Sean G. Kaufman

President and Founding Partner
Behavioral-Based Improvement Solutions

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Written Testimony

Review of CDC Anthrax Lab Incident

INTRODUCTION

Chairman Murphy, Ranking Member DeGette and members of the Sub-Committee – I am pleased to have the opportunity to appear before you today in regards to the recent CDC Anthrax Lab Incident.

I am Sean Kaufman, President and Founding Partner of Behavioral-Based Improvement Solutions, a small business providing professional development programs for individuals working in high-containment facilities (BSL3 and BSL4). I have trained thousands of individuals in biosafety related topics, offering insights and increasing skills needed to operate safely in high-containment laboratory environments.

I am a former employee of CDC and was involved in the Amerthrax response in Trenton, New Jersey. During this detail, I worked directly with postal employees exposed to Anthrax and provided the information and resources needed for the successful completion of their prophylactic treatment. During the past 10 years, I developed and directed the Emory University BSL3/BSL4 Science and Safety Mock Training Laboratory – a program providing simulation-based training for those working in high-containment facilities.

My background is in behavioral science and infectious diseases. I have always approached biosafety training from the belief that training is only effective if there is change in the thinking and behavior of those I train. Biosafety involves taking a plan, integrating human behavior, and achieving a consistent

desired outcome among individuals with different backgrounds, educational levels, and experiences. I continue to assist laboratory staff with their desire to go home at the end of the day - healthy and disease free, rather than presenting a hazard to their family, friends, and the general public.

OBSERVATIONS

To date, I wish to commend the transparency, communication, and investigative response of the Centers for Disease Control and Prevention (CDC). The protection of the workforce and communication with the general public has been a priority and demonstration of outstanding leadership. There is no doubt that the Centers for Disease Control and Prevention is a United States of America national treasure. Research done within the CDC laboratories assist frontline public health labs with the identification of and response to bioterrorism threats. The research which led to this incident requires interaction between research scientists and dangerous infectious diseases. Unfortunately, the risk of this work can never be completely eliminated. However, with a combination of biosafety controls, policies, oversight and workforce preparedness strategies - risks can be mitigated to acceptable levels.

Biosafety is a strategy aimed at minimizing the unintentional release of a biological agent during the interaction between a scientist and infectious diseases. Although most people spend their lives running away and avoiding infectious diseases, research scientists spend their lives running to and investigating how infectious diseases work. This does not make scientists adrenaline junkies. This makes scientists unique and difficult for the general population to understand. Many individuals cannot grasp the concept of why or how someone could work safely with dangerous infectious diseases – but it has and can be done effectively.

I have provided training to individuals (politicians, first responders, community leader) and know there is a great misunderstanding between what they think and what really happens in a high-containment

laboratory. Work within high-containment (BSL3 and BSL4) facilities is very strategic and deliberate. Millions of dollars are spent on engineering equipment designed to keep the agents scientists are working with contained within the laboratory environment. Thousands of dollars are spent on personal protective equipment designed to protect all portals of entry (not allowing the agent to enter the human body) should there be an unexpected incident (spill or BSC failure). Hundreds of hours are spent developing standard operating procedures (SOPs) which are designed to strategically mitigate risks associated with the laboratory work. Additional programs ensure scientists are trained, that compliance with SOPs occur, and that incidents are documented. Scientists also participate in medical surveillance programs and receive background checks to ensure security of the agents they work with. The magnitude of system failures that lead to a laboratory caused illness (or LAI) are great and uncommon.

It is my belief the general public is safer as a result of the research being done within the high-containment laboratories at CDC. However, no system is 100% fail safe. In an instant, one person can negate all controls mentioned above with a small deviation of behavior. This fact is something which has been and will remain the greatest challenge to safety in science.

The observations included in this testimony come from over 10 years of providing biosafety and leadership training to scientists working in multiple high-containment facilities in the United States of America and around the world. I have also trained all of the scientists involved in the CDC Anthrax Laboratory Incident on biosafety.

The Laboratory Director and two scientists involved in this incident are hardworking and accomplished scientific professionals. It is my belief this incident did not occur as a result of incompetence. I also believe this is not a problem of one or two scientists, it is a problem of a culture which exists within a specific organization.

The culture of an organization permits norms to be developed and it is within those norms that behavior is either deemed acceptable or not acceptable. All scientists involved in this incident sought counsel from manufacturers and leaders in other laboratories at CDC before and during the work leading to this incident. They did not act alone, irresponsibly, belligerently, carelessly, or with any intent to hurt themselves or others. At no time did any of these scientists believe they were doing anything wrong. They were operating at a professional standard, in an organization which had developed few controls surrounding the approval, adaptation, review, verification, and implementation of SOPs.

It is very clear to many that the greatest risk in a biological laboratory is not the agent, it is the people working with the agent. However, this incident along with other recent incidents has identified an even greater risk. The safety culture of the organization establishes performance expectations of scientists interacting with dangerous infectious diseases.

It is my belief the CDC high-containment laboratory safety culture largely contributed to this incident. The rush to discipline scientists who make unintentional errors is an indicator that leadership within CDC continues to look at who made the error instead of looking at what caused the error to occur in the first place. I believe CDC sets the standard and should spend more time reviewing organizational systems, controls, policies, cultural issues and attitudes toward safety.

Currently, the CDC Select Agent Program regulates many private, academic, and state laboratories working with biological agents found to be a serious risk to human health. Additional regulations are required for Tier 1 Agents.

It is my belief that the "Actions Already Underway and Plans for the Future" noted in the CDC Report on the Potential Exposure to Anthrax are actions which could have been implemented several years ago – after similar events had occurred. If implemented, these actions may have prevented the recent incident from occurring because they may have established a process for reviewing and approving

scientific inactivation protocols – increasing organizational performance expectations among CDC scientists.

At no time during this incident were the scientists or laboratory director doing anything that would put themselves or others at unnecessary risk (including the work with virulent agents). Decisions (specific to this incident) were made by intelligent and competent individuals for good reasons. An unintentional human error occurred. Hindsight is always 20/20 and moving forward, identifying solutions to effectively prevent this kind of event from happening again is essential.

Though individual actions must be assessed (to determine what happened), we must also include an assessment of the organizational culture which not only permitted but allowed for these actions to occur. This assessment will assist in determining if this incident is an isolated (blame falls on the individuals involved) issue and/or a systemic (organizational) issue. That being said, there is clear evidence with the recent reports of new and past CDC incidents, this incident is a systemic issue and not an isolated one.

When reviewing the incident details, this incident occurred as a result of many reasons in addition to problems with the organization's safety culture. The CDC Anthrax Lab Incident was also a result of a training failure. Biosafety training for scientists working in high-containment facilities consists of multiple phases. It is my belief the individuals involved in this incident were appropriately trained in biosafety. However, before working with a specific agent and in a high-containment laboratory - scientists must have a deep understanding of the agent they are working with and receive on-the-job training which would include the mastery of inactivation protocols.

It is my belief the scientist involved in this protocol did not receive adequate job specific training. This is a systemic problem not only for this laboratory at CDC but for the majority of research laboratories around the world. SOPs are written and passed on to scientists with the expectation that it can be

followed and reproduced with great consistency. Unfortunately, it is my observation that SOPs alone do not produce consistent results among different individuals. Therefore, it is critical that organizational leaders verify laboratory staff have the ability to demonstrate scientific SOPs as intended by the author of the SOP rather than the reader of it.

Another systemic issue which goes beyond the walls of CDC is the lack of continued professional development of those working in high-containment laboratories. Organizational safety requires frequent investment in the workforce instead of a "one and done" investment philosophy. Most scientists spend less than 1% of the total on-the-job time (40 hours a week x 46 weeks = 1840 hours x .01 = 18 hours per year) in professional development. These development opportunities play a critical role in controlling human risk factors related to this work by increasing situational awareness, which counters issues of perceived mastery, complacency, apathy, and outrage.

Assessing organizational culture, ensuring the workforce is adequately trained, and providing frequent professional development programs for scientists are great starts, but much more is needed.

I have never met a scientist who comes to work to intentionally infect themselves or others around them. However, one scientist behaving in a bubble among other scientists can produce unacceptable results. It is the responsibility of the organization to ensure SOPs are being followed. There must be accountability for scientists choosing not to follow SOPs. SOPs must be considered house rules and those working in the house (laboratory) are only as safe as the weakest family member (scientist choosing not to follow SOPs). Unfortunately, many organizations struggle to ensure the house rules are followed, as there are no regulatory actions for handling willfully non-compliant scientists. As a result, scientists start doing their own thing which then puts everyone in the laboratory at risk. Laboratory SOPs must be followed and consequences should be identified for when they are not.

As stated before, this incident did not involve scientists who intentionally chose not to follow SOPs. This incident also occurred because a process to review protocols for safety issues was not utilized.

When scientific protocols are not reviewed and vetted by peers to ensure all issues have been considered, things can be overlooked and incidents like this one can occur. In this case, not only was the scientist not SOP verified (meaning had not demonstrated the ability to follow the inactivation SOP as the author intended) but differences between the biological agents being worked on in one laboratory (*Brucella*) versus the other laboratory (*B. anthracis*) were not considered, and the SOP was not modified accordingly - leading to a sterility test being administered prior to complete inactivation of a biological agent.

Another systemic issue is the lack of communicated expectations from organizational leadership to research scientists. It is my belief that scientists be asked to formally agree to a set of behavioral expectations, established from previous laboratory incidents leading to illnesses or deaths. During the past five years, I have been successful in motivating many scientists to annually sign behavioral expectation contracts for working in biological laboratories.

The difference between a lesson learned and lesson ignored is change – and if CDC does not change as a result of this incident – the message will have been ignored and this incident could happen again. If change does occur, we must make sure it enhances safety and does not lead to a reverse safety issue (an action taken to increase safety but leads to an increase in risk instead).

I believe science has an outstanding safety record, however I cannot point to data or baseline information because it does not exist. We don't know how safe science is - primarily because there is an enormous need for the funding of research in biosafety – ensuring that what we are asking scientists to do (from a safety perspective) is effective and not wasteful of limited research dollars.

If there is any good coming out of this incident, it is the fact that others are learning from it. There is no doubt scientists and biosafety officers across the country are checking their freezers as a result of the recent Smallpox Incident. They are reviewing their chemical inactivation procedures as a result of this incident. Along with the issues identified above, there is a great need for the reporting, collection, and sharing of all laboratory incidents and accidents. This data base should be readily accessible so scientists and biosafety officers have an opportunity to learn from others instead of repeating the same errors.

CONCLUSIONS

It cannot be disputed research in biological laboratories has contributed to the reduction of mortality caused by infectious diseases. It also cannot be disputed that biological research is still greatly needed, not only for bioterrorism preparedness, but for newly emerging and existing infectious diseases.

It is my hope the CDC leadership accept responsibility for the safety culture which exists within the organization they are leading. I believe CDC has responded exceptionally well during this incident. Staff at CDC have communicated honestly, openly, and with great integrity. The steps which have been identified to move forward are a great start and if implemented will have a profound impact on safety within all laboratories at CDC. However, why these steps were not implemented earlier (as a result of previous incidents) is a question this committee should explore.

There will always be a risk when scientists interact with infectious diseases. However, risks can be adequately mitigated to ensure the health and safety of the scientist and general public. Science has been done safely for many years – and we are getting better with every year that passes. Though this incident did not pose a direct risk to scientists or the general public, it is an important wake up call.

I ask this committee to consider the message this hearing is sending to those watching. Somewhere out there may be a scientist or organization who finds something unexpected in a freezer or as a human-being makes an unintentional error. A choice will have to be made. Do I report this or not? I ask this committee facilitate a process which encourages organizations to report incidents and accidents – rather than punishing them for doing so.

It is my hope that any disciplinary measure taken by the scientists includes the opportunity to be a part of the solution. Organizations must defer from finding fault in who and instead begin focusing on what went wrong. Disciplinary actions which tarnish, damage, or terminate any future opportunity of scientists who make unintended errors as a result of the social norms (culture) within an organization – will do little in preventing this problem from occurring again.

In short, we must begin establishing an effective safety culture. A culture which 1) establishes expectations among scientists, 2) allows peers to review laboratory protocols, 3) holds scientists accountable to their SOPs, 4) provides continued development opportunities which minimize human risk factors, 5) implements validated safety methodologies, and 6) learns from outside laboratory incidents.

The United States of America remains the land of opportunity for scientists and biological research. Placing additional unfunded mandates and administrative tasks on scientists may push science and innovation outside of infectious disease research or worse – to other regions of the world.

I ask that this Committee continue to take a leadership role while considering the implications of this hearing and future legislation.

SUMMARY OF MAJOR POINTS

1. There is no doubt the Centers for Disease Control and Prevention (CDC) remains a national treasure and that research which increases the capacity of frontline public health laboratories to respond to bioterrorism events and newly emergency diseases must continue.

2. During this incident, CDC responded quickly and appropriately – protecting the workforce and informing the general public – demonstrating true leadership during a tough situation.

3. As long as scientists are human and humans are interacting with infectious diseases – science will never be 100% risk free. Human risk factors which include perceived mastery, complacency, apathy, and outrage will continue to pose a challenge to safety.

4. The biological agents and those working with the agents do not pose the greatest risk to safety. The safety culture within the organization (meaning the established social norms and performance expectations of the organization onto the scientists) poses the greatest risk to safety. The organizational safety culture sets parameters of what is defined as acceptable and unacceptable behavior.

5. This incident, along with other similar incidents - provides strong evidence that this issue a systemic (organizational) one throughout CDC high-containment laboratories rather than an isolated one (specific solely to this laboratory and scientists).

6. Preparing a scientist to work in high-containment laboratory consists of multiple phases of training (general risk, biosafety, agent specific, and job specific). This incident occurred as a result of a failure in job specific training with inactivation protocols.

7. The SOP which was used during this incident was not a new one. The SOP had been used in other laboratories at CDC and outside organizations. Additionally, the protocol was recommended by a manufacturer and validated by other scientists prior to being utilized in this incident. The failure to modify and approve the protocol from one laboratory to another led to this incident.

8. An effective safety culture includes the establishment of expectations among scientists, allowing for the peer review of all scientific protocols, holding scientists accountable for **intentional** SOP compliance violations, providing continued professional development opportunities (minimizing human risk factors), implementing validated safety methodologies, and accepting incidents as opportunities to learn (rather than restrict).

9. I believe science has an outstanding safety record, however I cannot point to a central database to prove this belief. Biosafety research funding is desperately needed to ensure what is being recommended to scientists is effective and not wasteful of limited research dollars.

10. Somewhere out there may be a scientist or organization who finds something unexpected in a freezer or as a human-being makes an unintentional error. A choice will have to be made. Do I report this or not? I ask this committee facilitate a process which encourages organizations to report incidents and accidents – rather than punishing them for doing so.