



June 22, 2010

The Honorable Bennie G. Thompson
Chairman
Committee on Homeland Security
United States House of Representatives
Washington, DC 20510

Dear Congressman Thompson:

The nation's State and local governmental laboratories performing testing of public health significance and their association, the Association of Public Health Laboratories (APHL), are in support of the majority of the provisions in H.R. 5498, Weapons of Mass Destruction (WMD) Prevention and Preparedness Act of 2010, but still have notable concerns with several lines of language that affect State and local governmental laboratories.

We would like to first thank the committee for their efforts to draft this much needed legislation and for the consideration of including several laboratory specific provisions. It is clear in reading the proposed legislation that much deliberation went towards increasing information sharing and collaboration amongst the agencies working with and possessing biological threat agents, and importantly funding specifics have been included for several of these initiatives. APHL fully supports language in Section 2132, Detection of Biological Attacks, which highlights the need for information sharing on detectors with all partners including laboratories and that an assay equivalency program for biological threat assays is implemented. Much of this work is ongoing via interagency and other stakeholder efforts and this legislation further enables collaboration to accomplish these tasks. As the committee is well aware, many of the State and local public health laboratories house equipment and staff for the BioWatch Program, a substantial investment which is costly to these jurisdictions. While we endorse statements outlining a fee-for-service or prepayment system for these laboratories, we respectfully request that the committee clarify that the fee-for-service system would be supplemental and not a replacement for the Public Health Emergency Preparedness (PHEP) Cooperative Agreement funding administered by the Centers for Disease Control and Prevention (CDC). APHL also welcomes the opportunity to work with our federal partners to develop such a fee-for-service system that supplements PHEP funding.

APHL also supports Section 2134, Establishment of the System Assessment and Validation for Emergency Responders (SAVER) Program. APHL has long called attention to gaps in developing standards for the evaluation of hand-held detectors, kits and assays.

8515 Georgia Avenue
Suite 700
Silver Spring, MD
20910-3403

240.485.2745 phone
202.485.2700 fax

www.aphl.org

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APHL supports the development of such standards, as well as comprehensive validation processes, competency assessments and training programs. APHL also recommends that the committee include language in this section to foster collaboration among federal agencies, first responders and State and local governmental laboratories to implement a comprehensive SAVER Program.

Since the 2001 anthrax attacks, the Laboratory Response Network for Biological Terrorism Preparedness (LRN-B) laboratories have faced substantial funding cuts, while being asked to support an ever escalating workload. Preparedness programs have evolved from a purely terrorist focus to that of all-hazards such as natural disasters, pandemics and nationwide outbreaks. Laboratories are routinely given new challenges while trying to survive in a complex economic climate. As such, APHL supports language in Section 2135, Payment for Bioterrorism Laboratory Services, that would establish a framework for reimbursement for State and local governmental laboratories that provide reference testing for the LRN-B. However, APHL recommends that the Committee consider adding language on the need for coordination with the Secretary of Health and Human Services (HHS) to ensure that HHS is aware of any agreements between federal agencies and members of the LRN-B. It is critical to ensure that HHS understands the response capacity of its LRN-B member laboratories.

Many State and local public health laboratories are members of multiple networks such as the LRN, the Environmental Response Laboratory Network (ERLN) and the Food Emergency Response Network (FERN). A lack of a unified response and direction can lead to human and equipment resources being counted as unique entities for each network, and lead to deficiencies for a timely response to simultaneous events. APHL is pleased with the multiple sections that provide direction and defines roles for the agencies involved in preparedness activities involving agents of WMD and supports these sections. Specifically, APHL supports Section 2136, Establishment of the Integrated Consortium of Laboratory Networks (ICLN), which allows for enhanced coordination of activities across the multiple laboratory preparedness networks. APHL recommends that the committee expand representation on these groups to allow for input from the State and local governmental laboratories that comprise the operational components of the various networks. APHL also recommends that the committee change the language on page 40, line 7, from “managed” to “coordinated” and further, that ICLN be appropriately resourced to perform its designated functions. Establishment and nurturing of the ICLN will provide the framework for a more coordinated laboratory response to a WMD event.

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Even though APHL strongly supports the aforementioned sections, there are continuing concerns with language in sections, such as Section 2104, Enhanced Biosecurity Measures and Section 304, Designation of Tier 1 Material Threat Agents. This language implies that the current Select Agent Program requirements are inadequate and need enhancement, without requiring a careful review of the effectiveness of existing regulations. APHL remains very concerned about the impact and cost of implementation of new personnel surety programs at State and local governmental laboratories. Laboratories performing testing of public health significance promote a culture of biosafety and biosecurity throughout their daily operations and especially in the laboratory suites that perform work using select agents and highly pathogenic toxins. Currently, governmental public health agencies are among the most highly regulated entities and undergo multiple inspections; and those that work with select agents are subjected to further regulations including the Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121), which are administered by HHS and the US Department of Agriculture. It is APHL's position that new personnel surety programs would be burdensome to the laboratorians without additional security benefit, and resources would be better spent on more definitive preventative measures. We also recommend that the final bill and or report language emphasize the need to include the public health laboratory community through APHL in the negotiated rulemaking process required in Section 2104. The negotiated rulemaking process should consider the impact of enhanced biosecurity requirements on national preparedness and response capacity, as further regulation may result in fewer laboratories capable of serving in the LRN.

Also of concern is the ambiguous language in Section 304, which describes the designation of Tier 1 Material Threat Agents. APHL and its membership cannot fully support this proposed language without knowing the final designation of the agents, how the new designation will differ from the current select agents and toxins list and the potential increased burden that comes from working with the new Tier 1 Material Threat Agents. Further, as written, the Secretary of the Department of Homeland Security (DHS) would be the lead agency in making the determination of the tiers. Based on our expertise, APHL supports the current Select Agent Program and recommends that DHS work in concert with the Secretaries of Health and Human Services and Agriculture to determine the Tier 1 Material Threat Agents. APHL supports the language in Section 209, Harmonization of Regulations, and recommend that similar language on DHS coordinating with other partners be included in Section 304.

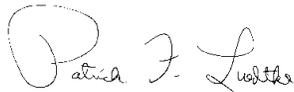
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Other areas of concern are Section 2131 and 2162. Section 2131 addresses the National Biosurveillance Strategy, but fails to include the need for coordination with HHS and USDA in developing this strategy. Domestic and international biosurveillance is highly dependent on the effectiveness of State and local public health systems. Section 2162 addresses the Environmental Recovery from Chemical, Biological, Radiological and Nuclear Attacks, but fails to outline the critical role of State and local governmental laboratories in this phase. As previously noted, many of these laboratories are members of multiple networks including the ERLN and LRN, both of which will play vital roles in assessing the scope of an attack and the remediation efforts. Resources are needed to support the ERLN and LRN to ensure that they are capable of meeting national response and recovery goals.

The State and local governmental laboratory members of APHL thank you and the House Homeland Security Committee for your efforts in creation of this necessary legislation. We look forward to working with committee members, federal agencies and other partners to ensure that the nation's public health laboratories are represented in legislation and appropriately resourced to ensure a rapid response to a WMD event.

Sincerely,



Patrick Luedtke, MD, MPH
President, 2010-2011



Scott J. Becker, MS
Executive Director

