA (which I knew to be incorrect based on my knowledge of OSHA and the requirement to conduct these surveys once an outbreak exists).

At the end of this meeting I was not confident that our employees would be screened or evaluated for this workplace exposure. Therefore, I utilized social media and email campaigns to inform our employees about symptoms related to Legionella and Pontiac Fever, including early flu like symptoms (slight fever, headache, aching joints/muscles, lack of energy, tired feeling and loss of appetite) or common pneumonia like symptoms (high fever, cough [dry first then phlegm producing], shortness of breath, chills or chest pains). If employees had any of these symptoms we instructed them to report to Employee Health. If the employees were turned away they were also told to notify the union.

After the meeting, I learned of several instances where employees who went to Employee Health for screening were turned away and made to feel they had no right to be there. Employees were also denied urine antigen tests. We reported this issue to management, and I was pleased that it was corrected in some cases but not consistently. For example, some employees were still not given the urine antigen test. Others were treated for bronchitis with azithromycin, which can cause false negatives if tested for Legionella later.

Director Wolf did send out a letter to employees (dated December 5th) but it placed more of the burden on employees to seek screening, instead of complying with the OSHA requirement that management first screen by reviewing time of leave records for absences of three days or more in a six week period.

I also learned during this process that OSHA guidance on Legionella requires the union to participate in inspections after an outbreak is confirmed, and the union should be jointly involved in potential abatement procedures and to participate in periodic collections of water samples. These requirements were never met.

I do want to commend management for not trying to exclude AFGE from the process of the Root Cause Analysis when the employee requested a union representative be present, or from the meeting with Congressman Tim Murphy when he came to the VA to inquire about the Legionella situation. More generally, I believe Director Wolf is genuinely concerned about the well-being of the patients and staff, and the VA is currently doing everything in its means to appropriately manage Legionella in our water system. However, there are still serious concerns regarding OSHA compliance.

Therefore, I urge that the following actions be taken in the future to prevent and remediate this type of outbreak, and to ensure the well-being of patients and employees.

- More training of management and rank and file employees on OSHA guidelines for inspections, notifications, screenings and PPEs;
- If elevated Legionella levels are detected, start using bottled water and limited showers immediately and continue doing this as long as a risk of outbreak exists;
- Review VA's practices of using employees other than certified plumbers to address these water system issues. Currently, the Pittsburgh VA Healthcare system has only one permanent, certified plumber whose primary role is inspector contractor work. The hands-on plumbing work is performed primarily by pipefitters and steamfitters instead of certified plumbers who typically do this work in the private sector;
- Revise VA procedures for testing of Legionella in the pipes, including improved communication between construction teams and infection prevention teams. Our piping system is complex and has many "loops" that require testing. Our construction is constant and sometimes requires shut off to water supplies. When water sits stagnant it can breed the Legionella colonies. We may need a stronger policy to demonstrate what happens when there is water interruption and to find ways to rid the system of the many "dead legs" that exist.

Thank you again for the opportunity testify.

APPENDIX A:

TIMELINE OF EVENTS SURROUNDING 2012 LEGIONELLA OUTBREAK AT PITTSBURGH VA HEALTHCARE SYSTEM

Prepared by Kathi Dahl, President, AFGE Local 2018

November 6, 2012

- AFGE received email notice about Sprinkler System interruption at University Drive due to a water line break.

November 14, 2012

- AFGE received email notice of Steam Outage at Heinz for steam line repairs. The following work was conducted: workers shut down the main steam service from the Boiler Plant to the hospital buildings, A/C shop technicians replaced 5 inch gate valve and failed gaskets on 8x5 gate valves and then returned steam service and HVAC systems to full operation. Building numbers affected were 32, 49, 50, 51, 52, 53, 54, 69, 70, and 71. This email included a utility outage contingency plan that indicated the steam outage would affect the entire Heinz campus except for the Villas. Domestic hot water was not available in the inpatient wings and conventional baths for patients were not available, patients instead used "bath in a bag." There was no space heating available so extra blankets were provided to the patient units. No steam available for cooking or dishwashing for food services. Boiler plant and AC shop had additional staff on hand to bring the boilers and campus steam supply back to operating conditions as soon as possible.

November 15, 2012

- AFGE received email regarding University Drive (UD) Emergency Heat and Flush for November 15–16. Work was conducted in the following affected areas:

Building 1, 3 West, 4 West, 5 West and Ambulatory Surgery Unit from 12am-7am on November 15–16, 2012. AFGE was informed FMS employees would notify the Patient Care Coordinators (PCC) when it was safe to use hot water once the flushing operations are completed.

- AFGE received email from one of our union safety stewards at Heinz at 2:11pm. He understood there was a problem at University Drive and there were several cases of bottled water that were sent to Oakland. He had heard Heinz would be under water shut down and 400 cases of bottled water were ordered. He wanted to know if the union safety officer James Dozier or I knew anything about the water shutdown. I responded to him that we had received notice of the water outage (but no information about the Legionella.)

November 16, 2012

- I received an email from AFGE Local 2028 Executive VP Boyd at approximately 12:17pm telling me that VAPHS Director Terry Wolf called the Heinz union office because she was unable to contact me. The Executive VP's email indicated that the Director informed him they were testing UD water supply for Legionella bacteria because some patients were not feeling well. He was also told that they would begin flushing the water supply with chlorine for 24 hours starting on Saturday, November 17 and then flush the water supply with regular water on Sunday, November 18 for the whole day. He was advised by the Director that employees would be instructed to use hand sanitizers for hand washing and use bath wipes in lieu of showers for patients. The Director told him that the water conservation would be in effect for at least 2 weeks while they wait for the culture results to come back. In addition, she had told him that testing would begin at Heinz as soon as possible. She informed him of a town hall meeting this same day at 12pm and 4pm at the Heinz and UD facilities. One of our safety Stewards at UD did attend this meeting with the Logistic team on Friday.
- Email from the Director's office was sent out to all VA employees regarding the restricted water usage at UD and Heinz campuses. This email went out at 12:36pm. The employees were instructed that effective immediately, there would be restrictions from using tap water for hand washing, drinking and bathing at UD and Heinz campuses for all patients, employees, volunteers and visitors. They encouraged everyone to use hand sanitizer when possible instead of hand washing with soap and water. They indicated the instances to use bottled water for hand washing was after care for a patient with Clostridium Difficile and when visibly soiled. At this time the Director's office provided numbers for incident command center and where to request hand sanitizer and signage.
- There was a town hall meeting scheduled for a 12–1pm live meeting, but the message was not forwarded to me until 12:41pm.
- I received an email from Highland Drive (HD) AFGE Local 3344 President Colleen Evans. She had forwarded me an email from Executive Leader Mona Melham dated Thursday November 15, 2012 at 8:16pm. This email was addressed to supervisors as a high alert message that testing the water system at UD revealed Legionella organisms similar to those recovered 20 years ago. She stated it was attributed to the failure of the old copper-silver system installed to specifically eliminate the organisms. She also indicated other hospitals in the Pittsburgh area were dealing with similar issues; efforts were underway to test the Heinz and HD campuses. She informed them that Legionella is a micro-organism (bacteria) that can cause pneumonia when inhaled by immunocompromised and/or debilitated patients. Legionella is easily treated with ciprofloxacin, azithromycin or erythromycin. She instructed the supervisors to refrain from using water fountains and sinks until further notice and that if they had to wash their hands to wear a mask to prevent inhalation of aerosolized droplets.
- HD AFGE Local 3344 President Colleen Evans included me in email at 1:04pm to executive leadership. In this email she wanted to know why she was hearing from bargaining unit employees about the Legionella outbreak, hot water flushing, potential fire hazards and "plans" to test water at Heinz and HD sites. She wanted to know why she had not received one notice from VAPHS leadership.

November 18, 2012

- I sent an email to James Rowlett (incident command) and Director Terry Wolf regarding employee concerns about hand hygiene and using the little bottles of water to do so. There was an issue where the employees were puncturing holes in the tops of the bottles to spray the water rather than pour the bottles in

order to conserve water. AFGE recommended for future incidents that management consider using 5 gallon water dispensers as often used by campers. Mr. Rowlett immediately responded and added Environmental Management Services (EMS) and logistics supervisors to advise them to be prepared to address this issue first thing Monday morning.
- I received a phone call from Marge Engwer (VA Safety Chief) that vendors were coming on Monday to provide hand washing stations.
- The Director's office sent out an email notification to all staff at 6:35pm that water restrictions were still in effect at University Drive and reminded everyone of the same information provided in the first Legionella notification to employees. They indicated this would be for approximately 2 weeks or until further notice.

November 19, 2012
- AFGE received an email from our union safety steward at 8:26am inquiring if we had been cleared to use the water. She indicated that they were taking necessary precautions in regards risks related to use of their postage and folder machine.
- AFGE Local 3344 President Colleen Evans sent another email at 9:21am as a follow up to the unanswered November 16 email stating again that restrictions and precautions were in place for UD and Heinz but she had still not received notification or information at HD. She asked someone to tell the union office if HD had Legionella in the water. She wanted to know if and when the water would be tested at HD. The Deputy Director David Cord responded to her at 9:48am indicating that he had a call scheduled with her at 10am and would update her then.
- By end of the day when I had caught up with the emails and activities up to this date, I became suspicious that we had not been informed in a timely manner about the Legionella. At 4:20pm I emailed Director Terry Wolf to request a meeting between her and the union to discuss the facts surrounding the Legionella situation at the VA. At this time I informed her that an employee had approached me earlier that day and had been diagnosed with bacterial pneumonia. The employee was out for 4 weeks and this was her first day back. I expressed concerns to the director as to whether the Legionella was related to her pneumonia. I also wanted clarification for the rumors about whether the wrong pipes had been flushed at Heinz. Some of the concerns I raised were whether cold water instead of hot water was being flushed and whether tap water was safe to be used to serve coffee. The Director forwarded the email to the Deputy Director David Cord, Associate Director, Chief of Staff Dr.Sonel, and Infection Control Chief Dr. Muder. Deputy Director Cord responded at 4:52pm that he was acting as Director and would be able to meet the following day at 1pm.

November 20, 2013
- We had a meeting between the union and management about Legionella at 1pm. Attendees included myself, Local 3344 President Colleen Evans, Local 2028 Safety Officer James Dozier, Deputy Director David Cord, Associate Director Lovetta Ford, Dr. Sonel, and Dr. Muder.
- At this meeting, the union expressed to leadership that as healthcare workers we understand the risk of exposures and that Legionella had been in the pipes for several years so this was not a surprise.
- We expressed concerns that VA was conducting heat flushes prior to our notification and that we were not notified in a timely manner. VA indicated that they did not heat flush the pipes. I told them I had a notice that they did. They insisted they did not. Deputy Director Cord stated that it would put me, as the Local President, in a difficult position if I had that information and was not able to share it with the employees.
- AFGE's concerns included the construction being conducted, all of the "dead legs" within the plumbing system, and VA's testing protocol since Legionella existed in the pipes since 1981. VA advised they were routinely monitoring the pipes. The union stated that OSHA provides routine maintenance guidelines for flushing pipes with the presence of Legionella. Deputy Director Cord stated they had been conducting routing maintenance and monitoring the piping system. The union stated that Legionella must be controlled since it cannot be eradicated from the pipes once it is there. He indicated they were monitoring levels of Legionella.

- VA verbally provided the union with the plan to treat the situation with hyperchlorination. They stated that they had contacted CDC and were following their guidelines.
- We requested the plan for employee exposures to Legionella. They indicated that healthy employees were not at risk. I reminded them that many of our employees are over 50, smokers, ex-smokers, diabetics, using corticosteroids and chemotherapy which could place them at risk. Leadership responded that Legionella is more likely to exist in our homes and is not necessarily contracted from the hospital. I reminded Dr. Sonel that Legionella was at the hospital and that if there were 2 or more diagnosed Legionella cases, OSHA recommends it be treated as a Legionella outbreak. I asked if they were going to survey employees that were out for more than 3 days to let them know that there was an exposure. They indicated they could not survey employees since it was a HIPAA violation. I responded that it was not a HIPAA violation and that if a Legionella outbreak occurs, OSHA requires that management to provide a survey letter to employees offering voluntary testing when an outbreak occurs. Management did not agree and did not commit to complete any survey.
- The union asked how we should respond to employees indicating they had or have pneumonia, respiratory symptoms or symptoms related to Pontiac Fever. Deputy Director Cord said they should go to their Personal Care Provider (PCP). I indicated that CA–2 forms should be completed for an occupational exposure. Once again they indicated the employees' illnesses may not necessarily be associated with hospital exposure to Legionella since they could be exposed at home. They also indicated that it was flu season and that might be the cause of their illness. Eventually, the VA agreed to evaluate employees if they reported to Employee Health. When I asked about the treatment plan, they said they would evaluate the employee and provide a chest X-ray and medicate with the antibiotic azithromycin. I was not confident at the end of this meeting that our employees would be screened and evaluated for this work exposure.
- The union utilized social media and email campaigns to inform our employees about symptoms related to Legionella and Pontiac Fever, including early flu like symptoms (slight fever, headache, aching joints/muscles, lack of energy, tired feeling and loss of appetite) or common pneumonia like symptoms (high fever, cough [dry first then phlegm producing], shortness of breath, chills or chest pains) to report to Employee Health. If employees were turned away they were instructed to notify the union.

November 21, 2012

- I forwarded the heat and flush announcement from November 14, 2012 to the Associate Director Lovetta Ford. She apologized and acknowledged the announcement; she explained that when she denied (during the November 20 meeting) the occurrence of pipe heating and flushing pipes prior to November 16, that she was referencing the corrective action from CDC.
- I received an email from Local 3344 President Colleen Evans that on November 20th, special showers were installed in 2 rooms on each floor of the consolidation building at UD.
- AFGE received an email from Occupational Safety Specialist for the VA Kevin Geeting that the deadline for submitting an application for the Voluntary Protection Program (an OSHA safety program) is approaching and he wanted continued commitment from the 2 locals regarding participation in the VPP application.
- AFGE received an update from Deputy Director Cord that all the shower heads were installed and they were able to place in line filters in the consolidation building to create 2 shower rooms for each floor. Hand washing stations would be available on November 25, 2013.

November 23, 2013

- AFGE received a copy of a complaint letter from OSHA and VA's response to their complaint. The letter stated, "Employees may potentially be exposed to a Legionella outbreak in the consolidation building." The response provided by VA Deputy Director Cord indicated that during routine testing, VA found some suspect samples of Legionella and they had contacted CDC for assistance. He also stated "no cases of employee exposure have been identified."

November 25, 2013

- AFGE safety officer James Dozier states to VA safety that it is imperative to have hand washing stations in the Nutrition and Food Services at UD and Heinz campuses due to food handling. Health and safety issues were expressed for patients and staff.

November 26, 2012

- AFGE Local 3344 President Colleen Evans informed VA Safety Officer Geeting that they were withdrawing support for VPP in light of several safety issues that had occurred recently where VA failed to include or inform her local. She expressed that she no longer had confidence that the union would be an equal and informed partner.
- I verbally informed VA Safety Officer Geeting that Local 2028 concurred with Local 3344's opinion and we would not be able to support VPP at this time.

November 30, 2012

- Water restrictions at UD were lifted but remained in effect for all other campuses until further notice.
- Hyperchlorination at HD was initiated due to some positive testing areas for Legionella. However, the treatment was moved to December 7–9.
- AFGE was notified that UD restrictions should remain in place for the ice machines. VA indicated that Facility Management Service would begin cleaning them over the weekend.

December 3, 2012

- AFGE Local 2028 Steward inquires about getting "water buffalos" in the villas. They did not receive hand washing stations for over 120 veterans and 60 employees. VA responded by sending hand washing stations that were no longer needed at UD.
- I informed Deputy Director Cord that I had an interview with the newspaper and had talked about four employees that I was aware of being treated for respiratory symptoms. I told him that I had advised the newspaper that the union is still content with the immediate response to the situation but would be monitoring how the employee exposures, if any, would be handled.

December 4, 2012

- Hand washing stations delivered to Building 69 Villas.
- AFGE began receiving inquiries from employees about an earlier pertussis scare which may have been due to a Legionella exposure. AFGE informed the Director about the employees' concerns on a phone call. She was very sincere and was concerned about the well-being of our employees and if they have any symptoms she wants them evaluated and treated.

December 5, 2012

- Deputy Director Cord phoned me to caution that my discussion with the newspaper bordered a HIPAA violation. I verbalized that I did not agree that my comments were violating any privacy issues. During this call I informed Deputy Director Cord I had been contacted by several news stations for on camera interviews and had declined, as advised by AFGE leadership. I informed him that all of my future communication with the media would be through AFGE leadership and the national Communications department.
- AFGE received information from a 5th employee that suggested that they may have had "Pontiac Fever" the week of November 5–9 on the same week of our Pertussis scare. He had received azithromycin.
- Director sends out an email to all employees stating that the VA is working to confirm specifics about the Legionella exposure. VA says they are trying to determine if illness reports are pertinent to the outbreak and the source of infection for each reporting employee who sought medical care for pneumonia in recent months. She provides a list of symptoms related to Legionella and tells employees to report to their PCP or Employee Health. If they have pneumonia, they should tell VA as soon as possible. This letter does contain all the language required by the OSHA sample letter.

December 18, 2012

- AFGE was interviewed by Joint Commission Bill McCully and Vicki Pritchard. The Joint Commission asked the union if something could be done to better protect employees. The union again requested urine antigen tests from the VA for those employees with symptoms.

December 19, 2012

- 2 plumbers came to the union office, expressing concerns that they may have to provide depositions. They expressed fear that management will try to place blame on the employees. They stated that they were never trained to do water treatments (Chlorination). They indicated that at the end of their shift on De-

cember 14 they were asked by their supervisor to sign a form that they were trained to do water treatments. They did not sign.

December 31, 2012

- AFGE received an email notice with a list of employees that were scheduled to meet with the Root Cause Analysis (RCA) team for the Legionella issue scheduled for January 3, 2013.

January 3, 2013

- RCA team conducts interview with a pipefitter and an infectious disease nurse.

January 9, 2013

- RCA team conducts interview with a plumber.

January 25, 2013

- AFGE received a communication from an employee voicing concerns about his qualifications to complete Heinz Mixing Valve Project as COR on this project.

January 30, 2013

- HR sends out OSHA notice to all employees of the employees' rights to access medical and workplace exposure records.

Executive Summary

As President of AFGE Local 2028, I represent approximately 2,500 non-management employees representing a wide range of positions at the University Drive (UD) and Heinz campuses of the Pittsburgh VA Health Care System. When the most recent Legionella outbreak occurred at the Pittsburgh VA, it was my job to ensure that employees receive adequate personal protective equipment, timely notices of exposures, and timely testing to ensure proper treatment, and to present employee concerns to management, especially when they were afraid of retaliation.

I was not aware of any potential Legionella outbreak at my facility until Director Wolf contacted the union on November 16, 2012. However, I soon realized that management may have learned about this outbreak much earlier than the union and employees were notified and that preventive measures such as bottled water for patients and staff, and masks and other personal protective equipment for plumbing staff were not provided timely, in violation of OSHA requirements and VA policy. Management was also unwilling to comply with the OSHA requirement to survey employees to identify individuals may have been absent due to Legionella-related illness. I was also disappointed in management's reluctance to properly test employees for Legionella.

Management also failed to comply with the OSHA requirement that the union participate in inspections after an outbreak is confirmed, be jointly involved in potential abatement procedures and participate in periodic collections of water samples.

I recommend the following actions going forward: (1) More training of management and rank and file employees on OSHA guidelines for inspections, notifications, screenings and PPEs; (2) Start using bottled water and limited showers immediately and as long as a risk of outbreak exists; (3) Review VA's practices of using employees other than certified plumbers to address these water system issues; and (4) Revise VA procedures for testing of Legionella in the pipes, improve communication between construction teams and infection prevention teams, better understand the impact water interruption and improve ways of ridding the system of the many "dead legs" that exist.

Submission For The Record

Testimony of: Edward Dudek, MPPM, Assistant Vice-President, Facilities, Engineering & Maintenance, UPMC Presbyterian Hospital; and Carlene A. Muto, MD, MS, Medical Director of Infection Prevention and Hospital Epidemiology, UPMC Presbyterian Hospital Center for Quality, Safety and Innovation

Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Subcommittee:

Thank you very much for inviting the University of Pittsburgh Medical Center (UPMC) to testify about the important issue of Legionella prevention in clinical settings. We are happy to be of assistance in providing an understanding of the UPMC

Presbyterian Hospital's various systems and controls employed to protect our water systems from contamination, specifically in this instance regarding legionella.

We are Carlene A. Muto, MD, MS and Edward Dudek, both of UPMC Presbyterian Hospital.

I, Carlene, am the Associate Professor of Medicine and Epidemiology and direct the Infection Control and Hospital Epidemiology program at UPMC. I am a member of the ID Epidemiology Research Unit. I received a Bachelor of Science Degree in medical technology from Bloomsburg University in Pennsylvania. After receiving a medical degree from Temple University School of Medicine in Philadelphia, I received training in infectious diseases and earned a Master of Epidemiology from the University of Virginia.

I, Edward, am the Assistant Vice President of Facilities, Engineering and Maintenance at UPMC Presbyterian Hospital. I have been with the hospital in a variety of roles for the past 25 years. I have held my present position for approximately six years, and I have served as the department head for about 12 years. I hold a Bachelor's Degree from the University of Pittsburgh, as well as a Masters of Public Policy and Management Degree from the University of Pittsburgh's Graduate School of Public and International Affairs. Additionally, I hold a Class 1 Engineer's License with the National Institute for the Uniform Licensing of Power Engineers and a Master Plumber's License with Allegheny County.

We cannot stress enough the truly collaborative approach to this issue. The Infection Control Department and the Facilities, Engineering and Maintenance Department work in tandem, with great success. Further, we do not want to portray ourselves as "experts" on Legionella or Legionella

prevention. Rather, we speak from the position of department heads that have been fortunate enough to have kept Legionella at bay. We can only speak to the technology, systems and controls used to protect the water systems at UPMC Presbyterian Hospital.

UPMC Presbyterian Hospital is a large academic hospital with 792 licensed beds. This facility is the flagship UPMC hospital and is where major surgeries, transplants and research are conducted. The facility also provides general care. The oldest part of the structure dates back to 1938 with additional wings and additions through the mid-1990s. Continual internal upgrades and construction have been conducted, and the facility has evolved in ways that I suspect are typical of many older hospitals.

We have within the facility, five separate and isolated domestic hot water systems; all have steam converter type water heating equipment with no storage tanks. Each of these individual systems has its own dedicated copper and silver ionization system consisting of a Liquitech controller and flow cell(s).

Copper and Silver Ionization System Components:

The copper and silver ionization systems are comprised of two primary components. The first component is the electronic controller which controls the amount of copper and silver ions that are released into the hot water system. The second component is the copper and silver flow cell. Within the cell are a number of copper and silver bars that are immersed in the hot water system's return piping, the number of which is determined by the volume of water that is being treated.

The controller sends an electric current at a determined amperage rate to the cell and directly to the immersed bars. The amperage from the controller to the cell regulates the rate at which the copper and silver bars are sacrificed, thus releasing ions into the water flow.

The composition of the bars is typically 70 percent copper and 30 percent silver. That composition can be changed if the operating characteristics of a particular system dictate that need. Typically, what would dictate that a change is required is a negative trend that is confirmed through atomic absorption testing of the hot water system. There are optional control devices that can be used, such as flow meters and continuous copper analyzers that can automatically adjust the output set point of the controller. However, the operating characteristics, the size, and the consistent flow rates of our systems provide a situation where a manual constant set point provides the most reliable operation that is confirmed through atomic absorption testing.

These are the components of a copper and silver ionization system, but proper operation can only be achieved in a properly-designed and fully-operational hot water system with a strong and consistent return loop. Inadequate flow, undersized pumps, or long lengths of pipes connecting the distil sites to the return loop will decrease the ability to properly sanitize the hot water systems. These issues with the return system can be an issue in older buildings or larger systems, but we address any such deficiencies through ongoing construction projects and through rou-

tine operation repairs. In extreme cases, the hot water systems may actually be split into a number of smaller systems.

Operation:

The systems operate by electrically sacrificing the copper and silver bars and introducing those minerals into the hot water system. The minerals are continuously circulated throughout the system, sanitizing all surfaces they come into contact with. A considerable amount of minerals are also captured within the bio-film on the interior pipe surfaces, providing residual sanitization if the system would be out of service for brief periods of time.

Any interruption of this type in excess of 24 hours would initiate discussion with the Infection Control Department to determine if additional steps are necessary. Over the past operations, we have never had an interruption in the system service of this type and duration.

The rate of sacrifice of the bars is controlled by the electronic controller through the output amperage setting. The amperage set point is controlled by one of three methods:

1. Constant Set Point - the amperage is set and remains at that level until it is manually changed.

2. Flow Rate - the amperage is raised or lowered in conjunction with the make-up flow rate of the cold water into the system. The set point is lowered at low usage times and raised as the water usage increases.

3. Constant Copper Analysis - there is an analyzer that constantly monitors the copper levels in the return loop of the hot water system. If the copper level drops below a predetermined set point, the amperage level automatically increases.

Again, due to the volume of water that our facilities use and after a decade of experience, we have found the Constant Set Point method to be the most effective in treating our system.

The set point is determined by the levels of copper and silver in the systems compared to the predetermined levels required by our Infection Control Department and the recommendations by the

Allegheny County Health Department. The copper and silver levels required are .2-.8 ppm and .02-.08 ppm, respectively.

Testing and adjusting:

The copper levels are tested two times per week using a hand-held device. During this testing, the copper levels are recorded as well as the amperage set point, the voltage reading, the hot water supply temperature, and the hot water return temperature. No system adjustments are made from these copper results.

The voltage reading is of particular importance during this inspection. If the voltage has increased significantly, it typically is an indication that the bars may be deteriorated to a level that affects their ability to sacrifice or are dirty. Either of these situations can affect the operation. If this situation exists, we change out the flow cell and/or clean the cell and sacrificial bars and verify that the system is operating appropriately.

Monthly, the Facilities, Engineering and Maintenance Department collects water samples from numerous areas throughout the building and from each individual hot water system loop. The copper and silver levels in these water samples are tested monthly through an outside laboratory using atomic absorption. All system adjustments are made based on the independent atomic absorption lab test results. The atomic absorption results are then sent to the Facilities, Engineering and Maintenance Department and Infection Control Department for review. If the levels are outside of the required parameters, there is a discussion between the two departments and the proper course of action is determined by the Infection Control Department.

Maintenance:

In addition to the cell in service on each system, there is a spare cell always on site. The cells in service are checked bi-weekly for operation and are cleaned as required. Cleaning is performed with a lime-removing chemical and a wire brush. During the bi-weekly maintenance, the cells are pulled from the system and cleaned or replaced. If the bars are sacrificed beyond approximately ‡" diameter, that cell is pulled and replaced with the spare, and the depleted cell is sent out to our local supplier to be rebuilt, replacing the sacrificial copper/silver bars.

Exception-Based Thermal Eradication:

If ion levels and test results are outside of set points, a collaborative discussion between the Facilities, Engineering and Maintenance Department and the Infection Control Department takes place to determine if the system(s) may be vulnerable to contamination. If it is determined that the system may be vulnerable to contamination, we perform a thermal eradication of the entire system. This is initiated and managed by the Facilities, Engineering and Maintenance Department and the Infection Control

Department in collaboration with Nursing, Clinical Operations and our Environmental Health and Safety Department.

This process provides a level of protection from contamination for a period, as the Facilities, Engineering and Maintenance Department addresses and investigates the cause for our readings straying from set point and system operations are restored.

In summary, Mr. Chairman, while copper-silver ionization is one of the most effective and cost-effective methods available, the success of any disinfection modality is dependent not only on the equipment, but also on the overall hot water system management, the consistency of Legionella surveillance, water monitoring, duration of the disinfection measure and cooperation among the Infection Control personnel, Engineering Staff and Administration.

Thank you, Mr. Chairman and committee members, for the opportunity to provide this testimony to you. We stand ready to answer any questions you might have.

Question For The Record

Letter From: Hon. Michael H. Michaud, Ranking Minority Member, Full Committee, To: Hon: Eric K. Shinseki, Secretary, Department of Veterans Affairs

March 5, 2013

The Honorable Eric K. Shinseki
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Mr. Secretary:

In reference to our Full Committee hearing entitled, "Analyzing VA's Actions to Prevent Legionnaire's Disease in Pittsburgh" that took place on February 5, 2013, I would appreciate it if you could answer the enclosed hearing questions by the close of business on April 15, 2013.

In preparing your answers to those questions, please provide your answers consecutively and single-spaced and include the full text of the question you are addressing in a bold font. To facilitate the printing of the hearing record, please e-mail your responses in Word format, to Carol Murray at *Carol.Murray@mail.house.gov* by the close of business on April 15, 2013. If you have any questions please contact her at 202–225–9756.

Sincerely,

MICHAEL H. MICHAUD
Ranking Member

CW:cm

Questions From: Hon. Michael H. Michaud, Ranking Minority Member, Full Committee, and Hon. Ann Kirkpatrick, Ranking Minority Member, Subcommittee on Oversight and Investigations To: Department of Veterans Affairs

Questions Submitted by Ranking Member Kirkpatrick

1. Please provide the Committee with a detailed timeline regarding when VA Pittsburgh Health Care personnel realized that they had a possible problem with controlling Legionella growth? What actions were taken, by whom, and were these actions appropriate?

2. What role does the National Infection Control Office have in educating, training, or oversight of the VA's national Legionella Prevention Program? Does VA plan to strengthen the role of this office in order to better coordinate responses to other Legionella outbreaks if they occur?

3. One of the recommendations of the CDC investigation was to improve communication between the laboratory or the infection prevention team and health care providers when a positive result is found. How does VA ensure that communication lines stay open and that everyone is trained on the proper procedures to follow?

4. One of the recommendations of the CDC report was to have persons responsible for carrying out the hospital's Legionellosis prevention plan, including infection prevention, facilities management, building engineering, and the Legionella laboratory, meet regularly in-person as a team to facilitate communication.

a. Has the VA implemented, or planned to implement, this recommendation?

b. What are the roles and functions of the Infection Control Committee at the facility level?

c. By what process or mechanism does facility Infection Control Committees have with VA Central Office?

5. One of the findings of the CDC points to VA's reliance upon an action threshold (30 percent of distal sites positive) to prompt remediation that may not be adequate since CDC found cases occurred when sampling indicated that less than 30 percent of sites were colonized.

a. Would you agree that this finding indicates that VA may need new standards for remediation?

b. Does VA have a plan to reevaluate some of the other existing policies and guidelines that may not be adequate when it come to preventing Legionella?

6. Since this outbreak, has VA done any nationwide polling of other VA facilities as to testing, surveillance and general compliance with existing policy?

a. Have you become aware of any other facilities that have had problems controlling Legionella?

b. Are best practices shared throughout the system and if so, how are they shared?

7. When were the employees notified of a possible risk for exposure to Legionella and what precautions were taken?

Responses From: Department of Veterans Affairs, To: Hon. Michael H. Michaud, Ranking Minority Member, Full Committee, and Hon. Ann Kirkpatrick, Ranking Minority Member, Subcommittee on Oversight and Investigations

1. Please provide the Committee with a detailed timeline regarding when VA Pittsburgh Health Care personnel realized that they had a possible problem with controlling Legionella growth? What actions were taken, by whom, and were these actions appropriate?

Response: Yes, the actions taken were appropriate given the information that was available at the time of the occurrence. VA Pittsburgh Healthcare System (VAPHS) has a history of performing routine environmental testing of its potable water system as well as an active infectious disease surveillance program. Three cases of Legionella pneumonia were diagnosed during the summer and late fall of 2012. Environmental testing had not demonstrated positive findings in areas the patients had occupied, yet it seemed feasible that the infections were hospital acquired given the incubation period of the disease. In October, 2012, VAPHS sent to the Centers for Disease Control and Prevention (CDC) three samples for testing (one environmental and two clinical). Also, late that month, CDC linked the two patient cases of Legionella pneumonia at VAPHS's University Drive campus and the environmental water sample within the facility. In early November 2012, VAPHS consulted with CDC and the Allegheny County Health Department (ACHD) to conduct a collaborative review of the Legionella observations. Below is the timeline of activities that progressed from the confirmation that there was a Legionella issue to present. It should be noted that there have been no new cases of hospital-associated Legionella since these measures were implemented.

- Beginning November 7, 2012, the CDC/ACHD team conducted a review of patient records and collected environmental samples for testing.
- On November 9, 2012, VAPHS cultured 44 water samples; slightly more than one-half of those samples tested positive for Legionella. The VAPHS promptly implemented an aggressive, multiphase water remediation effort per CDC recommendation. Phase one of this effort involved superheating the potable water system to 160 to 170 degrees Fahrenheit and then flushing this system with a goal of eliminating any existing Legionella bacteria. On November 14, 2012, VAPHS performed water system super-heating. As an added measure, VAPHS then hyper-chlorinated its water system and instituted water-use restrictions. Hyper-chlorination of the water supply began on November 16, 2012. VAPHS provided an alternate water supply in the interim.
- Water restrictions at the University Drive and HJ Heinz campuses were initiated on November 16, 2012. Restrictions were lifted on November 30 at the University Drive campus and December 7 at the HJ Heinz campus, when environmental cultures indicated successful remediation.
- On November 16, 2012, VAPHS leadership activated an incident command center, and tasked this center with clarifying facts and communicating news and updates to VAPHS Veterans and employees. The command center established a call center to answer questions from Veterans, staff, and family members. The command center also notified stakeholders of town hall meetings held by the VAPHS Director at all VAPHS campuses.
- Additionally, VAPHS notified providers to increase testing of both urine and sputum for evidence of Legionella infection, enhanced its mechanisms for reporting cases of Legionnaires' disease within VAPHS and to the Pennsylvania version of the National Electronic Disease Surveillance System (PA–NEDSS), and limited Veterans' environmental exposure to water while in the hospital.
- On December 6, 2012, environmental cultures for Legionella at the HJ Heinz campus were confirmed to be negative. VAPHS continues to conduct water testing in remediated areas every 2 weeks. Any areas that test positive are remediated again.
- The Veterans Health Administration (VHA) Central Office sent a team of clinical and environmental subject matter experts to review the events and issues surrounding the Legionella pneumonia cases and to review practices and protocols related to Legionella prevention and control. The team was at the facility from December 17, 2012 to December 18, 2012. They also focused on identifying lessons learned and understanding possible additional future prevention measures.
- On December 18, 2012, two surveyors from The Joint Commission (infection prevention and life safety) arrived at VAPHS to conduct an unannounced, for-cause survey. The Joint Commission may conduct a for-cause survey if the occurrence of an event creates either of the following situations: concern that a continuing threat to patients may exist; or, indication that the hospital is not or has not been in compliance with The Joint Commission policy. The focus of this visit was to evaluate the detection and remediation of Legionella. Interviews were conducted with senior leadership, engineering, infection prevention and control, and the union president. Tracers were completed through chart reviews of Legionella, transplant, and pneumonia cases. VAPHS has received The Joint Commission results. There were two findings. First, the surveyors observed that the hospital had not yet completed a mapping and inventory of the entire water piping system and indicated that this must be accomplished to identify areas of stagnation and "dead heading." Second, the surveyors observed that the infection prevention and control plan should be studied in an effort to reduce the number of entry points, and hence the potential for error. VAPHS received notification on March 1, 2013, from The Joint Commission, that the evidence of standard compliance has been accepted and no further response is required.
- The Office of Inspector General (OIG) agreed to examine this issue and VAPHS welcomed their review, which began on January 14, 2013. Findings from the OIG healthcare inspection were released on April 23, 2013.
- VAPHS has implemented several new approaches to maintaining open and clear communication between laboratory personnel, infection prevention and control practitioners, facilities management, and VAPHS leadership. These processes will ensure that all testing and remediation of distal water sites is clearly documented and that patient communication, in cases of possible Legionella exposure, can be quickly implemented along with appropriate intervention.

- VAPHS chartered a water safety committee with representation from facilities management, infection prevention and control, laboratory, the safety office, executive leadership, the research department, and local union officials. All aspects of Legionella control including water testing, water remediation, construction projects, and issues with water quality from the local water authority are discussed and interventions implemented where appropriate.
- VAPHS implemented a database project which required that every distal water outlet in the facility be uniquely identified with a number and barcode. As water samples are taken, the individual sink or shower is identified and linked to the specific sample. In the event that a sample result is positive for Legionella, an electronic work order would be placed and the individual number of that work order would be linked to the distal site and sample so that the remediation may be specifically identified and described. This system will facilitate the tracking and randomization of sampling sites as well as queries into areas where remediation has taken place so that trends may be identified. The database will also create a documentation trail which is searchable and easily monitored and audited. The capability exists to add events such as construction activities and newly installed distal water outlets.
- Institutional disclosures are scheduled through the middle of May 2013, to those identified as having a hospital-associated or probable hospital-associated case of Legionella. Over half the disclosures are complete.
- In accordance with current practice, Veterans who contract Legionella are told whether their infection was a result of exposure within the facility or from elsewhere in the community. In cases where Legionella is community-associated, testing of their home water system will be offered.
- A comprehensive water chlorination system will be installed for the treatment of all water entering all patient care campuses. This system will replace the chlorine drip system currently in place and will serve as a secondary Legionella mitigation control system. VAPHS is still considering options for chlorination systems due to the relative advantages and disadvantages of chlorine delivery methods. On February 19, 2013, a third party consultant arrived to assess the VAPHS water systems and provide recommendations for effective chlorination system options.
- VAPHS developed a scope of work to map the entire plumbing system, update diagrams, and identify unused plumbing sections (dead legs) in the system. The contract is on schedule to be awarded in May 2013. The goal is to eliminate areas of water stagnation that could lead to Legionella amplification. This was a recommendation of The Joint Commission and of the CDC.
- Decorative fountains and water features were drained and taken out of service since they were also identified as a potential source of infection. This was a specific recommendation of the CDC.
- Long-term Legionella mitigation plans include the installation of mixing valves on every point of use showerhead and faucet to allow circulating water temperatures to be increased to over 130 degrees Fahrenheit. The contract for this project was awarded on February 8, 2013, and work is expected to start in April 2013. The goal for project completion is August 2013. Increasing the temperature of circulating hot water was a recommendation of the panel of subject matter experts sent from VHA Central Office.
- VAPHS is following the water sampling protocol discussed and recommended by the CDC. VAPHS conducts sixty random samples across its three facilities every two weeks. Each sample is one liter in volume which is in accordance with the CDC recommendations. The CDC has recommended that bi-weekly sampling continue until good long-term control of Legionella can be demonstrated. The determination as to when good long-term control has been achieved will be made in close consultation with the CDC and any change in the sampling plan will be carefully documented and monitored but will remain well within the requirements set forth by VHA Directive.
- Any distal water outlets that show a result positive for Legionella will be retested after remediation until samples demonstrate that there is no further Legionella growth at that water outlet. All distal water outlets have been individually identified at all VAPHS campuses and water samples are tracked to the exact distal outlet.
- Any sites that test positive for Legionella will be remediated using the electronic work order process which will permit all sites, their sampling history, and remediation history, to be stored in a single database for accountability, monitoring, and process auditing.
- VAPHS continues to test any Veteran presenting with symptoms of pneumonia for Legionella infection with both urinary antigen and sputum tests.

- A small subgroup of the water safety committee has been tasked to study variables such as heat, pH, dissolved solids, and other organic matter that may impact the concentration of chlorine present in various sections of the plumbing system. The subgroup consists of VAPHS researchers with expertise in epidemiology and healthcare database design as well as the facilities manager, and representatives of facility leadership. A consultant specializing in the evaluation of plumbing systems utilizing chlorine-based Legionella prevention will also be included. The purpose of this subgroup effort will be to assess what relationships exist between chlorination levels in various plumbing segments and other variables present in the water such as temperature, pH, dissolved solids, and other organic matter. The findings will be informative for VAPHS policy and may lead to knowledge that can be informative for other healthcare facilities.
- The Allegheny County Health Department (ACHD) has recognized that Legionella exposure and infection is a matter of public health concern and requires a regional response that addresses mitigation strategies from a standpoint of public policy. To that end, ACHD has proposed a task force which would seek input from community and healthcare stakeholders in order to inform public policy regarding optimal strategies to mitigate Legionella risk on a regional level. VAPHS has expressed a strong level of interest in participating in the effort and a task force charter is pending.

2. What role does the National Infection Control Office have in educating, training, or oversight of the VA's national Legionella Prevention Program? Does VA plan to strengthen the role of this office in order to better coordinate responses to other Legionella outbreaks if they occur?

Response:

- The National Infectious Diseases Service (formerly known as the Infectious Diseases Program Office) had a primary role in developing Veterans Health Administration (VHA) directive Legionella prevention policies, along with other stakeholders such as engineering, public health and laboratory. The Infectious Diseases Program Office, Healthcare Engineering, and Pathology and Laboratory Medicine Service are listed in these policies as the national contacts for facilities that have questions about Legionella disease and prevention or request consultation on their policies or activities.
- When VHA Directive 2008–010 (Prevention of Legionella Disease) was published in 2008, the National Infectious Diseases Service had a primary role of communicating the new policy to facilities and numerous outreach modalities were used at the time. For example:
  - The Directive was e-mailed to the VHA Publications distribution group – the routine mechanism for distribution of new policies.
  - The Directive was e-mailed to key groups such as Infection Prevention and Control professionals across the country.
  - National phone calls with different stakeholders [e.g. Network leadership, facility leadership, facility Infection Prevention and Control professionals, and facility laboratory professionals] were held to provide education on the Directive's components.
  - In 2011, the National Infectious Diseases Service developed an educational information sheet for all facilities to reinforce and clarify components of the Directive.
- In recent months, the National Infectious Diseases Service has collaborated with VHA Office of Operations and Management program offices to reach out to facilities in numerous ways to again reinforce implementation of Legionella prevention policies. For example:
  - An Information Letter was published and distributed in January 2013 to emphasize the components of VHA's Legionella policies.
  - National phone calls have been held with various stakeholders, which have included Network Directors, and Engineering, Safety and Health Managers.
  - A memorandum was distributed by VHA's Office of Operations and Management reinforcing the need for facilities to follow VA's written Legionella policies.
  - An updated Information Letter was published and distributed in May 2013 to emphasize the components of VHA's Legionella policies.
- VHA has worked to strengthen and enhance its Issue Brief reporting system – a system in which facilities report issues to their Network Office, which then

can forward the issue to VHA Central Office and the appropriate subject matter experts/offices are informed and/or consulted.

- Legionella prevention is a multifaceted issue that involves numerous stakeholders – for example, infection prevention and control, engineering, operations, laboratory, and others – and these entities came together when the Directive policy was developed 6 years ago. Concerted efforts have also been made in recent months to improve routine communication between the National Infectious Diseases Service with other Central Office entities, such as Operations and Engineering, for the exact purpose of coordinating communications with facilities. Examples of this communication include:
  - Regular contact between Operations leadership and the National Infectious Diseases Services has been strengthened.
  - VHA National Infectious Diseases Service, the Office of Public Health, and Office of Operations and Management collaborated on an educational Information Letter on Legionella prevention.
  - National Infectious Diseases Service and Engineering jointly interface with facilities that request assistance regarding Legionella prevention.

3. One of the recommendations of the CDC investigation was to improve communication between the laboratory or the infection prevention team and health care providers when a positive result is found. How does VA ensure that communication lines stay open and that everyone is trained on the proper procedures to follow?

•

Response: VAPHS chartered a water safety committee with representation from facilities management, infection prevention and control, laboratory, the safety office, executive leadership, the research department, and local union officials. All aspects of Legionella control including water testing, water remediation, construction projects, and issues with water quality from the local water authority are discussed and interventions implemented where appropriate. This allows for rapid and thorough communication between the laboratory or infection prevention team and health care providers in the event of a positive result. In addition, identified training needs are reviewed and addressed through the use of competency validation with remedial education where indicated.

VAPHS implemented a database project which required that every distal water outlet in the facility be uniquely identified with a number and barcode. As water samples are taken, the individual sink or shower is identified and linked to the specific sample. In the event that a sample result is positive for Legionella, an electronic work order would be placed and the individual number of that work order would be linked to the distal site and sample so that the remediation may be specifically identified and described. This system will facilitate tracking and randomization of sampling sites as well as queries into areas where remediation has taken place so that trends may be identified. The database will also create a documentation trail which is searchable and easily monitored and audited. The capability exists to add events such as construction activities and newly installed distal water outlets.

4. One of the recommendations of the CDC report was to have persons responsible for carrying out the hospital's Legionellosis prevention plan, including prevention, facilities management, building engineering, and the Legionella laboratory, meet regularly in-person as a team to facilitate communication.

a. Has the VA implemented, or planned to implement, this recommendation?

- **Response: Yes.** VAPHS chartered a water safety committee with representation from facilities management, infection control, laboratory, the safety office, executive leadership, the research department, and local union officials. All aspects of Legionella control including water testing, water remediation, construction projects, and issues with water quality from the local water authority are discussed and interventions implemented where appropriate.

b. What are the roles and functions of the Infection Control Committee at the facility level?

Response: The committee reports to the executive leadership through the executive leadership board. The committee serves as a forum that brings key stakeholders and clinical service leaders together to establish an organization-wide, evidence-based infection prevention and control program that identifies risks for healthcare-

associated infection (HAI) and responds by reducing risks that may lead to the transmission and acquisition of HAI among patients, staff, volunteers, and visitors. The committee focuses on minimizing the risks for HAI through collaboration with other services in the medical center.

c. By what process or mechanism does facility Infection Control Committees have with VA Central Office?

Response: Infection control committees operate at the local facility level for local infection prevention and control decisions. Any identified issues or concerns raised to facility leadership can be forwarded to VHA Central Office using the Issue Brief reporting system – a system where facilities report issues to their Network Office, which then can forward the issue to VHA Central Office where the appropriate subject matter experts/offices are informed and/or consulted. In addition, local facility leaders can reach out directly to VHA services and program offices, such as the National Infectious Diseases Service, for consultative assistance and/or advice.

5. One of the findings of the CDC points to VA's reliance upon an action threshold (30 percent of distal sites positive) to prompt remediation that may not be adequate since CDC found cases occurred when sampling indicated that less than 30 percent of sites were colonized.

a. Would you agree that this finding indicates that VA may need new standards for remediation?

Response: A Work Group that consists of VA subject matter experts (e.g. engineering, infectious diseases, infection prevention and control, public health, occupational safety and health, laboratory, construction and facilities management) is actively meeting to review and revise existing VA Legionella prevention policies, including a review of remediation guidance. Numerous information resources are being used by the Work Group such as published scientific articles, CDC recommendations, information from professional groups [e.g. the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE)], and recent lessons learned.

b.Does VA have a plan to reevaluate some of the other existing policies and guidelines that may not be adequate when it come (sic) to preventing Legionella?

Response: Yes. The Work Group outlined in part (a) of this question is reviewing all aspects of current VA Legionella prevention policies. Numerous information resources are being used by the Work Group such as published scientific articles, CDC recommendations, information from professional groups [e.g. the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE)], and recent lessons learned.

6. Since this outbreak, has VA done any nationwide polling of other VA facilities as to testing, surveillance and general compliance with existing policy?

a. Have you become aware of any other facilities that have had problems with controlling Legionella?

Response: VA is not aware of any Legionnaires' disease outbreaks currently in other VHA facilities. VA Central Office is continuing to reach out to and assist any facilities regarding routine environmental controls to prevent Legionella.

b. Are best practices shared throughout the system and if so, how are they shared?

Response: Yes. VHA has a number of mechanisms to share best practices throughout the health care system. Formal and public mechanisms include the routine updating of directive policies, and the publication of information letters. Other mechanisms include national teleconferences, educational conferences, and webinar series to provide information to specific groups in the VHA health care system.

7. When were the employees notified of a possible risk for exposure to Legionella and what precautions were taken?

Response: Water restrictions at University Drive and HJ Heinz campuses were initiated on November 16, 2012, and were lifted on November 30, 2012, at the University Drive campus and December 7, 2012, at the H J Heinz campus, when environmental cultures indicated successful remediation. On November 16, 2012, leadership activated an incident command center, and tasked this center with clarifying facts and communicating news and updates to VAPHS Veterans and employees to

include: the establishment of a call center to answer questions from Veterans, staff, and family members and notifications of town hall meetings held by the VAPHS Director at all VAPHS campuses. An employee fact sheet was made available and additional information as well as questions and answers were posted on the facility's internet and intranet websites. Employees with concerns about their health status or risk of exposure were encouraged to contact the infection control and prevention program office or to report to employee health for evaluation.

Letter From: Hon. Michael H. Michaud, Ranking Minority Member, Full Committee, To: Dr. Lauri Hicks, D.O., Medical Epidemiologist, Division of Bacterial Diseases,Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

June 19, 2013

Dr. Lauri Hicks, D.O.
Medical Epidemiologist
Division of Bacterial Diseases,
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Dear Dr. Hicks:

Thank you for appearing before the Committee on Veterans' Affairs on February 5, 2013, to testify at the hearing entitled "Analyzing VA's Actions to Prevent Legionnaire's Disease in Pittsburgh". I appreciate the time and effort you gave as a witness before the Full Committee.

Following the hearing, the Committee wrote to you on March 5, 2013, requesting additional information. We have yet to receive your response. I have taken the liberty in attaching the letter and questions for the record. It would be greatly appreciated if you would respond to the attachment as soon as possible so we can finalize this particular hearing.

Committee practice permits the hearing record to remain open to permit Members to submit additional questions to the witnesses. Attached are additional questions directed to you.

In preparing your answers to these questions, please provide your answers consecutively and single-spaced and include the full text of the question you are addressing in bold font. To facilitate the printing of the hearing record, please e-mail your responses in Word format, to Carol Murray at *Carol.Murray@mail.house.gov* by the close of business on July 31, 2013. If you have any questions please contact her at 202-225-9756.

Sincerely,

MICHAEL H. MICHAUD
Ranking Member

CW:cm

Questions From: Hon. Michael H. Michaud, Ranking Minority Member, Full Committee, To: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

1. It seems that there is not a huge amount of consensus as to the best way to keep Legionella under control, what system to use, how often to test, how vigilant should a program be etc.

a. Could you please give us a quick synopsis of the CDC guidelines and how you work with other organizations to help guide them through the Legionella prevention programs?

b. What are the CDC reporting requirements in the case of an outbreak?

2. According to the CDC legionellosis is on the rise. The United States has seen an increase of 217 percent between 2000–2009.

a. What help do you need from us to formulate more of a national or federal program with a goal of coming to a better consensus on handling Legionella?

b. Do you think more focused research is needed?

c. What would a program like that look like?

Response From: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, To: Hon. Michael H. Michaud, Ranking Minority Member, Full Committee

1. It seems that there is not a huge consensus as to how to keep Legionella under control, what system to use, how often to test, how vigilant a program should be etc.

a. Could you please give a quick synopsis of the CDC guidelines and how you work with other organizations to guide them through the CDC Legionella prevention programs?

CDC published Guidelines for Preventing Health-Care–Associated Pneumonia, 2003 (Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee) in 2004.1 These guidelines are intended for use by public health authorities and other persons involved in preventing healthcare-associated infections. The guidelines provide information regarding how Legionnaires' disease cases should be identified, how to respond to cases that are healthcare-associated, and recommendations for remediation of water systems. CDC staff are liaison members to The American Society for Heating Refrigerating and Air Conditioning Engineers (ASHRAE) committees that publish Standards and Guidelines that focus on the environmental control of Legionella. ASHRAE Standard 12–2000, Minimizing the Risk of Legionellosis Associated with Building Water Systems, is used by facility managers, engineers, and public health authorities to address Legionella in the environment. Currently under public review, ASHRAE Standard 188, Prevention of Legionellosis Associated with Building Water Systems, when approved and published, will complement the ASHRAE Guideline. CDC subject matter experts worked with ASHRAE to develop the Standard, which provides a framework for preventing Legionella colonization of water systems. This ASHRAE Standard is the first document of this kind in the United States to focus on primary prevention.

CDC provides assistance, at the request of state and local health authorities, to identify the source for legionellosis outbreaks, conduct environmental and epidemiologic investigations, and provide recommendations to prevent ongoing disease. While CDC makes recommendations for short term remediation, CDC does not provide recommendations for long-term remediation, as there is no "one size fits all approach to Legionella control". Well-designed studies that address long-term remediation and prevention of Legionella colonization in water systems are needed.

b. What are the CDC reporting requirements in the case of an outbreak?

Legionellosis is a nationally notifiable disease. However, each state health department has the jurisdiction to establish the reporting requirements. Most states require that legionellosis cases be reported to the state department of health, and, in turn, the state department of health reports cases to CDC. As part of the reporting process, the state or local health department is asked to determine whether the case is associated with an outbreak. This determination is at the discretion of the reporter and is submitted at the time the case is reported. It is common for cases to be initially reported as sporadic and then later be identified as part of an outbreak after additional cases are reported. We recommend that all state health departments report outbreaks directly to CDC's Legionella program as soon as they are recognized, but it is at the discretion of the state public health authorities to determine the urgency of the situation and decide whether CDC's assistance is needed. CDC also has a surveillance system called The National Outbreak Reporting System (NORS), which is a web-based platform designed to support reporting to CDC by local, state, and territorial health departments in the United States of all waterborne disease outbreaks. States are required to report legionellosis outbreaks through this mechanism as well, but they are typically reported after the investigation is completed.

2. According to CDC, legionellosis is on the rise. The United States has seen an increase of 217 percent between 2000–2009.

a. What help do you need from us to formulate more of a national or federal program with a goal of coming to a better consensus on handling Legionella?

Based on current resource levels, CDC's priority is to respond to and stop disease outbreaks. CDC currently has a team of two epidemiologists and three laboratorians who work on Legionella routinely with others playing supporting roles and providing capacity for surge response. The team receives over 200 consultations and conducts an average of five field investigations each year. Much of what is known about Legionnaires' disease has been learned through outbreak investigations, but most, approximately 90 percent, of Legionnaires' disease cases are acquired in the community, and most cases are not associated with outbreaks. However, Legionella is one of the most common causes of waterborne disease outbreaks and is the most common cause of outbreaks associated with drinking water systems.

b. Do you think more focused research is needed?

There are gaps in knowledge related to Legionella and Legionnaires' disease. Research is needed to better understand both the human and environmental factors that are contributing to the increase in reported cases, as well as the major sources of infection in the community. Research is also needed to improve diagnostic testing and identify best practices for disease prevention and control. Development and evaluation of newer technologies to diagnose cases, particularly molecular testing and urine tests, could enhance disease detection. Studies should assess different strategies to prevent disease and outbreaks. Approaches to prevent Legionella growth in the environment need to be evaluated and to recognize and detect outbreak-causing strains. Well-designed studies that evaluate the different strategies and disinfection approaches to stop Legionella growth in the environment once it is detected are also needed.

c. What would a program like that look like?

This effort would include:

1. National, State, and local epidemiologic and laboratory capacity to detect, report, and investigate legionellosis cases, along with expanded engineering and environmental health expertise in the Legionella program;

2. Improved communication and education among healthcare providers and infection preventionists to improve testing practices and detection of legionellosis cases;

3. Partnerships with researchers in academia, healthcare, and government (including the Veterans Health Administration) to conduct well-designed studies aimed at evaluating the various prevention and remediation strategies in use and identify best practices for prevention and remediation;

4. Engagement with stakeholders to develop consensus on a set of national policies, standards and practices to reduce disease due to Legionella.

(1) Tablan, O. C., L. J. Anderson, R. Besser, C. Bridges, R. Hajjeh, CDC, and Healthcare Infection Control Practices Advisory Committee. 2004. Guidelines for preventing health-care—associated pneumonia, 2003: Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR. Recommendations and reports : Morbidity and mortality weekly report. Recommendations and reports / Centers for Disease Control 53:1–36.