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Energy and Commerce Committee
Oversight Investigations
2332 Rayburn House Office Building
Washington, DC 20515

Re: *CDC Anthrax Lab Incident* Hearing and Subsequent GAO Report *High Containment Laboratories: Recent Incidents of Biosafety Lapses*

Dear Oversight and Investigations Subcommittee Chairman Murphy and Energy and Commerce Committee Members,

The American Biological Safety Association (ABSA)[1] was founded in 1984 to foster biosafety as a scientific discipline and serve the growing needs of biosafety professionals throughout the world. The Association's mission is to provide a forum for the timely development and exchange of biosafety information. Our members are biosafety professionals who work in and around the labs discussed during the *Review of CDC Anthrax Lab Incident* hearings, in government, academic, private, and industrial settings, and our job is to help set and maintain the conditions in the lab that help protect workers, the public, and the environment from harm. **Never have ABSA's purpose and presence been more important than now. How can we help?**

As you heard during the hearing, the complex issues uncovered during the initial CDC incident investigation involve a variety of factors, including facility and equipment failures, safety and security lapses, inventory discrepancies, documentation and recordkeeping flaws, all of which are fundamental to a safely operating biological laboratory producing scientifically valid data. However, these fundamentals also hinge on a proactive culture of individual accountability and support from senior leadership in the organization (an institutional culture of safety), which are ongoing challenges for many types of labs. ABSA can provide recognized expertise in these matters, and can help comprehensively evaluate the "big picture" issues brought into the national spotlight, including the concepts of Unified Oversight, National Standards, and a review of the quantity and quality of laboratories conducting biological research in this country.

The testimony given by the CDC Director, Dr. Thomas Frieden, at your Committee's hearing on July 16th, 2014, indicated that the incident was the result of the CDC's culture of individually addressing mistakes, rather than globally addressing the pattern of issues that has afflicted the agency's labs over the years, and he spoke about an inadequate culture of safety at the CDC.[2] The testimony offered by the Government Accountability Office

[1] http://www.absa.org
[2] http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Frieden-OI-CDC-Anthrax-Lab-Incident-2014-7-16.pdf

(GAO) Managing Director, Dr. Nancy Kingsbury, indicated that the problems at the CDC are symptoms of a larger problem looming above the country's variety of high-containment laboratories.[3]

Indeed, this incident and the subsequent hearing and GAO report[4] underscore the need to treat the complex underlying issues our country's microbiological laboratories face holistically, rather than just treating an isolated symptom. Why are the issues complex? Because, as with any research, the mission is to explore a complex set of unknown factors, with the intent of discovering new ways to achieve social benefits. However, these unknown factors also create potential risks, such as *risks* of accidents or adverse discoveries. Each institution that conducts research must address risks that are reasonably foreseeable and control them as much as possible, without disrupting the discovery process. The question society and those determining the future of CDC's high-containment labs and our nation's thousands of biological labs must answer is whether the *potential risks* associated with discovering vaccines, therapies, and cures outweighs the *rewards* gained from these discoveries. When risks and benefits that are measured against the needs of the society are not well defined, the answers to these questions become less and less straightforward. When faced with unknown risks in research, the precautionary principle should be applied. We believe this approach should be applied in this situation as well.

The issues identified by the GAO should be carefully considered, and we would direct you to review the 2009 Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, for additional perspectives on how we could systematically improve our research laboratories' practices and oversight. There are benefits and drawbacks to any oversight system. Unified Oversight, if done correctly, could greatly improve the effectiveness of regulations placed on labs; if done incorrectly, it could add more layers of bureaucracy and red tape with little perceived benefit, creating even more confusion than already exists. Applying Unified Oversight to all biological research, rather than just to Biological Select Agents or Toxins (BSATs), or to all sectors of labs, whether government, private, academic, or otherwise, could potentially be extremely beneficial or it could be the beginning of the end, quite possibly directing researchers away from important science, discouraging a culture of safety, and burying administrators and researchers alike in paperwork.

Similarly, implementing national standards of operation of microbiological laboratories could work very well or fail miserably, potentially leading us back to yet another Congressional hearing ten years down the road, due to poor implementation, lack of resources, or not leaving room for the professional judgment of the scientists and biological safety professionals who understand the research being conducted at a given institution. **To go down these paths, we must make informed choices and those representing both sides of the spectrum must be given equal voices.** There are models in both circumstances from which we can learn, including the CEN Laboratory Biorisk Management Standard 15793[5] and our own ABSA High Containment Laboratory Accreditation Program as examples of best practices. There are international examples of oversight, such as the Canadian Biosafety Standards and Guidelines (CBSG) 1st edition. [6]. Additionally, we are confident that there are laboratories in this country that have already established a culture of safety and have rigorous biosafety practices. Looking more closely at these model institutions as part of a study of best practices will be useful as when considering the establishment of national standards.

The question of whether we have too many laboratories performing BSAT research (or other non-Select Agent research of concern) is time-dependent. In 2001, there were not enough BSAT labs, and so the Federal government funded construction and subsequent research in hundreds of locations. This decision was made rapidly, without a clear plan to provide resources to maintain the facilities or meet the ongoing administrative needs of these labs. Reducing the number of these labs now could lead to unintended consequences; what happens when we have another pandemic or biological terrorism event and it is determined that we had shut down too many labs? Public health, bioterrorism preparedness, and newly emerging pathogens (such as Middle East Respiratory Syndrome (MERS) or a new flu strain like H7N9) are all part of the equation: the labs in question are the very labs that have the capabilities and skills to respond to these situations. As part of this process, we must therefore assess and address the cyclic and reactive nature of scientific research funding to

[3] http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Kingsbury-OI-CDC-Anthrax-Lab-Incident-2014-7-16.pdf
[4] http://www.gao.gov/products/GAO-14-785T
[5] http://www.ebsaweb.eu/cwa_15793
[6] http://canadianbiosafetystandards.collaboration.gc.ca/cbsg-nldcb/index-eng.php

better understand and sustain what it is we truly need. **The question should not be how many high containment labs we have, but rather *is the amount of research being conducted adequate to protect our nation and global public health, and is it being done in a safe manner?***

Not discussed during the hearing or in related media coverage are other relevant initiatives related to laboratory safety that must be considered as part of this dialogue.
These initiatives include:

- Our country is facing major gaps in safety-related training and in creating safety cultures, particularly in universities, as highlighted by the untimely death of research technician Sheri Sangji[7] and subsequent prosecution of her employer at UCLA.
- A recent article notes that in the private industry sector[8], companies that hire college graduates find that they are not prepared to work safely in industrial laboratories.
- Additionally, the report "Reducing Investigators' Administrative Workload for Federally Funded Research,"[9] just released by the National Science Foundation, details the many layers of administrative obligations of researchers and openly questions the excessive bureaucracy in compliance.
- Other government laboratories have had similar experiences in terms of the challenge of balancing safety culture with a productive scientific environment[10].
- Finally, as we are actively experiencing a Convergence[11] of scientific disciplines (chemists, engineers, and physicists) that are using biological organisms in their research, we need to recognize that the oversight and standards we consider implementing could have a much more widespread impact than one may anticipate.

As a larger society, ignoring these issues while trying to figure out how to move forward to create safer biological research labs may leave enormous gaps in emerging solutions. We cannot address only individual issues without looking at the larger picture or we will find ourselves in a silo ignoring other potential problems, as Dr. Frieden claims the CDC has been guilty of doing when they attempted to address their past issues.

The rest of the world is watching how we move forward; we are *the* model. Dr. Frieden indicated that he must get it right this time for his institution. Similarly, if we don't get it right and think about this globally, we may think we are fixing today's problems but really we could just be creating more for tomorrow. **The science and the people conducting research will constantly evolve; we must implement solutions that can be flexible with that evolution.**

ABSA is comprised of more than 1,400 members, representing 37 countries as well as the U.S. ABSA members include microbiologists, veterinarians, industrial hygienists, engineers, architects, doctors, nurses, and other technical experts, who come from academia and research institutions, government laboratories, as well as private industry. ABSA can assist in developing lasting solutions. We have ideas, innovation, and know-how. **The repository of biological safety expertise is an available and essential partner to your Committee on Energy and Commerce, the research community, and others in exploring the current and future state of biological research in this country. We kindly ask for time to meet with you to discuss these issues further.** Please contact Edward J. Stygar, III, ABSA Executive Director, at ed@absaoffice.org or 866-425-1385.

Sincerely,

Marian Downing

Marian Downing, RBP, CBSP
ABSA President-Elect

Alexis Brubaker

Alexis Brubaker
ABSA Legislative Committee Chair

[7] http://sherisangji.com/
[8] http://cen.acs.org/articles/91/i18/Importance-Teaching-Safety.html
[9] http://nsf.gov/publications/pub_summ.jsp?ods_key=nsb1418
[10] http://www.nist.gov/public_affairs/releases/upload/root_cause_plutonium_010709.pdf
[11] http://www.nap.edu/catalog.php?record_id=18722