



October 27, 2009

The Honorable Joseph I. Lieberman
Chairman
Committee on Homeland Security and Governmental Affairs
United States Senate
Washington, DC 20510

Dear Senator Lieberman:

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 extremely concerned about the provisions that affect State and local governmental laboratories in S. 1649 and recommend that, at a minimum, Title I be struck from the bill.

State and local governmental laboratories performing testing of public health significance promote a culture of biosafety and biosecurity throughout their operations and especially in the laboratory suites that perform work using select agents and highly pathogenic toxins. These actions not only protect the laboratory workforce and the community where the laboratories are located, they are required to enable the scientific analyses that lead to improvements in the public's health.

All state and local governmental laboratories pursuing work with select agents must maintain compliance with the Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121), which are administered by the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) and the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture. This compliance is a critical requirement for these State and local governmental laboratories to serve as members of the Laboratory Response Network (LRN), which is responsible for safeguarding the health of the public through the early detection of attacks of bioterrorism, chemical terrorism, emerging infectious diseases and other public health threats. Additionally, many of these same State and local governmental laboratories also perform testing services for the Department of Homeland Security's (DHS) Biowatch program.

We are very concerned that the creation of another program in a separate agency that to be involved with the regulation of select agents will lead to multiple sets of compliance requirements, likely conflict in enforcement and create a duplication

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

240.485.2745 phone
202.485.2700 fax

www.aphl.org

The Honorable Joseph I. Lieberman
October 27, 2009

Page 2 of 3

of effort. If S. 1649 became law, the increased regulatory and paperwork burden on the already overwhelmed and understaffed governmental public health laboratories could lead to results that are diametrically the opposite of its intentions: a weakening of biosecurity, as laboratory professionals attempt to manage this burden instead of focusing their efforts on maintaining and improving biosecurity and biosafety. APHL urges you to omit Title I from the bill.

The establishment of two new listings for agents associated with bioterrorism, a Tier 1 agent list and a Registry agent list, will result in three lists of agents. Each list will require differing biorisk management policies and procedures. Tier 1 agents would also be found on the Select Agent List of Biological Agents and Toxins; whereas, Registry agents would not be included on the Select Agent List. This will ultimately be confusing and will set up well-intending laboratories for failure as well as discourage researchers and public health scientists from performing the necessary and important studies on these high-risk pathogens and toxins. An alternative approach to consider is the stratification of the existing Select Agents list by using a set of well-developed criteria and standards that could be developed by discussion among scientific experts from the CDC, HHS, APHIS and DHS. The "Select Agent" list has been stratified in other countries, and a review of their processes could be helpful in the development of appropriate and effective legislation.

S. 1649 was written prior to the issuance of reports from three major federal efforts to research, analyze and make recommendations for improvements in biosafety and biosecurity: the Executive Order 13486 Working Group, the National Academy of Sciences and the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight – all of which will soon be presented to the White House. These efforts carefully considered issues related to personnel security; the efficacy of regulations, procedures and oversight that protect against the deliberate use of biological select agents and toxins; stratification of the select agent list; physical security; transport of select agents and toxins; biosafety and biocontainment; and countermeasure dispensing. Legislating in advance of the critical findings would be questionable, at best.

The Honorable Joseph I. Lieberman
October 27, 2009

Page 3 of 3

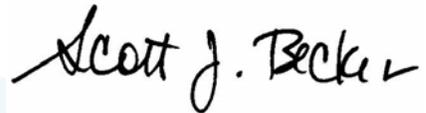
The Senate bill also seems to neglect several aspects of current law and practice, including the Select Agent Program coordination with Department of Justice and DHS to develop laboratory security guidance to assist registered entities in developing and implementing the required written security plans – fully utilizing the important security expertise of these agencies. CDC also has information sharing agreements with federal and state partners, including a Memorandum of Understanding with DHS to share information about registered entities and the agents they possess, a process in place for sharing information with the Federal Bureau of Investigation Weapons of Mass Destruction Directorate and a process in place to share information with state officials about the registered entities in their jurisdictions. A fuller appreciation of these activities would likely produce an improved bill.

The State and local governmental laboratory members of APHL are very willing to work with the Senate Committee on Homeland Security and Governmental Affairs to develop legislation that appropriately addresses the important need to improve biosafety and biosecurity. Thank you for your consideration.

Sincerely,



Susan U. Neill, PhD
President, 2009-2010



Scott J. Becker, MS
Executive Director