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STATEMENT TO THE COMMITTEE ON GOVERNMENT REFORM, SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS AND INTERNATIONAL RELATIONS

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Chairman and distinguished committee members, I am honored to appear before your committee to answer your questions regarding technologies and protocols for detecting anthrax and other biological agents. I am Colonel Erik Henchal, the Commander of the U.S. Army Medical Research Institute of Infectious Diseases, known as USAMRIID. USAMRIID has had a 34-year history of basic and applied research in the area of diagnosis, treatment and prevention of hazardous infectious diseases. Our efforts, especially over the past eight years, have been instrumental in the development of reagents and the evaluation of medical diagnostic systems and procedures that are playing an active role in our nation's defense and national security. During the 2001 anthrax attacks, I led a team that processed over 30,000 environmental samples and performed approximately 260,000 assays supporting the Senate, the Capitol Police, the FBI, the CDC, and other Executive Branch agencies. Dr. George Ludwig, who is USAMRIID's Chief, Diagnostics Systems Division and coordinates basic and applied research of medical diagnostics technologies for the Department of Defense, joins me today.

The tragic events following the terrorist use of the U.S. Postal System during the Fall of 2001 to deliver anthrax spores demonstrates that there is still much to be learned about the effects of this agent under conditions different from those encountered during natural outbreaks. In particular, the health effects of

aerosolized anthrax spores on various populations are poorly understood. The death of a possibly immunocompromised 94 year-old women from Oxford, Connecticut from inhalation anthrax after no known exposure suggests that some populations may be much more susceptible than others. The fact that relatively few cases of anthrax were observed among the large number of individuals potentially exposed to high concentrations of anthrax spores further complicates interpretation of the epidemiological data. Estimates for infectious or lethal doses of aerosolized anthrax spores are based upon studies with laboratory animals, not humans, and the values must be interpreted carefully. The most common figures quoted for lethal aerosol doses of anthrax are between 8,000 and 50,000 spores. This range reflects the dose estimated to be capable of killing one-half of the animals exposed.. There is substantial scientific uncertainty regarding the dose-response relationship; no scientific consensus has been reached on the lethal infectious dose in humans. As a result, we are concerned that any level of contamination with anthrax could potentially lead to harm to some exposed individuals. While any amount of contamination should be a concern , the context of the contamination must be carefully considered, especially when attempting to determine a forensic link to a purposeful release and when attempting to formulate health policy. The detection of spores in dust collected from an urban U.S. Postal Service facility would be a greater concern than finding spores in soil collected from a rural area. These differences illustrate the need to make use of all available expertise when making policy decisions from basic test data. At USAMRIID we err on the side of caution initially, but use all available resources to formulate a long-term response that is appropriate for the situation. This doctrine is routinely taught at USAMRIID to managers and technicians of field-deployed laboratory units.

[ETFC1] The events that unfolded at the Wallingford, Connecticut postal facility represent, to a large part, a lack of knowledge and experience with the biological data. In reality, local government officials and the postal service could not have anticipated the requirement for this knowledge or experience prior to the events of September and October 2001. Moreover, experience with anthrax spores was available at relatively few locations in the U.S. The lack of experience and knowledge exacerbated the problems with the post-attack response. First, methods for collecting samples consistent with the physical and biological characteristics of the material were poorly understood. Misunderstandings led to delays in reporting and in the implementation of workforce protective measures. Secondly, only a small number of laboratories were

capable of reliably detecting and identifying *Bacillus anthracis.* This resulted in the reliance upon procedures that were not adequately validated, producing disparate results and further delays in implementation of protective measures. We are pleased that through an ongoing collaboration among the Department of Defense, the Environmental Protection Agency, and the Centers for Disease Control and Prevention, validated methods and protocols will be developed later this year.

The most important lessons learned from these tragic events can be summarized in four basic points. First, in the absence of reasonable surety, always err on the side of caution. Second, develop procedures for validation of test data that are based upon sound and experienced scientific judgment, although testing in humans will prevent obtaining such data. [ETFC2]#2 is great, IF and only IF, you have the data or can generate it in a reasonable and cost-effective time frame - we still don't, nor will we ever have, exact data on the lethal dose for inhalation anthrax in humans upon which to establish baselines.
Third, make efficient and maximal use of available expertise to help develop concepts of operation that will provide the greatest margin of safety for the public. Finally, we must make every effort to ensure that this expertise, this national resource, is maintained and expanded by increasing opportunities for the dedicated scientists and technicians that have been responsible for preparing for this and future bioterrorism events.

I thank the subcommittee for its time, and we would be happy to entertain any questions.