

The logo for the Federation of American Societies for Experimental Biology (FASEB). It consists of the acronym "FASEB" in a bold, white, serif font, centered within a dark blue rectangular box. This box is enclosed within a thin, gold-colored border.

Federation of American Societies for Experimental Biology

— *Quality Life Through Research* —

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November 3, 2009

The Honorable Joseph I. Lieberman
Chair, Committee on Homeland Security
and Governmental Affairs
United States Senate
340 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Lieberman:

The Federation of American Societies for Experimental Biology (FASEB) respectfully requests that the Senate Homeland Security and Government Affairs Committee consider the following input on the Weapons of Mass Destruction Prevention and Preparedness Act (S. 1649). FASEB comprises 22 scientific societies representing approximately 90,000 biomedical researchers, including those actively engaged in biodefense research or fundamental and applied studies using select agents. The research community is committed to strengthening our nation's biosecurity and protecting our country against potential biological threats.

We commend your leadership and commitment towards strengthening the biosecurity of the United States, and FASEB appreciates the Committee's efforts to solicit feedback from the biomedical research and life sciences community. In fact, we would urge the Committee to consider delaying further action on Title I of this legislation until you have had an opportunity to integrate the recently released reports from the National Research Council, titled *Responsible Research with Biological Select Agents and Toxins*, and Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, as well as the soon-to-be released recommendations of the Executive Order Working Group on Strengthening Biosecurity. These groups have made careful and considered study of the laboratory biosecurity issues addressed by S. 1649, and we believe their valuable work should be taken into account before changes to the existing regulatory framework are implemented. However, in addition to recommending these important resources, FASEB wishes to share some more specific comments and concerns about the bill.

Role of the Department of Homeland Security: FASEB strongly supports the leading role of the Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) in overseeing the Select Agents and toxins regulations in partnership with the Department of Justice. In general, the Select Agent regulations have become part of the fabric of the research enterprise, and the scientific community has adapted to the current system. Initial implementation was not easy and concerns remain about delays in the registration

process and the costs of compliance, but overall, FASEB supports the current system of select agent regulations and believes it works quite well.

FASEB thanks the Committee members and staff for incorporating the scientific community's recommendation to make HHS the primary agency on the bill's proposal to register laboratories working with pathogens and toxins. However, we are concerned that a number of provisions in Title I of S. 1649 increase the role and authority of the Department of Homeland Security (DHS) in regulation of laboratories and pathogens. FASEB supports our colleagues at the American Society for Microbiology in their assertion that DHS has neither the appropriate expertise nor the experience in the biological sciences to assume a regulatory role for laboratory biosecurity.

Overlapping regulations: While provisions of the bill do make some effort to harmonize oversight of the multiple agencies involved in biosecurity regulation, FASEB is concerned the legislation would create redundant systems of regulation for controlled pathogens. As stated above, we do not believe DHS has the expertise to oversee a pathogen control program, nor does it make sense to subject the research community to multiple lists of regulated agents and overlapping rules. FASEB worries this will create confusion and discouragement among the research community which will delay important research advances in human health and biodefense. Moreover, the legislation provides considerable flexibility to DHS and HHS in determining which agents are to be regulated through the Tier 1 or Registry Agents system, and the criteria for defining a Tier 1 agent are ambiguous. We are concerned that such ambiguity could increase the breadth of regulated agents, and associated delays in maintaining compliance, with no commensurate increase in biosecurity. FASEB supports, in concept, the stratification of dangerous pathogens and their associated controls, as recommended by the National Research Council report, *Responsible Research with Biological Select Agents and Toxins*. A stratification of the select agents by risk category would allow a stratification of regulations, giving institutions greater flexibility in ensuring maximum security for the pathogens and toxins posing the highest risk, while enabling less costly, more reasonable, and risk-appropriate controls for less risky select agents. Unfortunately, the regulatory system described by the current bill falls short in achieving these objectives.

Finally, the legislation calls for inspections of laboratories working with pathogens by multiple agencies, including DHS, and suggests these inspections be coordinated to "to the extent practicable." Currently, many laboratories working with select agents report being subject to multiple inspections by a number of entities, including federal agencies such as HHS, USDA, and DOD, and local authorities, such as the health department or university health and safety office. These inspections typically take multiple days and involve large teams of inspectors. While FASEB appreciates the need to have thorough inspections of select agent facilities, in order to ensure security plans are being properly implemented, we are concerned that the standard of "practicability" is too vague a term and will result in increased cost of compliance and time away from important research.

Enhanced biosecurity measures: FASEB does not support the creation of a new system of regulations by DHS, particularly related to the creation of a personnel reliability program for biological laboratories. Following the identification of Dr. Bruce Ivins as the lead suspect in the 2001 anthrax attacks, questions have been raised about what could be done to mitigate the risk of an "insider threat." FASEB endorses the views of the National Science Advisory Board on Biosecurity (NSABB), outlined in their report *Enhancing Personnel Reliability Among Individuals With Access to Select Agents*, and the National Research Council's recommendations

in *Responsible Research with Biological Select Agents and Toxins*. In particular, we agree that the current Select Agent Program already contains sufficient personnel reliability measures through the Security Risk Assessment process. This seems to be underscored by the fact that neither the CDC nor the USDA has reported a single incident of theft or attempted theft of a select agent since the regulations were enacted. Moreover, many university research laboratories, particularly high-containment facilities, already have in place additional personnel reliability protocols, beginning with the hiring process, which may include background checks, drug testing, and medical examinations. Allowing research institutions to develop their own personnel reliability programs related to use of select agents enables the institution to work within the framework of hiring practices, applicable state laws, and risk assessment. We support the National Research Council's recommendation that personnel reliability is best assured through active management and ongoing training of laboratory personnel, and believe this should include regular performance evaluations and clear mechanisms for reporting concerns.

We agree with NSABB that greatly increasing requirements for personnel reliability, such as those used by the Department of Defense, would deter talented scientists from working with select agents and would be a significant drain on scarce resources, to the detriment of our nation's biodefense. In addition, FASEB is concerned that there is little evidence that methods used to assess performance reliability, such as psychological testing, are predictive of future criminal behavior. Given the lack of data showing that additional, stringent personnel reliability requirements would actually reduce the "insider threat," and the near surety that implementing these measures would harm ongoing and future biodefense research, moving forward with a personnel reliability program for select agents is unjustified. Finally, we reiterate our concern that DHS does not have sufficient or appropriate expertise to promulgate regulations related to laboratory personnel or training, as described in Section 102 of Title I. Rulemaking related to select agents and toxins should remain under the authority of HHS and USDA, wherein lies the appropriate expertise.

Registry of laboratories working with pathogens: FASEB believes that this bill reflects a lack of clarity between the concepts of biosafety and biosecurity. While the news media may use the terms biosafety and biosecurity interchangeably, there are distinct differences from a policy and regulatory point of view. Best practices in biosafety, which aim to protect personnel working in the lab from the materials with which they are working, greatly contribute to biosecurity, the goal of which is to protect dangerous biological materials from inadvertent or deliberate release. However, FASEB is concerned that issues related to biosafety, such as cases where lab workers are exposed to infectious agents or questions about the number of BSL laboratories, are being inappropriately used to justify more stringent biosecurity measures. For example, the exposure of a laboratory worker to a non-contagious pathogen such as anthrax during the course of handling it in the lab is of serious biosafety and occupational safety concern, and we believe it should be reported and steps taken to prevent future occurrences. But this does not constitute a biosecurity problem; there was no increased risk to anyone other than the lab worker.

FASEB does not oppose the creation of a federal registry of high-containment laboratories, as recommended by the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, and we believe there is benefit to setting minimum compliance standards, such as requiring all high containment labs comply with Federal biosafety guidelines, including the U.S.

Public Health Service's *Biosafety in Microbiological and Biomedical Laboratories* and *NIH Guidelines for Research Involving Recombinant DNA Molecules*. Yet we remain seriously concerned that the legislation is too vague in defining which laboratories or agents qualify for registry and gives the regulatory agency too much flexibility in making this determination. This could result in registry of labs which are handling biological material that poses no threat to the public or nation. Such over-reporting could be both a hindrance to security and will present an enormous compliance burden on research laboratories to the detriment of important health and biodefense research.

International measures to prevent bioterrorism: Although the legislation's aim to increase the standards of biosafety and biosecurity as well as to build scientific capacity worldwide is admirable, FASEB is concerned that Title III of S. 1649 may be perceived with substantial distrust by the international scientific community. We do not feel that it is appropriate for the United States to be dictating the laboratory practices or training of scientists in other nations. However, FASEB does believe there is a need to increase the biosafety and biosecurity capacity of our scientific partners, particularly in developing countries, and that this is best done through cooperative efforts actively engaging the research community. We recommend the Committee examine and consider supporting the ongoing efforts of a number of groups in this regard including, but not limited to, the National Science Advisory Board on Biosecurity, National Academy of Sciences, and the International Council for the Life Sciences. These groups have conducting workshops, building capacity, and increasing worldwide awareness of biosecurity issues in a manner that involves both the leadership and scientific community of other nations, substantially achieving the objectives of Title III. Working with scientific societies to create professional development or training opportunities in biosafety or biosecurity at international meetings might be another pathway the Committee would wish to explore.

Again, we thank you for considering these comments as the legislation moves forward. FASEB would be happy to provide any additional information you may need, and we look forward to working with you in strengthening our nation's biosecurity.

Sincerely,



Mark O. Lively, Ph.D.
FASEB President

