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July 3, 2008

The Honorable Richard Burr and The Honorable Edward Kennedy
United States Senate
Committee on Health, Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

To Senators Burr and Kennedy:

As a former Assistant Director in the Office of Science and Technology Policy, a former Chief Counsel of the Research and Innovative Technology Administration, U.S. DOT, and more than two decades of academic work and practice experience in environmental and public health regulations, and as the current Director of the Center for Biodefense, Law and Public Policy, and Professor of Law at Texas Tech University School of Law, and after serving as a consulting attorney on several high profile legal cases involving biosafety and biosecurity, I am pleased to comment on this bill, S.B. 3127.

The introduction of the S.B. 3127, *Select Agent Program and Biosafety Improvement Act of 2008,* introduced on June 12, 2008, to reauthorize the Select Agent Program, for the next five years, has been wisely approached through careful and deliberate consideration of the lessons learned from the first five years of the Select Agent Program. You and your Committee Staff are to be commended for the work undertaken to understand this complex and vital national biosafety and biosecurity need and for taking action when and where action is needed, where waiting would prove harmful to our national biosafety, biosecurity and research needs.

The current Select Agent Program consists of components which include registration of facilities, background checks for investigators, biosecurity measures for access to select agents, a reporting system for releases or losses of select agents, but some of its most vital elements for safety are left either too vague, or were not clearly implemented through regulations to ensure that the bill achieved its goals of safety of public health and national and homeland security.

Through the Center for Biodefense, Law and Public Policy and the Core for Law, Policy and Ethics of the Western Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research (WRCE), I conducted a survey of biodefense researchers during the first two weeks of September 2007, about their opinions concerning the select agent rules, 42 CFR §73, and the effectiveness of these rules in achieving their regulatory goal of national security and protecting public health. The

survey respondents were Principle Investigators from the WRCE, which includes the five state region of Texas, Louisiana, Arkansas, Oklahoma and New Mexico. The survey achieved a return rate of 55 out of the 80 PIs contacted. Currently, the same survey is being administered from a nationwide pool of respondent PIs from nine other RCEs. This research is supported by a grant from NIAID to the WRCE Law, Policy and Ethics Core through the Western Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research, NIH Grant Number U54 AI057156. Hereinafter, I will refer to this survey in this letter as "the Survey".

Here are some of the highlights of the findings:

► 93.6% of the biodefense researchers believe that select agents should be regulated. This tends to disprove some perceptions among policymakers than biodefense researchers oppose the regulations simply because they do not want to be regulated.

► The Biosafety in Microbiological and Biomedical Laboratories Manual (BMBL) is adopted by reference in the select agent rules, making it more of a voluntary guideline. Yet biological containment is one of the most critical factors in protecting public health, ranking in the top five most important aspects of the regulation by 61% of the respondents. When asked whether the BMBL should remain or be replaced by clear standards, there was a 2 to 1 choice that the BMBL should remain as guidance; while a significant 32% would prefer clear standards for biological containment rules. (Fig. 1)

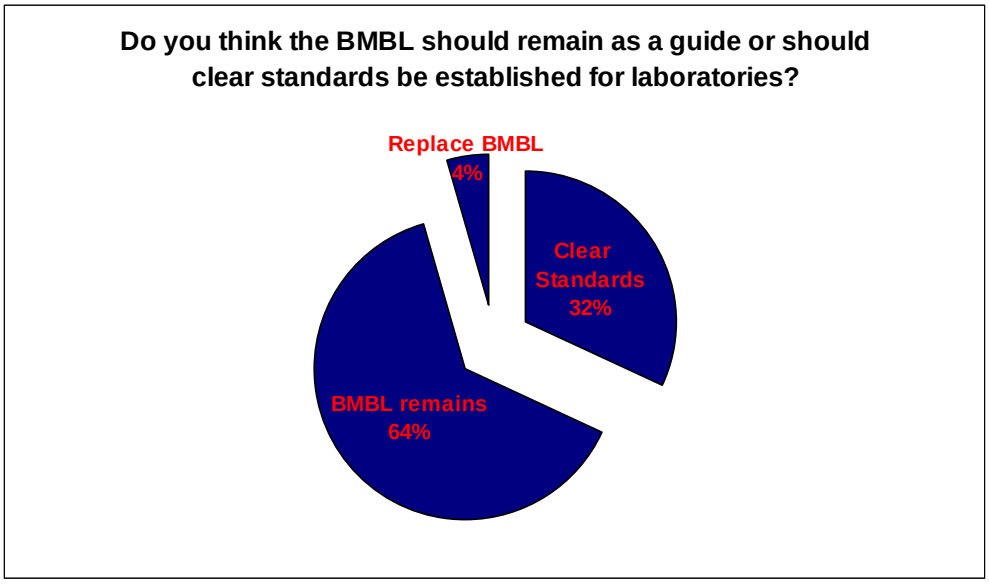

Fig. 1

► Respondents were asked to rank their concerns on a scale of 1 to 5, with 1 being the lowest, and 5 the highest. When asked about their level of concern about injury or death from their professional work with select agents, 72.6% responded with a 1 or 2, indicating a low level of concern. (Categories were collapsed into a 1-3 scale) (Fig. 2)

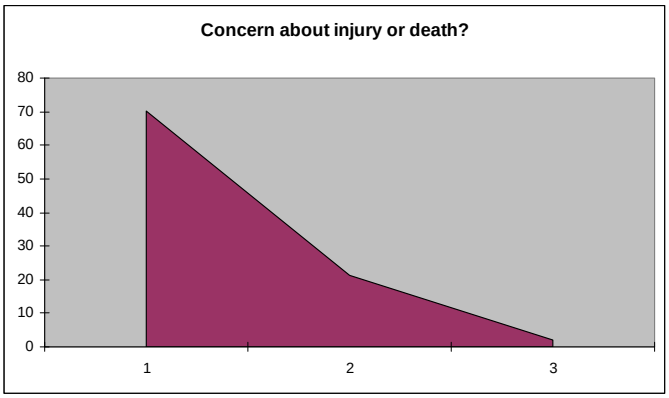

Fig. 2

► Respondents were also asked to rank their concern on the same scale, a scale of 1 to 5, with 1 being the lowest and 5 being the highest, about their level of concern about inadvertently violating the select agent regulations which might result in negative repercussions on their career. 49% responded with a 4 or 5, indicating a high level of concern. (Categories were collapsed into a 1-3 scale) (Fig. 3)

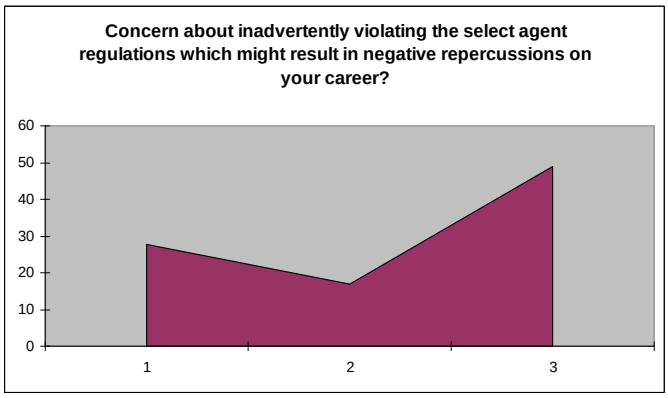

Fig. 3

► The resulting almost-mirror image graphs suggest that policymakers should consider the consequences of these results which indicate that concern for inadvertently violating the rules outweighs the concern for injury or death when working with potentially deadly select agents. This may have created the unintended consequence of making laboratories less safe, due to undue attention and anxiety about inadvertent violations of the regulations. The high level of concern for violating the rules also suggests that the regulations lack certainty and predictability.

This regional study of five states is the largest in terms of the number of PIs among the NIH Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research and served as a test survey for the national survey which is currently being conducted throughout the United States among the PIs and Co-PIs of nine of the ten Regional Centers of Excellence. Results of the national survey will be available at the end of August 2008.

I will proceed with an examination of S.B. 3127, by addressing it by Section, and provide empirical evidence from the Survey where appropriate and relevant, and my experiential practice and examples from my academic study and legal practice, where it is relevant.

The bill continues to delegate implementation authority to two agencies: the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS). In my opinion, this has presented some confusion to the regulated community, and I would like to see this bill expand its review of the program in Sec. 102 in its charge to the National Academies, to include consideration of this aspect of the Select Agent Program.

The bill is divided in two titles: the first title is the reauthorization of the select agent program and the second title is "biosafety improvements."

In the Title I, the reauthorization section, the Select Agent Program is reauthorized for the next five years --- 2009 through 2013. The current program was authorized from 2002 to 2007 and expired September 30, 2007.

Sec. 102 requires that the Secretaries of Health and Human Services and Agriculture contract with the National Academy of Sciences to conduct a review of the program, which is a wisely conceived priority for the Select Agent Program. The bill seeks a focus on the statutory goal of enhancing "biosecurity and biosafety in the United States," and how this program has impacted the work of researchers in "scientific advances" as well as "international scientific collaboration." The regulated community has been limited in their ability to work with select agents with their colleagues in other countries, often in the very countries where these diseases are endemic, because of regulatory barriers to collaboration. In the Survey, when researchers were asked what they considered to be the major problems or constraints in conducting international research on select agents and or Category A-C agents (which is a potential-use-as-bioweapons classification), 34% responded that one of the major problems or constraints was biosafety and security regulations pertaining to possessing, transporting, and working with select agents, including rules imposed on collaborating foreign institutions and investigators. This Sec. 102 is clearly responsive to the concerns and needs of the regulated researchers, and could go a long way in resolving this problematic feature of the Select Agent Program.

Sec. 103 of the bill requires the revision of the list of select agents to reflect current advances in science, without which, the originally conceived select agent definitions would become potentially marginalized and the rapidly growing field of research in genetically-modified-organisms and synthetically developed agents would quickly escape the scope of the Select Agent Program, leaving a gap in protecting public health and national security and homeland security. This bill adequately addresses that need and forestalls a public health risk by including these areas within the scope of the regulated select agents. Further, the bill addresses the consideration of listing agents which are "endemic" to the United States and provides that the status of "endemic" does not preclude their inclusion on the Select Agent lists. For example, this provision will inevitably address the issue of why *hanta virus*, a hemorrhagic fever virus endemic to the

United States, is not on a Select Agent list, even though it appears on a list of agents that are potential bioweapons. This bill establishes in its rule of construction, that the fact that an agent is "endemic" to the U.S., should not be a reason for excluding it from the list. This provision adequately addresses those questions which should be considered in identifying select agents which should be listed.

Sec. 104 of the bill addresses sharing information with trusted state partners. This section of the bill addresses the need for sharing information in events requiring public health or criminal investigatory state partners. Similarly, it effectively reflects the need recognized in HIPAA, to reveal protected health information to investigatory government agencies in the event of a public health emergency. The same need may arise in the context of any Select Agents or registered institutions which may be the subject of a public health emergency. However, it is my opinion that without harmonizing state laws or a statement of preemption for any state law contrary to these provisions, in this bill, the implementation of this section may not achieve the goals sought.

Sec. 105 addresses needed improvements to the inventory and monitoring regulations currently in effect, and requires a gap in the lack of guidance to be filled. The implementation of this section alone, could be the most substantive and significant improvement to the Select Agent Program. While regulatory agency officials made determinations from one registered facility to the next, about inventories, none of these interpretations were shared with the regulated community except the one that they were given on an inspection visit. For example, should vials of select agents in inventories be counted once a week, once a month or once a year? If they are sealed in a styrene storage box with a taped seal, how often should they be recounted. On such inspection visits, only that one facility would hear the answer to the question, and other facilities were left in the dark about the regulating agencies' stated opinions. Guidance on these questions, or simply anecdotal letters illustrating the application of their interpretations, made available to the regulated community would provide predictability and more certainty in registered institutions and for biodefense researchers, who themselves have the burden of compliance with their particular questions. An example of an individual researcher, is whether a collection of 25,000 vials or a collection of 10 vials should be handled in the same manner? Again, this bill will require issued guidance, remedying many of this problems which have plagued the regulating community. While guidance does not have the force of law, as statutes and regulations; the courts have shown a strong interest in referring to or using agency guidance in the absence of statutory or regulatory language.

This section, Sec. 105 also requires a benefit-burden analysis which is a much needed component of any regulatory program, and fills this wide gap in regulatory development. The problem of "regulatory mismatch" discussed in the administrative law literature, can be effectively addressed through this requirement to consider the effectiveness of the regulation against the burden, thereby assuring that the goals of the regulatory program are actually achieved through the regulatory means selected.

Sec. 106 seeks to bring clarity to a vague definition for variola virus in 18 USC §175c and the Attorney General with the Secretary of HHS are charged with defining the scope of the existing definition and issuing guidance to interpret the scope of the definition. In section (d) of the statue, "the term 'variola virus' means a virus that can

cause human smallpox or any derivative of the variola major virus that contains more than 85 percent of the gene sequence of the variola major virus or the variola minor virus." This statute is part of the criminal code. However, since variola virus is a listed select agent, it is critical to determine its precise definition, since experimentation and research is conducted on widely varying components of the virus, and without a precise definition, vagueness will lead to uncertainty.

Sec. 107 addresses the need for utilizing biocontainment laboratories for surge capacity needs in the event of a bioterrorism attack or a pandemic. These events may require testing exponentially increasing numbers of biological samples, in the days following an event, incident or cluster of illnesses, or agricultural event. In the days following the anthrax attacks in the fall of 2001, surge capacity for testing envelopes, packages alone, quickly overwhelmed existing public health facilities and many academic institutions with biocontainment facilities were called upon to assist in an unprecedented manner. This bill addresses that need, and calls upon all laboratories, not only biocontainment laboratories, to develop guidelines as part of the plan, for example CLIA laboratories which are otherwise excluded from the Select Agent Program. This bill recognizes the need to utilize laboratory capacity on a broad and inclusive scale, and insightfully identifies the scope necessary to adequately plan for surge events.

In Title II, addressing biosafety improvements, there are three parts: Sec. 201 for oversight of laboratories; Sec. 202 specifying training requirements; and Sec. 203 establishing an incident reporting system.

Sec. 201 defines a "high containment biological laboratory" as a BSL 3 or BSL 4, and requires an evaluation of the national need for such laboratories and an evaluation of the oversight of these laboratories. For this evaluation the bill requires the coordinated efforts of four cabinet level Departmental Secretaries: Health and Human Services, Agriculture, Defense and Homeland Security. The bill requires four specific considerations: (1) whether the construction of high containment biological laboratories, planned and in existence, "provide sufficient capacity for the needs of Government biodefense and infectious disease research"; (2) how lessons learned can be shared nationally and internationally; (3) whether guidance on laboratories is "adequate" and also how to improve and streamline the guidance; and (4) identify ways to streamline training and to provide minimum standards for training.

Part (1) addresses a question raised at a October 5, 2007 Congressional Committee Hearing, whether any Government agency or department knew how many biocontainment laboratories existed in the U.S. This bill, S.B. 3127, has explored and refined the question to seek an answer to what is the capacity need for the Government. A capacity need analysis will provide the foundation for other components of the bill, for example, planning for surge capacity.

Part (2) is vital and has been a missing part of the service needed to the regulated community. This part could be implemented through guidance much like other agencies, like EPA (guidance), the SEC (SEC letters) and the IRS which provide cases and their resolution or interpretation. Regulatory guidance has not been published by the

regulating agencies, to date, another important component of a more mature regulatory program.

Part (3) addresses the adequacy of incorporating the BMBL guidance into the regulation which provides recommendations, but is used for enforcement purposes, circumventing an important Due Process principle of our government which would require providing notice of how a party will be regulated. This vagueness is evident in the regulatory text at 42 CFR § 73.12 (a) which reads, "In developing a biosafety plan, an individual or entity ***should*** consider: (1) he CDC/NIH publication . . . [emphasis added]." In the Survey of biodefense researchers, the question was asked whether different guidance was needed, and 32% of the respondents wanted "clearer standards", and 4% simply wanted to replace the BMBL guidance. (See Fig. 1, above).

Part (4) effectively stabs in the heart, the beast that prevents this Program from providing Biosafety, and would thwart its goal of achieving public safety and protecting national security and homeland security. Minimum training standards will now be an essential component and threshold requirement for individuals who work with Select Agents. The current regulation, 42 CFR § 73.15 which addresses the provision of training by the institution requires only that "An entity . . .must provide information and training on biosafety and security to each individual . . ." and 42 CFR § 73.10(c) provides that "Each individual with access to select agents or toxins must have the *appropriate . . . education, training and/or experience*. . " [emp added]. This bill gives CDC and APHIS the authority to move forward, with advice, in developing more predictable requirements for regulated institutions and researchers, and essential components for national biosafety.

Sec. 202 takes Sec. 201's evaluative consideration one step further by specifying that the Secretary of HHS in coordination with the Secretary of Agriculture "and scientific experts" . . . "shall develop minimum standards for laboratory biosafety and biosecurity training for relevant personnel of high containment biological laboratories. Registration of researchers will then require evidence of meeting these minimum training requirements.

In the Survey, when asked about specific areas of training for working in biocontainment laboratories; 85.1% said that BSL training should be required; 53.2 % said that emergency response training should be required; and 85.1% said that regulatory compliance training should be required. This bill in Sec. 201(4) and Sec. 202, responds directly to the need for training standards, which is clearly indicated as an area of high importance to the regulated community. This bill identifies and provides for filling that regulatory gap.

Sec. 203 establishes a "Biological Laboratory Incident Reporting System" for "voluntary reporting of biosafety or biosecurity incidents of concern", and statistics on these reports "may" be collected and characterized where trends exist in order to make improvements in biosafety and biosecurity. The Secretaries (HHS and Agriculture) "shall contract with a public or private entity that does not regulate biological laboratories to administer the reporting system." The seven functions of this system are identified in the bill: "(1) receive and process incident reports; (2) analyze, interpret incident data, and

identify incident trends, (3) issue alert messages; (4) disseminate reports; (5) not have authority to direct corrective action or to initiate enforcement action; (6) ensure anonymity of individuals reporting to the system, to the extent permitted by law; and (7) conduct other activities as requested by the Secretaries."

The Survey analysis showed that there was a real desire on the part of the regulated community to have a resource for answering compliance questions without fear of civil or criminal prosecution. When asked whether they would use a hotline for anonymous compliance questions about the select agent regulations, 42.6% responded in the affirmative. This survey was conducted in the fall of 2007, during the widely publicized CDC suspension of the Texas A&M University registration to work with select agents, and this was a likely confounding external factor which contributed to this high, affirmative response.

This contract for providing compliance information must include attorneys who can offer the caller anonymity through protection through attorney-client privilege relationship, or anonymity cannot be assured, and the recipient of the call will be subject to subpoena or civil interrogation. However, the attorney-client privilege has its limits in law, and this is clearly addressed in the bill In response to the Survey results, the Center for Biodefense, Law and Public Policy has developed guidelines for such a call center, and is being made initially available to the NIAID supported Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research.

In summary, the regulated community, biodefense researchers and biocontainment laboratories and other institutions, have been inordinately concerned about inadvertently violating the select agent regulations, as shown in Figure 3, which in large part, can be explained by the vagueness and unpredictable enforcement standards of the training requirements, the inventory requirements, the reporting requirements and the infrastructure requirements. This bill goes to the heart of these issues and establishes improvements and fills gaps in the Select Agent Program in a way that can prevent our national biodefense research enterprise from being unnecessarily steeped in a regulatory quagmire that may have failed the Constitutional Due Process test had the regulation been judicial reviewed and in large part failed to meet the very goals of the statute in protecting public health and national and homeland security, while not unnecessarily impeding scientific advances.

Sincerely,

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