STATEMENT BY

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ON

Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness

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My name is Dr. Peter Shult and I am here today representing the Association of Public Health Laboratories, APHL. I am currently the Director of the Communicable Diseases Division of the Wisconsin State Laboratory of Hygiene. As its name implies, APHL is the association for state and local governmental laboratories that perform testing of public health significance.

Public health agencies worldwide have been tasked with leading preparedness and response planning efforts necessary to minimize the impacts of seasonal influenza epidemics as well as the next pandemic. In the case of pandemic influenza, it is currently highly unlikely that a well-matched vaccine, the best countermeasure, will be available when a pandemic begins. In addition, sufficient supplies of influenza antiviral medications might not be available. Consequently, current national plans for pandemic response call for attempting to mitigate the effects of a pandemic early on by relying on strategies for case containment (isolation and quarantine), social distancing (school closures and social distancing of adults in the community and at work) and infection control (hand hygiene, cough etiquette). Initiation of these rather drastic measures will require documentation of emergence in the U.S. of a novel influenza A subtype and confirmation of sustained community transmission of the virus. This will require laboratory testing; the responsibility for this testing role will rest with the public health laboratory – state and local governmental laboratories tasked with supporting their public health jurisdictions in preparedness and response activities.

Role of the public health laboratory

The public health laboratory is the leader in laboratory preparedness and response efforts. Public health laboratories, serve as reference labs in the Laboratory Response Network (LRN). They are a key national security asset, providing some of the most advanced and rapid testing available in the LRN. These laboratories are capable of performing tests to rapidly detect and identify highly dangerous biological agents. Public health laboratories also have established linkages with law enforcement, including the FBI, and utilize chain-of-custody and testing protocols consistent with legal evidentiary requirements. The state public health laboratory has developed a culture of emergency response. There is an expectation that we follow incident command structure, and that we have continuity-of-operations plans. We coordinate with other first responders, hazardous-materials teams and law enforcement on a regular basis responding to unknown threats and suspicious packages. We're emergency responders from the lab perspective.

The LRN was established to address only those agents that could be used for biological terrorism (BT). However, since that time, the LRN has been utilized to address non-terrorism agents as well, an "all hazards" philosophy. At the state level, infrastructure developed as a result of funding from the Centers for Disease Control and Prevention's (CDC) Public Health Emergency Preparedness (PHEP) Cooperative Agreements, like upgrading laboratory facility biosafety levels, purchasing state-of-the-art molecular detection equipment, and hiring staff with advanced diagnostics expertise, has significantly improved the public health laboratory's ability to respond to emerging diseases. In Wisconsin, we could not have weathered the SARS, monkeypox and mumps

outbreaks of recent years without the resources provided through the PHEP and LRN. These resources are also helping us improve annual influenza surveillance using state-of-the-art methods, and prepare for a potential pandemic. The public health laboratory will be an integral part of any public health response to pandemic influenza and must be included in comprehensive local, state or federal plans for preparedness and response.

Laboratory results are critical for influenza surveillance and for public health decisions during both routine "seasonal" influenza and during pandemic alerts and pandemic periods. Public health laboratories contribute significantly to surveillance efforts within each state and to national surveillance efforts as members of a network of World Health Organization collaborating laboratories, coordinated in the U.S. by the CDC. Specifically, public health laboratories provide highly accurate and rapid testing for confirmation and identification of "seasonal" influenza strains as well as newly emergent subtypes of influenza such as H5N1. This testing incorporates the use of newer state-of-the-art methods as well as traditional methods that require growing the virus. Laboratory testing is the only way to attribute "flu-like" illness to a specific pathogen, either influenza or one of the hundreds of other viral respiratory pathogens that circulate each year.

In addition, during "seasonal" influenza, laboratory testing is critical to:

- determine when, where and which strains and subtypes of influenza viruses are circulating;
- monitor the extent and duration of the epidemic;
- detect novel influenza subtypes such as H5N1;
- optimize the use of vaccines and antivirals including monitoring for antiviral resistance

Public health laboratories also provide virus samples to CDC for further characterization throughout "seasonal" and pandemic periods, and this information contributes to the selection of future vaccine strains. In fact, one of the viruses used to make last year's vaccine came from the Wisconsin State Laboratory of Hygiene.

Because of the potential introduction of a novel virus into the U.S. from international travelers, CDC now requires that states conduct year-round surveillance. Although it has become commonplace these days to think of planning for a pandemic only in terms of avian flu or more specifically H5N1, the reality is other avian influenza viruses have been implicated in human disease (including avian influenza H7N7, H9N2, H7N2, H7N3). It is essential that current influenza surveillance programs provide for rapid detection of <u>any</u> novel strain.

While the public health laboratory focus is on surveillance to support response and control measures, they must also work closely with private sector laboratories that provide diagnostic testing to support clinician diagnosis and treatment of their patients. Public health laboratories provide confirmatory testing for clinical laboratories, education to clinicians and clinical labs regarding the use and interpretation of rapid influenza tests,

and guidance for handling and submission of suspect pandemic strains from clinical and physician office laboratories. These are resource intense activities that are difficult to maintain without funding.

During the early stages and throughout a pandemic, additional goals for diagnostic testing at public health laboratories will include:

- detecting and confirming initial cases of pandemic influenza in communities and confirming that sustained person-to-person transmission has occurred to initiate targeted community-level interventions including containment (isolation and quarantine), social distancing strategies and infection control;
- differentiate patients with pandemic influenza from those infected with the "seasonal" strain or other respiratory viruses;
- monitor the pandemic's geographic and regional spread through laboratory testing;
- measure the impact of interventions such as vaccination, antiviral therapy, and non-pharmacologic interventions; and
- monitor the pandemic strain to determine the effectiveness of any vaccine (when available and the mergence of antiviral resistance

In addition to these direct response roles, we provide the diagnostic expertise in the development of pandemic preparedness and response plans and their exercise within states, and provide faculty and expertise to support CDC laboratory training efforts domestically and internationally. Public health laboratories also maintain a close working relationship with agricultural and veterinary diagnostic laboratories to monitor influenza activity within animal populations that may impact human populations.

While state public health laboratories have significant expertise in infectious disease testing, we heavily rely on the expertise at CDC to assist in outbreaks, and develop new methods for detection of emerging pathogens that can rapidly be deployed to our laboratories. CDC's influenza division has developed the advanced detection tools currently available in public health laboratories to detect and subtype the influenza A virus, to monitor seasonal circulating strains and detect novel viruses strains. Beginning in 2003, CDC has provided protocols and training for state public health laboratories to perform real-time RT-PCR for molecular detection of Influenza A & B viruses, and for subtyping Influenza A H1, H3, H5 and H7 subtypes. The currently circulating H5N1 strains have been undergoing rapid evolution, so it is essential that CDC continue to carefully monitor the performance of the real-time RT-PCR assays currently in use in public health laboratories by testing H5 samples received from other countries.

The CDC is also working with APHL and other partners on other critical issues related to pandemic influenza response. I have no doubt with the first emergence of a pandemic influenza strain—particularly if it happens to be H5N1—there will be a panic with consequent pressure on public health, including the laboratory, to respond immediately. How much laboratory capacity will be needed for surveillance and diagnostic support during the early stages of a perceived or real influenza pandemic affecting the U.S.?

What is the best way for public health and private sector laboratories to collaborate and support any surge in testing needs? There will, no doubt, be a need for other surge capacities to ensure adequate materials and supplies for diagnostic testing and enhanced transportation mechanisms to move these goods and supplies as well as patient specimens to the laboratories.

It is important to point out that currently there exist no stockpiles of critical laboratory supplies and materials analogous to those developed for pharmaceuticals and other critical emergency response supplies. This could prove to be a critical shortfall! These questions and issues are currently being addressed through an APHL/CDC clinical laboratory partner's workgroup. From a public health perspective, it is assumed that as the pandemic peaks, every ill patient will not need laboratory testing. However, the demand for testing from patients and doctors will rapidly outstrip testing capacities. These are critical issues that must be addressed pre-pandemic. APHL is also working with CDC to develop guidance on the use of various diagnostic tests from the introduction of the novel strain, through the peak of the pandemic, and into the recovery period.

Resources to support the public health laboratory

Traditionally public health laboratories have relied on state resources and the CDC's **Epidemiology and Laboratory Capacity (ELC)** funding to support laboratory influenza surveillance. In 2006, ELC provided $2.2 million to support epidemiology and laboratory activities for seasonal influenza surveillance across 50 states. Although supplemental funding has been appropriated for pandemic influenza preparedness, to date many public health laboratories have not benefited from these funds, despite increased expectations for rapid testing and year-round surveillance.

Substantial state public health laboratory capability and capacity to respond to bioterrorism, pandemic influenza and other public health emergencies has been developed in States over the last several years with the help of other federal funding sources. The degree to which this has been accomplished is related to the distribution of this funding to public health laboratories which has been highly variable on a state-by-state basis both in terms of the type and amount of funding received and the period of time over which it was received.

In general, **Public Health Emergency Preparedness (PHEP) funding from the CDC** has supported laboratories' efforts to:

- build state-of-the-art diagnostic capability and capacity for rapid and accurate laboratory diagnosis of primary agents of bioterrorism (BT) and other major public health threats such as SARS and pandemic influenza as a Laboratory Response Network Reference laboratory.
- develop state-based networks of clinical laboratories, and provide them with emergency response and specimen shipping guidelines and protocols, 24/7/365 state courier systems to ensure rapid transport of specimens, emergency

messaging and electronic data sharing capabilities, training in diagnostic testing to recognize and rule-out the presence of priority bioterrorism agents or other agents of public health importance.

- develop and support training programs for Hazardous Material teams to improve coordinated response to hazardous materials incidents involving "white powders" and other unknown substances,
- to support preparedness and response planning and develop emergency response protocols with other response partners including state food testing and veterinary diagnostic laboratories,) and Federal (CDC, FBI, USPS) response agencies.

The outcome of these efforts in Wisconsin and other states can be measured in part by the significant role the public health laboratory, with these enhanced capabilities and capacities, and the clinical laboratory networks, with whom they collaborate closely, played in a number of recent, high profile outbreaks including SARS (2003), Monkeypox (2003), pertussis (2003-06), mumps (2006), norovirus (2006-07) and the E.coli O157:H7 spinach outbreak (2006) to name but a few.

In addition to responding to bioterrorism, pandemic influenza and other public health threats, public health laboratories are serving an all-hazards mission, providing environmental testing for bioterrorism and chemical terrorism agents, participating in the Food Emergency Response Network sponsored by FDA and USDA, and responding, sometimes daily, to a host of unknown threat emergencies. DHS has created the Integrated Consortium of Laboratory Networks to address coordination and integration of the networks at the Federal level. The ICLN is charged with assuring coordination across the networks. The work of the ICLN has not yet been apparent to the front-line public health laboratory serving an all-hazards mission with diminishing resources.

In Wisconsin and in many other states, substantial laboratory emergency response capability, capacity and infrastructure has been developed. But this is only the beginning of addressing laboratory needs; what has been built needs to be sustained and this is where the greatest problem may lie.

Maintenance of what has been built in terms of emergency laboratory response capability much less continuous future improvements in diagnostic technology, information and data sharing, etc. now may be in jeopardy.

- Despite the ongoing threat of pandemic influenza and in the face of numerous infectious disease outbreaks many state and local public health laboratories have suffered recent substantial cuts in funding. In Wisconsin, FY 2007 PHEP funding to the public health laboratory was cut by nearly 60% and this cut will be carried over to FY 2008. ELC funding to the Wisconsin public health laboratory also has dropped substantially over the past 5 years.
- A number of state public health laboratories did not receive any ELC or Pandemic Influenza Supplemental funding and received substantially less PHEP funding than Wisconsin because these funds were not allocated to them by their states. Further cuts to these public health laboratories would be devastating.

- Costs (salaries, diagnostic equipment maintenance, materials, etc.) to maintain this laboratory response infrastructure are significant and, in fact, are increasing and will continue to do so.
- Direct state support of these emergency laboratory response efforts is variable and in many cases non-existent (this is the case in Wisconsin). This forces the laboratory to have to re-allocate their state funding allotment or perhaps collected fees to emergency preparedness and response at the expense of other laboratory activities that may still have public health importance.
- The clinical laboratories, who will be on the front line in response to public health emergencies such as pandemic influenza and bioterrorism and with whom the state public health laboratories have formed critical partnerships are now highly dependent on the public health laboratory for reference and confirmatory testing, training, communications and data sharing, emergency response guidance, etc. And the fact is, in many circumstances, the public health laboratory may not be able to mount an effective laboratory response to a public health emergency without their clinical lab partners.

Federal funding must continue to sustain the laboratory capability and capacity necessary to effectively support the public health response to pandemic influenza, bioterrorism and other public health threats, and the expanding all-hazards mission. What will be the outcome if funding of these laboratory efforts continues to diminish or is eliminated altogether?

- Diagnostic capability and laboratory technical expertise needed to respond to current and future threats within the state public health laboratory, the nation's LRN reference laboratories, will not be maintained.
- Adequate staffing levels of diagnostic and support personnel will not be maintained. This is a particularly bad outcome in terms of surge capacity needed during an influenza pandemic when perhaps 30% or more of the workforce may be incapacitated at various points of time during the pandemic.
- The ability to bring online the newest diagnostic technologies needed for response to current and future infectious disease threats will be severely diminished.
- The ability to sustain the highly effective network of LRN Sentinel clinical, LRN reference public health and other laboratories (food testing, veterinary), the very backbone of the LRN, will be lost.
- Training of clinical laboratorians in diagnostic procedure to support public health emergency response will cease to be available through the public health laboratory, the current major provider of such training.

Conclusion

In conclusion, the public health laboratory likely will be a critical component of the trigger that initiates the pandemic response plan and community mitigation strategies. The ability to confirm that a patient is infected with a novel strain of influenza resides

solely in public health laboratories. Public health laboratories must be prepared to provide crucial influenza diagnostic and surveillance services to quickly detect and monitor the progression of a novel virus and provide testing to support ongoing response decisions. Pandemic influenza preparedness plans depend upon the public health laboratory delivering effective and coordinated diagnostic services, results, and communication. Epidemiologic surveillance programs that monitor for pandemic influenza rely heavily on accurate laboratory testing and, therefore, must have timely information. Furthermore, in the event of pandemic influenza, the appropriate use of antivirals and vaccination can only be accomplished with public health laboratory support. Public health laboratories are now called upon to fulfill a pandemic and all-hazards public health and national security mission. Without sustained federal funding from CDC and other agencies, our ability to respond to the increasing number of potential threats will be compromised.

Appendix-Influenza Primer

Influenza is a major public health concern in the U.S. as well as globally. Two types of influenza, A and B, are responsible each year for **seasonal** epidemics that affect 5-20% of the population causing significant illness with resultant lost time from work and school across all ages. The highest rates of illness occur in the very young often resulting in severe illness and hospitalization. Young pre-school and school-aged children are also responsible for initial transmission of influenza in the community. The elderly, particularly those over the age of 65 also suffer high rates of hospitalization and a disproportionate percent (90%) of the mortality which totals over 35, 000 each year in the U.S. This morbidity and mortality occurs despite the availability of effective prophylaxis (vaccine) and treatment (antivirals) measures

In recent years, **avian influenza,** so-called "bird flu" also has become a major concern. Aquatic bird species world-wide serve as the natural host for all of the subtypes of type A influenza known. Usually these viruses cause little or no illness in their natural host. Occasionally, however, certain subtypes mutate and become capable of causing severe illness with very high mortality, particularly within domestic poultry populations. These novel subtypes can also become capable of infecting humans resulting in very severe disease with high mortality. This is the situation that has been unfolding in the Far and Middle East, countries of Africa and Europe with the emergence of the H5N1 subtype of influenza since 2003. Since then, this virus has been responsible for the direct death or slaughter of hundreds of millions of poultry in affected countries. In addition, 328 human cases with 200 deaths have been documented in 12 countries. Almost all of these human cases, mostly children and young adults, have resulted from direct contact with infected poultry; there is no evidence thus far of sustained human-to-human transmission. Should sustained human-to human transmission of this or another novel subtype of influenza A occur, the result would likely be a worldwide epidemic, or **pandemic of influenza.**

During the past century, 3 influenza pandemics occurred with the biggest occurring in 1918-1919. This *Great Influenza Pandemic* or *Spanish Influenza Pandemic* as it was called was responsible for over 20million deaths worldwide and over 500,000 deaths in

the U.S. while infecting an estimated 45% of the entire global population. The two subsequent pandemics in 1957 ("Asian influenza") and 1968 ("Hong Kong influenza"), although milder in terms of morbidity and mortality, nevertheless had profound impacts on the global population.

Most experts feel that another pandemic is inevitable and many feel that we are now overdue. With today's much greater population and global interconnectivity even a mild to moderate pandemic, similar to the last two, occurring as multiple waves over a period of two years or longer, would rapidly affect the world with rates of infection of up to 50%, mortality measured in the millions (100,000s in the U.S.) and severe social, infrastructure and economic disruptions.