

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing on “Federal Oversight of High Containment Bio-Laboratories”
Rep. Bart Stupak, Chairman
Opening Statement
September 22, 2009

Nearly two years ago, this Subcommittee investigated some highly troubling issues related to high-containment bio-labs, which are labs that handle some of the world’s most exotic and dangerous diseases, including anthrax, smallpox, foot-and-mouth disease, and Ebola virus.

At our October 4, 2007 Subcommittee hearing titled, “Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States,” we focused on the increasing numbers of high-containment bio-labs, otherwise known as BSL-3 and BSL-4 labs. The accidental or deliberate release of the dangerous agents handled in those labs could have catastrophic consequences. At our hearing, we examined whether the federal government should be doing more to keep track of these labs and ensure that they follow sound safety and security practices.

Since that hearing, important questions have remained alarmingly unanswered:

1. How many high-containments labs exist in the U.S., and how many do we really need?
2. How many labs have had serious accidents in which lab workers or the public could have been exposed to dangerous diseases?
3. How effective are the high-containment labs’ personnel reliability measures and inventory technology? What changes have they made to address the Department of Justice’s conclusion that a single Department of Defense employee caused the anthrax attacks of 2001?

We asked the Government Accountability Office (GAO) to look into these issues and today we will learn what they found.

Unfortunately, many problems still exist, such as:

(1) No single agency or office in the federal government keeps track of how many high-containment labs there are in the U.S., where they are located, what type of research they are doing, and whether they are safe and secure. In short, there still appears to be no adequate federal plan or effort to manage, much less coordinate, highly dangerous research.

(2) There are no universal standards for lab design, construction, or use. The Department of Health and Human Services publishes a guideline, “Biosafety in

Biomedical and Microbiological Laboratories” known as the BMBL. Labs that receive NIH grants must comply with BMBL guidelines, but private and other non-federally funded research facilities have no similar requirement. While Labs that handle select agents must obtain federal registration and certification, no accreditation or certification is required for labs working with dangerous organisms that are not on the Select Agent list such as SARS and West Nile Virus.

(3) There are no standards for biosafety training or the credentialing of high-containment laboratory workers. The Department of Health and Human Services only requires training of workers handling organisms on the Select Agent list.

(4) There are no standards or mechanisms for ensuring inventory control or personnel reliability. It is essential to lab security that lab workers undergo adequate screening and that the quantity of biological agents in a lab is tracked carefully. Failures in personnel reliability practices can be catastrophic. The 2001 anthrax attacks, which the Department of Justice has said was the work of one Department of Defense scientist, is a tragic example of this risk.

(5) Finally, the biolab community has no mechanism to catalog accidents and mishaps for collective analysis so lessons can be learned and shared to improve safety and security practices.

Unfortunately, what is clear is that federal policy on biosafety and security remains basically unchanged from what it was when we had our hearing two years ago. There is hope that this may change thanks to two reports which should be finalized in the coming weeks.

The “*Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*”, which is co-chaired by HHS and USDA, was a direct result of our hearing two years ago. The Task Force report will make important recommendations for improving biosafety in the U.S.

Another study, by the “*Executive Order Working Group on Strengthening the Biosecurity of the United States*”, which was created by President Bush’s executive order in January, will make recommendations on ways to improve the select agent program.

The Committee’s staff has been briefed about the process for preparing these reports, and we expect both within a few weeks. I look forward to hearing from the Administration on this important matter at that time.

Today we will hear testimony from the Government Accountability Office about its findings and recommendations concerning biolab safety and security. Their report titled **High Containment Laboratories: National Strategy for Oversight Is Needed**, was released yesterday.

We will also hear from a representative of the American Society for Microbiology who can share the perspective of those who operate and work directly with high-containment labs.

I look forward to hearing testimony today regarding how we can quickly and responsibly address this challenge and enhance our nation's biosafety and security. It is our hope that this Administration will act quickly to improve data about labs and improve lab safety and security.

Let me express my condolences to the family, co-workers and friends of University of Chicago Professor Malcolm Casadaban who died last week from what appears to be an infection he may have acquired from the lab while doing research on the plague. This highlights the fact that even more needs to be done to protect our scientists and the public inside and outside the lab.