

FEDERAL OVERSIGHT OF HIGH-CONTAINMENT BIOLABORATORIES

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED ELEVENTH CONGRESS

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CONTENTS

	Page
Hon. Bart Stupak, a Representative in Congress from the State of Michigan, opening statement	1
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement	3
Prepared statement	6
Hon. Donna M. Christensen, a Representative in Congress from the Virgin Islands, opening statement	10
Hon. Gene Green, a Representative in Congress from the State of Texas, opening statement	10
Hon. John D. Dingell, a Representative in Congress from the State of Michi- gan, prepared statement	12
Hon. Edward J. Markey, a Representative in Congress from the Common- wealth of Massachusetts, prepared statement	13
Hon. Joe Barton, a Representative in Congress from the State of Texas, prepared statement	15
Hon. Michael C. Burgess, a Representative in Congress from the State of Texas, prepared statement	18

WITNESSES

Nancy Kingsbury, Ph.D., Managing Director, accompanied by Sushil Sharma, Assistant Director, Applied Research and Methods, U.S. Government Ac- countability Office	21
Prepared statement	25
Ronald M. Atlas, Ph.D., Co-Chair, Committee on Biodefense, American Soci- ety for Microbiology	34
Prepared statement	37

FEDERAL OVERSIGHT OF HIGH-CONTAINMENT BIOLABORATORIES

TUESDAY, SEPTEMBER 22, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 11:00 a.m., in Room 2123, Rayburn House Office Building, Hon. Bart Stupak [chairman of the subcommittee] presiding.

Present: Representatives Stupak, Christensen, Green, Walden, Burgess and Gingrey.

Staff Present: Mike Gordon, Chief Investigative Counsel; Dave Leviss, Chief Oversight Counsel; Molly Gaston, Counsel; Scott Schloegel, Investigator; Jennifer Owens, Special Assistant; Paul Jung, Public Health Service Detailee; Lindsay Vidal, Special Assistant; Jen Berenholz, Deputy Clerk; Mitchell Smiley, Special Assistant; Matt Eisenberg, Staff Assistant; Alan Slobodin, Minority Counsel; Krista Rosenthal, Minority Counsel; and Peter Kielty, Minority Research Assistant.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. Today, we have a hearing titled Federal Oversight of High-Containment Biolabs. The chairman and ranking member will be recognized for 5-minute opening statements. Other members of the subcommittee will be recognized for 3-minute opening statements.

Nearly 2 years ago, this subcommittee investigated some highly troubling issues related to high-containment biolabs, 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.

On October 4, 2007, at a subcommittee hearing titled Germs and Viruses and Secrets: The Silent Proliferation of Biolabs in the United States, we focused on increasing the number of high-containment biolabs, 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, such as, number one, how many high-contain-

ment labs exist in the United States and how many do we really need; two, how many labs had serious incidents in which lab workers or the public could have been exposed to dangerous diseases; three, how effective are the high-containment labs' personnel reliability measures and inventory technology? What changes have been 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 no single agency or office in the Federal Government keeps track of how many high-containment labs there are in the United States, where they are located, what types 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. There are no universal standards for lab design, construction, or use.

The Department of Health and Human Services publishes a guideline, Biosafety in the Biomedical and Microbiological Laboratories, known as the BMBL. Labs that receive NIH grants must comply with BMBL guidelines, but private and other nonfederally funded 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 or West Nile Virus.

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. There are no standards or mechanisms for ensuring involuntary 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. Again, 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.

Finally, the biolab community has no mechanism to catalogue 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 the Federal policy on biosafety and security remains basically unchanged from what it was when we had our hearing 2 years ago. There is hope that this may change thanks to two reports that should be finalized hopefully in the next coming weeks.

The first is the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, which is cochaired by HHS and USDA, which was a direct result of our hearing 2 years ago. The task force report will make important recommendations for improving biosafety in the United States.

Another such study by the Executive Order Working Group on Strengthening the Biosecurity of the United States, which was cre-

ated by President Bush's executive order in January, will make recommendations on ways to improve the select agent program.

The committee staff has been briefed about the process for preparing these reports. It is hoped that these reports will be available in the next 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 of Microbiology, who can share the perspective of those who operate and work directly with high-containment labs. I look forward to hearing the testimony of our witnesses regarding how we can quickly and responsibly address this challenge and enhance our Nation's biosafety and security.

It is our hope that this new administration will act quickly to approve data about labs and improve lab safety and security.

Let me also express my condolences to the families and coworkers and friends of the University of Chicago professor, Malcolm Casabadian, who died last week from what appears to be an infection that 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.

With that, I will next turn to the gentleman from Oregon, Mr. Walden, please, for an opening statement.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you, Chairman Stupak. I appreciate the opportunity to join you at this hearing today.

I concur with your remarks and sympathies to the family of Malcolm Casabadian, and I think it is important to note that this was a Level 2 lab. We are dealing with Level 3 and 4 in this hearing today.

But it does raise the issue about how far down we need to go. And in this case, I guess they are still trying to figure out if the bacteria, *Yersinia*, that persisted in his blood that is related to the plague perhaps caused his death. And so, clearly, we need to be investigating these safety issues in all of our country's labs.

I also say, Mr. Chairman, that the Republican staff has come to learn that the NIH, as part of their stimulus dollars, now may have received upwards of a billion dollars to more rapidly build out these labs, which I think raises the issue about our need to do proper oversight not only of how stimulus dollars are being spent here but elsewhere throughout the government so the taxpayers' money is spent appropriately. So I would hope that our subcommittee would have a hearing on stimulus spending as it relates to the agencies under our purview.

Yesterday, the Government Accountability Office released a report addressing some of the issues raised at our previous hearing regarding increased oversight and improved safety measures at

these types of laboratories; and they are here today to discuss their findings. I appreciate that.

Just weeks after 9/11, our Nation faced a series of bioterrorist attacks where weapons-grade anthrax was delivered through the mail and five people died. Authorities now believe that one scientist who worked in one of our Nation's high-containment laboratories was responsible for those attacks. My office was in the Longworth Building in those days, and we were shut out of our office because of the anthrax that came into that building.

In response to the attacks, Congress increased funding to upgrade our Nation's biodefense program. The National Institutes of Health, NIH, which funds much of the lab research and construction, spent \$1.7 billion in 2007, compared to \$53 million on biodefense labs in 2001.

Now, that is a 32-fold increase in spending. Again, we understand that NIH is receiving stimulus dollars to add another billion dollars in spending for intramural/extramural facilities, and I think it will be important to note how that money is being spent, especially with such a steep increase in funding and the rapid expansion of the lab network. It is time to reexamine the Federal regulatory system to ensure safety and efficiency.

Our hearing on October 4th of 2007 examined the results of the Bioterrorism Act on Federal oversight of select agents. It identified a few gaps and questioned how these labs and Federal regulations would mitigate risks while increasing our defenses. Now, it has been almost 2 years since our last hearing, and it is evident both the Federal Government and the academic realm agreed with the sense of the subcommittee's hearing that there is a need for increased oversight and improved safety and security measures in high-containment laboratories.

As a result of the October 2007 hearing, the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight was created. That is cochaired by HHS and USDA, and their report, along with recommendations to improve oversight and safety, is scheduled to be released within the next week or two.

In January, then-President Bush, as you mentioned, Mr. Chairman, signed Executive Order 13486 which established the working group to examine how to strengthen laboratory biosecurity and safety in our Nation's high-containment labs. Now, the working group's report was completed and sent to the President in July; yet, to date, the administration has not publicly commented on nor released the report nor made any formal recommendations. The committee staff was told the administration has begun to collect and evaluate these reports and is in the preliminary stages of the policy process, yet a request for a briefing or a witness for the hearing from the White House was unanswered.

GAO's report highlights the pressing need for coordinated national oversight of our Nation's high-containment laboratories. GAO recommends the National Security Adviser name a single entity charged with government-wide strategic evaluation of high-containment laboratories including tracking our lab capacity, evaluating our country's needs and establishing our research priorities.

There seems to be some consensus within the scientific community that we already have oversight infrastructures in place within

the Department of Health and Human Services and the Department of Agriculture. I hope the administration utilizes this existing expertise instead of creating a centrally located biosafety—or shall I call it a Germ Czar—at the White House.

Other reports completed by the American Association for the Advancement of Science and the National Science Advisory Board for Biosecurity were issued earlier this year. These reports discussed ways to increase safety and security in our Nation's high-containment labs, focusing on personnel reliability and enhancing training programs. A lot of research and reports have been completed by our government and academic associations, and we are appreciative of those, but some of these reports have not been finalized and made public.

In turn, only Dr. Kingsbury from the GAO is here to discuss their report—which we appreciate—and answer our questions. But these facts suggest to me that this committee might have been better served by delaying this hearing for a week or two so we could have all of the reports before us before they were released, and various responsible Federal agencies could also send witnesses to give us a more complete view of what we face.

The oversight of our Nation's high-containment laboratories is an issue that is deserving of this subcommittee's attention. However, this hearing is not inclusive, I believe, or representative of all the work that has been done in this area, and we need to keep that in mind as we proceed.

I do want to welcome Dr. Atlas from the American Society of Microbiology, which has more than 40,000 members. We appreciate your being here representing the science and health professionals who staff these labs. Your input will be very valuable.

He will discuss the important roles these laboratories play in protecting our Nation, the importance of biosafety requirements for the labs and their personnel, and recommendations to improve biosafety training, oversight, resources, reporting, and biosecurity.

Thank you, Mr. Chairman, for holding this hearing. I look forward to working with you on this issue in the weeks ahead.

[The prepared statement of Mr. Walden follows:]

Opening Statement of the Honorable Greg Walden
Ranking Member, Subcommittee on Oversight and Investigations
“Federal Oversight of High Containment Bio-Laboratories”
September 22, 2009

Thank you, Chairman Stupak. I am pleased to join you in continuing this subcommittee’s investigation into the safety and security issues surrounding our nation’s high-containment laboratories. These kinds of facilities are known as bio-safety Level 3 and 4 laboratories, and they conduct research on highly infectious viruses and other biological agents. Yesterday, the Government Accountability Office (GAO) released a report addressing some of the issues raised at our previous hearing regarding increased oversight and improved safety measures at these laboratories, and they are here today to discuss their findings.

Just weeks after 9/11, our nation faced a series of bio-terrorist attacks where weapons-grade anthrax was delivered through the mail. Five people died. Authorities now believe that one scientist who worked in one of our nation’s high-containment laboratories was responsible for these attacks.

In response to the attacks, Congress increased funding to upgrade our nation’s bio-defense program. The National Institutes of Health (NIH), which fund much of the lab research and construction, spent about \$1.7 billion in 2007 compared to spending \$53 million on bio-defense labs in 2001. This represents a 32-fold increase in spending. (Recently, Minority Committee staff was told that some of the money NIH received as part of the national stimulus package is providing a boost to these high-containment labs.) With such a steep increase in funding and rapid expansion of the lab network, it was time to re-examine the federal regulatory system to ensure

safety and efficiency. Our hearing on October 4, 2007 examined the results of the Bioterrorism Act on federal oversight of select agents, identified a few gaps, and questioned how these labs and federal regulations would mitigate risk while increasing our defenses.

It has been almost two years since our last hearing and it is evident that both the federal government and the academic realm agreed with the sense of the subcommittee's hearing that there is a need for increased oversight and improved safety and security measures in high-containment laboratories.

As a result of the October 2007 hearing, the Trans-Federal Task Force on Optimizing Bio-safety and Bio-containment Oversight was created, co-chaired by HHS and USDA, and their report along with recommendations to improve oversight and safety is scheduled to be released within the next week or two. In January, then President Bush signed Executive Order 13486 which established a working group to examine how to strengthen laboratory bio-security and safety in our nation's high-containment labs. The working group's report was completed and sent to President Obama in July. To date, the Administration has not publicly commented on or released the report or made any formal recommendations. Committee staff was told that the Administration has begun to collect and evaluate these reports and is in the preliminary stages of the policy process, yet a request for a briefing or witness for the hearing from the White House was unanswered.

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our research priorities. There seems to be some consensus within the scientific community that we already have oversight infrastructures in place within the Departments of Health and Human Services and the Department of Agriculture. I hope that the Administration utilizes this existing expertise, instead of a creating a centrally located Bio-Safety or Germ Czar at the White House.

Other reports completed by the American Association for the Advancement of Science and the National Science Advisory Board for Bio-security were issued earlier this year. These reports discuss ways to increase safety and security in our nation's high-containment labs focusing on personnel reliability and enhancing training programs.

A lot of research and reports have been completed by our government and academic associations, but some of these reports have not been finalized and made public. In turn only Dr. Kingsbury from the GAO is here to discuss their report and answer our questions. These facts suggest to me that this committee might have been better served by delaying this hearing for a week or two until all of these reports were released and the various responsible federal agencies could send witnesses to provide a full compliment of viewpoints and discuss possible implementation ideas. The oversight of our nation's high-containment laboratories is an issue worthy of this subcommittee's attention; however this hearing is not inclusive or representative of all the work that has been done in this area.

I do want to welcome Dr. Atlas from the American Society for Microbiology, which has over 40,000 members, who is here as a representative of the scientists and health professionals who staff these labs. He will discuss the import role these laboratories play in protecting our nation, the importance of bio-safety requirements for the labs and its

personnel, and recommendations to improve bio-safety training, oversight, resources, reporting, and bio-security.

Thank you Mr. Chairman. I want to welcome and thank the witnesses for testifying today.

Mr. STUPAK. Ms. Christensen, opening statement, please?

OPENING STATEMENT OF HON. DONNA M. CHRISTENSEN, A REPRESENTATIVE IN CONGRESS FROM THE VIRGIN ISLANDS

Mrs. CHRISTENSEN. Thank you, Mr. Chairman, and thank you to you and Mr. Walden. I really appreciate the opportunity to take a second look at the lack of oversight on high-containment biolabs.

I recall from my time on the Committee on Homeland Security, when the National Institute of Allergy and Infectious Disease testified that they were in the process of building the two laboratories; and I am amazed to see how the number has grown in the public, academic and private sectors. But I am very concerned that—as I am sure are you, that there is no one agency that can tell us how many of these labs there are, and that some of the same uncertainties about what is exposure, how best to train and certify employees still exist. Not much seems to have changed since the 2007 report and hearing.

We all realize that we have to balance stimulating and supporting research with providing regulatory oversight, but the fulcrum really has to be the safety of the employees, the surrounding communities, and our country.

I look forward to the testimony. I thank Dr. Kingsbury and Dr. Atlas for being here today.

Mr. STUPAK. Mr. Green.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing on the Federal oversight of the high-containment biolabs in the U.S. This hearing is a follow-up one held by our committee in 2007. I look forward to hearing the testimony from the witnesses on the Federal oversight of the safety systems of these biolabs and how we can improve our evaluation and tracking section.

In Texas, the University of Texas Medical Branch at Galveston National Lab is one of the two national biocontainment laboratories constructed under grants awarded by the National Institute of Allergy and Infectious Disease, the National Institutes of Health. And I am proud to have much of this research being performed literally in the backyard of UTMB at Galveston. At this BSL-4 lab, research is conducted to develop therapies and vaccines and tests for diseases like anthrax, avian influenza, bubonic plague, Ebola, typhus, West Nile Virus, and tuberculosis. As a Nation, we need this work performed.

During my visits to UTMB, I learned firsthand about the measures that UTMB is taking to ensure that that lab is built with every contingency in mind, and I also learned about the comprehensive training program UTMB has in place.

I have a personal interest in the safety of biolabs because my daughter completed her fellowship at UTMB, and she worked some of the research conducted on the select agents at the operational BSL-4 and in that Galveston National Lab when it was completed. Due to the damage to the UTMB campus from Hurricane Ike, she unfortunately left Galveston, and now she is at the University of Nebraska working in infectious diseases.

But I also know that during Hurricane Ike that lab was the safest place to be on the Galveston Island. There was no loss, no exposure, and just a success on what had been done for a number of years; and the center grew even more. It withstood a Category 4 hurricane on a barrier island, so I think it is built pretty well.

As a parent to a researcher, I want to make sure that these biosafety labs adhere to higher safety training standards wherever they may be; and it was a source of personal comfort that UTMB had placed such an emphasis on safety training, safety of these labs across the U.S. Given the growth of these labs nationwide, I think we need to step up our safety training efforts, as well as structure within the existing agency, such as HHS or the Department of Agriculture, to track the growth of these labs.

I appreciate the witnesses here today. And my other hat, I serve on the Health Subcommittee, and a lot of those illnesses that these biolabs are working on are ones that we hope to be able—we hope they will never have to treat our constituents. But we also know in this world they may have to, so we need those labs here, doing their job.

Mr. STUPAK. For other members—and I know Chairman Waxman and others have submitted opening statements—their statements will be made part of the record.

[The prepared statements of Messrs. Dingell, Markey, Barton, and Burgess follow:]



Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing on "Federal Oversight of High Containment Bio-Laboratories"
Opening Statement of the Honorable John D. Dingell
September 22, 2009

Chairman Stupak, thank you for holding this hearing today on the challenges of and the need for providing oversight of high containment, also known as biosafety level (BSL)-3 and BSL 4, bio-laboratories in the United States. I am pleased the Committee is continuing its investigation into the world of high containment bio-laboratories that began in 2007. I also want to thank our witnesses, who provided useful insights and recommendations from which the Congress can determine the need for legislative action.

It is clear that high containment bio-laboratories are not only important for basic research of infectious diseases, but especially after September 11 and the anthrax attacks of 2001, they are a necessary component of our national effort to combat biological terrorism. However, in light of the Government Accountability Office (GAO) Report released yesterday and the testimony we will hear today, there is still an unsettling gap in federal oversight of high containment labs, which perform research on dangerous pathogens and emerging infectious diseases. For example, GAO testimony states there is no federal agency that knows the total number nor whose mission is to track the expansion of high containment laboratories. Thus, it is unclear whether we have a too few, enough, or too many of these laboratories in the U.S. Further, there is no national personnel training requirement for workers, personnel reliability standards to counter insider threats, nor is there a design, construction, and maintenance standard for these laboratories.

I would like to highlight one particular incident in the GAO report which relates to concerns I have expressed regarding the handling and research of Foot and Mouth Disease, a highly infectious animal disease. GAO reports that an accidental release of Foot and Mouth Disease in the United Kingdom was likely caused by poor maintenance of a bio containment facility coupled with a lack of clear lines of responsibility regarding the maintenance of shared infrastructure facilities. That outbreak caused U.K. taxpayers over \$3 billion. The incident underscores some of the dangers about the proposed National Bio- and Agro- Defense (NBAF) Laboratory to be constructed in Manhattan, Kansas, which will house research of FMD. Any release of FMD, whether an intentional insider release or accidentally caused by human error, poor construction or maintenance, could cause tens of billions of dollars in damage to our domestic livestock industry. The gaps identified in the GAO report regarding the lack guidelines for design, construction, maintenance, personnel reliability, and worker training further illustrate that we must be extremely cautious in deciding whether to build the NBAF in Kansas or any other high containment laboratories in the U.S.

I look forward to hearing our witness testimony which will help this Committee and the Congress best determine the next steps for oversight of high containment bio laboratories in the U.S.

Statement of Rep. Edward J. Markey
Oversight and Investigations Subcommittee Hearing on
Federal Oversight of High Containment Bio-Laboratories
September 22, 2009

Thank you, Mr. Chairman, for holding today's hearing on the government's oversight, or lack thereof, of high containment biological laboratories.

First of all, I would like to say that I am a longstanding supporter of biomedical research. I believe that medical research allows us to harvest cures from science's field of dreams, reaping enormous benefits for our society. Biomedical research that is conducted safely and ethically improves human health, strengthens our economy, and ultimately, saves lives.

Since the tragic anthrax attacks of 2001, our nation's research community has geared up to better prepare us against the very real threat of biological agents. The Bush administration increased research funds, workforce size, and the overall number of laboratories to go to battle against these agents. But they made these increases without a coordinated plan of attack, without keeping track of their work, and without mechanisms to evaluate their progress. That's like hitting the field for a football game without a playbook! They were unprepared and uncoordinated and this led to serious problems.

We learned in the last hearing on biolab safety in this subcommittee that our nation's biological laboratories are fraught with security and safety problems, endangering the safety and well-being of Americans who live in the vicinity of these laboratories. And recent revelations that the 2001 anthrax attacks were carried out by a scientist at a federal government laboratory raise additional questions about how effectively the government can oversee facilities it doesn't own or operate itself.

One of the newest high containment facilities is being built by Boston University in my home state, right in downtown Boston. This facility will include laboratories classified as Biosafety Level 4, which means that it will contain pathogens that have no cure, like the Ebola virus and the plague.

As you can imagine, some residents of Boston were not too pleased to have the plague right in their backyard, even though it is contained in a facility that's designed to be extremely secure. And imagine how they felt when the National Academies announced that the safety review conducted by Boston University was grossly inadequate, not scientifically sound, and not credible.

Thankfully, the former director of the NIH, Dr. Elias Zerhouni, intervened and pulled together a blue ribbon panel of science and safety experts to complete a thorough evaluation of the safety of the Boston lab.

The problems with the safety evaluation of the Boston University lab highlight the need for national coordination, planning, and oversight of high containment bio-labs. I look forward to today's testimonies and I hope that the GAO's recommendations are adopted by the time the Boston lab opens up next year.

**Opening Statement of the Honorable Joe Barton
Ranking Member, Committee on Energy and Commerce**

**Subcommittee on Oversight and Investigations Hearing:
“Federal Oversight of High Containment Bio-Laboratories”
September 22, 2009**

Thank you, Chairman Stupak and Ranking Member Walden, for holding this hearing. This is our second hearing on the safety and security at our nation’s high-containment laboratories. It has been almost two years since our initial hearing, and I look forward to hearing what actions have been taken by the federal government and the private sector to address some of the issues we raised at our last hearing to improve the safety and security at these labs.

In response to 9-11, the anthrax attacks, and the emerging threat of bio-terrorism, Congress passed the Bioterrorism Act in 2002. Among other things, this Act established a regulatory system at the Centers for Disease Control over the possession, use, and transfer of select agents and toxins. We also dramatically increased spending for building and expanding laboratories that research deadly germs and toxins. With increased funds and new regulations, high containment laboratories’ safety and security and personnel assurance measures were re-evaluated. These labs have to maintain a robust research agenda while simultaneously protecting the public and their own workers from the inherent dangers involved in researching dangerous pathogens. Strict safety rules and guidelines are required to protect against leaks, losses, or theft of these deadly materials.

This hearing re-examines several issues raised at our 2007 hearing. The Government Accountability Office issued a report yesterday once again highlighting the need for improved and coordinated federal oversight of high containment laboratories. Several other reports have either been issued or are about to be released. These include reports by the National Science Advisory Board for Bio-security and the American Association for the Advancement of Science, as well as a report by the Trans-Federal Task Force on Optimizing Bio-safety and Bio-containment Oversight. In addition, former President Bush signed Executive Order 13486 in January which established a working group to examine how to strengthen laboratory bio-security and safety in our nation's high-containment labs. The working group's report was completed and sent to President Obama in July. To date, the Administration has not publicly commented on the report or recommendations. Committee staff contacted the National Security Council and requested a briefing and or testimony for today's hearing, but no response was given.

Over the past two years, it appears that invested parties from the government and academia have been examining ways to increase oversight and safety. Congress and the President need to work together to develop a policy that is both protective of the public health as well as conducive to maintaining a strong network of high-containment labs and scientists.

While we discuss the possible gaps in federal and institutional oversight of high containment laboratories, we should also realize that the work performed in these high-risk laboratories is critical to our nation's defense and health. Dedicated scientists and lab staff conduct truly critical research into bio-defense and vaccines in these labs. One day, the work they do may save the lives of millions. One of our witnesses today is Dr.

Atlas from the American Society for Microbiology. He will offer a valuable perspective as a representative of those who work in the field.

I believe that the government, the private sector, and universities can figure out how to conduct research into the agents of bioterrorism and that they can also figure out how to protect lab workers and the public at the same time. Our country needs both of those jobs done, and done well.

Thank you, Mr. Chairman. I welcome all the witnesses.

**STATEMENT OF
CONGRESSMAN MICHAEL C. BURGESS, M.D.
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
SEPTEMBER 22, 2009 HEARING
“Federal Oversight of High Containment Bio-Laboratories”**

For several weeks now, I have been awaiting an O&I hearing my good friend Bart Stupak had noticed regarding moving bio-security research from Plum Island inland. I'm not sure what Speaker Pelosi is doing but instead of giving Bart a hearing on Plum Island like he noticed, we get a hearing on bio-laboratories as a whole.

And what did we get from the delay in timing and overbroad topic?

Nothing. This hearing can hardly be considered well thought-out and executed.

On September 15, 2009 we had a vote on H. Res. 317 recognizing Kansas as the appropriate state for the National Bio and Agro-defense Facility, with the language of the resolution proudly touting that 45% of the fed cattle in the United States and 40% of the hogs produced in this country are in Kansas. Considering that food-and-mouth disease, which is the primary research being done at Plum Island, is a disease which can spread with devastating swiftness from humans to cattle and hogs ... shouldn't we have done our O&I hearing on the scientific evaluations being done at DHS before we voted on a resolution saying that Kansas was the best pick?

In fact, the GAO stated that foot-and-mouth disease research shouldn't be moved inland for this very reason -- and certainly not to an area with lots of cattle and hogs!

I'm glad I voted against that resolution for that very reason. We need to have some common sense here in Congress.

Also, what is Nancy Pelosi doing putting forth an O&I hearing on an issue which touches DHS, USDA, HHS, CDC and The White House's NSA – not to mention the private sector – with one witness from the GAO and one witness from the private sector and no one from the federal government?

We already have an Executive Working Group on this very topic who, in July, sent to President Obama a report on “Strengthening the Bio-security of the United States” as well as a Trans-Federal Task Force on “Optimizing Bio-safety and Bio-containment Oversight.”

Why could we not have had these reports paneled before us today and not just the GAO??

Our committee is not a classroom for mere esoteric discussion and thought. We are not interested in purely academic conversation about omnibus changes to an issue which clearly has simply been suffering from merely a lack of communication and basic oversight.

For instance, today's GAO report states that twelve federal agencies play a role in our biodefense, but information about what they are doing are unknown. Why is this? Don't these federal agencies have phones and emails? Can't they just go and have meetings with each other and tell them what they are doing? Why do they need a Biodefense CZAR on top of DHS and The White House to coordinate information?

I am deeply disturbed by the notion put forth by the GAO that there needs to be YET ANOTHER layer of oversight for our

federal government when it comes to our homeland security. After all, we have given them the legal authority under BARDA and tens of billions of dollars of hard-earned taxpayer dollars to function. If they aren't functioning, then we need to have them here and held accountable.

Thank you.

Mr. STUPAK. That concludes the opening statements by members of the committee. I now call our witnesses.

On our panel we have Dr. Nancy Kingsbury, who is the Managing Director of Applied Research and Methods at the U.S. Government Accountability Office; Dr. Sushil Sharma with the GAO; and Dr. Ronald Atlas, who is the cochair of the Committee on Bio-defense at the American Society for Microbiology.

STATEMENTS OF NANCY KINGSBURY, Ph.D., MANAGING DIRECTOR, ACCOMPANIED BY SUSHIL SHARMA, ASSISTANT DIRECTOR, APPLIED RESEARCH AND METHODS, U.S. GOVERNMENT ACCOUNTABILITY OFFICE; AND RONALD M. ATLAS, Ph.D., CO-CHAIR, COMMITTEE ON BIODEFENSE, AMERICAN SOCIETY FOR MICROBIOLOGY

Mr. STUPAK. Welcome to our witnesses.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that you have a right under the rules of the House to be advised by counsel during your testimony. Do you wish to be represented by counsel?

Everyone is indicating "no."

All right. Then I am going to ask you to please rise, raise your right hand and take the oath.

[Witnesses sworn.]

Mr. STUPAK. The witnesses replied in the affirmative.

We will hear a 5-minute opening statement from our witnesses. You may also submit a longer statement, and it will be in the record.

STATEMENT OF NANCY KINGSBURY, Ph.D.

Ms. KINGSBURY. Mr. Chairman and members of the subcommittee, we are very pleased to be here to discuss our report on the national strategy for high-containment laboratories in the United States that deal with dangerous pathogens. Our report on those matters was released yesterday, as you mentioned in your opening statements.

Such high-containment laboratories have proliferated in recent years. This report focuses on the proliferation in the West, but similar things are done in other countries.

In 2007, we reported on several issues associated with the proliferation of these labs in the United States and some of these risks posed by biosafety incidents that occurred in the past. The FBI's allegation in August 2008 that a DOD scientist was the sole perpetrator of the 2001 anthrax attacks raised additional concerns about the possibility of insider misuse of high-containment lab facilities, materials and technology. Highly publicized laboratory errors and controversies about where high-containment labs should be located had raised questions about whether the governing framework, oversight and standards for biosafety and biosecurity are adequate.

In this context you asked us to address the following questions:

To what extent and in what areas has the number of high-containment labs increased in the United States?

Which Federal agency is responsible for tracking the expansion of high-containment laboratories in determining the associated aggregated risks?

And what lessons can be learned from highly publicized incidents at high-containment laboratories and actions taken by the regulatory agencies?

We have three basic findings to report:

First, since 2001 the number of BSL-3 and BSL-4 labs in the United States has increased, and this expansion has taken place across Federal, State, academic and private sectors. Information about the number, location, activities and ownership is available for high-containment laboratories that are registered with CDC's or USDA's select agent programs, but not for those outside those programs.

The expansion that began after the anthrax attacks in 2001 lacked a clear, coordinated national strategy. Decisions to fund construction of high-containment labs were made by multiple Federal agencies in multiple budget cycles. Federal and State agencies, academia and the private sector considered their individual requirements, but an assessment of national need was lacking. Even now, after more than 7 years, we were unable to find any projections based on a government-initiated strategic evaluation of current and future capacity requirements linked to national public health goals. Such information is needed, we think, to ensure that the U.S. will have facilities in the right place with the right research capabilities.

Second, no executive or legislative mandates directs any single Federal agency to track the expansion of all high-containment labs. Accordingly, no Federal agency knows how many such labs exist in the United States and no single agency is responsible for determining or are able to determine the aggregate risks associated with the expansion of these labs. Consequently, no Federal agency can determine whether high-containment lab capacity is now less than, meets or exceeds the national need.

Finally, four highly publicized biosafety incidents in high-containment labs, as well as evidence in scientific literature, demonstrate that while laboratory accidents are rare, they do occur, primarily due to human error or systems failures.

One of the incidents we reviewed involved the allegations that Dr. Bruce Ivins of DOD was the source of the 2001 anthrax attack. These allegations highlighted two lessons: First, an ill-intentioned insider could pose a risk by removing dangerous material from a high-containment lab; and second, it is impossible to have 100 percent effective inventory control of biological material with currently available technologies. Such inventory control is possible for nuclear material and for chemical material, but because biological material grows and expands, there are currently no available technologies.

At Fort Detrick, USF procedures for the control of inventories and the unrestricted use of lab facilities allegedly allowed Dr. Ivins the opportunity to pursue his own ends. As the number of high-containment labs increases, there will inevitably be an increase in the pool of scientists with expertise, and thus, the corresponding risk from insiders is likely to increase.

Taken as a whole, these incidents we reviewed demonstrate failure of systems and procedures meant to maintain biosafety in high-containment labs. They reveal the failure to comply with regulatory

requirements that were not commensurate with the level of risk to public health posed by the lab workers and the pathogens in the lab, and the failure to fund ongoing facility maintenance and monitor the operational effectiveness of lab physical infrastructure.

In conclusion, I want to stress that oversight plays a critical role in improving biosafety and ensuring that high-containment labs comply with regulations. However, some aspects of the current oversight programs provided by the CDC and USDA are dependent upon entities monitoring themselves and reporting incidents to Federal regulators.

Furthermore, personnel reliability programs have been established by 2001 to counter insider risks, but their cost, effectiveness and problematic impact has not been evaluated.

If an agency were tasked or a mechanism were established with the purpose of overseeing the expansion of high-containment labs, it could develop a strategic plan to ensure that the number and capabilities of potentially dangerous high-containment labs are no greater or no less than necessary. It could balance the risks and benefits of expanding such labs and it could determine the type of oversight needed.

To address these issues we recommended that the National Security Adviser, in consultation with the Secretaries of Health and Human Services, Agriculture, Defense, and Homeland Security, and the National Intelligence Council and any other departments and agencies that are appropriate, identify a single entity charged with periodic strategic evaluation of high-containment labs that will determine the number, location and mission of laboratories needed to effectively meet national goals to counter biot threats, the existing laboratory capacity within the United States, the aggregate lists associated with the expansion and the type of oversight needed.

It could also develop in consultation with the scientific community national standards for the design, construction, commissioning and operation of high-containment laboratories, specifically including provisions for long-term maintenance, which is an area that we are quite concerned about.

We also recommended that the Secretaries of Health and Human Services and Agriculture develop a clear definition of exposure to select agents—some of these incidents suggest that there is some confusion in that regard—and a mechanism for sharing lessons learned from reported laboratory accidents so that best practices for other operators for high-containment laboratories can be identified and distributed.

Recognizing that biological inventories cannot be completely controlled at present, we also recommended that the Secretaries of HHS and Agriculture review existing inventory control systems and invest in and develop appropriate technologies to minimize the potential for insider misuse of biological agents.

Finally, should the Secretaries consider implementing a more stringent personnel of liability program for high-containment laboratories, employees to deal with insider risks, we recommended that they evaluate and document the cost effectiveness and programmatic impact of such a program.

We did obtain written comments on the draft of our report from the Secretaries of Health and Human Services and Agriculture. HHS and Agriculture concurred with our recommendations that were directed to them. The Executive Office of the President and the National Security Council did not provide any comments.

Mr. Chairman, this concludes my prepared remarks, and I will be happy to answer any questions that you or your colleagues may have.

Mr. STUPAK. Thank you.

[The prepared statement of Ms. Kingsbury follows:]

United States Government Accountability Office

GAO

Testimony
Before the Subcommittee on Oversight
and Investigations, Committee on Energy
and Commerce, House of Representatives

For Release on Delivery
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HIGH-CONTAINMENT LABORATORIES

National Strategy for Oversight Is Needed

Statement of Nancy Kingsbury, Ph.D.
Managing Director
Applied Research and Methods



Mr. Chairman and Members of the Subcommittee

We are pleased to be here to discuss our report on a national strategy for high-containment laboratories that deal with dangerous pathogens—also known as biosafety level-3 (BSL-3) laboratories and biosafety level-4 (BSL-4) laboratories—in the United States, which was released yesterday.¹ The number of high-containment laboratories working with dangerous biological pathogens have proliferated in recent years. In 2007, we reported on several issues associated with the proliferation of high-containment laboratories in the United States, including risks posed by biosafety incidents that have occurred in the past.² The Federal Bureau of Investigation's allegation in August 2008 that a scientist at the U.S. Army Medical Research Institute of Infectious Diseases was the sole perpetrator of the 2001 anthrax attacks raised additional concerns about the possibility of insider misuse of high-containment laboratory facilities, material, and technology. The public is concerned about these laboratories because the deliberate or accidental release of biological agents can have disastrous consequences by exposing workers and the public to dangerous pathogens. Highly publicized laboratory errors and controversies about where high-containment laboratories should be located have raised questions about whether the governing framework, oversight, and standards for biosafety and biosecurity measures are adequate.³ In this context, you asked us to address the following questions:⁴

1. To what extent, and in what areas, has the number of high-containment laboratories increased in the United States?
2. Which federal agency is responsible for tracking the expansion of high-containment laboratories and determining the associated aggregate risks?

¹GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-574 (Washington, D.C.: Sept. 21, 2009).

²GAO, *High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, GAO-08-108T (Washington, D.C.: Oct. 4, 2007).

³G.K. Gronvall et. al., "Letter to Senator Edward Kennedy and Senator Richard Burr," Center for Biosecurity, University of Pittsburgh Medical Center, March 3, 2009.

⁴The request letter contained several questions. In agreement with our requester, we revised the questions as stated.

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3. What lessons can be learned from highly publicized incidents at high-containment laboratories and actions taken by the regulatory agencies?

To answer these questions, we interviewed federal agency officials as well as experts in microbiology, reviewed literature, conducted site visits, and surveyed 12 federal agencies to determine if they have a mission to track high-containment laboratories in the United States. We also interviewed officials from relevant intelligence agencies to determine if they have a mission to determine insider risks in high-containment laboratories. The expert panel that reviewed this report comprised scientists with substantive expertise in microbiological and select agent research and the operation of high-containment laboratories.

We conducted our work from September 2005 through June 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The Number of High-Containment Laboratories Is Increasing in Different Sectors throughout the United States

We found that since 2001, the number of BSL-4 and BSL-3 laboratories in the United States has increased, and this expansion has taken place across federal, state, academic, and private sectors and throughout the United States. Federal officials and experts believe that while the number of BSL-4 laboratories in the United States is known, the number of BSL-3 laboratories is unknown. Information about the number, location, activities, and ownership is available for high-containment laboratories that are registered with the Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) or the United States Department of Agriculture's (USDA) Animal and Plant Health and Inspection Service (APHIS) select agent programs, but not for those outside the program. The recent expansion of high-containment laboratories in the United States began in response to the need to develop medical countermeasures and better risk evaluations after the anthrax attacks in 2001. Understandably, the expansion initially lacked a clear, governmentwide coordinated strategy. In that emergency situation, the expansion was based on individual agency perceptions of requirements relative to the capacity their high-containment labs required as well as the availability of congressionally appropriated funding. Decisions to fund the construction of high-containment labs were made by multiple federal

agencies in multiple budget cycles. Federal and state agencies, academia, and the private sector considered their individual requirements, but an assessment of national needs was lacking. Even now, after more than 7 years, GAO was unable to find any projections based on a governmentwide strategic evaluation of future capacity requirements set in light of existing capacity; the numbers, locations, and missions of the laboratories needed to effectively counter biotreats; and national public health goals. Such information is needed to ensure that the United States will have facilities in the right place with the right specifications.

**No Federal Agency
Has the Mission to
Track the Expansion
of All High-
Containment
Laboratories and
Regulate Biosafety in
the United States**

Currently, no executive or legislative mandate directs any federal agency to track the expansion of all high-containment laboratories. Because no federal agency has the mission to track the expansion of BSL-3 and BSL-4 laboratories in the United States, no federal agency knows how many such laboratories exist in the United States. While there is a consensus among federal agency officials and experts that some degree of risk is always associated with high-containment laboratories, no one agency is responsible for determining, or able to determine, the aggregate or cumulative risks associated with the expansion of these high-containment laboratories. As a consequence, no federal agency can determine whether high-containment laboratory capacity may now meet or exceed the national need or is at a level that can be operated safely.

**Lessons Learned from
Four Incidents
Highlight the Risks
Inherent in the
Expansion of High-
Containment
Laboratories**

Four highly publicized incidents in high-containment laboratories, as well as evidence in the scientific literature, demonstrate that (1) while laboratory accidents are rare, they do occur, primarily because of human error or systems (management and technical operations) failure, including the failure of safety equipment and procedures; (2) insiders can pose a risk; and (3) it is difficult to control inventories of biological agents with currently available technologies. It has been suggested that personnel reliability programs would mitigate the insider risk. The National Science Advisory Board for Biosecurity reported that there is little evidence that personnel reliability measures are effective or have predictive value in identifying individuals who may pose an insider risk. (4) Continuity of electrical power is vital for the safe functioning of high-containment laboratories, in particular since maintenance of essential pressure differentials using electrically driven fans provides an important barrier for preventing the uncontrolled release of agents.⁶⁵ Lapses in electrical power that occurred at a CDC laboratory raise concerns about standards in high-containment laboratory facility design, management of construction, and operations.

Taken as a whole, these incidents demonstrate failures of systems and procedures meant to maintain biosafety in high-containment laboratories. For example, they revealed the failure to comply with regulatory requirements, safety measures that were not commensurate with the level of risk to public health posed by laboratory workers and pathogens in the laboratories, and the failure to fund ongoing facility maintenance and monitor the operational effectiveness of laboratory physical infrastructure.

Conclusions

Oversight plays a critical role in improving biosafety and ensuring that high-containment laboratories comply with regulations. However, some aspects of the current oversight programs provided by the Departments of Health and Human Services and Agriculture are dependent upon entities monitoring themselves and reporting incidents to federal regulators. Since 2001, personnel reliability programs have been established to counter insider risks, but their cost, effectiveness, and programmatic impact have not been evaluated.

In conclusion, proliferation of high-containment laboratories is taking place in all sectors. Furthermore, since no single agency is in charge of the current expansion, no one is determining the associated aggregate risks posed by the expansion. As a consequence, no federal agency can determine whether high-containment laboratory capacity may now be less than, meet, or exceed the national need or is at a level that can be operated safely.

If an agency was tasked or a mechanism was established with the purpose of overseeing the expansion of high-containment laboratories, it could develop a strategic plan to (1) ensure that the number and capabilities of potentially dangerous high-containment laboratories are no greater or less than necessary, (2) balance the risks and benefits of expanding such laboratories, and (3) determine the type of oversight needed.

Such an agency or mechanism could analyze the biothreat problems that need to be addressed by additional BSL-3 and -4 laboratories, the scientific and technical capabilities and containment features that such laboratories need to have, how the laboratories should be distributed geographically, and how the activities of the laboratories would be coordinated to achieve intended goals. The agency or mechanism responsible for overseeing the expansion of high-containment laboratories could also be responsible for coordinating with the scientific community to develop guidelines for high-containment laboratory design, construction, and commissioning and training standards for laboratory workers; providing definitions for

exposure; developing appropriate inventory control measures; and providing guidance on the most efficient approach to personnel reliability programs.

Overall, the safety record of high-containment laboratories has been good, although a number of weaknesses have become apparent over time. Consequently, along with expansion there needs to be a commensurate development of both operational and oversight procedures to address known deficiencies and, as far as practicable, proactively evaluate future risks.

Laboratory operators, in collaboration with regulators, need to develop and work through potential failure scenarios and use that information to develop and put in place mechanisms to challenge procedures, systems, and equipment to ensure continuing effectiveness.

Recommendations for Executive Action

To address these issues, we recommended that the National Security Advisor, in consultation with the Secretaries of Health and Human Services (HHS), Agriculture, Defense (DOD), and Homeland Security (DHS); the National Intelligence Council; and other executive departments as deemed appropriate identify a single entity charged with periodic governmentwide strategic evaluation of high-containment laboratories that will

(1) determine

- the number, locations, and mission of the laboratories needed to effectively meet national goals to counter biotreats,
- the existing capacity within the United States,
- the aggregate risks associated with the laboratories' expansion, and
- the type of oversight needed, and

(2) develop, in consultation with the scientific community, national standards for the design, construction, commissioning, and operation of high-containment laboratories, specifically including provisions for long-term maintenance.

We recommended that the Secretaries of HHS and USDA develop (1) a clear definition of exposure to select agents and (2) a mechanism for sharing lessons learned from reported laboratory accidents so that best practices—for other operators of high-containment laboratories—can be identified.

Should the Secretaries consider implementing a personnel reliability program for high-containment laboratories to deal with insider risk, we recommended that they evaluate and document the cost, effectiveness, and programmatic impact of such a program.

Recognizing that biological agent inventories cannot be completely controlled at present, we also recommended that the Secretaries of HHS and USDA review existing inventory control systems and invest in and develop appropriate technologies to minimize the potential for insider misuse of biological agents.

Agency Comments and Our Evaluations

We obtained written comments on a draft of our report from the Secretaries of HHS and USDA. The Executive Office of the President: National Security Council did not provide comments. HHS and USDA concurred with our recommendations that were directed to them.

Mr. Chairman, this concludes my prepared remarks. I would be happy to respond to any questions that you or other members of the subcommittee may have at this time.

Contact and Acknowledgments

If you or your staffs have any questions about this report, please contact me at (202) 512-2700 or kingsburym@gao.gov or Sushil K. Sharma, Ph.D., Dr.PH, at (202) 512-3460 or sharmas@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Amy Bowser, George Depaoli, Terrell Dorn, Jeff McDermott, Jean McSween, Jack Melling, Ph.D., Corey Scherrer, Linda Sellevaag, and Elaine Vaurio made key contributions to this testimony.

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Mr. STUPAK. Dr. Atlas, opening statement, please, sir.

STATEMENT OF RONALD M. ATLAS, Ph.D.

Mr. ATLAS. Thank you, Mr. Chairman, members of the subcommittee. I want to thank you for the opportunity to testify on behalf of the American Society for Microbiology.

When I began my career 40 years ago, we thought we had conquered infectious diseases, but in fact that is not the case. We have newly emerging infectious diseases every year, whether it is SARS or multidrug and extremely drug-resistant tuberculosis or the recurrent outbreak of the H1N1 influenza. And these outbreaks of disease have not only public health but also economic and political repercussions, and therefore we need to carry out research to find the therapeutic vaccines, diagnostics and other ways of coping with these diseases.

In other words, we must continue to perform research on pathogenic microorganisms, and much of that research needs to be performed in high-containment laboratories where the safety of the scientists working on the organisms, as well as the public, can be protected. These are not weapons laboratories; rather, they are research laboratories where investigations are carried out with the aim of protecting public health.

Inevitably, as we have seen in the tragic case in Chicago, at least from the reports, there is risk to the scientists and perhaps to the community when we work with these organisms. And accordingly, the American Society for Microbiology has strongly supported responsible regulation, oversight, practices and guidelines that improve laboratory biosafety and protect laboratory personnel, the public and the efficacious performance of the research that leads to vaccines, therapeutic drugs and diagnostics that we need. And over the years we have reached a balance, at least for the moment, between the safety practices that are carried out in the laboratory and the ability to perform research.

Although these procedures, when properly followed, do provide a level of safety to the workers in the community, the ASM feels that we continuously need to review these practices and to find new and better ways to move forward.

During the past 2 years, the ASM has met with the Trans-Federal Task Force on Biosafety and Biocontainment Oversight and the Executive Order Working Group on strengthening the biosecurity of the United States and made a number of recommendations to those groups. Clearly, there is a need to ensure adequate training and strict compliance to provide the levels of protection engendered in existing biosafety procedures, as well as those that may be proposed.

The ASM has made a number of recommendations which I would like to summarize for you.

First, the Biosafety and Microbiological and Biomedical Laboratories Manual, or the BMBL, which contains the core guidelines for the safe operation of all microbiological laboratories, should be the subject of regular biennial review and update, as needed. The BMBL, along with the NIH guidelines for recombinant DNA research, are essential reference documents. We need to continuously examine these, update them, and provide more guidance for the

community and to develop specific competencies for biosafety training and recommended procedures for incident reporting. The ASM view is that the CDC, NIH, and USDA should take the lead for BMBL revisions, but there should be input through from the community.

Second, the list of pathogens designated as select agents and those requiring BSL-3 and BSL-4 containment should be regularly updated; and again, we would urge that a scientific community that is broadly based help to guide the development of these lists.

Third, there should be mandated training and performance requirements for biosafety personnel overseeing the safety of high-containment laboratories. And again, the NIH and CDC should make educational training programs available, and we should continuously look to the standards that need to be achieved.

Fourth, the select agent regulation should be revised to change the requirements for inventory of vials and select agents. Laboratories should be accountable for which agents they possess and where these agents are located, but counting of vials that are in a freezer when we are dealing with live organisms provides a false sense of security and does not really help in protecting the Nation.

Fifth, the NIH requirements that foreign institutions must have comparable facilities and standards that are U.S. Collaborative should be changed to remove hurdles for international collaboration. We have been struck by the UTMB experience where they no longer can get strains of hemorrhagic fever viruses into the United States because the laboratories overseas that, in fact, are holding those organisms may not meet U.S. standards.

Six, the Congress should enhance funding, as needed, to ensure the upkeep of the high-containment laboratories. Now that many of these laboratories have been constructed, they should be concerned that they continue to meet the high standards to which they were built.

Seven, we need an improved system for surveillance and reporting of laboratory-acquired illnesses. This should be done in a way where we learn lessons from incidents which, unfortunately, occur rather than trying to hide these incidents for fear of recrimination.

And finally, we should be examining very carefully the costs and benefits of potential accreditation systems. In this regard, we see the current select agent regulations as providing a pseudoaccreditation. There are standards, there are inspections; as has been pointed out, this does not exist for the nonselect agents, and I think we need to examine the potential value of moving forward.

We would note that the American Biological Safety Organization, ABSA, is in fact in the process of developing a voluntary accreditation system. I think we need to look at that. But moreover, we really need to develop the standards and look to what we need to hold the labs accountable for and have a system in place where we can assure this committee and the Nation that we are complying.

In conclusion, I think we have made tremendous strides over the past years in moving towards meeting the needs of the Nation both in terms of the research and the safety. More needs to be done. We need to do this carefully and in a considerate way, so we don't upset an apple cart and put the Nation at risk.

Thank you, Mr. Chairman, and I look forward to your questions.
[The prepared statement of Mr. Atlas follows:]



Public and Scientific Affairs Board

**American Society for Microbiology's testimony before the Committee on Energy and Commerce Subcommittee on Oversight and Investigations on Federal Oversight of High Containment Bio-Laboratories
September 22, 2009**

The American Society for Microbiology (ASM) is pleased to testify before the House Energy and Commerce Committee Subcommittee on Oversight and Investigations hearing on Federal Oversight of High Containment Biolaboratories.

My name is Ronald Atlas and I am CoChair of the ASM Public and Scientific Affairs Board Committee on Biodefense and a Past President of the ASM. I am also Professor of Biology at the University of Louisville. The ASM is the largest single life science Society in the world with a membership of about 40,000 scientists and health professionals. ASM members are involved in basic and applied research, clinical laboratory testing and public health activities that are focused on developing new preventions, therapies and cures for infectious diseases. To meet the challenges of emerging and reemerging infectious diseases, microbiologists work in laboratories in which highly pathogenic agents are stored and studied. The ASM is interested in assuring that such agents are maintained in a manner that is safe for laboratory personnel and the public.

Infectious diseases remain among the most difficult global health challenges accounting for about one quarter of all deaths. Newly recognized infectious diseases occur almost yearly, as evidenced by influenza A (H1N1), avian influenza (H5N1), multidrug and extensively drug resistant agents (MDR-TB/XDR-TB), and severe acute respiratory syndrome (SARS), just in the last decade alone. These episodes have public health as well as economic and political repercussions. It is critical that scientists in the public and private sectors and health professionals have appropriate facilities and laboratories for the development of new therapies, diagnostics, and prevention and detection methods aimed at reducing the risk of infectious diseases. For example, it is essential that investigators in industry and academia have the proper facilities to work on these infectious agents to develop new vaccines and drugs for which in some cases there are few to no existing therapies. Today 30-40 percent of XDR-TB strains are untreatable with existing drugs and these strains are becoming more common and widespread. An H1N1 vaccine could not have been rapidly or safely developed without existing research laboratory infrastructure.

Research on pathogenic microorganisms, which is critical for the health and security of the public and the nation, must be performed safely. Accordingly, the ASM has consistently supported responsible regulation, oversight, practices and guidelines that improve biosafety in laboratories and help to protect laboratory personnel, the safety of the surrounding communities, and the efficacious performance of the research that leads to the vaccines, therapeutic drugs, diagnostics, and other measures that are so needed today to protect the public against the plethora of infectious diseases that occur in the United States and globally.

During the past two years, the ASM has met with and provided recommendations to the Trans Federal Task Force on Biosafety and Biocontainment Oversight and the Executive Order Work Group on Strengthening the Biosecurity of the United States. We understand that these groups have undertaken extensive consultation with the public health and research community and that they will soon release reports and recommendations regarding biosafety and biosecurity. We recommend careful consideration of their recommendations, as well as a thoughtful and deliberate approach to any additional or new requirements for biosafety and biosecurity in laboratories. It took a number of years and substantial effort to arrive at the careful equilibrium that currently exists to oversee and manage research activities. We believe that precipitous, excessive policy changes could upset this delicate balance and, therefore, should be considered in the context of the critical need to conduct public health activities, clinical diagnostic testing and research on pathogens that will lead to new and improved vaccines, therapeutics, diagnostics and other measures to protect against infectious diseases, whether naturally occurring or the result of an intentional act.

The ASM would like to comment on 1) the need for biocontainment laboratories, 2) the select agent regulations, 3) the importance of biosafety for laboratories and laboratory personnel and 4) recommendations to improve biosafety. A number of our recommendations continue to reflect those we made to the Subcommittee in 2007 and subsequently to the federal agency groups addressing biosafety, biocontainment and biosecurity.

1) The Need for Biocontainment Laboratories High containment laboratories should be constructed and maintained to ensure the safety of the laboratory workers and the broader community. Newly emerging and reemerging infectious diseases are appearing at the same time that microbial resistance to standard therapeutics is on the increase. This lethal combination of events presents enormous challenges to public health. In an age of extensive international air travel and commerce, infectious diseases have become a security issue for every nation on the globe, including the United States. Despite the best efforts of government agencies, the public may be at risk for exposure not only to infectious diseases arising within the United States but also at risk to infectious diseases outside our borders.

Over the past thirty years, public health agencies have confronted a myriad of infectious diseases, such as pandemic influenza, HIV/AIDS, extensively drug resistant tuberculosis (XDR TB), SARS, methicillin resistant *Staphylococcus aureus* (MRSA) Ebola hemorrhagic fever, Lyme disease, toxic shock syndrome, Legionnaires' disease, hantavirus pulmonary syndrome, West Nile fever, and others. According to the CDC, 75 percent of these emerging and reemerging infectious diseases, including SARS, hantavirus pulmonary syndrome, Nipah virus encephalitis, influenza, and West Nile fever, are zoonotic, which means that they are transmitted from animals to humans. Although terrible to contemplate, we must also confront the possibility of misuse of science. As the scientific community responds to emerging, reemerging, and drug resistant diseases, it also must prepare to deal with the possibility of an intentional misuse of science for the creation, or spread, of infectious diseases.

Public health and safety depends upon skilled and highly trained microbiologists and other health professionals to make every effort to find methods to prevent, diagnose, and treat infectious diseases and to respond rapidly to emerging and reemerging diseases and threat of bioterrorism. To meet these challenges, scientists and public health professionals must have laboratories in which pathogens may be stored and studied in a manner that is safe for microbiologists and to the community-at-large.

Congress recognized the seriousness of the threat of bioterrorism in the aftermath of the 2001 anthrax crime and increased appropriations for biodefense research. In early 2002, the National Institute of Allergy and Infectious Diseases (NIAID) convened a panel of experts, the Blue Ribbon Panel on Bioterrorism and its Implications for Biomedical Research. This Panel provided guidance on the future biodefense and emerging diseases research agenda, research resources, facilities and scientific personnel. The capacity of existing biocontainment facilities were determined to be inadequate to meet needs for biodefense and emerging diseases work. New facilities at BSL 3 and 4 levels of containment needed to be constructed so that the necessary research to protect the nation could be conducted safely and to provide surge diagnostic capacity in the event of a bioterrorism attack or a pandemic disease outbreak. The NIAID has funded 2 National Biocontainment Laboratories and 13 Regional Biocontainment Laboratories to provide safe and secure space for biodefense and emerging diseases research. These laboratories help support the network of 10 nationwide multidisciplinary Regional Centers for Excellence for Biodefense and Emerging Infectious Diseases Research that the NIAID has established to meet the growing challenge of infectious diseases and to combat the threat of bioterrorism.

The establishment of new biocontainment laboratories has been done openly and under the scrutiny of local municipalities and a federal regulatory and oversight system. They have been constructed in accordance with environmental impact assessments and other applicable standards for biosafety. The new BSL3 and BSL4 laboratories constructed with funds provided in part by

the National Institutes of Health (NIH) have been subject to rigorous oversight by NIH/NIAID program staff throughout all phases of design and construction. They are a critical resource in the nation's response to the public health issues posed by emerging and reemerging infectious diseases.

2) Select Agent Regulations The select agent regulations already provide mandatory oversight of biosafety and biosecurity for laboratories working with these agents, including all private as well as public laboratories. These laboratories are subject to federal laws, regulations and policies which seek to ensure a safe and secure environment in which to conduct research on dangerous pathogens and toxins. They must follow biosafety procedures to protect personnel working in the laboratory and the outside community. The select agent regulations specify reporting requirements for any significant problems, violations, or any research related accidents and illnesses. Institutions are also required to comply with the CDC and US Department of Agriculture APHIS Select Agent regulations if they possess, use, or transfer select agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety. These regulations mandate an FBI security risk assessment for individuals authorized to have access to select agents, incident response plans, and a security and safety plan to safeguard the select agents (42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121). The ASM recommends regular review of the select agent regulations. This review should involve the broad scientific community. As needed the lists of agents and the requirements of the regulations should be modified to ensure appropriate biosecurity and biosafety.

The ASM has consistently supported the leadership role of the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) and the US Department of Agriculture Animal Plant Health Inspection Service (APHIS) in administering the select agent and toxin regulations for facilities that possess, use or transfer select agents and toxins. The HHS, CDC and APHIS are experienced and knowledgeable about infectious diseases involving select agents and toxins. The HHS, CDC and APHIS are committed to the protection of public health and safety. We recommend that any changes needed to improve biosafety and to ensure biosecurity in laboratories build upon existing HHS and USDA programs, including the Select Agent program, rather than through new statutory programs. We continue to support locating the Select Agent Program at the HHS/CDC for human and overlap agents and at the USDA/APHIS for animal and plant pathogens because these agencies have the appropriate public health expertise, laboratory experience in the life sciences and oversight capacity for biosafety and biosecurity.

3) The Importance of Biosafety Requirements for Microbiology Laboratories and Personnel The Biosafety in Microbiological and Biomedical Laboratories (BMBL) must set the standards for the safe handling of infectious agents in the laboratory and best practices to ensure

biosafety. Laboratories with capacity at BSL3 and BSL4 are designed to maximize the safety of laboratory staff and minimize the potential that a pathogen could escape.

There is already extensive government guidance, oversight and regulation of activities involving microbes and toxins. The Biosafety in Microbiological and Biomedical Laboratories, BMBL, 5th Edition, published by the CDC and NIH, describes microbiological practices, laboratory facilities and safety equipment for work with infectious agents. Through the BMBL, CDC and NIH have set standard procedures to be followed when working with infectious agents. There are also additional guidelines that come from other documents. The shipment of infectious agents is regulated by the DOT, Department of Commerce, CDC and USDA. Bloodborne pathogens are regulated by OSHA. The NIH Guidelines for Research Involving Recombinant DNA Molecules establish safety guidelines for research with recombinant DNA, including recombinant DNA research with infectious agents. They require institutions receiving NIH funding to have Biosafety Officers and Institutional Biosafety Committees (IBCs). The NIH Office of Biotechnology Activities provides resources and training on the role and responsibilities of IBCs, which examine research protocols, expertise, potential hazards and containment plans. Many institutions assign IBCs broader responsibility for overseeing research with nonrecombinant infectious agents.

4) Recommendations to Improve the BMBL, Lists of pathogens, Training, Oversight, Inventory, International exchange, Transportation, Resources, Reporting and Accreditation

Although there are procedures in place for providing biosafety if properly followed, there is an ongoing need to review and enhance biosafety. In this regard, there is a need to ensure adequate training and strict compliance to provide the levels of protection engendered in those procedures. Laboratory workers who handle infectious pathogens are at potential risk of acquiring an infection. Therefore, adequate training in microbiological practices and biosafety is essential to working safely with hazardous biological agents, and protecting the public health. Exposure and risk may be prevented or minimized by rigorous implementation of appropriate laboratory practices and containment, safety equipment, improvement and maintenance of facilities, and formal, validated training of technical, support and administrative personnel. Laboratory risk assessment is very important because it enables the selection of the appropriate microbiological practices, safety equipment and facility safeguards for research and testing.

With these considerations in mind, ASM makes the following recommendations:

Biosafety in Microbiological and Biomedical Laboratories Manual (BMBL): The BMBL should be subject to regular biennial review and update as needed. More guidance is needed on specific competencies for biosafety training and recommended procedures for incident reporting.

The CDC, NIH and USDA should take the lead for BMBL revisions and for maintaining the currency of the list of organisms requiring containment. There should be a broad advisory committee that includes representation from the relevant scientific and biosafety organizations. The BMBL should be published in hard copy and made widely available, with aggressive communication to all involved parties for use as a reference for biosafety. It is important to establish the rules for biosafety and then accumulate suggestions for modifications based on experience and evolving scientific knowledge. Compliance with the BMBL biosafety and biosecurity standards should be a term of award by all federal agencies and there should be assurance that institutions are adhering to the BMBL.

Lists of Pathogens: Lists of pathogens designated as select agents and those requiring BSL 3 and 4 containment should be regularly updated. The CDC, NIH and USDA should review and update the BMBL list of agents biennially as is required and more often as needed. A scientific advisory committee to help guide which organisms are included should be established. There is also need to harmonize internationally the appropriate levels of containment for pathogenic microorganisms.

Training: There should be mandatory, periodic training for all personnel working in BSL3 and BSL4 laboratories. Learning competencies should be established for biosafety training and formal training programs should be required and documented. The training that laboratory personnel receive should be validated to ensure the adequacy of biosafety knowledge. Not only should laboratory personnel be properly trained, but also those who are responsible for facility operations, equipment and management should receive appropriate training. This training is needed to ensure that all personnel in laboratories where work with biohazardous are competence to work at a level that provides for their own safety and that of the community.

The NIH Regional Centers of Excellence serve an important role for training and exchange of information about biosafety practices. Their role should be encouraged and enhanced. As these Centers develop it will be important to learn from experience, share information, and implement improved procedures to protect the safety of workers and the wider community.

Oversight: There should be mandated training and performance requirements for biosafety personnel overseeing the safety of high containment laboratories. The NIH and CDC should make educational and training programs available. Oversight of biosafety at multiple levels is essential. Harmonized integrated systems of oversight of all pathogens are needed. Institutional Biosafety Committees, Biosafety Officers and Laboratory Directors, which evaluate risk and safety issues at the local level, as well as the institutionally designated Select Agent Responsible Officials, should ensure institutional adherence to the BMBL, the NIH Guidelines, and other applicable regulations for laboratory safety and security.

The CDC and NIH should ensure that good communication channels are in place for biosafety personnel to assist them in making informed decisions about risk management. The NIH and the CDC should consider further guidance and outreach activities for biosafety personnel to assist them in regulatory interpretation and containment for research on highly infectious agents and new scientific techniques, where guidance and uniformity of risk information may not be well established. Biosafety personnel should work closely with researchers in containment settings to review and improve safety procedures that protect public health. The occupational health clinic (or other medical oversight) is also an important part of open communications between those laboratory workers and the biosafety officers.

The NIH should ensure that biosafety personnel have a clear understanding of the circumstances for consulting with the NIH Office of Biotechnology Activities on research containment and regulatory issues. The BMBL and the NIH Guidelines are essential reference documents for biosafety practice and oversight and should be required for institutions conducting research. The CDC and NIH should work with research institutions, and the scientific and biosafety communities to ensure that current biosafety guidelines, regulations for biosafety and biosecurity are well understood, appropriate and implemented to ensure safe laboratory procedures. Understanding and adhering to biosafety principles and practices, risk assessment, appropriate containment and facility safeguards will contribute to safe laboratories, research and testing.

Inventory: The select agent regulations should be revised to change the requirements for inventory of vials of select agents. Given the intrinsic biological properties of microbes, the actual counting of vials is meaningless, ineffective, misleading and should not be required. Rather laboratories should be accountable for which agents they possess and where these agents are located.

International Exchange: The NIH requirements that foreign institutions must have comparable facilities and standards to their US collaborators should be changed to remove hurdles for international collaboration. The current requirements are impeding collaborative research on infectious diseases and making it difficult to share reagents, antigens and to exchange biological samples and specimens. Many of the agents of concern only produce disease outside the United States and studies involving them require that we have a robust and fruitful scientific exchange with international colleagues. It is critical to maintain collaboration with foreign researchers on science and public health, particularly on infectious diseases where extensive work is done internationally. It is vital to ensure the open flow of biological samples into the United States and the shipment of samples abroad.

Transportation: A single web site with up to date information on how infectious agents should be transported should be created. Distribution of microorganisms for identification, research, reference production, and diagnostic purposes is essential to public health and scientific progress. Safe handling that minimizes risk is essential. Effective communication from regulators such as DOT, Department of Commerce, and USDA will aid compliance with regulations.

Resources: The Congress should enhance funding, as needed, to ensure the upkeep of high containment laboratories are met and that there are adequate funds for biosafety needs, including personnel training. Biocontainment laboratories are expensive and a large investment, not only in the cost of construction, but in the cost of operations, maintenance, training, oversight and community relations. The design and building of biocontainment facilities requires careful guidance from funding agencies, the development of useful standards for biosafety experts and managers over the life-cycle of the laboratory. Facilities must ensure that maintenance and renovations do not result in breaches of containment.

The needs for additional support for biosafety oversight and maintenance of biocontainment laboratories should be evaluated to ensure there is adequate institutional, agency and community support. It is important that the investments made to date by the government in these laboratories be sustained to ensure their continued safe operation.

Reporting: An improved surveillance and reporting of laboratory acquired illness and response should be established, even for those incidents not covered by the Select Agent regulations. There should be a reporting requirement for illnesses suspected of being laboratory acquired. Incidents of laboratory acquired infections have been documented in the United States. Notifiable infectious diseases must now be reported to local and/or state public health agencies to enable assessment of risk and response and to alert physicians and the public to take appropriate steps, if necessary. However, data on whether the infection occurred in a laboratory is not routinely collected for many reportable diseases. CDC and local/state public health authorities should work with institutions, investigators and biosafety personnel to analyze occurrences of laboratory acquired illnesses and to provide reports and information in a way that will help reduce the risk and reoccurrence of any incidents. Improved reporting of laboratory acquired illness, investigation and response would provide valuable lessons for maintaining safe conditions in research and clinical laboratories. To prioritize interventions and to determine the effectiveness of those interventions.

Accreditation: Accreditation of high containment laboratories may be desirable and the costs and benefits should be carefully explored. Any accreditation of laboratories should be well defined and standards would need to be established before such a program is undertaken. The

select agent regulations already require facilities to be registered, to undergo a safety and security risk assessment, to clear personnel with access to select agents and to be inspected. The scientific community is greatly concerned about issues surrounding laboratory accreditation and should be fully engaged and consulted during federal decision making on standards, guidelines, and the process for any accreditation program. A formal assessment should be undertaken to evaluate the costs, benefits and efficacy of registering and/or accrediting high containment laboratories. The study should address: which high containment laboratories, if any, should be registered and or accredited; who should be responsible for registration and or accreditation and what should be the budgetary considerations and how costs associated with accreditation should be covered.

In conclusion, the laboratory infrastructure in the United States has made tremendous strides in the past decade to meet the challenges of emerging diseases and biothreats. This progress is based on the careful balance of research needs and regulatory oversight. Any changes to the current system should be carefully considered and crafted to ensure this delicate balance is not upset and impedes research and countermeasures development. These changes should also be considered with input from the scientific and public health community. We should take steps to enhance biosafety and assure biosecurity of high containment laboratories by increasing awareness within the scientific community, improving federal government guidance, establishing standards for biosafety and, carefully evaluating moving toward a defined accreditation system. To enhance biosafety we need to build on the culture of responsibility across the scientific community and enhance a culture that embraces the premise that the misuse of science is absolutely wrong and that good laboratory practices should be required. Awareness and education are the most critical components. The ASM would be pleased to work with Congress and the oversight agencies to accomplish these tasks.

Mr. STUPAK. Thank you both for your testimony.

One of the things we have learned from the oversight hearings is that there is no Federal agency in charge of the expansion of the high-containment labs. I think the average citizen would be surprised to learn that the government doesn't even know how many BSL-3 labs there are in the United States.

On Table 3 from the GAO report—you might want to put it up on the monitor—we see that the number of BSL-4 labs has increased even since 2007 when we held our first hearing. There are now two more BSL-4 labs that are fully operational in the United States since our 2007 hearing. There are also seven more BSL-4 labs currently under construction.

So if we go back and we look at your Figure 1 in the GAO report and Figure 1 on our monitor, we can see locations of the BSL-4 labs are being built right now across the United States. When these labs become operational, we will have double the BSL-4 capacity in the United States without any Federal agency analyzing whether this is appropriate needs for our country.

And if we look at Figure 2 in the GAO report, we can see that the number of BSL-3 labs has continued to increase in the same period of time. Table 4 shows there are about 1,400 BSL-3 labs in the United States, and these are only the BSL-3 labs registered with the Federal Government. We can only guess how many there are out there, because they don't have to register unless it is handling one of those agents.

Do you have any concerns about the increase we have seen in the number of high-containment labs?

Ms. KINGSBURY. Yes, sir.

Mr. STUPAK. Could you explain your concerns.

Ms. KINGSBURY. Well, the concern is, there may be a need for this number of laboratories, but nobody is looking at the total picture. Nobody is looking at what the public health and public safety research needs are, and linking that to where labs are built and how many of them we need. And if you look at the combination of Table 4 and Table 5, which are the labs that are registered with APHIS at the Department of Agriculture, you end up with more than 1,600 BSL-3 labs out there. That just seems like a lot.

Mr. STUPAK. You mentioned the Department of Agriculture, and Dr. Atlas, in your report and letter that you sent after our last hearing—were you the author of that letter or was there a team that did that?

Mr. ATLAS. We have a team.

Mr. STUPAK.—you mention about—because of APHIS and the Department of Ag there, because 75 percent of the new infectious disease we are seeing actually comes from animals passed to humans; is that correct?

Mr. ATLAS. That is correct.

Mr. STUPAK. Dr. Atlas, do you have any concerns about this increased number of labs we are seeing?

Mr. ATLAS. I don't think I have the same sort of concern that is expressed in the GAO report because I see these labs as safe labs. If you tell me that we are creating more safe infrastructure within the Nation, where research can be performed, that is something that I support.

So from that sense, no, I don't have the same concern in terms of safety when you tell me it is a safer laboratory structure.

Now, is it more safe than we need? I guess I don't see things that way.

Mr. STUPAK. Let me ask you this question. In your October 4th letter, and it was updated in July of this year for this hearing, on the second page it says, "Facilities at BSL-3 and -4 levels of containment have been constructed because the number and capacity of existing biocontainment facilities were determined to be inadequate to meet the needs for biodefense and emerging disease work."

What is the right number then? What is the right number we need of Level 3 and Level 4 labs?

Mr. ATLAS. I don't know the right number overall. Certainly there was an assessment done at the National Institutes of Health that suggested we needed something on the order of 10 to 15 regional laboratories to cover the Nation that would provide core resources for the research and potential surge capacity if we had a major outbreak.

Beyond that, a number of institutions have seen the need or desirability to have small laboratories where they could do research on agents in a safe manner.

Mr. STUPAK. My concern is—and I think Dr. Kingsbury pointed out—unlike, let's say, nuclear material, with these agents, they are always growing, expanding. And in looking at the GAO report, and even your report or your testimony, one of these errors we have is human error and it just comes inherent with the job. And with nuclear, we try to contain it, we try to have less people handling it, less chance of error.

Doesn't the same logic hold true here that the more labs you have, the more scientists and researchers you have handling this, the more likely a disaster, not just within the lab, but escaping outside the labs?

Mr. ATLAS. Not if we have the appropriate safety standards, and I think that is where we would put our emphasis on increasing the training and the resources to ensure that all of the workers in the laboratory are performing safely. I think it is important—

Mr. STUPAK. But there really is no safety. It is on-the-job training, isn't it? If I am a researcher, it is basically—I don't go to some school to learn how to do it.

Mr. ATLAS. There are safety courses that are offered.

Mr. STUPAK. But not required.

Mr. ATLAS. They are not required, and therefore you are correct that much of the training is on the job.

I think what the ASM would propose is that we, in fact, move to a system with national standards that would establish minimum guidelines for the training and that we provide the resources where we can assure this committee that anyone who is walking into a laboratory where dangerous agents are contained is adequately trained; and further, that we instill in the community a culture of responsibility with a zero tolerance for not following the procedures.

Mr. STUPAK. Sure.

Let me ask you this. If you go back to Figure No. 3 that we had up—it is in the GAO report.

It is Figure No. 2 where you went from about 400 BSL labs in 2004 to almost 1,400 in 2008. Can you find that chart?

The question I want to ask—that is 2004, and we go up to almost 1,400. Were these labs always in existence, and they never reported the select agents they are dealing with? I mean, how—

Mr. ATLAS. That is probably true. What this graph represents is the number of laboratories, I believe, registered for work with select agents. It does not necessarily represent the construction of new laboratories.

Mr. STUPAK. No; I know that. If I have a university, I may have many labs within my university structure.

If you are supposed to be registered before, is there that much more interest in these 80 select agents; or have they always been doing the work, and we never knew about it? Which once again shows no coordination or no one is in charge here.

Mr. ATLAS. In post-2002, the Nation has made a significant investment in bioterrorist-related or potentially related organisms. That has brought a great deal—as pointed out, we went from a very small budget to a \$1.7 billion sort of investment in research that was largely in the research to be conducted rather than construction of new laboratories. And that has led to a number of individuals joining in the effort to develop vaccines against Ebola and anthrax and the other diseases, to protect the Nation about what is now seen as a new threat from the misuse of biological weapons.

Mr. STUPAK. It is sort of like what Mr. Walden said: We put the money out there and suddenly everyone became BSL-3 labs that do research. They follow the money and not necessarily the threat?

Mr. WALDEN. I didn't say that.

Mr. STUPAK. I know you didn't say that. I'm summarizing.

It almost seems like if we throw money out there, suddenly we are all BSL-3 and BSL-4 labs.

Mr. ATLAS. Certainly, when I testified before the Congress in the 2002 era, there was a perception that we had a tremendous threat facing us, and we had to combat that threat by racing to develop stockpiles of vaccines and therapeutics that could be moved across the Nation.

We needed better vaccines; when we looked at some of the ones we had, we decided they weren't safe enough. Smallpox vaccine that you and I once used, we weren't going to give to our children; we wanted something safer than that.

We called upon the National Institute of Allergy and Infectious Disease to move forward with that. And, in fact, it has been a tremendous investment, that has been brought forth with congressional support and fervor, because the Congress was very worried about this disease. The community has responded by trying to perform the needed research, and that has led to an expansion.

Mr. Stupak. Mr. Walden.

Mr. WALDEN. Thank you, Mr. Chairman.

I have the dubious honor of representing the area with the largest biological attack on U.S. soil. The Bhagwan Shree Rajneesh set up encampment in southern Wasco County outside the town of Antelope. They concocted a little mixture that they then spread in the

salad bars in the city and poisoned hundreds of people. It took the Federal Government more than a year to admit that it was actually a biological attack, this Salmonella strain that they spread.

So I take this issue real seriously and realize there is a threat that if the folks in that encampment could pull it off, it could happen by a serious terrorist somewhere.

Do you think there is still a pretty good threat against the country?

Mr. ATLAS. We understand that there is a threat of criminal activity and terrorism and that we need to be vigilant.

From the community's perspective, we need to develop a true taboo against the use of biological weapons. It is a zero tolerance—nowhere, no-how, no one—which also suggests that the community must be your eyes and ears and that we need a system whereby the community can responsibly report any suspicious activities that might represent misuse, and that the community has zero tolerance for a lack of adherence to biosafety procedures.

Mr. WALDEN. So, Dr. Atlas, I think that is a very salient point.

Is there such a system in place where scientists who observe something they believe to be inappropriate can effectively communicate that to somebody who can do something about it, at least check?

Mr. ATLAS. I don't think we have an adequate coordinated system of knowing who to call, other than your local FBI office, which may not have the ability to adequately understand the information.

Certainly, the American Society for Microbiology has put forth and is putting forth every day to our members a code of ethics that calls upon them to only use the science for the betterment of humankind and to report to appropriate authorities any potential misuse of the science.

Mr. WALDEN. Dr. Kingsbury, I haven't had a chance to thoroughly go through your report, but did you look at those issues at the GAO?

Ms. KINGSBURY. The issues you are talking about, the outbreak in Oregon?

Mr. WALDEN. No. I am sorry. I moved off that into what Dr. Atlas is suggesting, that there isn't a really good reporting mechanism for scientists to feed in observances of misuse of some of these agents.

Ms. KINGSBURY. There is really not, in any of the programs that we see.

Mr. WALDEN. Did you review that in the course of your investigation, though, that issue?

Mr. SHARMA. We looked at it in context of the Department of Defense and the Department of Energy, which do have a personnel reliability program. Even in those highly intrusive programs, there is no mechanism whereby a coworker can report on his coworker.

Mr. WALDEN. Do you make recommendations in your report about such a system?

Mr. SHARMA. We made a recommendation that the Secretary of HHS and Agriculture—if they decide to implement this as a way to mitigate the inside risk, that they should consider the cost and impact of this program.

Now, let me just say within the Department of Defense we talked to a number of scientists who are working in BSL-3 and BSL-4 labs and they all unanimously said that a determined scientist, despite the intrusive nature of the PR people, as they are called, can easily take the material out. There is nothing there that can stop a determined scientist.

Mr. WALDEN. So, in other words, there is nothing we can do to stop a mad scientist from taking the pathogens out and doing whatever they want to do with them.

Ms. KINGSBURY. We already have laws against doing what some people might do to harm people.

Mr. WALDEN. Is there a way to do some presecurity clearance? I don't want to bog down our whole research system.

Ms. KINGSBURY. That is what a personnel—a more stringent personnel security program would probably require. There is a cost to that. And the whole basis for our concern about the growth in the number of laboratories is grounded in the fact that this Federal Government needs to make some hard choices about costs.

So you can't do that if you are not doing an evaluation of what things cost and what you are getting from them.

Mr. WALDEN. And what the risk is.

Ms. KINGSBURY. What the risk is, exactly right.

Mr. WALDEN. We have heard these four incidents and then the latest, which was actually the Level 2 lab. How many are there?

If you had 1,600 labs—by the way, that doesn't mean 1,600 separate buildings; is that right? As the chairman said, you have got multiple labs that are in the same center.

Ms. KINGSBURY. Can be, but nobody knows how many there are.

Mr. WALDEN. Does each agency that has labs know how many labs that they have? Does HHS know how many labs they have? Does USDA know how many labs they have?

Ms. KINGSBURY. The Federal agencies probably do, yes.

Mr. WALDEN. So somebody knows, silo by silo, agency by agency, what labs they have?

Ms. KINGSBURY. Which ones have been built by the Federal Government. But these labs are being built by the State government, they are being built in the private sector, they are being built by other than the Federal—

Mr. WALDEN. If I wanted to go out and build a lab and deal with these agents at Level 3 or 4, can I do that and not tell anybody?

Ms. KINGSBURY. You can't do it and not tell anybody if they are on the select agent list.

If they are not on the select agent list, then, yes, you can. All you have to do is get the money for it.

Mr. WALDEN. And the select agent list is the one that has the worst of the worst?

Ms. KINGSBURY. Most of the worst of the worst.

Mr. WALDEN. So that raises the issue, should other agents be put—who gathers up the select agent list?

Ms. KINGSBURY. CDC and the Department of Agriculture, separately for human pathogens and plant and animal pathogens.

Mr. WALDEN. All right. You said you thought there were too many labs at 1,600.

Ms. Kingsbury. We said we don't know whether there are too many, whether there are too few.

Mr. WALDEN. I thought you said earlier today that you thought there were too many.

Ms. KINGSBURY. I very carefully said, we need to find out how many are really out there, we need to look at the national strategy, the current consideration of the biothreat and decide whether that amount of capacity is less than we need, the same of what we need—and so we have got it right by guess—or more than what we need.

And if I were a betting person, my bet would be on more.

Mr. WALDEN. We have more labs than we need?

Ms. KINGSBURY. There is a very, very large capacity to do this kind of work, and without looking again at the threat, without looking again at how much we really need, in comparison, at least at the Federal level, to the other needs facing our Nation today, I think that is a very important analysis that should be done.

Mr. WALDEN. But you haven't done that analysis, so that would be a personal opinion?

Ms. KINGSBURY. It is our view that the analysis should be done. It would not be appropriate for GAO to do it. GAO would argue that the executive branch has the responsibility for doing that.

Mr. WALDEN. And would it be helpful—I assume when these other reports come out or are finalized by the Obama administration that you all will take a look at those before going forward.

Ms. KINGSBURY. We will be very interested in looking at them in the context of some of our other ongoing work. Or if this subcommittee would like to ask us to do that, we can do that as well.

Mr. WALDEN. Wouldn't that round out your report?

Ms. KINGSBURY. It might.

Mr. WALDEN. Thank you. My time has expired.

Mr. STUPAK. Mr. Green for questions.

Mr. GREEN. Thank you, Mr. Chairman.

You and the ranking member asked some of the best questions. And why don't we have some type of mandatory certification, whether it is filled by State government or private entity.

Dr. Atlas, is there any reason you can think of of not having some registration between these Federal agencies that oversee it?

Mr. ATLAS. I think the only issue from the community is the question of overregulation. A registration per se without requirements for performance doesn't get you very far. When you begin to impose inspections and other performance requirements, the question is, are they really helping you in terms of improving safety or security or are they paperwork.

Mr. GREEN. When you are talking about BSL-3 or BSL-4 lab regulation and inspected on an annual basis, it doesn't seem like—and some standards, I would hope, whether they are State-owned or privately owned, they would have their own safety standards, it would be common between these companies and State governments or even the Federal government.

Mr. ATLAS. For the most part, I think that is true, and certainly when we are dealing with the select agents, there are regular and sometimes multiple inspections by different agencies.

And for those labs, going back to the earlier question, the government knows exactly where they are, they know which agents are there, they know their performance requirements, and they have copies of all of their manuals of operating procedures.

It is the other naturally recurring agents, whether it be the current influenza virus that is circulating or SARS when it broke out, that that was put into a laboratory, where we are not seeing the same oversight that we see for the select agents.

Mr. GREEN. And I agree with you we don't want to stop the research because I agree with H1N1, that we couldn't be on where we are at now in the development without lots of different folks looking at it and different not only government agencies but non-government. But it just seems like between the Department of Agriculture and NIH or FDA we could have a Memorandum of Understanding so they would have the same standards and they would split up the requirements, that they would have common standards to the benefit of the labs.

Mr. ATLAS. To some extent there is certainly coordination between agriculture and HHS on many of these issues. I think what the ASM has proposed is that we have a full study of cost and benefit of moving towards standards, figure out what those standards would be and then see whether or not it is appropriate to institute an accreditation system across all the high containment labs. We are not ready to sort of jump off the bridge and say "mandate that" until we understand the cost benefits and what we would be looking at, but we think that that sort of study and examination ought to be done and done now.

We have made that recommendation before both the Executive Order Working Group and the Trans Federal Task Force. I don't know whether or not that has been accepted and whether that will move forward.

Mr. GREEN. Dr. Kingsbury, in your testimony you talked about the decreasing budgets particularly for the agencies. And yet with a proliferation of the number of BSL3 labs, the doubling the BSL4, and nearly increase of 1,400, are we not seeing these agencies respond because they don't have the funds to develop this coordinated effort?

Ms. KINGSBURY. That is part of the issue I suspect. It is also behind our concern about if you are going to have this many laboratories you really need to think ahead about how you are going to fund them from a maintenance perspective. So it is all tied up in the same thing. I think what agency officials that we met with told us about this issue of interagency coordination is no one agency currently believes that it has the authority to direct another agency to do anything about the labs it funds. And so each agency may know what they have, but nobody, and one of the reasons we directed some of our recommendations to the National Security Council and the National Intelligence Council is that it would take something at that level, at the White House level, to figure out what needs to be done to give a single entity sufficient authority to do the kinds of things we are talking about here.

Mr. GREEN. So you don't think you would need legislation, it could actually be done under current regulations?

Ms. KINGSBURY. I am not sure whether we need legislation or not frankly. I am looking forward to these reports that we have been talking about because we have some expectation that that issue maybe taken up.

Mr. GREEN. Thank you, Mr. Chairman. I am all out of time.

Mr. STUPAK. Mr. Gingrey, questions, please.

Mr. GINGREY. Mr. Chairman, thank you and, Mr. Chairman, I apologize to our witnesses, Dr. Kingsbury and Dr. Atlas, for being late. I had a press conference, but I am glad I didn't miss this. I know it is a very important hearing, Mr. Chairman, and I appreciate your holding it.

Dr. Atlas, let me ask you this. You reference the need for careful consideration of recommendations regarding new requirements for biosafety and biosecurity in laboratories in light of the very careful equilibrium that currently exists to oversee and manage research activities, and you also state that excessive policy changes could upset the delicate balance.

Dr. Atlas, what could be the impact on our scientific community if we were to pursue a policy, certain changes that did upset that delicate balance, what would be the consequences of that?

Mr. ATLAS. The consequence is that the Nation would be less safe. If we don't carry out the research that we need on infectious disease, if we have scientists abandoning work on pathogens to work in other areas, then, in fact, we are not going to have the vaccines we need. We are not going to have the therapeutic drugs, and we are going to see that we cannot contain outbreaks of disease. If you went to an extreme, you just wouldn't have a vaccine for H1N1 coming in a few weeks.

So we need to ensure that we are not having a burden on the community that causes scientists to say, I am going to go work elsewhere. That is the call for careful evaluation. It is not a call for no regulation, no oversight. Quite the opposite. It is a call for carefully considered, appropriate regulation and oversight. What one doesn't want is a knee-jerk reaction that says, oh, my God, we have to do something, let's do it today without thinking through the consequences, but once you have broad input from the community with leadership of HHS and USDA, the ASM thinks we can move ahead and continuously improving the system and that we need to have that done on a regular basis. It is not a one-time affair.

Mr. GINGREY. Dr. Atlas, thank you, and I appreciate it. I want to use my remaining time to also ask Dr. Kingsbury a very important question as well. To my knowledge, Dr. Kingsbury, two government reports were recently completed that deal with the subject of strengthening oversight of biosecurity in the United States, one completed by the Executive Working Group and, in fact, sent to the President in July, the other I understand just completed by the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, which is chaired by HHS and USDA, as you know. Given the subject matter of these yet to be released reports, I am wondering whether you think this hearing might have been better served or could be better served with these reports available for us to consider?

Ms. KINGSBURY. "Might" may be a good word, but we don't substitute our judgment for the committee chairmen about when they want to have a hearing.

Mr. GINGREY. I am not really asking you to second guess the chairman. I am just asking you your opinion in regard to these reports.

Ms. KINGSBURY. I am here to report to our work, sir, not my personal opinions.

Mr. GINGREY. Thank you very much. I will ask Dr. Atlas the same question in my remaining time.

Mr. ATLAS. I think the answer is we would be happy to meet with your staff or your committee again once those reports are issued to continue our dialogue.

Ms. KINGSBURY. We just talked recently, a few minutes ago, about the possibility of the chairman asking us to look at those reports and give him our views.

Mr. GINGREY. Certainly. Well, again let me just say I think it is important that we, Mr. Chairman, maybe I would suggest that you strongly consider having a hearing, another hearing once those reports are released in light of this hearing today, and with that, Mr. Chairman, I will yield back my time, and I thank both witnesses for their response.

Mr. STUPAK. Thanks, Mr. Gingrey. Mr. Burgess for questions, please.

Mr. BURGESS. Thank you, Mr. Chairman. I apologize for being late.

Mr. Chairman, I guess the question may have already been asked to you and we can discuss this afterwards, I don't understand why we don't have someone from the Department of Homeland Security here on the panel.

Now the Department of Homeland Security recently selected Kansas as the site for the new foot and mouth disease facility. Are level 4 labs, and I will ask this to both of our witnesses, are level 4 labs appropriate for inland research diseases such as foot and mouth disease? Wouldn't it have been better to hold the hearing before we held the vote? You don't have to answer the second part.

But is an inland facility appropriate for this monitoring and research on a very contagious illness? Because 40 percent, 45 percent of the Nation's cattle traverse the State of Kansas at some time in their lives.

Ms. KINGSBURY. It was a very large number in a recent resolution discussion in the House about that. We issued a report recently that looked at the question not asking our opinion per se about whether it is appropriate to put a facility on the mainland as opposed to an island, but rather looking at the evidence that the Department of Homeland Security put forth in making that decision and concluding, as they clearly did conclude, that there is no risk of doing foot and mouth disease research on the mainland, or essentially no risk. Then the facility that is being talked about is going to do more than foot and mouth disease, but the thing that has continued to concern us is that, A, foot and mouth disease is the most infectious virus on the planet, and, B, the research on that requires research with a lot of very large animals. And so the whole design and operational structure of that facility on the main-

land where cows are in the neighborhood has not yet been laid out in a way that we would conclude, and our experts would conclude, has demonstrated that it is safe to do foot and mouth disease research in particular in that facility.

Mr. BURGESS. When do you expect that we will have the availability of that information, or will this just be information that is gained along the way after the facility opens?

Ms. KINGSBURY. Well, the Kansas State University folks and the people who are putting that facility where they have selected to put it in the Department of Homeland Security will have to develop a design for the building, they will have to develop operating protocols, they will have to develop all of the things about how you would contain an outbreak if it did get out, and so forth. And those are the things that aren't developed yet but hopefully would be developed before any of that virus actually enters the building.

Mr. BURGESS. "Hopefully" may be a good word there as well.

Dr. Atlas, do you have anything to add to that.

Mr. ATLAS. I think that one can design and operate a BSL4 agricultural facility safely. As to the exact location, the risks, I will leave that to the DHS and the community. But clearly the Kansas community wanted that facility there for that, in that location. It was not a matter of their saying, the Federal Government is putting something where we don't want it.

It was also clear that Plum Island either needed massive renovation or the facility needed to be relocated to a location where the scientific community would join in the critical research that is needed as was pointed out not only on foot and mouth disease but on many of the other agriculturally relevant agents that would be worked on there.

So something had to be done to provide an adequate facility, and my contention is that you can build an adequate facility and locate it in an appropriate place.

Mr. BURGESS. An observation from Galveston a year ago of course Hurricane Ike ravaged the island as even today had some difficulty recovering but a brand new biodefense laboratory that at that point was not occupied but certainly came through what I would regard as a very serious stress test came through with pretty much flying colors. These labs are expensive to build. They are expensive to maintain. Is the funding level for both the building and the maintenance, are those funding levels adequate? Is that something that is receiving the appropriate amount of scrutiny and the appropriate amount of monitoring?

Ms. KINGSBURY. We didn't directly look at what the funding level would be. There is an initial funding being discussed in current appropriations discussion, but what the entire facility will end up costing I think I would argue we don't know yet.

Mr. BURGESS. What about the maintenance dollars?

Ms. KINGSBURY. We are very worried about the maintenance issue. The outbreak of foot and mouth disease in Great Britain was directly tieable to a maintenance issue in a relatively older facility. So as these facilities age, it will be very important to continue to pay attention to how much maintenance is going to be necessary and to provide the support for doing that.

Mr. BURGESS. And the fact that that has to go through our annual appropriations process makes for some additional uncertainty.

Ms. KINGSBURY. In a time of very high budget constraints.

Mr. BURGESS. Sure. And again, Mr. Chairman, I think that is something this committee needs to pay particular attention to as we go through the next several years because as we have seen from our appropriators before, and I understand the difference between an authorizer and an appropriator. If you go up to the NIH, all the buildings were named for an appropriator, there is none named for an authorizer. I do understand the difference between an authorizer and appropriator, but it is certainly our job to keep up the oversight on that and when, as correctly Dr. Kingsbury pointed out, as those budgetary dollars are squeezed, we need to make certain that areas where legitimate functions of government are not compromised.

I will yield back the balance of my time. Thank you.

Mr. STUPAK. Thank you, Mr. Burgess.

A couple of questions if I may. On page 32 you have table Number 10 which shows the 12 Federal agencies that have the BSL3 and BSL4 labs, but none of them outside their own agency know how many labs that really exist BSL3 or BSL4, correct?

Ms. KINGSBURY. That is correct.

Mr. STUPAK. You indicated in your testimony, how many of these 12 agencies, I think people would be surprised even the Department of the Interior has these labs, how many of them have personnel reliability measurements or protections of the 12 agencies? The Department of Defense you said, does anybody else?

Ms. KINGSBURY. We don't think so. Do we?

Mr. SHARMA. Department of Energy.

Mr. STUPAK. Because of nuclear labs?

Mr. SHARMA. Within the last year they have begun to implement a personnel reliability program.

Mr. STUPAK. Just last year?

Mr. SHARMA. Yes.

Mr. STUPAK. So of the 12 agencies, the only robust one would be Department of Defense, Energy is starting, so we have 10 more without any kind of measurement. OK.

Dr. Atlas, do you think academic and private institutions, do you think they should be registered labs level 4 and level 3? Do you think they should be registered with the government?

Mr. ATLAS. And I think the question is what comes with the registration? If you just mean someone should send you a note that says we have a laboratory and it doesn't bring anything else about, I don't see much value. But there is also very little burden, so you are not going to get resistance to that. I think the Census, if you are going to register the labs you ought to be asking additional questions, and that is where the devil will be in the details about what it means to register and potentially be accredited at the end of the day. So I do see a value in a system that ensures increased biosafety, that reassures this committee and the public at large that what is going on in the laboratories is being appropriately done.

Mr. STUPAK. We don't know what is going on in laboratories unless they tell us, right? And if you are one of these select agents,

you are level 3 or you are level 4, so why would there be a reluctance to register with the government the labs?

Mr. ATLAS. I think first of all for the select agents, they are registered. Everybody has to go through a clearance process. The government knows exactly where those laboratories are and everything that is going on in those laboratories. If you talk about laboratories which might be isolating a new and emerging infectious disease organism, there are questions about how quickly and who you would tell and what you are doing particularly if you in the private sector.

Mr. STUPAK. Let's say I am at a level 3 lab and I am not doing a non-select agency. Shouldn't I still register with the government? One of the questions that has been going around here this morning is how many labs do we need. If we have 2,600 level 3 labs do we need 2,600?

Mr. ATLAS. I think it would go back to the question how many of these are coming from government funding? That is how much is the government investing versus someone sees an opportunity to develop a vaccine, is willing to invest in that vaccine or therapeutic drug development of which we have a real problem getting people to invest, but if companies see that and they build a laboratory to safely perform the work to develop a new vaccine against influenza virus, they ought to be able to do that I would argue, that that is part of the entrepreneurship of this country. Now should they have to do it safely? Absolutely.

Mr. STUPAK. Sure, but one of the criticisms has been we have thrown a lot of money at this issue since 2002. If there is a lot of BSL3 labs out there that could do the work, why would the government build more BSL3 labs because we don't know if they are going to exist if we are not registered. I guess that is the part I am trying to get at.

Mr. ATLAS. I am not convinced that the government is spending a lot on building new laboratories. That was not as I saw it part of the GAO report was actually the dollars going into the labs. It was charts that showed an increase in the number of registered laboratories which may represent academic and private sector as well as the public sector.

Mr. STUPAK. And we don't know, we don't know how many there are. Even you point out in your testimony that the real expense is not just building but the maintaining because of the high level of sophistication you need to maintain a level 3 or level 4.

Mr. ATLAS. I think going back to the earlier question, that is where the ASM would also register our concern, is that we have to be vigilant about ensuring maintenance.

Mr. STUPAK. You make a number of recommendations about seven I heard here today and in the letter you sent in 2007 you had a number of them, and a lot of them probably would not require Federal rules or laws such as increased training or reporting of incidents but has ASM membership, have you taken it upon yourself to do this without government regulation or government lead here and reporting incidents and doing training, you mentioned training? Why doesn't the organization do it instead of having government mandates?

Mr. ATLAS. I think we look to the CDC and NIH to impact, take the leadership role in guiding the community in this regard. They are the primary authors along with USDA of the BMBL, and the ASM is seeking increased input into that process. But in terms of developing a responsible culture of reporting incidents, that I think needs to be within a government function.

Mr. STUPAK. I am just a little surprised. You are a scientist. I would think you would want to take the lead here in the development without government intervention or telling you how to do it.

Mr. ATLAS. Where ASM comes from would be working with the government to in fact see that a system is implemented, not trying to undermine or circumvent what properly would be a role of public health.

Mr. STUPAK. Mr. Walden.

Mr. WALDEN. Thank you, Mr. Chairman. Dr. Atlas, I sure appreciate your testimony and comments today. I especially when you said that you wouldn't necessarily want the government deciding somebody couldn't open the lab to go figure out the new and latest vaccine, I don't want a government complete takeover of this whole process. What I want is to make sure those labs are safe and secure. And I think it makes sense that we kind of know what is out there, where they are, and I appreciate your testimony too and you talk about just sending in a note saying I am a lab and I am here doesn't really accomplish the goals of safety and security. And so I appreciate what you have had to say today.

You also had some really I thought good recommendations that you shared with us and I understand also shared with the Trans-Federal Task Force and the Executive Working Group.

How were those recommendations received by those two organizations?

Mr. ATLAS. Well, we are waiting to see the report which we have not seen. They certainly had broad input not only from ASM but many other organizations shared viewpoints with both of those groups. They held public hearings. We attended those. There was broad input, and now we, like you, wait for the outcomes of that.

Mr. WALDEN. And I appreciate that and we look forward to their response. My understanding is there are 242 entities doing this type of research that are registered, which then among those entities constitute the 1,362 laboratories. So in a given university setting we can be sending Federal tax dollars in to do this research toward H1N1 vaccine or toward anthrax vaccine or whatever we have decided as priorities, that goes into those 242 entities and within wherever they do their research they are multiple lab, right?

Mr. ATLAS. Yes. And how they decide to define a lab which may be that the animal facility may be one laboratory and then the room where you actually do research outside of the animals could be a second lab. One of the issues pointed out in the GAO report is that we do not have a standard definition for what constitutes a laboratory. We do have a definition of what an entity is that has to report that they have a select agent, but it has to be a contiguous property.

Mr. WALDEN. So let me switch gears for a second. If you were the National Security Council and you were advising the President,

who would you pick as the lead agency to oversee this national lab network?

Mr. ATLAS. I would see it from a safety perspective and a public health perspective and in turn to HHS, so the ASM as consistently sought the leadership of HHS and USDA and not supported in prior testimony a DHS oversight of that because we have seen it as a broad public health issue which then does combat pathogens which potentially are misused, but we are looking at the broad emergence of infectious diseases.

Mr. STUPAK. And that would also bring in CDC and their experts into that process.

Mr. ATLAS. Certainly CDS, NIH within the HHS context is there. Now ASM did support within the oversight system the involvement of the Department of Justice and the FBI clearance process for who could enter select agent labs, it wasn't just saying put public health in charge where there are security concerns, but it did say if at the end of the day we are really concerned with protecting public health and animal health then the agencies that have experience in those areas ought to be the lead agencies.

Mr. WALDEN. Dr. Kingsbury said there are long-term maintenance issues and they are quite concerned about them.

Can you, representing those working in these labs, can you talk to us briefly, I know I have a minute left, in terms of those maintenance issues that are out there?

Mr. ATLAS. What we what we saw in the foot and mouth incident in England does raise the issue of maintenance, and certainly what we see in the academic community is you get the money up front for something and they will let the facilities run down, you never see them in any university I have been associated with, to have an adequate maintenance budget. So you keep deferring your maintenance. And in these facilities you can't afford to do that. There really does need to be adequacy and oversight of maintenance.

Mr. WALDEN. Thank you. I appreciate your testimony, both of you, today. Thank you, Mr. Chairman.

Mr. STUPAK. Mr. Gingrey, questions?

Mr. GINGREY. No, Mr. Chairman.

Mr. STUPAK. Mr. Burgess, any follow-up?

Mr. BURGESS. Yes, Mr. Chairman, if I could just ask a general question. I guess Dr. Kingsbury, but Dr. Atlas, please feel free to weigh in as well. With regards to Plum Island, do we have a ballpark estimate as to what it would cost to do those upgrades that you alluded to that might be quite costly?

Dr. KINGSBURY. First of all, we would have to recognize that Plum Island has done already spent a lot of money upgrading their current facility. And when they made an application, if you will, to be considered in this recent decision process, they identified another part of their island where they could build the kind of facility that would need to be built to do the broader range of research. That is relatively costly compared to exactly the same building on the mainland because all the materials have to be shipped onto the island. So the DHS has always made that point as one of the reasons that they don't find the Plum Island solution attractive.

But you could build almost the same kind of building there. It is just a matter of whether the additional cost is prohibitive. There

have been expressed concerns about recruiting scientists to work on an island. It is a fairly pleasant 45-minute ferry trip to get there. We have done it. It hasn't seemed to be a big deal with respect to recruiting enough scientists. That remains to be seen if we were going to try to do that. But we recognize in our report that Plum Island has already invested a great deal in upgrading their current facility and for a 50-year-old building, it is in pretty good shape.

Mr. BURGESS. So in a dollar-to-dollar comparison, Plum Island versus an inland facility the cost is about the same but there are logistic issues that would make the building easier?

Ms. KINGSBURY. It would cost a lot of money.

Mr. BURGESS. But there are also security issues that will cost money at an inland facility that are perhaps not calculated in this equation?

Ms. KINGSBURY. That is correct, and DHS did not take that cost and those designs into account in making their decision.

Mr. BURGESS. Just going back to Mr. Walden's point for a moment about the HHS ultimate being the one who has the supervisory role, does there need to be an entity that oversees HHS on that because of the security concerns that exist that Mr. Walden was bringing up? I hesitate to use the word "czar," but does there need to be a bio czar that is looking at this from more of a security standpoint?

Mr. WALDEN. No more czars.

Ms. KINGSBURY. We focused most of our work on the biosafety side of these issues, not the biosecurity side. Some of our colleagues testified this morning on a physical security examination that they did of several of the BSL4 laboratories. The problem there is what is the actual threat and what is the experience that has happened over the past years of anybody breaking into a lab, and we are not aware of any incidents. That would suggest that physical security upgrades may or may not be needed.

Mr. BURGESS. On visiting the new lab in Galveston, I was impressed with the security. Always of course you do have to ask yourself what is the threat from an internal disruption or an Earth, someone who is working in the facility that decides to take a different approach to their employment. So what do we have available to help us with that?

Ms. KINGSBURY. Well, that is what a personnel reliability program would help with, but again even in that case there has been only one alleged case of an insider doing illegal things in the way that we all worry about. And so I think to study it and to think about how you are going to invest the taxpayers' money, looking at the question from a somewhat broader context really is important, including how much of this research capacity do we need? We have built a lot of it as we have been talking about through this whole hearing there is a lot of young scientists out there getting very interested in these kinds of jobs. What happens if the funding for supporting that research dries up? Where are those scientists going to go with the skills that could make them insider threats if they were to get upset?

So those are the kinds of issues that we think need to be studied in evaluating the national need here in comparison to other national needs.

Mr. BURGESS. Thank you. Thank you, Dr. Kingsbury.

Mr. Chairman, I will yield back the balance of my time.

Mr. STUPAK. Thank you. Let me just ask a question here. Mr. Burgess and Mr. Gingrey brought up Plum Island. Both you and Dr. Sharma did the report, the GAO report on moving the foot and mouth disease off Plum Island to the mainland, right?

Ms. KINGSBURY. That is correct.

Mr. STUPAK. And if I remember correctly GAO did not conclude that the DHS study showed that foot and mouth disease can be done safely on the mainland?

Ms. KINGSBURY. That is correct. I am not going to take a case, Dr. Atlas's belief that it could be done, but the evidence that we were given in the environmental impact statements, and so forth, do not demonstrate that point.

Mr. STUPAK. Very good. Any other questions?

Mr. BURGESS. Mr. Chairman, I would just ask unanimous consent that my opening statement can be inserted in the record.

Mr. STUPAK. We have done it earlier but fine. It will be entered.

I want to thank the witnesses for their testimony.

I want to be sure that GAO continues its oversight of the domestic and international lab proliferation. Dr. Kingsbury, your team has done good work, and I would ask that the GAO review the two reports which will hopefully be out in the next few weeks. Around here they always say a few weeks always means a few months, the one being Trans-Federal Task Force for Optimizing Biosafety and Biocontainment Oversight and the Executive Order Working Group on Strengthening the Biosecurity of the United States. This subcommittee would be interested in the proposals set forth in these two reports. We are asking that GAO assess any recommendations set forth in those reports and report back to us with your assessment. Will you do that for us?

Ms. KINGSBURY. Yes, sir.

Mr. STUPAK. Thank you, and that concludes our hearing. Members will have—

Mr. WALDEN. Can I ask while we are together here just two questions? One we had asked you and Chairman Waxman about the opportunity to do an oversight hearing and invite up the auto czar from the White House. We haven't gotten a response to that letter from the end of June.

Mr. STUPAK. There have been a number of conversations going back and forth. I think the 28th is the end of the program, and speaking with some of the interest groups they said wait until we get the program done and we will see what went wrong and what went right with it. So there is still some interest in doing one. Yes.

Mr. WALDEN. And the other issue involves insurance. I know that you and Mr. Waxman sent a letter to 52 heads of insurance companies asking for their financial information. I am wondering if we are any closer in knowing when we might have a hearing involving that issue.

Mr. STUPAK. We are kicking around some calendar dates. As you know, the majority leader has just given us some dates back, if you will, some Fridays, there has been some discussions if we are here on Thursday can we do a Friday morning hearing to get some of them done. We would like to have some hearings, not just on the

insurance industry but also what is the effect on small businesses and the cost of health insurance. I look forward to spending the next month and doing some hearings on insurance. I know we all have an interest in that.

Mr. WALDEN. So within the next 30 days we may have multiple hearings on these issues?

Mr. STUPAK. We would like to assess how does the information come in and where we are going with it.

Mr. WALDEN. Will we be looking at other contributors to that cost equation other than just the executive comp on insurance companies?

Mr. STUPAK. What is the cost on small businesses, if you have some examples, we would be happy to hear it. I just received one yesterday, about 30 percent increase for a small business.

Mr. WALDEN. I was a small business owner for 22 years. I never throw the dart high enough on the budget planning board.

Mr. STUPAK. Is the 33 percent increase going into health care or is it going into other objects? That is what we want to know.

Mr. WALDEN. Thank you very much.

Mr. STUPAK. Thank you.

Mr. BURGESS. Mr. Chairman, along that same line, if I could ask you or the ranking member, has that information that was gathered from those companies, has that been, has the majority staff shared that with the minority staff?

Mr. STUPAK. Everything we have, we haven't even received everything from every request we have made but the information we received, minority class—staff—and they are class, has had access to it, and then it will continue, continue to have access to it.

OK, committee will provide and members have 10 days to submit additional questions for the record. So if there are any more questions we will get them to the appropriate party. That concludes our hearing. The meeting of the subcommittee is adjourned.

[Whereupon, at 12:30 p.m., the subcommittee was adjourned.]