Additional Comments on Titles II-III of S 1649

August 25, 2009

Title II, Response to a Weapon of Mass Destruction Attack

Section 211—Bioforensics Capabilities and Strategy
(c) The National Bioforensic Repository Collection “shall maintain a national bioforensics repository collection.” In (3) Participation (A), agencies with a “biological agent or toxin collection that is useful for the bioforensic analysis of biological incidents, performance of biological threat agent characterization studies or development of bioforensics assays shall provide all relevant biological agents and toxins as determined by the Secretary, which shall not include variola virus, to the national bioforensics repository collection.” The Secretary shall encourage the contribution of public and private biological agent and toxin collections to the national bioforensics repository collection that were collected or created with support from a federal grant or contract…access is allowed to the collection by agencies and public and private entities.

Comment: A centralized, comprehensive repository maintained by one source could help to ensure access to forensically important agents for criminal investigation and improved microbial forensic technology. However, the repository will be costly; the draft does not provide for funding and resources. Management issues, including protection of intellectual property, will have to be considered.

Title III, International Measures to Prevent Biological Terrorism

Section 301—International Threat Assessment: Tier I Pathogen Facilities
(a) Not later than 6 months after enactment of the bill, the Director of National Intelligence, in coordination with the Secretaries of State, Homeland Security, HHS and the heads of other appropriate agencies shall complete a global review of international biological security threats to the United States. The review shall identify the location of biocontainment facilities handling an agent or toxin designated as a Tier 1 agent under Section 351A(a)(2) of the Public Health Service Act or Section 212(a)(2) of the Agricultural Bioterrorism Protection Act of 2002…and other dangerous pathogens outside the United States; describe the security measures of the facilities…assess global biological risks, including by describing regions or countries with the greatest biological security risk, taking into account the presence and capabilities of a foreign terrorist organization, the location of highest risk pathogen collections and the location of biological laboratories operating with inadequate security measures and assess gaps in knowledge about international biosecurity threats.

Comment: It will be difficult to identify the international laboratories that are working with “Tier I” agents. Almost any public health, clinical or veterinary laboratory in another country could possess pathogenic agents. It is unclear by what standards security measures will be determined to be inadequate.
Section 302—Strengthening International Biosecurity

(b) Authorized activities (1) Reducing and Securing Dangerous Pathogen Collections—The Secretary of State shall provide assistance to remove or consolidate Tier 1 agents and other dangerous pathogen collections spread among multiple locations within a country or region into facilities with appropriate safety and security; provide assistance to replace dangerous or obsolete pathogen isolation techniques with modern diagnostic tools to improve safety and security and to reduce the number and size of dangerous pathogen collections in high risk regions and countries; encourage countries to eliminate stores of “Tier I” agents and other dangerous pathogen collections in exchange for facilitating access to state of the art civilian research at international facilities, provide assistance to identify and secure “Tier I” agents and other dangerous pathogen collections in high risk regions and countries...(2) Prevention and Protection—The Secretary of State shall raise awareness of international biological threats with foreign governments, academic institutions, and industrial laboratories handling “Tier I” agents and other dangerous pathogen collections through conferences, seminars and workshops; provide physical security upgrades at high risk laboratories; train foreign partners in high risk regions on best laboratory biosecurity practices within facilities handling Tier 1 agents and other dangerous pathogen collections; assist foreign countries in establishing personnel reliability measures as part of a comprehensive laboratory management system; partner with foreign governments, laboratories and scientists in activities that strengthen and reinforce best biological safety and security practices within facilities handling Tier 1 and other dangerous pathogen collections.

Comment: “other dangerous pathogen collections” is unclear. We have already commented on issues surrounding the establishment of another list of Tier 1 agents. This section is dependent on which agents are included.

(3) Science and Technology Exchange
The Secretary of State shall promote research and development collaboration on highly infectious human, animal and plant disease agents in facilities with appropriate safety and security measures; provide opportunities for foreign scientists particularly those located in highest risk countries …to receive training in the United States on biological safety and security best practices, standard operating procedures and maintenance for high containment facilities and facilitate the secure exchange of research samples between laboratories in the United States and foreign national laboratories for the development of vaccines and diagnostics for Tier 1 agents and other dangerous pathogens.

Comment: The DHHS, CDC, NIH, FDA and USDA need to be consulted and involved in these activities and issues. It is critical that these public health, science agencies be involved.

Section 502—Guidelines Concerning Weapons of Mass Destruction
The Secretary of Homeland Security shall develop guidelines …for responding to an explosion or release of nuclear, biological, radiological or chemical material
Comment: The DHHS needs to be consulted and involved on issues involving public health and biological, chemical or radiological agents.