ABSA International's Response to
Proposed Legislation for a Centralized Management Strategy for Biosafety, Biosecurity, and Biorisk Management

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ABSA International (ABSA), founded in 1984, promotes biosafety and biosecurity as independent scientific disciplines (www.absa.org). Biosafety and biosecurity are critical to the conduct of safe, innovative microbiological and biomedical activities, including research into emerging pathogens such as SARS-CoV, SARS-CoV-2 (COVID-19), Ebola, and many others. ABSA membership comprises 1550 Biosafety/Biosecurity Professionals (B/BSPs) from over 24 countries, with approximately 90% of them practicing in the US. Our professional organization includes highly educated, experienced, and credentialed experts in risk assessment, biosafety, biosecurity, dual use research of concern, biorisk management, and biocontainment as well as microbiology, immunology, and virology. Collectively, ABSA's B/BSPs possess unparalleled experience in ensuring biosafety and biosecurity at the international, national, state, and local levels. B/BSPs are employed by public and private entities, and within federal and state public health laboratories, hospitals and clinics, educational institutions, animal research facilities, and industrial laboratories to ensure compliance with regulations and implement and develop best practices. They also are policy advisors, inspectors, emergency responders, and thought-leaders focused on ensuring the safety and security of laboratory workers, the public, and the environment.

ABSA was recently apprised of draft legislation establishing a national commission for biosafety and biorisk management (housed either independently or within an existing federal agency) that is currently under consideration. ABSA recognizes the significance of such noteworthy legislation impacting both our profession and the scientific enterprise that we support. However, while containing several beneficial components that ABSA supports, the legislation in its current form is overly prescriptive, broadly applicable to all pathogens without regard to risk, and does not adequately consider operational implications. We respectfully submit this statement to offer ABSA's professional perspective on the proposed legislation.

ABSA welcomes and strongly encourages further discussion by all stakeholders regarding this important and timely effort. We believe such legislation, which will have wide-reaching and unintended effects, both nationally and internationally, is deserving of historical perspectives, experiences, and considerations that our membership can provide. For example, in reference to the establishment and implementation of the Federal Select Agent Regulations, there are important lessons learned that can be shared regarding how compliance can be achieved without adversely impacting progress to scientific research, public health, and education. It is imperative to investigate and understand the macro and micro level implications of such legislation and to proceed with care and dialogue to establish a centralized oversight authority to address the true risks of working with biological agents and materials.

ABSA International Supports:

1. **Coordinated efforts.** ABSA supports coordinated implementation of biosafety and biosecurity policies at the national and local levels that facilitate the progress of science while reducing redundancy in oversight and eliminating non-risk informed mandates. We support adaptable, agile, and adroit efforts that respond to and anticipate technological advancements.

2. **Reporting systems.** ABSA supports building trusted incident reporting systems. Such systems must be thoughtfully designed and administered with the goal of improving biosafety and biosecurity by creating a way to learn from others without adding additional burden and/or punitive effects for individuals or entities.
3. **Laboratory standards.** ABSA supports the harmonization of laboratory guidelines and standards, based on well-developed, informed, and transparent criteria, and the creation of coordinated resources that enable B/BSPs to implement cohesive programs. Existing guidelines and standards should be assessed to determine those that have served the B/BSPs and the biological laboratory community well in implementing biosafety/biosecurity practices.
4. **Training standards and curriculum.** ABSA supports the strategic development of training frameworks to guide the deployment of standards and curricula aimed at protecting workers, the community, and the environment. Such offerings would be adaptable by local B/BSPs based on entity-specific risk assessment.
5. **Workforce development.** ABSA strongly supports workforce development for B/BSPs and the entire ecosystem that supports B/BSPs, especially efforts to incorporate biosafety/biosecurity into all levels of STEM education. The current pandemic has proven the biosafety/biosecurity profession essential to the world's response to emerging and re-emerging infectious diseases and workforce development must be nurtured, promoted, and elevated.
6. **Funding for research.** ABSA strongly supports funding for applied biosafety/biosecurity research that expands the current body of peer-reviewed literature B/BSPs rely on for evidence-based risk assessment. However, while the proposed Commission could investigate and set funding priorities, such funding should be administered by a Department or Agency other than the proposed Commission in order to avoid possible conflicts of interest.
7. **Input from B/BSPs.** ABSA supports open dialogue and opportunities to collaborate in developing legislation that will significantly impact biosafety and biosecurity in the US and worldwide. We believe such communication is foundational. Subject matter experts from within our membership, representing a diverse cross-section of on-the-ground realities, are ready to assist in shaping any resulting regulations.
8. **Input from others.** ABSA supports partnering with the National Academies to co-lead an effort seeking input from organizations that represent the scientific community, associated safety professions, federal agencies with overlap responsibilities, state government partners, the education sector, security professionals, and industry groups. This critical effort would examine the current biosafety/biosecurity landscape and recommend a framework that meets the spirit of the proposed legislation, while providing a more strategic and pragmatic structure for implementation.

ASBA International does not support:

1. **Broad, non-specific legislation.** ABSA does not support non-risk informed legislation or regulations. This particular bill casts such a wide net that the burden of implementation would far outweigh any benefits. We believe that legislation must be aimed at specific, identifiable risk reductions, while accommodating rapid scientific advancement and emerging agents. We believe that legislation should provide a solution for real problems, in a meaningful way, through regulations that reduce actual risks instead of perceived risks.
2. **Non-pragmatic government oversight.** The scope of what will be applicable under the proposed legislation is, in ABSA's professional judgment, massive in scale and operationally

untenable while yielding very few meaningful results. The cost-benefit outcome does not justify the current proposed legislation.

3. **Failure to consider past regulatory burdens.**
    a. This legislation indicates an intent to treat all microorganisms with any pathogenic properties as though they fell under the Federal Select Agent Program (FSAP), which currently regulates activities with high-consequence pathogens. Operating under the FSAP is extremely labor-intensive for institutions, laboratories, and governmental employees, and creates a large burden on entities that participate in the program. When this program was initiated, the administrative and financial burden caused a large number of institutions to cancel research programs, destroy collections of cultures, and decline to engage in regulated research. Overly broad legislation such as the proposed bill will have a far-reaching effect, including a loss of teaching programs, loss of research, and loss of diagnostic and response capabilities.
    b. Additionally, this legislation indicates an intent to create a comprehensive oversight body but only mentions one current regulatory oversight process, the Federal Select Agent Program (FSAP). There is no mention of or consideration to the existing oversight of recombinant and synthetic nucleic acids, existing permitting programs, dual use research of concern (DURC) or pathogens of pandemic potential (3PO) policies.
4. **Unfunded mandates.** ABSA does not support unfunded mandates that burden institutions with non-risk-informed regulatory oversight that cripples valuable scientific progress. Legislation must include provisions to adequately and purposefully support the cost of implementing the additional regulatory requirements.

Research and public health endeavors that safely isolate, manipulate, and propagate pathogenic or genetically modified microorganisms, including recent SARS-CoV-2 vaccines and diagnostics, are possible because of parallel developments in biosafety and biosecurity. The credibility, success, and continuity of these operations were built on proven containment principles, facility design, and biosafety/biosecurity practices and procedures that have prevented occupational infections, release of the organisms into the environment, and intentional theft or misuse. B/BSPs have an extensive and successful portfolio partnering with a wide range of professionals and providing expertise and leadership to achieve safe and secure working environments. In order to attain an optimal piece of legislation to establish a national commission on biosafety and biorisk management, ABSA International believes that a thorough, thoughtful discourse is necessary. Thank you for the opportunity to provide comment on this important initiative. We welcome further dialogue that will strengthen the proposed legislation and position the US to lead the world in achieving risk-informed oversight of pathogens.

Points of Contact:

Edward J. Stygar, III, Executive Director (ed@absaoffice.org)
LouAnn C. Burnett, MS, CBSP(ABSA), President (louann.burnett@gmail.com)