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Working Group on Strengthening the Biosecurity of the United States
Attn: Laura Kwinn, PhD,
Office of Medicine, Science and Public Health, Office of the Assistant Secretary
for Preparedness and Response
U.S. Department of Health and Human Services
330 C Street, SW., Room 5123
Washington, DC 20201

REF: Interagency Working Group Recommendations on Strengthening Laboratory Biosecurity
(Executive Order 13486)

Dear Working Group Members:

The American Association for the Advancement of Science (AAAS), the world's largest multi-disciplinary scientific society and the publisher of the journal *Science*, has for many years engaged in programs related to the role of science in national security. Preventing individuals who may have ill-intentions access to select agents, while promoting safe and responsible conduct of research, is critical for scientific advancement, public health response, and national and international security. AAAS has been active in engaging the broad scientific community on a range of biosecurity issues from pathogen security to public health.

We support the U.S. government's efforts to evaluate existing laws and regulations pertaining to laboratory biosecurity. AAAS has recently engaged members of the scientific community to solicit their perspectives on select agents, oversight of high containment laboratories, and biosafety training and vetting of personnel seeking to gain access to those laboratories. The following recommendations reflect those perspectives:

- **The U.S. government should conduct a comprehensive review of the costs and benefits of the Select Agent Program (SAP) and associated policies to determine the actual effects of these policies on national security, scientific advancement, international collaboration, and public health response.** This review should include an evaluation of the costs of compliance with the SAP as it currently exists and the potential economic and institutional impacts if the SAP were to be changed.
- **The U.S. government should develop a common set of security requirements among U.S. agencies that fund select agent research.** As one example, requirements for vetting personnel are not always consistent across agencies or even with the SAP security risk assessment. These inconsistencies are problematic for non-governmental research institutions and could negatively affect compliance, research costs, and the time available for research. Requirements for securing laboratory facilities also differ among agencies.

- **The U.S. government should establish an integrated, consistent inspection system for security audits.** In addition to state and federal oversight of environmental, transportation and worker safety, certification of clinical research (if applicable), and accreditation of animal use (if applicable), high-containment laboratories that house select agents are inspected by the Centers for Disease Control and Protection and/or by the Animal and Plant Health Inspection Service as part of the Select Agent Program. Independent of the SAP, federal agencies that fund select agent research, like the Departments of Homeland Security and Defense, also conduct their own inspections and have their own requirements with which institutions must comply. The different requirements can in some cases conflict with one another. Preparation for an inspection is extremely time-consuming and can cost an institution up to \$50,000; thus the requirements should be consistent across agencies.
- **The federal government should take into consideration existing institutional biosafety training practices when developing rules and recommendations for assuring personnel reliability for non-governmental research institutions.** Existing governmental personnel reliability programs (PRP), as implemented at the U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID) and Lawrence Livermore National Laboratory (LLNL), often include psychological evaluations, drug and alcohol testing, and in the case of LLNL, security clearances. These types of programs may be too elaborate and cost-ineffective for what is really needed in academia. Current employment and biosafety practices (including competency training, continual mentorship, and didactic training) in many non-governmental facilities may address most of the security concerns related to the 'insider threat' without the added financial or resource burden associated with the full PRP. Rules should be rationalized for specific kinds of institutions.
- **A national, anonymous database cataloging laboratory exposures with infectious biological agents and corrective actions should be created.** Such a database could promote information sharing about laboratory hazards and lessons learned among biosafety professionals and institutional administrators to prevent future incidents. While the CDC does have such a database, it is not available to biosafety professionals of high-containment laboratories.

AAAS thanks the interagency working group for providing the opportunity to present perspectives from the scientific community regarding the existing laboratory biosecurity infrastructure.

Should you have any questions or require further information, please contact Kavita Berger, Ph.D., at 202-326-7027 or kberger@aaas.org.

Sincerely,



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