

**ABSA**

American Biological Safety Association

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November 19, 2007

RE: Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information (June, 2007)

Secretary

Paul J. Meechan, PhD, RBP, CBSP
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Dear Sir or Madam;

The American Biological Safety Association (ABSA) is an international group of biological safety professionals that is recognized as one of the world's foremost resources on biological safety practices. We believe our obligations include providing leadership in the realm of biosafety and biosecurity as well as to provide commentary on proposed legislation and other regulatory framework that have the potential to impact the biological sciences and related industries. In this context, we have reviewed the *Proposed Framework for the Oversight of Dual Use Life Sciences Research*. We have the following comments to share with you.

Treasurer

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General Comments

ABSA is supportive of the efforts of the National Scientific Advisory Board on Biosecurity (NSABB) in drafting the *Proposed Framework for the Oversight of Dual Use Life Sciences Research*. We believe that this proposal is thoughtful and considers the importance of striking a reasonable balance between responsible biosecurity oversight and providing the appropriate support to facilitate progress and discovery in the numerous biological sciences research enterprises, including academia, health care and industry.

Past-President

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Specifically, we believe that it is appropriate for a principal investigator (PI) to perform the initial review of his or her research with regard to potential dual use. The PI, we believe, will be the best informed person regarding the specific goals of their own research agenda.

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In this regard, we agree with the NSABB that additional training of PIs is needed to provide the necessary tools to conduct this initial review.

Executive Director

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We support the NSABB recommendation that the Federal government should develop training and guidance materials that can be used as educational resources at the local level. This would greatly assist the local institutions as well as provide a framework for consistency and comprehensiveness in the local training efforts.

ABSA supports the NSABB approach to provide latitude to each institution to establish a local review entity that best fits with its capabilities, circumstances, and culture. The NSABB has offered several options for consideration, including employment of established Institutional Biosafety Committees (IBCs), the creation of new committee entities and commercial IBCs. We applaud this flexibility and the NSABB focus on process and outcome in lieu of a prescriptive regulatory approach. In short, we support the promulgation of guidelines, not regulation.

We whole-heartedly support the NSABB contention that established oversight mechanisms do not unduly burden or slow progress of life sciences research.

We share the NSABB concern regarding the promulgation of another unfunded mandate and strongly support the NSABB recommendation that the federal government ensure that sufficient resources are provided to institutions to fulfill their responsibility.

While ABSA is supportive of this NSABB draft *Framework*, we do have several recommendations for improvement. We all recognize that training is needed for the PI to conduct an initial assessment for dual use potential as well as for institutional entities (e.g. IBCs) to continue this review. We believe that it will be critical that this training include strategies for conducting a security risk assessment. While we recognize that risk assessments have been conducted for many years in the realm of Biosafety, as required by the NIH *Guidelines for Research Involving Recombinant DNA Molecules*, for example, we believe that a slightly different paradigm and tools are required for conducting a biosecurity risk assessment.

ABSA thus recommends that the NSABB provide information and educational resources in biosecurity that could be adapted for use at the local level. These resources should include information on how to conduct a risk assessment of research for dual use potential, how to differentiate between dual use research and dual use research of concern (DURC), and guidance on determining the degree of risk of misuse that is presented by various types of research.

ABSA appreciates the opportunity to have shared our perspective with you. Please do not hesitate to contact us with your questions or if ABSA can be of assistance to you in this important effort.

Sincerely,

A handwritten signature in black ink that reads "Christina Z. Thompson". The signature is written in a cursive, flowing style.

Christina Z. Thompson, MS, RBP, CBSP
President