

David R. Snyderman, MD, FACP testimony before the U.S. House of Representatives Committee on Science and Technology September 9, 2008 for the hearing entitled “Biobanking: How the lack of a coherent policy allowed the Veterans Administration to destroy an irreplaceable collection of Legionella Samples”

I am Dr. David R. Snyderman, MD, Chief of the Division of Geographic Medicine and Infectious Diseases, Tufts Medical Center, Boston, Ma and Professor of Medicine and Microbiology, Tufts University School of Medicine. I offer my C. V. which outlines my training and expertise in the fields of microbiologic research, as well as clinical research within the field of infectious diseases. Due to time constraints I will not go into details about my training or publication record which are listed on my C.V. but I will say for the record that I conduct studies in infectious diseases using the microbiology laboratory and am nationally and internationally recognized for my research. I have been funded by the NIH for many years for many of the studies I have published. I have collaborated with Dr. Victor Yu in a variety of studies conducted over the past 20 years or more. Many of these have been published in the highest level journals within the field of clinical

infectious disease and microbiology. Let me also state that I have publically praised the VA healthcare system in an editorial I wrote for the Mayo Clinic Proceedings regarding quality of care around central line associated infections. So I come to this proceeding, as someone who recognizes the value of the VA healthcare system. I have never been an employee of the VA but have worked as a medical resident in the Boston VA and volunteered in the Atlanta VA while I was employed by the Centers for Disease Control. I am trying to offer as dispassionate and objective opinion as possible.

I have been asked by the staff to comment on a number of issues pursuant to these proceedings, including the value of the resource of the Special Pathogens laboratory at the Pittsburgh VA hospital as well as the studies which were foreclosed by the destruction of the isolates, and the value of the research conducted by Dr.'s Yu and Stout. I have also been asked as to how I learned of the destruction of the isolates housed in the Special Pathogens laboratory, to comment on my actions, and to comment on changes and policies Congress should consider in order prohibiting such actions from happening in the future.

First, let me say from the outset that the question should be broadened to include isolates other than Legionella, since many of the isolates housed in

the Special Pathogens laboratory were microbiologic species of bacteria and fungi other than Legionella.

I first learned that there was a problem in the Special Pathogens laboratory in July 2006. I actually called Dr. Yu in late June or early July of that year to discuss a case of a very rare disease, Legionella endocarditis. I wanted him to try to isolate the organism from a heart valve that needed to be replaced in a patient I was consulting on. Our laboratory had not been able to isolate the organism but there was a strong suspicion that Legionella was causing the disease based on several factors. Since treatment requires 6 months or more of therapy, I wanted to get as definitive an answer as possible. I knew that Dr. Yu had the expertise to perform specialized studies on the valve, including the use of molecular diagnostic tools. He told me that he would try to perform the studies, to hold onto the blood cultures and he would give me instructions as to how to send them. After some time, he told me he would not be able to perform the studies and indicated the laboratory would be shut down. I was quite disturbed and asked if there was anything I could do. I subsequently wrote to the VA hospital administration in Pittsburgh protesting this action, as well as Senator Specter and some in the Pennsylvania Congressional Delegation. I later found out, much to my dismay, that the isolates from the whole collection were destroyed. I

eventually wrote the Viewpoints piece for the journal Clinical Infectious Disease, which is the official clinical journal of the Infectious Disease Society of America. I have appended the Viewpoints article for submission with my testimony.

With respect to the research done by Dr. Yu and Dr. Stout, one can only conclude that it is of the highest caliber in the world. They are internationally recognized for their work and expertise in Legionella as well as other pathogens and their laboratory set the standard for our understanding of the environmental control for Legionella.

If I may read into the record part of the Viewpoints piece, I believe the Committee will get a flavor for the value of the collection.

“Dr. Yu established a series of national and international collaborations to elucidate our understanding of the microbiologic and clinical management issues of bacteremia due to many different organisms. These studies were seminal in many respects. They changed our understanding of the relationship between appropriate and inappropriate therapy, the relationship between the minimum inhibitory concentrations of isolates to outcome, and the molecular epidemiology of relapse and reinfection as well as relatedness of strains throughout the world. The studies are far too numerous to articulate in detail or even list here in total, but they include studies of the

major pathogens that confound us today, including *Staphylococcus aureus* (6-8), *Pseudomonas aeruginosa* (9), extended spectrum beta-lactamase producing *Klebsiella pneumoniae* (10-12) Enterobacter species (13), *Stenotrophomonas maltophilia* (14), Enterococcus species (15,16), *Bacteroides fragilis* (17), *Streptococcus pneumoniae* (18-20), and Candida species (21-23). The concept was simple, observe the clinical presentation of bacteremia or fungemia, and follow outcomes while correlating the microbiology to the outcome. The studies were all prospective and the isolates collected and sent to a central laboratory (the Pittsburgh VA special pathogens laboratory) for more definitive analysis. Each of the studies emanating from this collection has changed our knowledge base and contributed significantly towards optimal management of patients with these infections.

Capturing the isolates and making sure they were sent was an important and difficult task-especially for fastidious organisms like *S. pneumoniae* and *Bacteroides* species. Given the international component, as well the requirements for sending specimens across national borders, these studies were difficult to perform. All studies were approved as per local IRB requirements and permits were obtained from regulatory authorities. Nevertheless, the number of studies and important insights total well over a 100 peer-review articles and have provided important information that correlates outcome with the use of certain antibiotic classes as well as levels of susceptibility. Some of the studies have challenged prevailing dogma and helped provide data for the CLSI.

I also go on to point out “These isolates were accrued purely for the advancement of science and the beneficiaries of these studies were the patients infected by these microbes. Moreover, these isolates and samples would have proven invaluable in the future in that these strains would enable comparison over time for changes in pathogen virulence, antimicrobial susceptibility correlation with outcome, and changing genetic diversity as well as the development of new molecular tests.”

The value of the collection is that it was linked to clinical outcomes. This kind of collection does not really exist anywhere in the world and these

studies are really quite difficult to organize and complete. The reason this is so important is that one can correlate microbiologic factors to clinical outcomes, and with a large number of patients and specimens to study, one can control for confounding variables such as underlying host factors, which might relate to the clinical outcome. The committee should also note that one of our studies on pneumococcal bacteremia was given a national award at the annual meeting of the Infectious Disease Society of America, the Emanuel Wolinsky award, as the best clinical paper for the year.

The studies which were foreclosed by the destruction of these isolates included any study of new pathogenic factors that might be related to microbial pathogenesis in a variety of organisms, changing microbial diversity which we recognize as continually evolving, and factors that might relate to antimicrobial resistance and susceptibility. While these organisms exist in nature and can be grown from the environment as well as people, the fact that there was a collection of organisms linked to outcomes made the collection invaluable to science.

It would have been relatively simple to maintain the collection since many organisms are maintained in freezers in a holding solution. Some agreement should have been entered into between the parties that wanted to close the lab and Dr.'s Yu and Stout in order to give them time to make arrangements

for transport of the specimens to another laboratory. To just destroy the specimens as was done was a wanton thoughtless act. It is for this reason that I wrote my Viewpoints piece for publication and appended a petition which has been signed by a number of clinical and microbiologic research scientists throughout the world.

Destruction of Isolates from the Pittsburgh Veterans Affairs Laboratory

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The Pittsburgh Veterans Affairs hospital administration closed the research laboratory directed by Victor Yu and Janet Stout and destroyed isolates collected as part of a series of clinical studies over 25 years. This article discusses the implications and protests such destruction as an affront to science and scientific study. A petition signed by 243 individuals accompanies this article.

The Pittsburgh Veterans Affairs (VA) Special Pathogens Laboratory, headed by Victor Yu, MD, and Janet E. Stout, PhD, was terminated by the Pittsburgh VA administration in July 2007, under protest from Dr. Yu. During the administrative dispute, the collection of clinical specimens and microbiological isolates obtained by investigators from around the world were destroyed. These materials were collected as part of numerous prospective observational studies and infection control–related studies. For almost 30 years, Drs. Yu and Stout set the standards for our understanding of the epidemiology of *Legionella* infection, as well as for our understanding of the control of environmental *Legionella* infection.

Dr. Yu also established a series of national and international collaborations to elucidate our understanding of the microbiological and clinical management issues of bacteremia due to many different or-

ganisms. These studies were seminal in many respects. They changed our understanding of the relationship between appropriate and inappropriate therapy, the relationship between the MICs of isolates and outcome, the molecular epidemiology of relapse and reinfection, and the relatedness of strains throughout the world. The studies are far too numerous to articulate in detail or even to list here in total, but they include studies of the major pathogens that confound us today, including *Staphylococcus aureus*, *Pseudomonas aeruginosa*, extended-spectrum β -lactamase–producing *Klebsiella pneumoniae*, *Enterobacter* species, *Stenotrophomonas maltophilia*, *Enterococcus* species, *Bacteroides fragilis*, *Streptococcus pneumoniae*, and *Candida* species. The concept was simple: observe the clinical presentation of bacteremia or fungemia, and follow outcomes while correlating the microbiology to the outcome. The studies were all prospective, and the isolates were collected and sent to a central laboratory for more-definitive analysis. Each of the studies emanating from this collection has changed our knowledge base and has contributed significantly toward optimal treatment of patients with these infections. Moreover, the careers of a number of

prominent academicians were launched when they coordinated these large-scale studies and had the opportunity to analyze the data as trainees.

Capturing the isolates and making sure they were sent to the laboratory was an important and difficult task—especially for fastidious organisms like *S. pneumoniae* and *Bacteroides* species. Given the international component, as well the requirements for sending specimens across national borders, these studies were difficult to perform. All studies were approved in accordance with local institutional review board requirements, and permits were obtained from regulatory authorities. Nevertheless, the number of studies and important insights total >100 peer-review articles (see References [online only] for selected articles) and have provided important information that correlates outcome with the use of certain antibiotic classes, as well as levels of susceptibility. Some of the studies challenged prevailing dogma and helped provide data for the Clinical and Laboratory Standards Institute.

All of these isolates, many of which were still being studied, were destroyed. The samples were incinerated without warning or notification to Drs. Yu and Stout, such

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that it became an irrevocable action. These isolates were accrued purely for the advancement of science, and the beneficiaries of these studies were the patients infected with these microbes. Moreover, these isolates and samples would have proven to be invaluable in the future, because having these strains would enable comparison over time, for changes in pathogen virulence, antimicrobial susceptibility correlation with outcome, and changing genetic diversity, as well as the development of new molecular tests. Their destruction can by no means be considered to be justifiable. Add your name to the petition or review details at the Call for Inquiry Web site (<http://www.legionella.org/vaspl.asp>). It is in this context that this petition is being published.

PETITION FOR VA ACCOUNTABILITY

We, the undersigned, respectfully request that VA Central Office convene an investigative committee to review the actions of the Pittsburgh VA Healthcare System regarding the closure of the Special Pathogens Laboratory and the destruction of a scientifically valuable collection of microorganisms.

The collection of microorganisms was created and preserved by Victor L. Yu, MD and Janet E. Stout, PhD over a 25-year period in the Special Pathogens Laboratory in Pittsburgh. The entire collection was incinerated without informing Drs. Yu and Stout. This action was taken despite efforts by Drs. Yu and Stout to appropriately transfer the collection to the University of Pittsburgh.

The collection contained stored patient sera, urine samples from patients infected by unusual *Legionella* species and respiratory tract specimens yielding rare *Legionella* species dating back to 1979. Among the several thousand *Legionella* isolates destroyed were environmental and patient isolates from 20 VA hospitals experiencing outbreaks of hospital-acquired Legionnaires' disease. For some of us, *Le-*

gionella isolates from our VA hospital were among those destroyed.

These *Legionella* isolates and specimens were being stored for future epidemiologic investigation; providing an invaluable resource for elucidating the source of Legionnaires' disease at VA Medical Centers. As importantly, emergence of resistance of *Legionella* to disinfectants has been reported by us and the storage of the original isolates from each hospital allows documentation of this possibility in the event of failure of disinfection. Finally, molecular fingerprinting would allow individual VA hospitals to ascertain the source of the infecting *Legionella* in VA patients should future outbreaks occur.

Among the isolates in the collection were several thousand well-characterized microorganisms from multinational observational studies. These disease-causing strains of *Pseudomonas aeruginosa*, *Enterobacter* species, *Enterococcus* species, *Bacteroides fragilis*, *Stenotrophomonas maltophilia*, *Klebsiella* species, *Candida* species and *Cryptococcus neoformans* were also destroyed.

This unique collection of specimens and isolates were being used to develop new diagnostic tests, new therapies, and to study resistance and mechanisms of disease transmission. The results of these studies benefited veterans nationwide.

To remove the appearance of impropriety, we request that an outside scientific body with no relationship to the VA be convened to ascertain the appropriateness of this action.

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Biography

David R. Snyderman, MD, FACP is currently Chief of the Division of Geographic Medicine and Infectious Diseases and Hospital Epidemiologist at Tufts Medical Center and Professor of Medicine and Pathology, at Tufts University School of Medicine.

He went to Williams College and graduated with highest honors in Chemistry (1968) and graduated from the University of Pennsylvania School of Medicine (1972) where he was awarded the Dr. A.O.J. Kelly prize. He was an intern and resident in medicine at Tufts-New England Medical Center, and spent two years in the Epidemic Intelligence Service at the Centers for Disease Control. He was a clinical and research fellow in infectious diseases at Tufts-New England Medical Center before joining the faculty. He is board certified in medicine and infectious diseases.

Dr. Snyderman has been involved in both antibiotic resistance related research, epidemiologic research and clinical care for over 30 years. He has had an ongoing interest in anaerobic infections as well as an interest in Cytomegalovirus in solid organ transplantation. He developed Cytomegalovirus Immune Globulin, brought it to licensure and was awarded a citation from the Massachusetts Department of Public Health for his efforts. He has been a Teaching and Research scholar of the American College of Physicians. He has published over 250 peer reviewed original articles, book chapters and reviews, co-edited 13 Year Books of Infectious Disease, 5 Yearbooks of Medicine and published one book. He was the recipient of the Ken Kaplan award, given annually

to the “outstanding infectious disease clinician” by the Massachusetts Infectious Disease Society, and he has also received a Distinguished Faculty award from Tufts University School of Medicine. He is also a co-recipient of the Emanuel Wolinsky award, given annually for the best clinical paper published in the Journal Clinical Infectious Diseases. He sits on the editorial boards of the Journals Transplantation, Clinical Infectious Diseases, and Mayo Clinic Proceedings. He is nationally and internationally recognized for his clinical and microbiologic research in the field of infectious diseases.