

Statement for the Record
(as delivered)

Alan M Pearson
Director, Biological and Chemical Weapons Control Program
Center for Arms Control and Non-Proliferation, Washington, DC

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For the Hearing "Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States"

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Thank you for inviting the Center for Arms Control and Non-Proliferation to testify today about the recent expansion of high containment laboratory research facilities and activities in the United States. Since 1980, the Center has been working to protect the American people from the threat of nuclear, chemical and biological weapons. The issues being considered today are integral to achieving that goal.

Over the last six years, the Federal government has dramatically increased US research and development activity and infrastructure focused on biological weapons agents. The data are clear: annual R&D funding up six fold since FY2001, with over \$3.3 billion proposed for next year; more than two dozen large new high-containment research facilities funded specifically to work with bioweapons agents; over 15,000 individuals approved to work with bioweapons agents.

This expansion recognizes our need for a national biodefense program. But it is not an unalloyed good – it also creates risks to laboratory personnel, public health and national security, especially since it is taking place against a backdrop of inadequate regulation of and transparency about the activities being conducted.

When more dangerous research is performed by more people in more locations, there are simply more opportunities for significant biosafety or biosecurity breaches to occur. The most obvious risk is that of a laboratory accident which sickens or kills a laboratory worker or people in the surrounding community. Worse, if the accident involves an agent such as the 1918 influenza virus, which was reconstructed at the CDC in 2005, it could start a global pandemic. Any person can legally possess the genome of this killer virus today. A second, particularly acute risk is that the very labs designed to protect against bioweapons may become a source for them. The easiest way for a sub-state enemy such as Al Qaeda to obtain a bioweapons capability is for it to penetrate an existing research project that uses bioweapons agents. Nor

should we ignore the possibility that a US biologist may become disgruntled or turn rogue while working in one of these labs.

Some types of contemporary pathogen research taking place in these laboratories increase risk further still. For instance, efforts to deliberately enhance the virulence or transmissibility of pathogens to better understand how they cause disease are inherently more risky than experiments of the past. They are also dual-use in nature – the knowledge and materials generated from such experiments can be used for either hostile or peaceful purposes. Of particular concern in this regard is threat assessment research, typically classified research which involves the exploration of offensive aspects of biological weapons agents and delivery mechanisms, perhaps including the exploration of potential new bioweapons agents, for defensive purposes.

Looking internationally, each of these concerns associated with the proliferation of high containment research facilities and activities becomes amplified. Our actions, taken for the best intentions of protecting our nation, also provide a plausible justification for others to do the same.

There is a critical need for rigorous oversight and maximal transparency to mitigate the risks I have described. However, the findings of the Sunshine Project and others, the Texas A&M affair, and the significant gaps in implementation of the Select Agent Rule, conclusively demonstrate that our biosafety and biosecurity system is plagued by significant and systemic weaknesses, including inadequate monitoring, oversight and transparency of research activities and high containment facilities.

New risks necessitate corresponding changes in risk mitigation efforts. The US biosafety and biosecurity system can and must be made more coherent, more comprehensive, more effective, and more transparent. The key to achieving this is legislative action. Among the recommendations included in my written testimony, I would like to highlight the following:

First, Congress should mandate the establishment of a universally mandatory and transparent Biosafety/Biosecurity Incident Reporting System.

Second, Congress should mandate a national licensing system and registry for all BSL-3 and BSL-4 facilities in the United States, including an integrated and effective auditing process. Licensing and registration are key to both effective oversight and comprehensive strategic planning.

Third, Congress should mandate Institutional Biosafety Committee review of all research projects involving bioweapons agents and other high-risk pathogens and activities.

Fourth, Congress should make these requirements legally mandatory for all institutions – government, academic and private – not just those receiving funds from NIH, and for all relevant research whether classified or not.

Fifth, compliance requires effective monitoring and enforcement – a law not monitored and enforced may be little better than a voluntary guideline. Congress should seriously consider consolidating all CDC and NIH OBA responsibilities and authorities relevant to monitoring and enforcing the above requirements into a single office located within the Office of the Secretary, DHHS

Last, Congress should modify Section 351A(h) of Title III of the Public Health Service Act to more narrowly and accurately define necessary and appropriate requirements for withholding information about activities involving potential bioweapons agents; as currently written, this Section is hurting biosafety, biosecurity, and national security by impeding public accountability of our institutions and Federal agencies, and by reducing our ability to reassure others that our bioweapons-related R&D activities comply with our obligations under international law

Effective oversight and transparency of high containment research facilities and activities will contribute to enhancing public health and national security. It is the absence of adequate and appropriate oversight and transparency that is adding to the risks we face today. Each of the actions I have suggested can be reasonably implemented. Each will help reduce the risk to our nation and its people arising out of our own activities and institutions.