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November 29, 2018

Robert P. Kadlec, MD, MTM&H, MS HHS Assistant Secretary for Preparedness and Response U.S. Department of Health & Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Dr. Kadlec,

The American Biological Safety Association International (ABSA International) is an association whose roots began in 1955 when professionals from Camp Detrick, Pine Bluff Arsenal, and Dugway Proving Grounds met to discuss related biosafety (biological safety) concerns in U.S. Army biological laboratories. ABSA International has grown to include professionals at the forefront of biological safety and security at the local, regional, national and international levels in college, university, clinical, government and private research facilities. ABSA International is greatly encouraged by the inclusion of risk assessment, risk management goals, threat principles, and the comprehensive nature of biological hazards presented in the recently released 2018 National Biodefense Strategy (referred to as the Strategy from herein). The Strategy appears well devised and poised to take full advantage of existing national and international biological safety and security programs and infrastructure. ABSA International hereby offers our full support and desires to engage in partnership toward success of this effort. ABSA International is a valuable resource to reach the stated goals, and its members, already interconnected internationally, stand ready to engage with your agencies in the implementation and sustainment of the Strategy.

Each of the Strategy's five goals include objectives in which biosafety and biosecurity professionals currently function and should contribute to directly or in a supportive role.

Goal 1 "Enable Risk Awareness to Inform Decision-Making Across the Biodefense Enterprise" includes objectives that require significantly overlapping skill sets and duties that biological safety professionals routinely exercise and are expert in, such as risk assessment and mitigation strategies to identify emerging biological and technical

hazards. Biosafety professionals also function in convergent disciplines as they work to protect humans, animals, plants, the environment, and patients, where the risk assessment indicates the need.

Goal 2 "Ensure Biodefense Enterprise Capabilities to Prevent Bioincidents" is of particular interest as it accurately defines the overarching goal of the biosafety profession. Biological safety professionals work tirelessly to ensure that biological incidents do not occur or are identified and contained at the source. ABSA International pursues these objectives vigorously, providing guidance and training to members and first responders on the development and implementation of best practices. Members currently review and revise published guidance, and disseminate pertinent regulations and industry standards. Of great interest to our members is the Strategy's call for applied biosafety research as a way to streamline and tailor biosafety and biosecurity in a manner that better serves the needs of the scientific community.

Goal 3 objectives for laboratory preparedness, emergency response, decontamination, and research define biosafety competencies promoted by ABSA. ABSA further offers laboratory accreditation for microbiological and clinical laboratories, a service in-line with the successful accomplishment of Goal 3.

Goal 4 objectives for real-time research and safe materials transport; and Goal 5 objectives for safe recovery as applied to locations where biohazards are handled and stored; are all areas to which ABSA International could contribute.

Finally, biosafety professionals enthusiastically support a culture of responsibility in the life sciences. ABSA members develop and apply multiple behavioral-based training methodologies to their campuses designed specifically to advance a culture of research responsibility. ABSA International now leads the International Biosafety Month (originally National Biosafety Month; derived from the White House Stand Down and NIH National Biosafety Month in 2014) and other initiatives to establish cultures of safety and a credentialed workforce of biosafety and biosecurity professionals to serve in this country and around the world.

Evidence abounds that the fields of Biosafety and Biosecurity are increasingly intersecting with the sphere of biodefense, and that in many cases the lines of demarcation are blurred:

- Baskin, C.R., and Zelicoff, A.P., Ensuring National Biosecurity: Institutional Biosafety Committees. Academic Press, 2016, eBook ISBN: 9780128018606, paperback ISBN: 9780128018859.
- 2. D. Perkins, K. Danskin, A.E. Rowe, A. A. Livinski, The Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences: A Comprehensive Literature Review. Applied Biosafety 23(4)1:12. http://journals.sagepub.com/doi/abs/10.1177/1535676018778538.
- U.S. Department of Health and Human Services. Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens 2017. https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf.
- 4. Federal Experts Security Advisory Panel. Guiding Principles for Biosafety Guidance. Ensuring Institutional Compliance with Biosafety, Biocontainment, and Laboratory Biosecurity Regulations and Guidelines. https://www.phe.gov/s3/Documents/FESAP-guiding-principles.pdf.

As your implementation plans develop, we consider it advantageous for the United States Government to engage ABSA International and its members as a partner and a resource in strengthening our national biodefense. ABSA International has much to offer to this initiative and we sincerely hope you will respond to this inquiry and establish a partnership with ABSA International for future contributions.

Sincerely.

Domenica (Dee) Zimmerman

President

Edward J. Stygar III
Executive Director