THE THREAT OF BIOTERRORISM IN AMERICA: ASSESSING THE ADEQUACY OF THE FEDERAL LAW RELATING TO DANGEROUS BIOLOGICAL AGENTS

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES

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THE THREAT OF BIOTERRORISM IN AMERICA: ASSESSING THE ADEQUACY OF THE FEDERAL LAW RELATING TO DANGEROUS BIOLOGICAL AGENTS

THURSDAY, MAY 20, 1999

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

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 2322, Rayburn House Office Building, Hon. Fred Upton, (chairman), presiding.

Members present: Upton, Burr, Bilbray, Ganske, Blunt, Bryant, Bliley (ex officio), Stupak, Green, McCarthy, and DeGette.

Also present: Representative Markey.

Staff present: Tom DiLenge, majority counsel; Kevin Cook, professional staff member; Anthony Habib, legislative clerk, and Edith Holeman, minority counsel.

Mr. UPTON. The subcommittee will be in order.

We are here today to hold an oversight hearing on the adequacy of the current Federal laws and regulations relating to dangerous biological agents. The concern here is not just the potential for these agents to be used for terrorism, or other criminal purposes; but also the clear threat to public health and safety posed by inadequate controls on who can possess these deadly agents, for what purposes, and under what conditions.

In response to similar concerns, Congress passed the Anti-Terrorism Act in 1996, part of which was designed to begin imposing some controls on the transfer of certain biological agents that pose an extreme risk to human health such as anthrax, the plague, smallpox, and the ebola virus. That task fell to the Centers for Disease Control and Prevention, "CDC." These rules require that those who send or receive specified agents must first register with the CDC. CDC is supposed to take steps to assure itself that the recipients are legitimate and competent users of these deadly agents, which do have useful scientific and medical purposes beyond their potential for weaponization.

What the rules don't require, however, is equally important to understand. The rules only cover those who acquire these agents through some self-disclosed transaction with another legitimate supplier. They do not cover those who surreptitiously acquire these agents through less formal transfers, or who culture these organisms on their own from naturally occurring sources. The rules also

do not cover those who receive these agents prior to their effective date of April 15, 1997, which has provided quite a large loophole in the coverage of these controls.

So far, the number of registering entities has been limited to a small universe of well-known academic, Government, and commercial labs. This small number, about 120 facilities out of a pre-rule estimate of 200-300 registrants, suggests that there may be substantial non-compliance with the CDC rules. The current rule's focus on transfers, rather than possession, probably encourages such non-compliance; since it would be difficult for an enforcement agency to demonstrate that a possessor violated any transfer rules, unless the possessor is actually caught in the specific act of transferring or receiving.

I also have concerns about whether CDC has the necessary resources to fully ensure that even those facilities that do self-register are capable and equipped to handle these highly dangerous agents in accordance with CDC's biosafety guidelines. CDC has not conducted any preapproval inspections of registering facilities; although recently CDC has begun to conduct inspections of already-registered facilities, completing roughly a dozen such inspections, to date. In one of these cases, CDC had to order a suspension of all work on a dangerous agent, because of the facility's significant non-compliance with the prudent safety procedures.

Biosafety, while certainly important, often does not address the related issue of biosecurity, that is: are these facilities making sure that these deadly agents are secure from theft, or removal by internal and external sources? I understand that CDC is in the process of revising its biosafety guidelines to include recommended assessments of physical security, which is certainly a good start. But as our CDC witnesses today previously testified, it seems clear that many of our excellent research facilities have not given the same level of concern to security as they have to safety. While there are only a few cases they know about in which deadly agents have been taken from lab for criminal purposes, we should not take too much comfort in that fact.

As we will hear today, there are questions as to whether these labs, and other possessing entities such as hospitals, maintain sufficiently strict inventory and tracking controls over these agents. Thus, they may not even know if anything is missing. Also, there is no current requirements that facilities report the theft or loss of such agents to authorities. So, again, we don't always know what we don't know.

All of this suggests that we need to consider reasonable safety measures to further enhance our competence in the safety and security of dangerous biological agents. While we should not act in a manner that discourages legitimate and necessary scientific research into these same organisms, the public policy history in this area has been one of reaction to bad events, rather than pro-active thinking. I think that waiting for some deadly terrorist attack with these agents to occur before taking further action is not only shortsighted, but would also poorly serve the American people.

As FBI Director Freeh has stated, we are dealing with a low-probability event, but with certain extreme, catastrophic consequences. We need to be prepared for those consequences, but we

also need to do what we can and what is reasonable to prevent such a catastrophe from occurring in the first place.

As an editorial in the Washington Post stated last year, our current laws on who can gain access to anthrax, or other deadly, disease-causing microbes have, "A real gap, one that may offer unstable characters too wide a defense when caught red-handed with materials that could cause widespread damage." The Post went to say that while the legitimate uses of these materials should be respected, it is worth considering whether those who keep biological agents should be obliged to notify Federal authorities. It is also worth considering whether law enforcement should really carry the burden of proving that someone in authorized possession of biological warfare agents actually means to use them.

I hope that today we can begin such a bipartisan discussion. I welcome all of our witnessers to the hearing. I recognize, now, Mr. Stupak, from Michigan.

Mr. STUPAK. Thank you, Mr. Chairman. When the majority staff started looking into the issue of the control of special biological agents, it was billed as a review of whether the regulations controlling the transfer and shipment of these agents, and numerous other dangerous biological materials, are working. These regulations resulted from an incident in which an individual misrepresented himself and obtained botulism from a commercial laboratory. Now shippers and receivers have to register with the Centers for Disease Control and follow other procedures.

These regulations seem to be working well for the narrow purposes for which they were intended. Whether they work for the broader purpose of preventing future bioterrorism is questionable. If you believe that there are bioterrorists lurking around every corner—as many seem to—the threshold question for this committee is whether putting special biological agents in the unregistered, unarmed, untrained, unknowing, anonymous hands of the Federal Express, or UPS, or the U.S. Postal workers for shipment is adequate protection. First, do these people know what they are handling? Are they trained to handle it? Can they be trusted? These are the first questions I would ask before I talked about weaponizing private laboratories doing non-military research.

But as the testimony today will make evident, events have overtaken such illogical review. Last week, the administration issued a statement indicating that it was proposing to criminalize the unauthorized possession of these biological agents, require some background or security checks for all persons working in laboratories with these agents, and hold accountable people who knowingly disregard public health and safety when handling these agents.

The statement is vague in the extreme. But it appears to require a massive new regulatory scheme that is so controversial inside the administration that it forced major revisions in CDC's testimonies yesterday, and delayed receipt of the Justice Department, FBI, and HHS testimony until close to midnight, last night. We now seem to be discussing to what extent should we weaponize the control of these agents from the cradle to the grave, similar to our controls of nuclear materials. Who should do it? Who should pay for it? The shipping remains in the hands of commercial couriers.

The entertainment and news media have spun out numerous scenarios of terrorists who attack entire cities with biological weapons. However, it is extremely difficult to weaponize these agents effectively, even with a national effort. The real reasons that scientists work with these agents and other dangerous, infectious viruses and toxins, and send them from one lab to another, is for public health purposes: to identify and protect us from epidemics of infectious diseases that have, and still do, sweep through parts of the world.

This is a greater—and a more certain—threat than bioterrorism has ever been. Over 100,000 Americans die every year from infectious diseases, and $30 billion is spent in direct-treatment expenses. Most of the people who have died from laboratory handling of these agents and other infectious materials in the United States have been the dedicated workers in universities and private laboratories who are accidently infected while doing this vital research. On the other hand, the crimes involving these agents have not been by terrorists, but by laboratory personnel attempting to infect their personal enemies.

How real is the threat? Many experts believe that no terrorist today has the expertise to develop and effectively disseminate bioweapons. We know it is difficult enough to require concerted national efforts by trained scientists to develop the agents used, and more importantly, design effective delivery systems. As staff was told by FBI this week, Russia employed 600,000 people in its biological weapons program.

The question, then, is whether we want to treat all of the laboratories doing non-military disease research with these biological agents as weapon laboratories, with the security and control that we provide our nuclear weapons laboratories. This committee is very familiar with the security at weapons laboratories. They are federally controlled. They were constructed to be physically isolated and tightly guarded. There are many layers of physical security barriers to protect nuclear materials. Materials are heavily guarded and escorted when they leave the facilities. It can take months to arrange a shipment. Persons working with special nuclear materials and classified information have security clearances. No foreign nationals, even those with permanent residency, are allowed to work in these areas. The cumulative cost is billions of dollars.

Is this what we want for every laboratory that works with special biological agents, usually for vaccine purposes? They were not built with that tent. It would be extremely difficult to retrofit them to achieve that security level. Who will pay for it? What will the regulatory and inspection scheme be? Will the laboratories just drop the work because it has become too burdensome to do?

Some have suggested a regulatory and inspection scheme similar to that of the Nuclear Regulatory Commission for civilian nuclear power plants. Who will do it? The Centers for Disease Control, which has responsibility for implementing the shipping regulations, clearly does not want to do it.

CDC is a premiere, public-health research agency with no expertise in regulatory or law enforcement. The shipping regulations were the first this agency ever issued. It also has a strong desire to keep paramount its collaborative scientific relationship with the laboratories, as it told us in no uncertain terms, in the testimony

it submitted yesterday. Yesterday, someone removed the objections out of the CDC's testimony, which we will, hopefully, get to talk about later.

Should a new agency be set up specifically for this purpose? What role will the inspection agency play in biological weapons convention? My sense, Mr. Chairman, is that there is a rush for action many have claimed credit for. But no one has really thought through these issues. I hope we don't suddenly start down the road where we put more burdens on the CDC where they are not trained, or their mission statement is for that, and we hamper our research in biological and disease control.

With that, I yield back, Mr. Chairman.

Mr. UPTON. Thank you, Mr. Stupak. I recognize the chairman of the full committee, Mr. Bliley.

Chairman BLILEY. Thank you, Mr. Chairman. The threat of bioterrorism can be overstated, but the importance of today's hearing cannot be. This committee's oversight has revealed, as we will hear today, that improving controls on dangerous biological agents is something that this country has only just begun to take seriously.

There are a few documented instances of terrorists using biological agents. But a greater number of cases show that terrorists and other criminal elements have either acquired or tried to use these agents, or actively considered such use, as in the case of the World Trade Center bombing. Indeed, the cult that carried out the Sarin gas attack in Tokyo's subway attempted to use anthrax and other biological agents against innocent populations on nine prior occasions.

Fortunately, terrorists employing such agents have had relatively little success so far. But we should not allow that fact to lull us into a false sense of security. Both the FBI and the CIA have expressed publicly their concerns that terrorist interest in biological agents is growing in breadth and sophistication and that disturbing trend represents one of the gravest threats to our national security. In fact, the President and other senior administration officials have indicated their belief that such a terrorist attack is "highly likely" to occur in this country in the foreseeable future, and have sought more than a billion dollars to enhance our Nation's capabilities to respond to a biological or chemical attack.

We also have every reason to believe that the level of technological capability among terrorists will continue to grow, making it more likely that they will be able to effectively employ these deadly agents. Experts tell us that some terrorists have been perfecting aerosol dissemination of these agents—the most dangerous kinds—and others have been developing ever-more lethal forms of these agents to increase their deadly impact.

Thus, while our limited experiences with past acts of bio-terrorism should inform our policy judgments, they must not dictate our conclusions about what the future holds in this area. And what we don't know is often times worse than what we do know. What we do know is that the consideration of further reasonable precautions certainly is warranted.

I think it is fair to say that the minimal Federal controls in this area would come as quite a surprise to the average American citizen. As we will hear today, we permit anyone in this country—in-

cluding felons, foreign nationals from sensitive countries, and members of extremists groups—to lawfully possess even the most deadly biological agents, including anthrax, the plague, and the ebola virus. They don't even have to notify or register with any Federal agency or gain government approval to possess them. It doesn't matter if they have a legitimate scientific purpose, or even if they are credentialed scientists. It also doesn't matter if they possess these public health hazards in their garages or in their basements—they do not have to be in the confines of a legitimate or secure research laboratory. Simply put, if the FBI can't prove their intent to the agents as a weapon, current law can't touch these people, despite the real threat that their possession may pose to public health and safety.

I am pleased that this committee is following-up on the good start made by our Senate colleagues last spring, when a bipartisan chorus of Senators raised similar questions to a similar panel of witnesses. At that time, the administration pledged to move quickly to assess whether new laws were needed. Yet when this committee began our oversight in January, the administration was still missing in action—despite the efforts of some individuals to press the issue forward. And when the President announced his anti-terrorism initiatives earlier this year without any mention of our lax Federal laws on biological agents, I urged him to consider ways to keep these deadly organisms out of the wrong hands in the first place.

I wrote the Attorney General several months ago to express my concern that the administration's review of current bioterrorism laws was not receiving the priority it deserved. While I have yet to receive a response, I am pleased that today's hearing seems to have prompted the administration toward action. I understand that we will hear today some general ideas from the administration on how Congress could begin to fix this problem, and I look forward to receiving and reviewing more concrete proposals as we move beyond oversight and into the legislative arena. Thank you, Mr. Chairman.

Mr. UPTON. Thank you. I recognize Ms. McCarthy, for an opening statement.

Ms. MCCARTHY. Thank you, Mr. Chairman, for conducting this hearing and for the panelists you have brought together. I would like submit my remarks for the record and move on to the testimony.

[The prepared statement of Hon. Karen McCarthy follows:]

PREPARED STATEMENT OF HON. KAREN MCCARTHY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mr. Chairman, I would like to thank you for holding this hearing and to thank our witnesses for joining us today. We will be asking some difficult questions today. The end of this century is an exciting time, with many innovative technological advances to improve the public health and quality of life. At the same time, these same technological advances bring new threats to our safety and well being.

Many scientists and laboratories across this country are working diligently to find cures and vaccines for the diseases which threaten our health. These same labs are responsible for dealing with emergencies when a virus or other biological agent gains exposure in a community. In order to accomplish this work, biological agents must be transported quickly from lab to lab so that experts can work together to identify a sample and develop an intervention plan.

The scientific community has a history of dealing effectively and safely with these biological agents. We must therefore be careful to preserve the integrity of the scientific community. Scientists need to work with their peers and to have access to the materials and other resources to protect us from these biological agents.

In the past several years, however, new threats have emerged. In the wrong hands, biological agents can be used to infect individuals with dread diseases. As such, we must examine this issue closely now.

This balancing act will be the key to finding a sound solution to a pressing problem. I applaud the Administration's initial efforts to solve this pressing problem, and I urge the Administration to continue to pursue this issue until it is resolved. I look forward to our discussion today and to reviewing the President's plan to address this issue, and I hope that we will all work towards a consensus that allows us both to protect against terrorists and to foster scientific advancement. Thank you, Mr. Chairman.

Mr. UPTON. I appreciate that. All members of the subcommittee will have a chance, by unanimous consent, to enter their remarks into the record as part of their opening statement. Mr. Blunt.

Mr. BLUNT. Thank you, Mr. Chairman. Thank you for conducting this hearing.

I think it is clear to all of us that there has been a change in the world in the last decade. The world is, in a macrosense, a much safer place; but in a micro-sense, it is a much more dangerous place. This may be the single biggest concern in that area, that microarea, of things that can happen, as the Chairman has mentioned, and the administration says is highly to happen. I think our experience in Iraq has given us plenty of evidence of the difficulty of monitoring the potential production, outside this country, of these kinds of agents. I believe we have to be working hard now to avoid reacting at some future time with that 72-hour solution. It will be tempting for people to rush to the podium and say, "Here is what we should do to prevent these kinds of things from every happening again."

I think your hearing, and the leadership of you and the chairman of the full committee on this issue, gives us a chance to think in advance of that action occurring of what we could do to prevent it from ever happening the first time; and what we could do to react, and the best possible way, if it does happen. I think it is an area of substantial concern and very appropriate for you to have this hearing on. I am pleased that you are having it and am glad to be part of it.

Mr. UPTON. Thank you. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I will submit my full remarks. I have some concerns and look forward to the panel today. Coming from Houston, where we have a strong petrochemical industry, the right-to-know issues are very important. I know in the last year or so, the CDC has taken position, often times, that communities don't have that right to know what laboratories or companies are shipping. Also, even the shippers, maybe, don't have the proper labeling, or the proper knowledge by the UPS, FedEx, or our own Postal Service going from lab to lab. I would hope we could also explore those avenues. I look forward to the hearing.

[The prepared statement of Hon. Gene Green follows:]

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

Mr. Chairman, I would like to start by thanking you for holding this important hearing on a subject that has been the topic of much speculation and fear. I would

hope that one of the results of this hearing is a better understanding of the threats to the American people from bioterrorism, and that we can begin to separate what is truly dangerous and what is nothing more than hype.

We come together today to examine a threat, a by-product of the modern world in which we live—the threat of bioterrorism.

Since the tragedies of such attacks as the World Trade Center and the Oklahoma City bombing, the federal government and Congress have taken a much more active role in attempting to manage this threat, balancing the needs of different sides, but seeking above everything else to protect the safety of the American people.

The stated purpose of this hearing is explore whether or not existing federal law is adequately protecting our homes and families, and whether or not it should be strengthened. There also appears to be some debate over which agencies should take the lead, not only in enforcing current law, but also administering any new guidelines that might come from this Congress.

I would like to raise additional concerns. Being from Houston, with its strong petrochemical industry, the right-to-know issues has long been important to the communities that I represent.

From what I understand, the CDC has taken the position that communities do not have the right-to-know what laboratories or companies are shipping, receiving or experimenting with these potentially deadly biological agents.

That is a position I would strongly disagree with. People should be able to know if dangerous hazards are being stored near their homes and businesses.

Also, the lack of access to this information impedes the ability of state and local officials to prepare evacuation plans and to ensure the safety of citizens should a disaster strike.

Another issue of concern to me is the shipment of these biological agents. As I understand it, many of these materials are shipped from lab to lab via overnight delivery services, such as UPS or FedEx.

I am concerned about the level of notification that these shippers receive. Are they being properly notified of the contents of these packages so that they can treat them with the extreme care that such dangerous materials require?

While an accident has never happened, one can only imagine the tragedy that could result from a simple auto accident involving a delivery service van. If the agents contained in a package on that van were somehow released, hundreds of people could be exposed before anyone knew of the danger.

Finally, another issue of concern to me deals with the personnel who handle these agents in the labs. While I think we all agree that keeping people with criminal pasts away from these materials is desirable, who will be responsible for conducting these background checks?

Also, many of the people involved with these agents do not have criminal records, at least not until they misuse them. Background checks will not halt their access to dangerous agents.

Furthermore, with the many university labs that are involved in legitimate research, undergraduate and graduate students from abroad handle these materials every day. Would background checks unreasonably delay their ability to work with these materials, thus crippling vital research?

Mr. Chairman, I hope that we can get answers to some of these questions and I look forward to the testimony of the various representatives gathered before us today.

Mr. UPTON. Thank you. Mr. Bilbray.

Mr. BILBRAY. Yes, Mr. Chairman. I would like to echo the comments of my colleagues on, especially, the issue that we are addressing this item with a cool, calm approach; without feeling that we have to do anything, or everything even, if it may not work out. I think too, sadly, in the past Congress waited for a crisis to occur, and then, basically, approached the old argument of, "Just do something"—not really considering if it will actually address the problem and comprehensively solve the issue.

I appreciate the chance that we are able to discuss this in the realm of practical application, of real threat, and real answers. I have to really commend my colleagues on both sides of aisle of saying that we need to talk about what is the reality out there; and what are approaches that can actually address the issues, rather than just give a cosmetic veneer to the fact that we, somehow,

solved it for now. Then, when the problem arises, we will say, "We have to do more," even though it is not substantive.

Thank you, Mr. Chairman. I yield back my time.

Mr. UPTON. Thank you. Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. I, too, would add my appreciation for this hearing. As my colleagues from Missouri and California have alluded to in their statements, it is good that we have these hearings now, and begin to discuss this most serious issue in a calm and cool atmosphere, rather than as a reaction to a tragic situation that could occur in the future.

As we are seeing more and more today with our society, it is certainly not beyond the realm of probability that we could have an incident involving this type of terrorism. I am not talking simply about foreign terrorists, but about our own people in this country performing such an act. I think that not only do we need to begin to look forward to that situation and be prepared, but maybe even taking steps today can actually prevent such situations from occurring.

As a former United States Attorney, I am concerned with enabling our law enforcement personnel to effectively fight crime, and, in this case, terrorism. I know this committee and its staff has worked very diligently with interviewing interested people from the law enforcement community, as well as the scientific and pharmaceutical communities.

As happens with all issues up here, it seems, you have different opinions. We all recognize that there is a problem here, and that there is a potentially larger problem. How do we deal with that? How do we reach that solution when different groups from different perspectives have different solutions?

I am confident, that as we work through this process in this subcommittee and the full committee, and perhaps even at the congressional level and in legislation, a fair balance can be achieved to protect. It is almost like you are making the Second Amendment argument on guns. It is somewhat analogous to that: differentiating the people who want to lawfully use these chemicals and who have a need to do that, from those people who would misuse those chemicals to commit crimes. That is where you draw the line. This is the important issue that we, as the Congress, must decide.

I look forward to hearing the distinguished panelists today, and the testimony that will come forward in helping to assist us to do this. There are very important matters that we have to deal with here. I thank, again, the Chair for convening this hearing.

Mr. UPTON. Thank you, Mr. Bryant.

Again, I wanted to make the announcement that all members of the subcommittee will have a chance, by unanimous consent, to put their opening statement into the record.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. RICHARD BURR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Thank you, Mr. Chairman, and I will keep my statement brief. It is said that the use of a biological weapon on a civilian population by terrorists is a low probability event, but one that would have very high consequences. As such, we cannot ignore any aspect of our country's policy on combating terrorism—especially bioterrorism. If we don't get it right the first time, thousands of lives could be in jeopardy.

Preparing for a biological weapons attack is unlike preparing for any other mass-casualty event. There is the distinct possibility we would never know who carried out an attack. We would not likely see fire engines and police cars rushing to the scene, as we might in a chemical weapons attack. We would not likely see ambulances rushing to the scene to carry away the wounded. More than likely, we would witness only crowded doctors' offices and emergency rooms. Those affected by the attack might only exhibit cold- and flu-like symptoms, days after initial exposure, and get sent home for bed rest. Only on a second visit to the hospital would we begin to realize the magnitude of what had happened.

It is crucial that this Congress take steps to plug the gaps that exist in current law regarding possession and transfer of dangerous biological agents, and I look forward to hearing the testimony today. I was pleased to hear the President address this issue in announcing his omnibus crime bill, and I look forward to seeing the legislative proposals.

Having said that, Mr. Chairman, I am also hopeful this subcommittee, as well as the full committee, will continue to examine our nation's bioterrorism policies and programs. This year's budget saw a massive increase in the amount of funding requested to support those policies and programs, and we have a responsibility to examine the effectiveness of them. Thank you, Mr. Chairman.

PREPARED STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Chairman, I am pleased you have called this hearing. In the past few years, Congress and the Administration have worked closely together to develop a comprehensive national strategy to address the potential threat of bioterrorism. Federal agencies have also effectively coordinated their work with medical and scientific experts, as well as State and local law enforcement and public health authorities.

Today, however, we will focus on important but unresolved questions about how we should allocate responsibilities and which policies are most appropriate to pursue. For three years, the Centers for Disease Control and Prevention (CDC) have had the job of registering facilities transferring select biological agents, such as Ebola virus and the botulism bacterium, which potentially pose a severe public health threat.

The Administration's forthcoming proposal to expand the law to newly monitor those who possess such biological agents raises a question which I am very concerned about—who will inspect facilities or scrutinize researchers for compliance? Who will act as the enforcer?

CDC is internationally respected for its scientific and public health expertise. It is not primarily a regulatory agency. It relies upon the cooperation of our country's research community. CDC personnel do not, by and large, carry a badge to work.

I want to emphasize from the onset that—regardless of the merits of new controls on the possession of select biological agents—burdening CDC with new regulatory duties of inspection and verification seems to me to be inconsistent with CDC's mission of public health surveillance and disease prevention. I fear it would be inimical to their collaborative work with the research community here and abroad. And perhaps most importantly, it would be an ill-considered revision of CDC's existing priorities for responding to bioterrorism, which were clearly and intelligibly articulated by the CDC to Congress as recently as a month ago.

Again, I thank the Chair for calling this hearing. This Subcommittee has an important role to play in assuring that our national preparedness against the threat of bioterrorism is founded on well-reasoned policy.

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

Thank you, Mr. Chairman. When the majority staff started looking into the issue of the control of special biological agents, it was billed as a review of whether the regulations controlling the transfer and shipment of these agents and numerous other dangerous biological materials were working. These regulations resulted from an incident in which an individual misrepresented himself and obtained botulism from a commercial laboratory. Now shippers and receivers have to register with the Centers for Disease Control and follow other procedures.

These regulations seem be working well for the narrow purpose for which they were intended. Whether they work for the broader purposes of preventing future bioterrorism is questionable. If you believe that there are bioterrorists lurking around every corner—as many seem to—the threshold question for this Committee

is whether putting special biological agents in the unregistered, unarmed, untrained, unknowing, anonymous hands of Federal Express or UPS or the U.S. Post Office workers for shipment is adequate protection. First, do these people know what they are handling? Are they trained to handle it? Can they be trusted? These are the first questions I would ask before I talked about weaponizing private laboratories doing nonmilitary research.

But as the testimony today will make evident, events have overtaken such a logical review. Last week, the administration issued a statement indicating that it was proposing to criminalize the unauthorized possession of these biological agents, require some background or security check for all persons working in laboratories with these agents, and "hold accountable" persons who "knowingly disregard public health and safety" when handling these agents. The statement is vague in the extreme, but it appears to require a massive new regulatory scheme that is so controversial inside the administration that it forced major revisions in CDC's testimony yesterday and delayed receipt of the Justice, FBI and HHS testimony until after 7 p.m. last night. We now seem to be discussing to what extent we should "weaponize" the control of these agents from the cradle to the grave—similar to our controls of nuclear materials—who should do it and who should pay for it. But the shipping remains in the hands of commercial couriers.

The entertainment and news media has spun out numerous scenarios of terrorists who attack entire cities with biological weapons. However, it is extremely difficult to weaponize these agents effectively even with a national effort. The real reason scientists work with these agents and other dangerous infectious viruses and toxins and send them from one lab to another is for public health purposes: to identify and protect us from epidemics of infectious diseases that have and still do sweep through various parts of the world. This is a greater and more certain threat than bioterrorism has ever been. Over 100,000 Americans every year die from infectious diseases, and $30 billion is spent in direct treatment expenses.

Most of the people who have died from laboratories' handling of these agents and other infectious materials in the United States have been the dedicated workers in university and private laboratories who are accidentally infected while doing this vital research. On the other hand, the crimes involving these agents have not been by terrorists but by laboratory personnel attempting to infect their personal enemies.

How real is the threat? Many experts believe that no terrorist today has the expertise to develop and effectively disseminate bioweapons. We know it is difficult enough to require concerted national efforts by trained scientists to develop the agents used and more importantly design effective delivery systems. As staff was told by the Federal Bureau of Investigations this week, Russia employed 600,000 people in its biological weapons program.

The question then is whether we want to treat all of the laboratories doing nonmilitary, disease research with these biological agents as weapons laboratories with the security and control that we provide our nuclear weapons laboratories. This Committee is very familiar with the security at the weapons laboratories. They are all federally controlled. They were constructed to be physically isolated and tightly guarded. There are many layers of physical security barriers to protect nuclear materials. Materials are heavily guarded and escorted when they leave the facilities. It can take months to arrange a shipment. Persons working with special nuclear materials and classified information have security clearances. No foreign nationals, even those with permanent residency, are allowed to work in these areas. The cumulative cost is in the billions of dollars.

Is this what we want for every laboratory that works with special biological agents, usually for vaccine purposes? They were not built with that intent, and it would be extremely difficult to retrofit them to achieve that security level. And who will pay? What will the regulatory and inspection scheme be? Will the laboratories just drop the work because it is too burdensome to do?

Some have suggested a regulatory and inspection scheme similar to that of the Nuclear Regulatory Commission for civilian nuclear power plants. But who will do it? The Centers for Disease Control, which has responsibility for implementing the shipping regulations, clearly does not want to do it. It is a premier public health research agency with no expertise in regulatory or law enforcement. The shipping regulations were the first this agency has ever issued. It also has a strong desire to keep paramount its collaborative scientific relationship with the laboratories and told us so in no uncertain terms in its submitted testimony. But yesterday someone removed those objections out of CDC's testimony, which we will talk about later. Should a new agency be set up specifically for this purpose? What role will the inspection agency play in the Biological Weapons Convention?

My sense, Mr. Chairman, is that in the rush for action many have claimed credit, but no one has really thought these issues through.

Mr. UPTON. We are delighted to have this first panel with us today. They include Mr. Jim Reynolds, Chief of the Terrorism and Violent Crime Section of the Criminal Division of the Department of Justice; Mr. Robert Burnham, Chief of Domestic Terrorism Section from the National Security Division of the FBI; Dr. Bill Raub, Deputy Assistant Secretary for Science Policy from HHS, and Dr. Stephen Ostroff, Associate Director of Epidemiologic Science from the National Center for Infectious Disease of the Centers for Disease Control and Prevention.

Gentlemen, we have a longstanding rule as part of this subcommittee that it is our practice to have you testify under oath. Do any of you have an objection to that?

Under the rules of the house, each of you is entitled, if you wish, to be advised by counsel. Do any of you wish to be advised by counsel?

Good. In that case, if you will please rise and raise your right hand.

[Witnesses sworn.]

You are now under oath. Your statements are made part of the record. We would like to limit your opening testimony to 5 minutes. I have this little egg timer, here, that you will be able to watch. Mr. Reynolds, we will start with you. Thank you for being here this morning.

TESTIMONY OF JAMES S. REYNOLDS, CHIEF, TERRORISM AND VIOLENT CRIME SECTION, CRIMINAL DIVISION, DEPARTMENT OF JUSTICE; ROBERT M. BURNHAM, CHIEF, DOMESTIC TERRORISM SECTION, NATIONAL SECURITY DIVISION, FEDERAL BUREAU OF INVESTIGATION; WILLIAM F. RAUB, DEPUTY ASSISTANT SECRETARY FOR SCIENCE POLICY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEPHEN M. OSTROFF, ASSOCIATE DIRECTOR FOR EPIDEMIOLOGIC SCIENCES, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION; ACCOMPANIED BY JONATHAN RICHMOND, DIRECTOR, OFFICE OF HEALTH AND SAFETY, CENTERS FOR DISEASE CONTROL AND PREVENTION

Mr. REYNOLDS. Thank you, Mr. Chairman, and good morning. I welcome the opportunity of joining with you this morning on behalf of the Department of Justice in this important hearing.

There is a growing consensus emerging among law enforcement officials that the most serious form of terrorist threat confronting the United States relates to the potential use of a biological weapon. This view is shared by a number of academics and healthcare professionals.

One expert in the field has suggested that of all of the weapons of mass destruction, it is biological weapons that are the ones most feared. Yet, they are the ones that the United States is, in the judgment of that official, least prepared to deal with. Similarly, an HHS official has advised a congressional committee recently that a bioterrorist event is different from all other forms of terrorism in

its potential to precipitate behavioral responses such as panic, civil disorder, and pandemonium.

At the end of December of last year, the Attorney General sent to Congress a 5-year, counter-terrorism and technology and crime plan. In that plan, there was reference to the fact that intelligence information suggests growing interests by terrorists—both within the United States and abroad—to explore the potential use of biological weapons. This growing interest is reflected, also, in the increase in the number of investigations in this area that the Bureau is conducting. Mr. Burnham will address that later.

The potential for mass casualties in the event of a terrorist act committed with biological agents underscores the critical need to prevent such acts. HHS has advised a House committee that measures that will deter or prevent bioterrorism will be, far and away, the most cost-effective means to counter such threats to public health and social order. As a Government, we are spending vast sums on preparing for response to an eventual weapons of mass destruction attack. While those efforts are critically needed, the most effective way to counter the potential of bioterrorism is to prevent it.

As you know, the President announced last week that his crime bill would include provisions relating to possession of biological agents. More specifically, the lead line of items in the bill—which is undergoing finishing touches at this point, and will be transmitted to Congress soon—includes possession of biological agents where that possession is not justified for a peaceful purpose; unsafe handling of biological agents with conscious disregard for public health and safety; unregistered possession of select agents; knowingly perpetrating a hoax regarding biological agents, and possession of select agents by restricted individuals.

Under current law, we have two provisions that are key to addressing biological terrorism. We have 18 U.S.C. 175, which addresses possession of biological agents for use as a weapon; and we have 18 U.S.C. 2332(a), which addresses the use of biological weapons. However, by the time that biological material is weaponized, it may well be too late to prevent the weapons from being used and to prevent an attack of potentially catastrophic proportions.

When the Attorney General testified, approximately a year ago, before Senate committees, she mentioned the need for a focus on the potential for additional legislation in this area. She advised those committees that we recognize that any criminal statutes that might be enacted to address this concern will require a careful balance between safety and the requirements of legitimate scientific researchers, on whom we are dependent for medical and technological advances. However, when a person who lacks requisite scientific training, or who has demonstrated record of irresponsible conduct possesses highly lethal substances for which they have no legitimate use, there is a clear public safety concern.

Following that statement by the Attorney General, we have worked with HHS for the past year to try to tailor an incisive form of legislation that will balance the law enforcement need with the needs of the medical and scientific communities. We believe that balance can be achieved. Together with HHS, we look forward to

working with the Congress and the private sector scientific community to achieve successful legislation. Thank you, Mr. Chairman.

[The prepared statement of James S. Reynolds follows:]

PREPARED STATEMENT OF JAMES S. REYNOLDS, CHIEF, TERRORISM AND VIOLENT CRIME SECTION, CRIMINAL DIVISION, UNITED STATES DEPARTMENT OF JUSTICE

I am James S. Reynolds, Chief of the Terrorism and Violent Crime Section of the Criminal Division, United States Department of Justice. It is my pleasure to appear before you today to discuss the existing federal statutes relating to dangerous biological agents and toxins and possible statutory improvements designed to facilitate law enforcement in preventing potentially catastrophic acts of terrorism utilizing such agents.

A growing consensus has emerged among law enforcement officials involved with counterterrorism that the most serious form of terrorist threat confronting the United States relates to the potential use of a biological weapon. This view is shared by numerous academics and health care professionals.

Dr. D. A. Henderson, Director of the Johns Hopkins Center for Civilian Biodefense Studies, recently advised a Senate subcommittee that "of the weapons of mass destruction, the biological ones are the most greatly feared but the country is least well prepared to deal with them." Subcommittee on Labor, Health and Human Services, Education and Related Services of the Senate Committee on Appropriations, Hearing on Bioterrorism (March 16, 1999).

Similarly, Dr. Margaret A. Hamburg, Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services recently advised a House subcommittee that "a bioterrorist event is different from all other forms of terrorism in its potential to precipitate mass behavior responses such as panic, civil disorder and pandemonium." Subcommittee on Public Health of the House Committee on Health, Education, Labor and Pensions (March 25, 1999).

The Five-Year Interagency Counter-Terrorism and Technology Crime Plan which the Attorney General submitted to Congress on December 31, 1998, noted that there is increasing intelligence of interest by terrorists in the use of biological weapons both in the United States and abroad. This growing interest in biological agents and their potential for use as weapons is reflected in the significant increase in the number of cases the FBI has encountered over the past few years involving biological agents and toxins, including hoaxes and threats involving such materials.

The potential for mass casualties in the event of a terrorist act committed with biological agents underscores the critical need to prevent such attacks. As Dr. Hamberg noted in her March 25, 1999, testimony before a House subcommittee, "measures that will deter or prevent bioterrorism will be far and away the most cost effective means to counter such threats to public health and social order."

As a government, we are expending vast sums to prepare for the eventuality of an attack involving weapons of mass destruction. While those efforts are critically needed, the most effective way to counter a biological weapons attack is by preventing it. To facilitate that paramount objective, improvements to existing federal statutes are needed. That is why the President announced last week that his 21st Century Crime Bill will:

> strengthen our efforts to combat international crime and terrorism. The threat of weapons of mass destruction is real, and increasing in an age of technological change and open borders. The bill will make it a federal crime to possess the biological agents used in such weapons without a legitimate peaceful purpose.

More specifically, the crime bill, which is currently undergoing some finishing touches and will be transmitted to Congress soon, will keep dangerous biological agents and toxins out of the wrong hands by establishing criminal penalties for:

—possession of biological agents not justified by a peaceful purpose;
—unsafe handling of biological agents with conscious disregard for public health and safety;
—unregistered possession and unauthorized transfer of select agents;
—knowingly perpetrating a hoax regarding biological agents; and
—possession of select agents by restricted individuals.

Section 2332a of Title 18, U.S. Code, currently makes it a crime to use, or to threaten, attempt, or conspire to use, a weapon of mass destruction which involves a disease organism. Similarly, section 175 of Title 18, U.S. Code, makes it a crime to knowingly possess, or to threaten, attempt, or conspire to possess, any biological agent, toxin, or delivery system for use as a weapon.

While these statutes are of value to law enforcement, they require a close nexus between the possession of a biological agent and its use as a weapon. However, by

the time a biological weapon or device has been created or is under development, it may be too late to undertake action to prevent a biological weapons attack. Law enforcement needs a means to intervene earlier in the chain of events that could lead to the potentially catastrophic use of a biological weapon.

When the Attorney General testified on April 22, 1998, before the Senate Select Committee on Intelligence and the Subcommitee on Technology, Terrorism and Government Information of the Senate Judiciary Committee, she noted that mere possession of a biological agent, without proof of its intended use as a weapon, is not a crime under federal law, notwithstanding the existence of factors which raise serious questions concerning the individual's ultimate reason for possessing the agent. The Attorney General went on to state that:

> We recognize that any criminal statutes which might be enacted to address this concern will require a careful balance between public safety and the requirements of legitimate scientific researchers on whom we are dependent for medical and technological advances. However, when a person who lacks the requisite scientific training or who has a demonstrated record of irresponsible conduct possesses a highly lethal substance for which he has no legitimate use, there is a clear public safety concern.

Consistent with these statements by the Attorney General, the Department has worked closely during the past year with representatives of the Department of Health and Human Services and other components of government to develop the legislative proposals contained in the crime bill. I will review briefly some of our areas of focus. It should be stressed, however, that the objective throughout has been to facilitate the efforts of law enforcement in preventing acts of bioterrorism while respecting the needs of legitimate scientific researchers to have access to biological agents and toxins.

Last October, Congress enacted the Chemical Weapons Convention Implementation Act which prohibits the possession of toxic chemicals and their precursors, unless they are held for legitimate purposes. We believe that this approach is appropriate as well in the context of biological agents. It is important that criminal law reach possession where, under the circumstances, the type or quantity of the biological agent or toxin possessed is inconsistent with peaceful purposes.

Moreover, a statutory approach directed at unjustifiable possession should encompass both select (highly lethal) agents as well as other harmful agents. The select agents designated by the Centers for Disease Control do not encompass all lethal agents; moreover, nonlethal agents may cause widespread and serious injury. This is demonstrated by a recent case in Texas where a hospital laboratory technician spread shigella over donuts causing nineteen individuals to become ill. Similarly, in a well-known 1985 Oregon case, members of a cult spread salmonella over restaurant salad bars causing serious illness to hundreds of individuals. Neither of the agents involved is on the CDC select agent list as, we are advised, they are not highly lethal and because they are widely and routinely handled by clinical and diagnostic laboratories.

Another concern with the current regime, from a law enforcement perspective, relates to the potential that laboratories with inadequate safeguards will serve to allow terrorists and others with criminal intent to gain access to dangerous biological agents. This could be addressed through a reckless handling provision which would reach the reckless or unauthorized removal of agents from legitimate facilities and would allow law enforcement to take action against those who do so.

Such a statutory provision would focus on those who, with conscious disregard of an unreasonable risk to public health and safety, handle biological agents or toxins in a manner which grossly deviates from accepted norms. Currently, no federal criminal penalties attach to such conduct. Such a provision would reach home laboratories operating with grossly inadequate or nonexistent safeguards of the kind police discovered in the 1997 Milwaukee case involving Thomas Leahy, who operated a basement laboratory containing various biological substances, including ricin, and in the 1992 case in which one of the members of the Patriots Council manufactured ricin in his basement.

Negligence or accidental conduct would not be captured. Rather, to be covered, the conduct would have to be undertaken with conscious disregard of an unreasonable risk to public health and safety and in gross contravention of accepted norms. Such a measure would effectively complement the regulatory regime relating to safety and security.

Another focus of the crime bill relates to current law and CDC implementing regulations, which require only registration of entities that transfer or receive select agents. Entities must report (subject to verification by inspection) that they meet certain bio-safety recommended practices in order to obtain and maintain a registration. As we have seen in recent cases, there are individuals who cultivate select

agents, such as ricin, and are therefore outside the reach of the CDC regulation. The crime bill has a proposal to address this concern. The creation of a reporting requirement regarding possession of select agents would recognize that authorities should be aware of who is handling the most deadly biological agents. The Department of Justice is aware of CDC's concerns about adding this reporting function to its public health mission. The appropriate locus of this additional responsibility is under consideration within the Administration.

Existing criminal statutes relating to biological agents also fail to effectively address hoaxes, an increasingly common occurrence. Current law requires evidence of a threat to use a biological weapon or a threat to develop or possess biological agents for use as a weapon. The FBI has seen a significant increase in the number of cases involving hoaxes, many of which do not fit neatly into the current statutory scheme because they do not constitute the type of threat addressed under existing law. We have therefore included in the crime bill a false reporting provision to address the types of cases law enforcement is increasingly encountering.

In addition, as the Attorney General has previously noted, there may be specific factors that raise questions regarding the suitability of an individual to possess deadly biological agents and that should prompt special scrutiny before such possession is permitted.

These are generally the types of measures which would improve the ability of law enforcement to prevent dangerous biological substances from falling into the wrong hands and afford law enforcement an essential edge in preventing biological terrorism by allowing early intervention in the sequence of events leading to such catastrophic acts.

At the same time, as the Attorney General noted in her April 22, 1998, testimony, any legislative proposal should pursue a highly tailored approach which is minimally intrusive on the legitimate research community. As we have examined these issues, the Attorney General's admonition in this regard has served as a guiding principle. We believe that it is possible to enhance federal law in the interest of public safety while not impairing legitimate scientific endeavors, including important research on measures to counter bioterrorism. We recognize, however, that it is no simple task to craft legislation that successfully achieves both of these objectives, and that, in addition to the involvement of the Department of Health and Human Services, it is also important to involve the medical, scientific, and research communities.

Among the substances that comprise potential weapons of mass destruction, our laws leave us most vulnerable in the area of biological weapons. While bioterrorism may be low volume, it has potentially enormously high consequences. The President's proposed crime bill will prepare us not only to respond to a completed act, as is occurring under the Nunn-Lugar-Domenici Amendment to the DOD Appropriations Act for FY97, but also to employ every effort to prevent the occurrence of such an act. Law enforcement action under the measures we have been involved in developing might prove to be infrequent but, when needed, the availability of effective measures could be the difference between prevention and catastrophic consequences.

Thank you for the opportunity to appear before you today. I will now be pleased to respond to any questions that you may have.

Mr. UPTON. Thank you, Mr. Reynolds.

Mr. Burnham.

TESTIMONY OF ROBERT M. BURNHAM

Mr. BURNHAM. Good Morning, Mr. Chairman and members of the subcommittee. I would like to thank you for the opportunity to speak to you this morning.

I am here primarily to discuss the law enforcement concerns regarding existing Federal statutes, particularly as they pertain to the threatened use and possession of biological agents. We believe these existing statutes have significant gaps, which the President will propose to fill when he submits his crime bill to Congress.

Our response to these threats is constantly evolving. Over the last several years our knowledge and experience in this area has expanded tremendously. The large number of cases we have addressed over the last 3 years has highlighted certain vulnerabilities

in the current legislation, which could significantly hamper future investigations.

Weapons of mass destruction-type cases, primarily those cases dealing with the threatened use or procurement of chemical and biological materials with intent to harm, has steadily increased. I cited the numbers—I will not go through them here—in my written statement, which I have provided to the committee.

Of concern, however, is that fact that under existing Federal statutes, there is no prohibition on any individual possessing any biological agents, regardless of the lethality or whether the individual has a legitimate use for the agents. A brief discussion of several cases will serve to highlight these concerns.

The case involving Larry Wayne Harris garnered national attention, based upon his interest in biological weapons agents. In 1995, Harris ordered three vials of Yersinia pestis from a culture company. This is the causal agent for bubonic plague. After the vials were sent to Harris, he called to inquire about them from the company from which he ordered the vials, and the company became suspicious. After consulting with the Centers for Disease Control and Prevention, law enforcement was contacted and the vials were recovered from the glove compartment of Harris' vehicle.

Although Harris claimed to be a microbiologist who was writing a training manual for the Aryan Nations, he certainly did not have the facility, or the training, necessary to properly handle the material. However, he had broken no law in possessing the agent, nor in maintaining it in his glove compartment. Ultimately, he was charged under the Fraud by Wire statute for fraudulently using a laboratory registration number when ordering the agent. A misdemeanor would exist today for such conduct under CDC transfer regulations.

An individual by the name of Thomas Leahy came to the attention to the FBI in 1997, when he was arrested for shooting his stepson in the face. In basement of Leahy's home was a makeshift laboratory, where field tests indicated that he had produced ricin. Leahy was initially indicted for the possession of the biological agent ricin for use as a weapon, in violation of title 18, section 175, of the Biological Weapons and Anti-Terrorism Statute, or "BWAT." After further laboratory analysis, it was determined that he was growing botulism, and had produced nicotine sulfate which he mixed with DMSO, a solvent, and placed into a spray bottle. As the case progressed, it became apparent that proving that he intended to use the ricin as a weapon would be difficult. It was only after a superseding indictment for the weaponization of the nicotine sulfate, that Leahy agreed to plead guilty to violation of the BWAT statute. Until evidence developed regarding the weaponization of the nitrate sulfate, there was no clear basis for a successful prosecution.

In another case, in 1995, an individual by the name of Thomas Lavy entered into Canada from Alaska on his way to North Carolina. Lavy was stopped by Canadian customs officials who discovered in his vehicles guns, a significant amount of cash, and white-supremacist literature. Also discovered was a container of white powder, which Lavy readily identified as ricin. The Canadians took

the powder and released Lavy. Sometime later, the FBI was advised of the incident by the Canadian authorities.

In the interest of public safety, an investigation was initiated. Lavy was subsequently arrested, and a search of his home conducted. Lavy was in possession of a large quantity of castor beans, from which ricin is derived, but stated that he had not produced more ricin. Under law at that time, he had perpetrated no clear threat. Consequently, the mere possession of the ricin was not, in and of itself, a violation of Federal law.

Finally, in 1995, four members of the Patriots Council, an extremist group with anti-Government, anti-tax ideals that advocated the overthrow of the U.S. Government, were arrested for plotting to kill a U.S. Marshall with ricin. They had produced the ricin in a home laboratory, and planned to mix the ricin with DMSO, a solvent which they then would smear on the door handles of the Marshall's vehicle. The plan was thwarted, however, and the four men were convicted. The FBI was able to discover and prove their plan to use the ricin as a weapon. Again, had the subjects' threat to murder the Marshall with ricin not been discovered, the outcome of the case may have been different.

If possession of this biological agent without a legitimate purpose were illegal, individuals acting in instances such as this could be thwarted prior to the development of proof of the intended or actual use of the agent as a weapon.

In addition, as you are all aware, there has been a rash threats around the country involving anthrax. These threats have affected businesses, schools, hospitals, and even courthouses The cost of the responses to these threats is significant. For example, Los Angeles estimated that the cost to respond to the onslaught of threats it received around the New Year in 1999 was $1.5 million. Fortunately, the redirection of these emergency responses did not have an adverse effect on the Los Angeles' area ability to respond to these crises.

I could cite numerous other examples where time and resources were expended in response to these threats. I believe, however, the cases aptly illustrate why passage of effective legislation addressing threat and false reporting of information regarding biological agents is imperative as a deterrent to the massive outlay of money and resources needed to respond to these bogus threats. To date, most of these threats have involved specific communicated threats to use a biological agent. Fortunately, we have not as yet had a major incident involving the actual release of a biological agent, such as anthrax.

Several cases, however, have involved vague or veiled threats stating only that anthrax had been released. In addition, others have involved callers who have merely advised, in an apparent non-threatening manner, that anthrax had been released. The net effect has been highly disruptive for the responding community. Under existing legislation regarding biological weapons, there must be an actual threat to use these agents as a weapon to be considered a violation. Individuals that have caused these mass disruptions could potentially evade prosecution by claiming they had not communicated a threat to use a biological agent as a weapon. This issue has already been raised by the courts. We believe that a pro-

vision criminalizing false reporting requirement would remedy weaknesses in current law.

Again, I thank the committee for allowing me to testify today. I am available for any questions you may have.

[The prepared statement of Robert M. Burnham follows:]

PREPARED STATEMENT OF ROBERT M. BURNHAM, CHIEF, DOMESTIC TERRORISM SECTION, FEDERAL BUREAU OF INVESTIGATION

Good morning Mr. Chairman and Members of the Subcommittee, my name is Robert M. Burnham, and I am the Chief of the Domestic Terrorism Section at FBI Headquarters. My current responsibilities include national oversight and management of the Domestic Terrorism Operations, Weapons of Mass Destruction and Special Events Management Programs for the FBI. Thank you for this opportunity to speak to you this morning about the Threat of Bioterrorism in America. I am here primarily to discuss the law enforcement concerns regarding existing Federal statutes, particularly as they pertain to the threatened use and possession of biological agents. We believe that these existing statutes have significant gaps, which the President will propose to fill when he submits his Crime Bill to Congress.

Our response to these threats is constantly evolving and over the last several years our knowledge and experience in this area have expanded tremendously. The large number of cases we have addressed over the last three years has highlighted certain vulnerabilities in the current legislation which could significantly hamper future investigations.

Weapon of Mass Destruction (WMD) type cases, primarily those cases dealing with the threatened use or procurement of chemical and biological materials with intent to harm, have steadily increased. In 1996, 37 cases were opened by the FBI. In 1997, there were 74 cases opened, of which 22 were related to biological agents. By 1998, the FBI opened 181 cases, 112 of which were biological in nature. In 1999 there have been 123 WMD cases, 100 of which have been biological. In 1998 and 1999 combined, over three-quarters of the cases opened have threatened a biological release, and the biological agent most often cited in 1998 and 1999 has been anthrax.

Of concern is the fact that under existing federal statutes, there is no prohibition on any individual possessing any biological agents regardless of their lethality or whether the individual has a legitimate use for the agents. A brief discussion of several cases will serve to highlight these concerns.

The case involving Larry Wayne Harris has garnered national attention based upon his interest in biological weapons agents. In 1995, Harris ordered three vials of Yersinia pestis from a culture company. Yersinia pestis is the causal agent for bubonic plague. After the vials were sent Harris called to inquire about them and the company from which he ordered the vials became suspicious. After consulting with the Centers for Disease Control and Prevention(CDC), law enforcement was contacted and the vials were recovered from the glove compartment of Harris's vehicle. Although Harris claimed to be a microbiologist who was writing a training manual for the Aryan Nations, he certainly did not have a facility or the training necessary to properly handle the material. However, he had broken no law in possessing the agent, or in maintaining it in his glove compartment. In fact he was ultimately charged under the Fraud by Wire statute for fraudulently using a laboratory registration number when ordering the agent. A misdemeanor would exist today for such conduct under CDC transfer regulations.

An individual by the name of Thomas Leahy came to the attention of the FBI in 1997 when he was arrested for shooting his stepson in the face. In the basement of Leahy's home was a makeshift laboratory where field tests indicated that he had produced ricin. Leahy was initially indicted for possession of the biological agent ricin for use as a weapon in violation of Title 18, Section 175, the Biological Weapons Anti-Terrorism Statute (BWAT). After further laboratory analysis it was also determined that he had attempted to grow botulism and had produced nicotine sulfate which he mixed with DMSO, a solvent, and placed in a spray bottle. As the case progressed it became apparent that proving Leahy intended to use the ricin as a weapon would be difficult. It was only after a superseding indictment for the weaponization of the nicotine sulfate that Leahy agreed to plead guilty to a violation of the BWAT Statute. Until evidence developed regarding weaponization of the nitrate sulfate, there was no clear basis for successful prosecution.

In another case in 1995, an individual by the name of Thomas Lavy entered into Canada from Alaska on his way to North Carolina. Lavy was stopped by Canadian Customs officials who discovered in his vehicle several guns, $98,000.00 in cash and

white supremacist literature. Also discovered was a container of white powder which Lavy readily identified as ricin. The Canadians took the powder, and released Lavy. Sometime later, the FBI was advised of the incident by Canadian authorities and in the interest of public safety an investigation was initiated. Lavy was subsequently arrested and a search of his home conducted. Lavy was in possession of a large quantity of castor beans, from which ricin is derived, but stated that he had not produced more ricin. Lavy committed suicide while in a detention facility awaiting adjudication. He had perpetrated no clear threat; the mere possession of the ricin was not itself a violation of federal law.

In 1995, four members of the Patriots Council, an extremist group with anti-government and anti-tax ideals that advocated the overthrow of the U.S. Government, were arrested for plotting to kill a U.S. Marshal with ricin. They had produced the ricin in a home laboratory and planned to mix the ricin with DMSO, a solvent, which they would then smear on the door handles of the Marshal's vehicle. The plan was thwarted, however, and the four men were convicted. The FBI was able to discover and prove their plan to use the ricin as a weapon. Again had the subjects threat to murder the Marshal with ricin not been discovered, the outcome of the case may have been different. If possession of this biological agent without a legitimate purpose were illegal, individuals acting in instances such as this could be thwarted prior to the development of proof of the intended or actual use of the agent as a weapon. Merely possessing this biological agent, without intent to use it as a weapon, would not have constituted any crime under existing federal law.

As you are all aware, there has been a rash of threats around the country involving anthrax. These threats have affected businesses, schools, hospitals, and even court houses. The cost of the response to these threats is significant. For example, Los Angeles estimated that the cost to respond to the onslaught of threats they received around the New Year in 1999 was one and a half million dollars. Fortunately, the redirection of these emergency response assets did not have an adverse effect on the Los Angeles area's ability to respond to other crises. The arrest of two individuals involved in making threats in California was well publicized, and as a result of those arrests there was an immediate drop in the number of threats received throughout California. However the frequency of these threats still has the potential to desensitize people to the possibility of an actual attack and is of concern.

I could cite numerous other examples where time and resources were expended in response to these threats. I believe this aptly illustrates why passage of effective legislation addressing threat and false reporting of information regarding biological agents is imperative as a deterrent to the massive outlay of money and resources needed to respond to these bogus threats. To date, most of these cases have involved specific communicated threats to use a biological agent. Fortunately, we have not as yet had a major incident involving the actual release of a biological agent such as anthrax. Several cases have involved vague or veiled threats stating only that anthrax had been released. In addition, others have involved callers who have merely advised in an apparent non-threatening manner that anthrax had been released in the building. The net effect has been highly disruptive for the responding community. Under existing legislation regarding biological weapons, there must be a threat to use these agents as a weapon to be considered a violation. The individuals who have caused these mass disruptions could potentially evade prosecution by claiming they had not communicated a threat to use the biological agent as a weapon. This issue has already been raised by the courts. We believe that a provision criminalizing false reporting requirement would remedy weaknesses in current law.

As I have stated previously, the interest in biological agents and weapons continues to grow. Intelligence has indicated that terrorist groups, both foreign and domestic, have demonstrated an interest in acquiring biological materials and knowledge. In addition, literature containing recipes and modes of dissemination are available through "how to" literature and over the Internet. Whether the cases involve mere threats or actual possession of biological material, the disruption and potential damage to the public is potentially devastating. New legislation is needed to adequately support the agents and prosecutors who work to protect the public from those who would misuse biological agents as a weapon, and those who capitalize on the fear and panic that can be derived from the mere threat of a biological attack. The President's proposed Crime Bill will address these needs.

Thank you for you consideration today, and I will answer any questions you may have.

Mr. UPTON. Thank you very much.

Dr. Raub.

TESTIMONY OF WILLIAM F. RAUB

Mr. RAUB. Thank you, Mr. Chairman. My colleagues and I at the Department of Health and Human Services welcome your interest in deterring would-be terrorists from using hazardous biological materials to harm the civilian population and create widespread civil unrest.

Dr. Ostroff from the Centers for Disease Control and Prevention will describe the activities of that agency in regulating the transfer of certain hazardous organisms and toxins, otherwise known as "select agents," between facilities that require them for various research, testing, or educational purposes. I will present the HHS perspective regarding further steps that might be taken to prevent biological terrorism.

During the past year, the Department of Justice has been leading an effort within the executive branch to examine current statutes related to terrorist or other criminal use of hazardous biological materials; to identify needs for new criminal provisions that might deter such actions, and to develop legislative proposals to meet those needs. HHS staff have participated in the interdepartmental discussions.

As the President indicated in his statement last week, he plans to send a broad-ranging crime bill to the Congress in the near future. That bill is to include proposals related to hazardous biological materials and biological weapons. Specific candidate provisions now are under consideration by the President and his senior advisors.

The principal concerns within the executive branch that led to the development of those provisions are as follows: one, although transfer of select agents between facilities is regulated through Part 72 of Title 42 of the Code of Federal Regulations, the current rule does not cover possession by facilities or individuals when no transfer is involved. Two, individuals who possess hazardous biological materials of a type or in a quantity not justified by a peaceful purpose are a danger to society. Current statutes are insufficient to discourage such behavior. Three, an analogous concern about danger to society and limitations of current statutes exists with regard to individuals who handle hazardous biological materials knowingly, recklessly, and in conscious disregard of public health and safety.

Four, a hoax or other false report regarding hazardous biological materials warrants either criminal or civil penalty, commensurate with the nature of the act. Five, the question of who should have access to select agents in research in public health laboratories requires careful attention. Research with select agents is, and must continue to be, an integral part of our anti-bioterrorism strategy. The challenge is to effect appropriate protections against misuse of select agents, while ensuring the strong, sustained program of research that enhanced national security demands.

My HHS colleagues and I look forward to release of the President's legislative proposals and the ensuing discussions with the Congress, the scientific and public health communities, and the general public. We are prepared to contribute to those discussions to the best of our ability. Thank you, Mr. Chairman.

[The prepared statement of William F. Raub follows:]

PREPARED STATEMENT OF WILLIAM F. RAUB, DEPUTY ASSISTANT SECRETARY FOR SCIENCE POLICY, OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, OFFICE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Thank you, Mr. Chairman. My colleagues and I at the Department of Health and Human Services (HHS) welcome your interest in deterring would-be terrorists from using hazardous biological materials to harm the civilian population and create widespread civil unrest. Dr. Ostroff of the Centers for Disease Control and Prevention will describe the activities of that agency in regulating the transfer of certain hazardous organisms and toxins ("select agents") between facilities that require them for various research, testing, or educational purposes. I will present the HHS perspective regarding further steps that might be taken to prevent biological terrorism.

During the past year, the Department of Justice has been leading an effort within the Executive Branch to examine current statutes related to terrorist or other criminal use of hazardous biological materials; to identify needs for new criminal provisions that might deter such actions; and to develop legislative proposals to meet those needs. HHS staff have participated in the inter-Departmental discussions. As the President indicated in a statement last week, he plans to send a broad-ranging crime bill to the Congress in the near future. That bill is to include proposals related to hazardous biological materials and biological weapons. Specific candidate provisions now are under consideration by the President and his senior advisors.

The principal concerns within the Executive Branch that led to the development of those provisions are as follows:

1. Although transfer of select agents between facilities is regulated (Part 72 of Title 42 of the Code of Federal Regulations), the current rule does not cover possession by facilities or individuals when no transfer is involved.

2. Individuals who possess hazardous biological materials of a type or in a quantity not justified by a peaceful purpose are a danger to society, but current statutes are insufficient to discourage such behavior.

3. An analogous concern about danger to society and limitations of current statutes exists with regard to individuals who handle hazardous biological materials knowingly, recklessly, and in conscious disregard of public health and safety.

4. A hoax or other false report regarding hazardous biological materials warrants either criminal or civil penalty commensurate with the nature of the act.

5. The question of who should have access to select agents in research and public health laboratories requires careful attention. Research with select agents is and must continue to be an integral part of our anti-bioterrorism strategy. The challenge is to effect appropriate protections against misuse of select agents while ensuring the strong, sustained program of research that enhanced national security demands.

My HHS colleagues and I look forward to release of the President's legislative proposals and the ensuing discussions with the Congress, the scientific and public health community, and the general public. We are prepared to contribute to those discussions to the best of our ability.

Mr. UPTON. Thank you. Extra bonus for not having this thing ring [referring to timer].

Dr. Ostroff.

TESTIMONY OF STEPHEN M. OSTROFF

Mr. OSTROFF. Hopefully, I won't take more than a minute or 2 of his time. Thank you, Mr. Chairman. Let me point out that I am joined by Dr. Jonathan Richmond, who is Director of CDC's Office of Health and Safety.

We are pleased to have the opportunity to describe CDC's role in regulating the shipment of select agents which have the potential to cause substantial harm to human health. Along with the other agencies represented at this hearing, CDC and its partners in the public health community share concerns about the growing threat of the use of biologic agents by individuals and groups for illegitimate purposes.

It should be noted that, in general, the safety record of the shipment of these agents for research has been good. Each year in this country, thousands of samples of infectious agents are shipped

without incident. Shipment of these agents between medical and research facilities is essential to advance medical research and to aid in the diagnosis and treatment of infectious diseases.

Historically, CDC has been responsible for providing guidance to the research and medical community about how to safely package and ship biohazardous materials. The Antiterrorism and Effective Death Penalty Act of 1996 required the Secretary of Health and Human Services to promulgate new regulations expanding CDC's traditional role by placing additional controls on the shipment of select agents that could be used for bioterrorist purposes. In response to this mandate, and acting from our perspective as a public health agency, CDC set about the task of developing regulation which would balance the need for appropriate safeguards, without unduly restricting the legitimate scientific and research community from working with these agents.

This community encompasses governmental agencies, academic centers, and private entities, which include the pharmaceutical industry and research laboratories. In developing and implementing the regulations, CDC worked extensively with our traditional scientific and public health partners, and with non-traditional partners in the relevant law enforcement agencies. We did so, even as we recognized that such a regulatory role for CDC would adversely impact the longstanding working relationship with many of our partners.

Since implementation of the regulation through May 17 of this year, a total of 123 facilities have submitted applications and been registered with CDC to ship or receive at least one of the microbes or toxins on the select agents list. Approximately 41 percent of these facilities are academically based; 23 percent are governmental, and 36 percent are private or commercial entities. Cumulatively, these facilities have informed CDC of almost 700 transfers, all of which have occurred without incident.

CDC continues to receive approximately five new applications per month to register as a select agent shipping facility. The application process requires facilities to go through a checklist which establishes whether the facility needs to be registered, and then to submit information demonstrating that the appropriate standards are in place to ensure agents can be handled in a safe manner. This is the application packet.

The standards are based on the CDC/NIH guidelines entitled, "Biosafety In Microbiologic and Biomedical Laboratories," or the "BMBL." The third edition of the BMBL has been the version in use since the select agent regulation was developed. A new edition will be issued in the near future. This new edition contains a section on biosecurity, and explicitly informs users about the registration requirement for transfer of select agents.

During the application review process there is repeated interaction between CDC and the applicant before a permit is issued. If there are any questions about the legitimacy of information conveyed on the forms, an inspection would be performed prior to issuance of the registration. CDC policy requires that each facility be inspected, at least once, over their 3-year registration period. To date, only 15 of the 123 facilities have been inspected; but it is

worth noting that the pace of inspection has picked up significantly over the last several months.

The select agent rule is only one facet of CDC's activities to protect our Nation's health from the threat of bioterrorism. In keeping with its public health mission, CDC has now been given responsibility to work with our traditional partners to upgrade the public health infrastructure to meet this threat. In many instances, the partners that we work with are the same ones which we are required to regulate under the select agent rule.

Significant gaps remain in our ability to prevent and mitigate bioterrorist incidents. These run the gamut from an unprepared public health community, to the need for criminal sanctions for inappropriate possession of biological agents for nefarious purposes. We are in full agreement that there is a need to close these gaps as rapidly and effectively as possible. We believe it is critical that any additional safeguards be balanced against other important concerns; notably, the need to support legitimate research involving these substances.

Today there is a need to expand research involving select agents, not to constrain it. We must bring the best and brightest minds to bear on the development of better vaccines, antiviral agents, antibiotics, and other therapies for exposure to, or illness from, biological agents. To do so, we need to ensure that restrictions on possession or handling of biological agents do not have a chilling effect on the willingness of scientists and research establishments to take part.

In conclusion, a strong and flexible public health infrastructure is the best defense against any disease outbreak, whether it is natural or intentional. Addressing the threat of bioterrorism requires an unprecedented level of cooperation and partnership, bringing together agencies with diverse missions. CDC fully supports criminal sanctions designed to capture and punish those who seek to, or do, possess any of these agents for nefarious purposes. However, these sanctions must be carefully developed to ensure that they do not unduly curb the research vitally needed to best prepare our Nation to respond effectively to a bioterrorist attack.

Thank you very much for you attention. We will be happy to answer any questions that you have.

[The prepared statement of Stephen M. Ostroff follows:]

PREPARED STATEMENT OF STEPHEN M. OSTROFF, ASSOCIATE DIRECTOR FOR EPIDEMIOLOGIC SCIENCE, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION

Good morning. I am Dr. Stephen Ostroff, Associate Director for Epidemiologic Science, National Center for Infectious Diseases at the Centers for Disease Control and Prevention. I am pleased to be here to describe CDC's role in regulating the shipment of select agents that are capable of causing substantial harm to human health.

OVERVIEW OF CDC'S REGULATION

In recent years, the threat of illegitimate use of infectious agents has attracted increasing interest from the perspective of public health because certain select agents could seriously compromise human health and safety. In general, the safety and security record in the sale and transfer of these agents and substances for research has been good. Each year in the United States, thousands of samples of infectious agents are shipped without incident. Moreover, continuing the shipment of

infectious agents between medical and research facilities is necessary to further medical research and the diagnosis and treatment of infectious diseases.

Historically, CDC has had the responsibility for providing guidance to the research community for safely packaging and shipping biohazardous materials. The Antiterrorism and Effective Death Penalty Act of 1996 required the Secretary of Health and Human Services to promulgate new regulations which resulted in a significantly expanded CDC role by placing additional controls on the shipment of selected etiologic agents that could be used for bioterrorist purposes. In response to the mandate, a final regulation was published in October 1996 which became effective on April 15, 1997. CDC has worked extensively with our partners in the scientific community to develop and implement the regulation, even though we believe the regulatory framework has adversely impacted the longstanding working relationships with some of these partners.

The regulation placed additional shipping and handling requirements on facilities that transfer or receive select agents that are capable of causing substantial harm to human health. For purposes of the regulation, a select agent is defined as a microorganism (virus, bacterium, fungus, rickettsia) or toxin, including genetically modified or genetic material from those select agents, listed in the regulation.

The regulation was developed in consultation with an interdepartmental workgroup, composed of representatives from within the Department of Health and Human Services (HHS) and from other Departments and Agencies, including the Departments of Justice (DOJ) and Defense (DOD). The goal in developing the regulation was to balance the need to assure the availability of materials to the scientific and medical community for legitimate research purposes with the imperative of preventing access to these agents for other uses. This regulation is designed to ensure that these infectious agents are shipped only to institutions or individuals equipped to handle them appropriately and only to those who have legitimate reasons to use them without posing undue burdens on the legitimate user community. The regulation is based on key principles of ensuring protection of public health without encumbering and discouraging essential and legitimate scientific and medical research.

The regulation was designed to establish a system of safeguards to be followed when specific agents are transported; collect and provide information concerning the location where certain potentially hazardous agents are transferred; track the acquisition and transfer of these specific agents; and establish a process for alerting appropriate authorities if an unauthorized attempt is made to acquire these agents. The rule includes six fundamental components: (1) a comprehensive list of select agents; (2) registration of facilities transferring these agents; (3) transfer requirements; (4) verification procedures including audit, quality control, and accountability mechanisms; (5) agent disposal requirements; and (6) research and clinical exemptions.

(1) Select Agent List

The regulation includes a list of select agents subject to the rule. This list includes approximately 40 viruses, bacteria, rickettsiae, fungi, and toxins with the potential to cause substantial harm to human health. All materials that are known to contain or are reasonably suspected of containing a select agent, unless exempted as a human or veterinary clinical specimen, are subject to the regulation. The list is not meant to be static and agents can be added or deleted as appropriate.

(2) Registration of Facilities Handling Select Agents

Commercial suppliers of select agents, as well as government agencies, universities, research institutes and private companies that seek to transfer or receive these agents, are required to register with CDC and obtain a unique site registration number. The registration process requires that a responsible facility official certify that the facility and its laboratories meet the Biosafety Level 2, 3, and/or 4 standards for working with dangerous pathogens as described in the 3rd edition of the *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories* (BMBL). An updated version of the BMBL will be published soon. Additional requirements for handling toxins are found at 29 CFR 1910.1450—"Occupational Exposure to Hazardous Chemicals in Laboratories." The facility's unique registration number indicates that the facility is registered to work with select agents at a prescribed biosafety level. The number also is used to help validate all requests for transfer of dangerous human pathogens.

(3) Transfer Requirements

Prior to transferring a select agent, both the shipping and receiving parties must complete required sections of an official transfer form. This form lists the agents and requires information about the requestor as well as the transferor, including

their registration numbers, the type and amount of agent requested, and the proposed use of the agent. This form must accompany the purchase order and requests for obtaining these agents. Both the requesting and transferring facilities must retain a copy of this form. In addition, a copy is sent to CDC for documentation, and to be available to federal and authorized state and local law enforcement authorities if needed. The form also can be used for tracking purposes.

(4) Verification Procedures

To ensure management oversight of the transfer process, each facility shipping or receiving a covered select agent must designate a responsible facility official. The responsible facility official for the requesting facility must sign each request. The responsible facility official sending the agent must verify that the recipient holds a currently valid registration number, indicating that the recipient has the required biosafety level capability. If the responsible facility official is unable to validate the necessary information, the official contacts the CDC for assistance. If appropriate, law enforcement authorities would be notified. Copies of the completed form are required to be kept by both the requestor's and transferor's facility. Receipt of an agent must be acknowledged by the recipient within three working days.

CDC may inspect a facility, with or without cause, to verify registration information and to ensure that the facility meets the appropriate biosafety level requirements and complies with the regulation. Routine inspections have been completed at 10 registered facilities.

(5) Agent Disposal Requirements

Select agents must be stored securely in accordance with prudent laboratory practices, and facilities must have in place procedures for the appropriate disposal of the agents. Disposal of select agents must be at the facility, by known effective methods. CDC must be notified of the disposal or complete consumption of a select agent.

(6) Research and Clinical Exemptions

Licensed vaccines containing less pathogenic strains of some of the select viral and bacterial agents are exempted from the list of agents. Transport of clinical specimens for diagnostic and verification purposes are also exempt, as are certain toxins used for legitimate medical purposes or biomedical research. However, isolates of agents from clinical specimens must be destroyed or sent to an approved repository after diagnostic procedures have been completed. Otherwise, such isolates cannot be transferred to another site unless the receiving site is registered.

IMPLEMENTATION STATUS

As of May 17, 123 facilities have completed the application process and are now registered, including facilities at universities, government agencies, private research institutions, and commercial businesses. CDC has received transfer documents for more than 500 shipments of select agents.

CDC has developed a computerized database to track applications, registrations, and select agent transfers. A paper file is also kept on each registered facility. All files are stored in accordance with HHS data security policies. CDC has worked closely with FBI personnel to ensure that the FBI and other authorized law enforcement agencies have access to the information if necessary.

CDC'S ROLE IN ADDRESSING BIOTERRORIST THREATS

In the past year CDC has gained a greater responsibility to enhance our nation's public health capacity to respond to the threat of biological terrorism. A primary role of CDC is prompt detection of disease threats which are naturally occurring or intentional. This requires careful monitoring by effective disease surveillance systems, backed by the capacity to investigate and control outbreaks of a variety of health problems in a timely manner.

As the nation's disease prevention and control agency, it is CDC's responsibility to provide national leadership in the public health and medical communities in a concerted effort to detect, diagnose, respond to, and prevent illnesses, including those that occur as a result of a deliberate release of biological or chemical agents. This task is an integral part of CDC's overall mission to monitor the health of the U.S. population.

In 1998, CDC issued *Preventing Emerging Infectious Diseases: A Strategy for the 21st Century,* which describes CDC's plan for combating today's emerging diseases and preventing those of tomorrow. It focuses on four goals, each of which has direct relevance to preparedness for bioterrorism: disease surveillance and outbreak response; applied research to develop diagnostic tests, drugs, vaccines, and surveillance tools; infrastructure and training; and disease prevention and control. This

plan emphasizes the need to be prepared for the unexpected—whether it be a naturally occurring influenza pandemic or the deliberate release of anthrax by a terrorist. Copies of this plan have been provided to the Subcommittee.

LAW ENFORCEMENT AND CDC'S PUBLIC HEALTH MISSION

In this larger context of responding to bioterrorist threats, there are certain areas where further work is needed to develop appropriate safeguards against the threats to public health and safety presented by biological agents, toxins, and delivery systems.

CDC appreciates the need to craft appropriate restrictions and sanctions for improper possession and handling of these substances. We believe it is critical for safeguards to be carefully balanced against other important societal concerns, notably the need to support and encourage legitimate and important research involving these substances. Federal Government agencies are actively collaborating with the private sector on a wide range of research efforts addressing the bioterrorism threat and these efforts need to be expanded. We must bring the best and brightest minds to bear on the development of vaccines, antivirals, antibiotics, and other therapies for exposure or illness due to biologic agents; to develop and test protective equipment; and to develop reliable, rapid assays capable of detecting minute concentrations of biologic agents.

CONCLUSIONS

In conclusion, a strong and flexible public health infrastructure is the best defense against any disease outbreak—naturally or intentionally caused. To meet the challenges posed by infectious diseases, including outbreaks that may result from bioterrorism, we must strengthen our capacity to detect and respond to infectious diseases. CDC's on-going initiatives to strengthen disease surveillance and response at the local, State, and Federal levels can complement efforts to detect and contain diseases caused by the biological agents that might be used as weapons. Addressing the threat of bioterrorism requires an unprecedented level of cooperation and partnership, bringing together agencies with diverse missions. These include public health and law enforcement agencies, civilian and military agencies, and public and private organizations. Finally, CDC fully supports criminal sanctions designed to capture and punish those who possess these agents for nefarious purposes. These sanctions need to be carefully developed so that they do not unduly curb the research vitally needed to prepare our nation to respond effectively to a bioterrorist attack in order to minimize its consequences.

Thank you very much for your attention. I will be happy to answer any questions you may have.

Mr. UPTON. Thank you.

The normal way that we do this is that each member gets 5 minutes to get questions and answer back. If we need to go to a second round, we will. So, I get to start.

I guess my first question is, as we begin to look at the administration's proposal as part of the new crime package that we expect in the near future, are all of you, certainly, your agencies, but are you, as individuals, part of the working group to try to come with the exact language in terms of the five proposals that are out there: the possession, unsafe handling, unregulated passage or transfer, the hoax, and the restricted individual language? Are each of you part of that discussion group?

Mr. REYNOLDS. Mr. Chairman, I have been personally involved from Justice, along with some of the people that work in my section. We have interrelated since May of last year with CDC. I can give you the names of the people, if you are interested.

We have also interrelated, more recently, with the General Counsel's Office of HHS, and with the Assistant Secretary's Office, from which Bill Raub comes. We consult with the FBI, as needed, for technical guidance on the law enforcement side. So, all of the components represented here have been involved in this process.

Mr. UPTON. Mr. Burnham?

Mr. BURNHAM. Yes. A representative from my section, with the FBI, has been taking part with HHS, DOJ, and CDC in this, for some time now.

Mr. UPTON. Dr. Raub?

Mr. RAUB. Yes, Mr. Chairman. I have been part of some of the discussions with Mr. Reynolds, along with our General Counsel and other officials in the Office of the Secretary. As a scientist, I am not actually involved with drafting legislation, but have tried to contribute ideas toward the development of the goals and principles of this work.

Mr. OSTROFF. I think that my comments would be the same. Basically CDC has, indeed, been involved in the development of the language. I, specifically, have not been. Although, on some occasions I have been able to comment on some of the specific language.

Mr. UPTON. Do any of you have a sense as to when the work will be completed, and that part of the proposal will be ready to be sent up to the Hill?

Mr. REYNOLDS. Our hope is that it will be in the very near future. There has been intensive effort.

Mr. UPTON. A couple of weeks?

Mr. REYNOLDS. Since I don't control that process, I can't give you a specific timeframe. Certainly, we would be optimistic that it would be within the next couple of weeks.

Mr. UPTON. Does anyone disagree with that? One of the reasons that I thought this hearing was important is that I remember reading about the Harris case in Nevada. I was appalled, stunned, all those words that describe, certainly, my attitude about it. As I think about it, there really isn't, despite the work that is done, particularly with the CDC, a requirement out there at all that would show, if a transfer is being made, there is actually a loss with regard to shipment. Is that right? If a shipment was made from one company to an individual, is there any requirement at this point?

Mr. OSTROFF. Well, what the select rule stipulates is that both the shipper and the receiver must verify that the shipment has been sent, and that the shipment has been received. Within 72 hours of the supposed time of receipt, the recipient must notify CDC of that receipt.

Mr. UPTON. How does it usually get shipped? What type of carrier, UPS or FedEx?

Mr. OSTROFF. There can be a variety of ways that these agents would be shipped. Some of the ways that you stated would be correct. They would be shipped through the mails; through courier; or in some cases, they would be hand-carried.

Mr. UPTON. I know in reading through the testimony and looking to the next panel, there seems like there is some disagreement with regard to the restricted individual: whether the individual should actually file some type of statement with regard whether they have been convicted of a felony, similar to what we have for guns, the Brady Bill. Are we close to resolving this between HHS, CDC and law enforcement?

Mr. REYNOLDS. It is certainly our hope that it is near to resolution.

Mr. UPTON. Can you just comment, at all, and tell me where we are with regard to that regulation?

Mr. REYNOLDS. I think all the issues have been identified. There has been a productive discussion. HHS has expressed its views. The Justice Department and FBI have expressed their views. The matter is ready for decision. We would anticipate that it will be resolved very quickly.

Mr. UPTON. Okay. Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman. There has been a lot focus, thus far, on law enforcement and crimes and things like that. I am sure that I don't have to remind anyone on the committee that as the Oversight and Investigation for Commerce Committee, we do not have jurisdiction over that aspect. That property lies with the Judiciary Committee.

I am happy to go there, because my background is in law enforcement. I am very comfortable discussing law enforcement issues on what should and can be done. I think we have to watch our questions and discussion about where we do have jurisdiction, which are laboratories—Federal control over those labs.

While there has been a lot of testimony about crimes and crime packages, we really don't have jurisdiction. So, I am going to try to limit my questions to where we do have some jurisdiction. I would like to go back to Dr. Ostroff on the regulations—the shipping. You mentioned UPS and Federal Express. Any courier can actually ship that stuff, for you, right?

Mr. OSTROFF. That is correct.

Mr. STUPAK. So are there any requirements, or guardians of these biological agents when they leave the laboratory and give it to UPS? Do you know who they are? Are they trained to handle it? Are they armed? How do you do it; just bring it down to your friendly shipper and let her go?

Mr. OSTROFF. Most of the requirements revolve around how the materials are packaged. That has traditionally been what CDC's involvement has been: to ensure that they are properly packaged so that they don't break; they don't open during shipment, et cetera. It has not been in the area of the security aspects of the package itself.

Mr. STUPAK. You package it up really well. UPS comes to the door to take your package, right? Do you check to see if he is UPS? Do you check to see if he has security clearance? Do you check to make sure he knows where it is going? Do you do any of that?

Mr. OSTROFF. Well, I personally can't speak to that.

Mr. STUPAK. Well I don't think that you personally do it, but someone in your agency?

Mr. OSTROFF. Jonathan, would you care to specifically answer that—if I could have Dr. Richmond to, since this is his particular area?

Mr. STUPAK. Sure.

Mr. RICHMOND. The process at CDC is quite well controlled.

Mr. STUPAK. At CDC. I agree. I am going to leave CDC. I am going through the door. What controls it after it leaves my door?

Mr. RICHMOND. None, that I am aware of.

Mr. STUPAK. The only other control on your pick-up is when it lands at University of Michigan laboratory. There is a check-in pro-

cedure there. So what happens between CDC and University Michigan? We have no controls, no rules, no regulations, or know who is even doing it. Is that correct?

Mr. RICHMOND. That is correct.

Mr. STUPAK. Shouldn't we do something about that aspect, if we are concerned about it going in the wrong hands?

Mr. RICHMOND. It is an area where I don't have expertise.

Mr. STUPAK. Mr. Reynolds, is there something we should do about that: the shippers and handlers after they leave the CDC and before it gets to the lab on the other end?

Mr. REYNOLDS. Well, certainly we are concerned that it be a secure form of shipment. We are not particularly expert on the CDC regs. We do ship classified information by couriers, consistent with rules that exist within the executive branch. I think, certainly, it merits an examination of what the rules are concerning the forms of shipment.

Mr. STUPAK. But once it leaves CDC, it is not secure anymore, is it?

Mr. REYNOLDS. Once it leaves the shipping entity, whatever the shipping entity is, it is proceeding by the packaging of whatever the authorized courier is. You are correct in the sense that it is not secure in the sense of an armed guard.

Mr. STUPAK. Yes, well, not even armed guards. These are just people that are handling it. It may go from—CDC is in Atlanta?

Mr. OSTROFF. Right.

Mr. STUPAK. It goes from Atlanta. It goes up to Nashville; switches planes—show the commercial—going overnight; people throwing it up onto the railing. It ends up at University of Michigan, 48 hours later. What happens in between, there is no security, right?

Mr. REYNOLDS. From law enforcement we are concerned that there not be an opportunity for the loss of the material, or for criminals to obtain the material.

Mr. STUPAK. We are concerned, but there is nothing there to alleviate those concerns, currently.

Mr. REYNOLDS. There is the CDC regulation process and the CDC oversight process. That is what is currently there.

Mr. STUPAK. But it doesn't cover that, does it? Once it leaves CDC, there is no rules or regulations. Correct?

Mr. REYNOLDS. There is, in place, whatever CDC has put in place. That is all I can say.

Mr. STUPAK. Nothing?

Mr. OSTROFF. That is correct. As I mentioned, our regulations involve how it is packaged.

Mr. STUPAK. And after it is packaged, we are out of it.

Mr. OSTROFF. Right.

Mr. STUPAK. Thanks.

Mr. UPTON. Mr. Bilbray.

Mr. BILBRAY. Let us follow-up on that. The package, itself, is prepared for shipment. What is the labeling on the outside of the package? What does the courier see?

Mr. OSTROFF. There are biohazard stickers. It indicates "infectious agent."

Mr. BILBRAY. So, the defense of stealth is not there, basically. Of course, it does not indicate what it is.

Mr. OSTROFF. Correct.

Mr. BILBRAY. The biohazard sticker could be anything from the shipment of material that has been taken from a cancerous liver to a biochemical agent? I am just saying that from my environmental health background, I know that even the waste from surgical operations are tagged as biowaste. The indicator is basically consistent?

Mr. OSTROFF. Yes.

Mr. BILBRAY. Okay. I think that biggest issue here that the gentleman from Michigan was looking at is that the security of stealth of somebody trying to intercept a shipment. First of all, they need to know what is in the shipment. There is so much of it going on, it could be anything. I mean, it could be somebody's kidney that is being sent out for laboratory testing. But the fact is, the lack of knowledge of what is in that shipment is probably the best defense based on a stealth approach.

The danger is not so much physically securing the object, as much as securing the information on what that object is. What is the security of the information that is being transmitted between agencies and between groups? In other words, the information being sent to the University of Michigan is that on this day we are going to send you this product and it has anthrax in it. The question is: what kind of security do we have there? I hope that gentleman from Michigan understands where I see it coming.

Mr. OSTROFF. Well, again, the requirements stipulate that the shipper and the recipient have to communicate, ahead of time. Obviously, they would not be shipping it to the recipient unless there has been some sort of communication. There is a transfer document that gets received by the recipient indicating what will be shipped, and what they will be receiving. Again, the recipient must verify the validity of that information, as well as the content of the package. They also are, certainly, informed of who needs to be informed if there are any problems.

Mr. BILBRAY. Okay. I would say that I would see more threat—more security problems—from the information, than even the physical package, itself. There are so many packages flying around that if there isn't that information, it really is a needle in a haystack for anyone trying to intercept something that can be used. I would say, strongly, the information side may be the side that does not seem like a big deal up front, but may be considered that.

In the other issue, you were talking about an individual who acquired the substance that was in the glove compartment of his car. How did he gain access to that again? Can you review that? Did he physically go in; sign for it, or did he have it shipped to him?

Mr. OSTROFF. It was shipped to him.

Mr. BILBRAY. Shipped to him. What documentation did he have to show? Did he have to show that he was over 21, or 18?

Mr. BURNHAM. I believe I testified regarding this. I think he falsified whatever CDC has for a number. He had a false registration number. He sent it in and received it that way. That is why he was ultimately indicated under the Fraud by Wire statute.

Mr. BILBRAY. I am just questioning. One of the concerns we talk about is, you know, can my 14-year-old son get a weapon that might be able to be used? Even if it was a black-powder, antique pistol that fires one shot, there are certain procedures he has to go through.

Mr. OSTROFF. Congressman, if I could point out that that incident happened before the select agent rule came into force. That was actually the genesis of why the select agent requirements were developed. So, he didn't have a CDC registration number to be registered as a select agent, because the rule was not in place.

Mr. BILBRAY. Now we have that firewall?

Mr. OSTROFF. Correct.

Mr. BILBRAY. Thank you, very much. I yield back.

Mr. UPTON. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I want to follow-up both my colleagues, Mr. Bilbray and Mr. Stupak. Dr. Ostroff, CDC has 11 centers around the country. How many regulations has CDC promulgated, to date, based on the shipping biomedical waste?

Mr. OSTROFF. Well, not waste specifically, but biological agents. This is the only regulation.

Mr. GREEN. Okay, so one. With only one regulation, do you consider yourselves a law enforcement or inspection agency, like the Food and Drug Administration?

Mr. OSTROFF. No, sir.

Mr. GREEN. I was looking at testimony that was submitted earlier, and the testimony that we received today. The difference in your testimony was that on page nine of the old testimony, "CDC is not a law enforcement agency and such responsibilities are considered beyond CDC's expertise." It goes on down. The ending says, "Nevertheless, CDC cannot function effectively. Our developing a primary law enforcement regulatory role is beyond, and in many respects, contrary to its mission, staffing and expertise."

Why was this taken out in the last couple of days?

Mr. RAUB. May I comment?

Mr. GREEN. Mr. Raub?

Mr. RAUB. My understanding is that, when the draft statements were reviewed centrally within the administration by the Office of Management and Budget, there was a concern that statement might be interpreted that the crime bill—to which both Mr. Reynolds and I have alluded—was, in fact, completed. To the best of my understanding, it is not. I think the intent was, simply, not to suggest or imply that work was complete and, therefore, had certain provisions, including ones that might materially change the role of the CDC.

Mr. GREEN. Okay. I look forward to seeing the bill. I would hope that the bill would not make the CDC the enforcement mechanism. Again, I think it is much past your role and scope. Maybe that is one of the suggestions that the bill may do. Again, since we haven't seen, and I know you are drafting it, that is not necessarily what this is. It doesn't relate to the bill. It talks about the concern the CDC has from the earlier responsibilities. CDC doesn't have any considerable law enforcement skills, I assume. I have never thought of CDC as a law enforcement-type agency.

Mr. OSTROFF. Yes, nor have I.

Mr. GREEN. And I imagine no one else there. Hopefully, the bill will not make you a law enforcement agency. Obviously, I have confidence in the folks at the other end of the table that can help you.

Dr. Ostroff, do you still have concerns about the law enforcement duties that you may have under current provisions?

Mr. OSTROFF. Well, I think what we can say is that there can be an inherent conflict between our primary public health mission, which is a very collaborative working relationship with a variety of partners—whether they are State and local health departments; whether they are academic facilities; whether they are private entities—and the need to regulate under this particular provision. So there is the potential inherent conflict.

Mr. GREEN. And I can understand. I think all of us do. To follow-up my colleagues, for example, if a local lab has a biohazard label, and FedEx, UPS or the Postal Service picks it up, do they assume liability for that? I don't know about the Postal Service, but FedEx and UPS. If one of their vehicles has an accident, who has the liability for that at that time?

Mr. OSTROFF. I can't answer that particular question. We could certainly look into it.

Mr. GREEN. Again, I think all of us are concerned, like each of you at the table are, on the effectiveness of both current law and also, hopefully, the bill that is going to be sent up as soon as possible, because of the concern that not only we have. Again, I appreciate the chance for you testify today and raise a lot more questions. Thank you, Mr. Chairman.

Mr. UPTON. Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman. Let me ask you, is the CDC comfortable with the role that they are being slotted into?

Mr. OSTROFF. Well that is, obviously, not an easy question to answer. I think that what I can say is that we have attempted, to the best of our abilities, to implement the regulations and carry them forth. I think it has been obvious in some of the statements that it has not been easy for us to do this, because it is a relatively nontraditional role for us to take.

Mr. BURR. Do you have sufficient resources to do it?

Mr. OSTROFF. We are in the process of expanding, for instance, the number of inspectors that we have, so that we can increase the pace of inspection. As I mentioned, we do have a commitment to inspect all registered facilities at least once during the 3-year time period. We got a fairly slow start in doing that.

Mr. BURR. What specific budget requests have you made to be able to carry that out, if any?

Mr. OSTROFF. There was a budget request in this fiscal year for $1 million to carry out this program.

Mr. BURR. So $1 million will assure us that all of the functions of CDC, relative to this issue, will be carried out.

Mr. OSTROFF. With the regulation, as it is currently written. That is correct.

Mr. BURR. Do you think that is a sufficient resource, from a monetary standpoint?

Mr. OSTROFF. Again, we have been able to expand our activities, now that there are resources, to conduct this program. I will say

that if our responsibilities are expanded, we will need additional resources.

Mr. BURR. Mr. Burnham, does a million dollars give you a comfort level that you can reassure this committee that they can carry out their role? You, as law enforcement, does a million dollars give you a comfort level?

Mr. BURNHAM. Again, that is kind of out of my purview. I do have an interest in control, because from a law enforcement standpoint we are interested in who ultimately ends up with it. As I said in my testimony, under law, absent an indication it is to be used as a weapon—or intent to use it as a weapon—there is no violation. I don't think I can comment other than that.

Mr. BURR. Does the FBI believe that the current CDC regulations governing the transfer of biological weapons are adequate to prevent would-be terrorists or criminals from acquiring such materials?

Mr. BURNHAM. Again, I am not an expert on CDC controls. While we do have controls, we don't have the select agents.

Mr. BURR. But you are the law enforcement arm that will look at this coordinated effort. I guess what I am asking is that CDC is part of this effort to give us the assurance—or to give the FBI the assurance—that would-be terrorists won't have access.

Mr. BURNHAM. Well, we would work with CDC. We have been working with CDC and HHS. We will continue to.

Mr. BURR. Is the FBI currently involved in the process of approving the registration of facilities and transfers of biological agents?

Mr. BURNHAM. No.

Mr. OSTROFF. No.

Mr. BURR. Does the CDC and law enforcement communicate? Do you sign off on the license approvals?

Mr. BURNHAM. No.

Mr. BURR. Would you like to?

Mr. BURNHAM. Again, that is kind out of the purview of what I am here testifying about. Again, we are talking with CDC, HHS and the Department of Justice on this.

Mr. BURR. Let me ask it this way: does the CDC contact the FBI and say, "We have an application for a license, could you do a background check on this individual?" Do we do that?

Mr. BURNHAM. No.

Mr. BURR. Does the FBI believe the current CDC regulations are guidelines regarding facility security; that it is adequate to ensure the safety and security of select biological agents that are there? In other words, have you done a security review of all these facilities out there, and come to the conclusion that their security there is good enough to assure us that those agents stay there?

Mr. BURNHAM. No, we haven't.

Mr. BURR. Have we ever had, Mr. Reynolds, any biologics that might be missing in the system?

Mr. REYNOLDS. We have had some potential indication of items that may be missing. But there has never been a question as to whether we have an inventory control problem, or materials that actually walked out of the facility.

Mr. BURR. Is there any requirement that the laboratories, or facilities, report on inventory shortages?

Mr. REYNOLDS. The requirements that exist right now are the ones that are contained in the CDC regulations. That, to my knowledge, is all that exists.

Mr. BURR. I would ask unanimous consent to continue on and go in reverse order.

Mr. UPTON. Dr. Ganske.

Mr. BURR. Oh, I am sorry. I didn't see Dr. Ganske come in. I would ask unanimous consent for 1 additional minute just to finish this question.

Mr. UPTON. Go ahead.

Mr. BURR. Is there a requirement in this proposal that CDC notify the FBI, if they discover some shortage, loss, or possible theft of such an agent?

Mr. REYNOLDS. Well let me say this, I don't think that we view that any Government agency would have to have a statutory requirement to do that. Our anticipation, right now, is that CDC would do that. We have been contacted, on occasion, by CDC expressing concern in something that they have observed.

Mr. BURR. I look forward to the second round. Thank you.

Mr. UPTON. Mr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman. Mr. Burnham, in your testimony you mentioned ricin several times. This is a question for you, or anyone else on the panel. Can you tell me what it is, chemically? How is it produced? What does it do physiologically?

Mr. BURNHAM. Well it is a biological agent. It is a produced from the castor bean. As to the actual effects, I know what the ultimate effect is: death. As to the sickness you may go through, or the symptoms, I am not sure.

Mr. GANSKE. Maybe, Dr. Ostroff, can you expand on that?

Mr. OSTROFF. I am not quite as familiar with the toxins as I am with the biological agents, because I work in the National Center for Infectious Diseases. Ricin very rapidly induces paralysis and death.

Mr. GANSKE. Has it been proven that it can be absorbed using DMSO?

Mr. BURNHAM. No.

Mr. GANSKE. Okay. Dr. Ostroff, in your testimony on page two you say, "This regulation is designed to ensure that these infectious agents are shipped only to institutions or individuals equipped to handle them appropriately; and only to those who have legitimate reasons to use without posing undue burden on the legitimate user community."

Can you take us on a step-by-step description of what happens when a lab gets a request to send out some of these infectious agents?

Mr. OSTROFF. Well, as far as a request, or are you talking about the application process to become registered in order to be able to ship?

Mr. GANSKE. Well, we may hit the latter, in a minute. Let us say that a lab that has an infectious agent gets a request to send it out somewhere, to somebody. What happens?

Mr. OSTROFF. Right. Again it depends if they are already registered under the select agent rule, or if they are new. What they would have to do is they would have to determine whether or not

the requestor also is registered under the select agent rule, because our requirements are that they can only ship one of these select agents to someone who is also registered.

The request has to be submitted——

Mr. GANSKE. How do you know that they do that?

Mr. OSTROFF. Excuse me?

Mr. GANSKE. How do you know?

Mr. OSTROFF. What they have to do is they have to notify us.

Mr. GANSKE. So, when they get a request to send an agent out, then they are supposed to let you know?

Mr. OSTROFF. Only if they intend to actually honor that request. If they choose not to honor that request, then there is no need for them to notify us—unless they have some particular question about the validity of the request. But that is not a requirement.

Mr. GANSKE. They have a form they fill out and send to you? They give you a phone call?

Mr. OSTROFF. They send us a form.

Mr. GANSKE. Okay. Can they send it out before they hear back from you?

Mr. OSTROFF. No.

Mr. GANSKE. What do you do when you get that request?

Mr. OSTROFF. We verify the accuracy of the information that is on the form. Again, the requestor cannot be the only individual requestor. Each facility has to have what is known as a "responsible facility official," who has to double co-sign the form itself. The responsible facility official cannot be somebody directly related to that particular work. Usually it is the biosafety officer for the institution. So there are a number of redundant steps that would assure that the potential recipient has a legitimate reason to make that request.

Mr. GANSKE. So only authorized recipients can get the material?

Mr. OSTROFF. Yes.

Mr. GANSKE. So both the sender and the receiver have to get an authorization?

Mr. OSTROFF. Correct. They have to be registered.

Mr. GANSKE. But the problem is that a bunch are not registered.

Mr. OSTROFF. Well, again, it has always been difficult for us to determine the total universe of facilities that ultimately would be registered because they wish to ship or receive one of these agents. What I can say is we are unaware of any shipments that have occurred to, or from, non-registered facilities.

Mr. MARKEY. Mr. Chairman?

Mr. UPTON. The gentleman from Massachusetts.

Mr. MARKEY. Mr. Chairman, I am not a member of the subcommittee.

Mr. UPTON. Some of us breathe in relief of that.

Mr. MARKEY. I request, at your sufferance, that I be allowed for a brief period of time.

Mr. UPTON. Knowing of your interest—particularly you authorship of a number of regulations in laws written with regard to shipping—I certainly don't have any objection. We will yield you 5 minutes.

Mr. MARKEY. Thank you, Mr. Chairman, very much. I appreciate your indulgence. I authored, with John Kasich and Joe Kennedy on

the House side, and Senator Hatch on the Senate side, the Infectious Agents Control Act of 1996.

Mr. UPTON. Excuse me. I will restart you time. A vote has started. Mr. Burr has gone over to vote and he will come back. We will continue with this panel. If members that would like to go vote and come back to do a second round, that will be terrific. We will start your time over, Mr. Markey.

Mr. MARKEY. That became part of the Antiterrorism and Effective Death Penalty Control Act of 1996.

I wrote to CDC, early last year, to get a status on the implementation of the regulations that have been put on the books. At a briefing, I received in response to that letter—and was shocked to find out that—as of April 1998, that only 62 facilities had registered, and only 142 transfer shipments had been recorded. So based on the testimony, it is clear that some improvement has been made—not much—but some. It is now 123 facilities, and over 600 transfers.

Dr. Ostroff, why has it been so difficult to get greater compliance?

Mr. OSTROFF. Well, again, Congressman, we don't have any information suggesting that there has not been compliance. The likelihood is that in some instances, for a variety of reasons, some facilities have chosen not to go the route of registration.

Mr. MARKEY. How many facilities do you believe are out there?

Mr. OSTROFF. Well, again, that has been a very difficult number to come up with. The estimates have always been that as far shipment and receipt are concerned, the number is probably somewhere in the range of 250-300.

Mr. MARKEY. You have now registered 123?

Mr. OSTROFF. Correct. Again, there are about five new facilities, per month, that are now coming on to register.

Mr. MARKEY. What grade would you give the industry in terms of their cooperation on this matter? It has been years, now. You know where they are. You know how many facilities there are.

Mr. OSTROFF. I think that there has been a great deal of cooperation.

Mr. MARKEY. So you would give them an "A" for their cooperation?

Mr. OSTROFF. "A-minus."

Mr. MARKEY. An "A-minus," interesting. I wouldn't give them an "A-minus," at all, sir.

Following-up on Mr. Green's question regarding CDC continuing to do law enforcement work, who, in your opinion, is better able to do that work, Dr. Ostroff?

Mr. OSTROFF. I think that, as far as who is in the best position to administer any expansion of a program like this, I think that a variety of different models would have to be explored. Clearly, there needs to be some collaborative effort between the public health scientific community and the law enforcement community.

Mr. MARKEY. How many inspections have been done?

Mr. OSTROFF. To date, 15.

Mr. MARKEY. Only 15.

Mr. MARKEY. Have any of the facilities had serious problems?

Mr. OSTROFF. One.

Mr. MARKEY. Could you tell us what that problem is?

Mr. OSTROFF. Let me turn to Dr. Richmond to specifically address that, since he is more knowledgeable about what was found.

Mr. RICHMOND. That particular facility had indicated that they were capable of working at what we would call a Class A, Level 3. On inspection, we found they were not in full compliance with that. We suspended their activities for shipping and receiving.

But in the process, we are also working very cooperatively with the institution to try to remedy and rectify that. It is our intention to assist them in becoming fully compliant.

Mr. MARKEY. What was the public risk that this facility posed?

Mr. RICHMOND. It was not necessarily a public risk, so much as it was a risk to the investigators. That is what the biosafety manual clearly focuses on.

Mr. MARKEY. Could you explain that, the risk to the investigators?

Mr. RICHMOND. It was a question of not having appropriate containment; not having appropriate facilities in which to do the work. Airflow systems were out of balance; access by people walking through the corridors—it was not a controlled environment.

Mr. MARKEY. So——

Mr. UPTON. Mr. Markey?

Mr. MARKEY. Yes, sir.

Mr. UPTON. I wonder if——

Mr. MARKEY. I would be glad to yield to the gentleman.

Mr. UPTON. What were the agents?

Mr. RICHMOND. It was bacterial agents that were being prepared in quantity to be shipped to a research facility.

Mr. UPTON. Specifically, what were the agents?

Mr. RICHMOND. I don't recall, sir.

Mr. UPTON. Could you provide that to the committee, please?

Mr. RICHMOND. Absolutely.

[The following was received for the record:]

The agent involved was a fungal agent called *Coccidioides immitis.*

Mr. MARKEY. So in conclusion, Dr. Ostroff, you don't believe, then, that we have a China problem here? We don't have the kind of issues that now surround our nuclear weapons laboratories? You think the industry has cooperated sufficiently; we can give them an "A-minus," and they just need a little bit of improvement?

Mr. OSTROFF. Again, we have no evidence that anyone has thought to circumvent this particular regulation by illegally shipping.

Mr. MARKEY. Thank you, Mr. Chairman.

Mr. UPTON. We will move into round two. I have a basic question that I want to make sure that I understand. It is going into the some of the questions that Mr. Markey, and some of the others, asked.

It is my understanding that there is no current requirement that labs should notify the FBI in case of loss, or theft, for unregistered companies, right? If you are registered with CDC and the shipment does not show up for whatever reason, there is a requirement that they alert the CDC. That is the case.

Mr. OSTROFF. Yes.

Mr. UPTON. But if it is unregistered, then there is really no checks at all, is that correct?

Mr. OSTROFF. Well, if it is an unregistered facility, they should not be shipping or receiving. That wouldn't be legal.

Mr. UPTON. If you are unregistered, you are not supposed to be doing it, but there is no check. There is no verification. There is no way of finding out whether or not that is actually happening. Isn't that right?

Mr. OSTROFF. That is correct.

Mr. UPTON. The way that you are registered really dates back to the old regs that were put into effect that if you had it since 1997. So all those folks who had it prior to 1997, there is no requirement for them to register at all.

Mr. OSTROFF. Unless they intend to ship or receive.

Mr. UPTON. The administration proposal that is soon to be sent up to the Hill, does it include any jurisdiction on re-registering those folks that are not required to register today, in other words, those that had it prior to 1997?

Mr. OSTROFF. The proposal will include aspects that extend the coverage to include those who possess, but don't intend to ship or receive.

Mr. UPTON. So the whole universe will be included?

Mr. OSTROFF. Correct.

Mr. UPTON. Everybody supports that? Does CDC, HHS, everyone support that?

Mr. OSTROFF. Yes.

Mr. UPTON. Mr. Reynolds?

Mr. REYNOLDS. Well, I don't want to prejudge the bill that actually ends up here. It is a difficult task to come up and testify about a prospective bill when you don't have the bill and we don't have the final version. That has not been an area, in recent time, that has been controversial.

I think there is agreement on the need to close the gap from where we are right now where we cover transportation, or shipment in and shipment out of the organization; but we don't cover the manner in which they possess it. We don't require a reporting of possession. What we would like in this legislation, through an unsafe handling provision, is a statutory provision that would give us a basis to address that laboratory that grossly deviates from the accepted standards, and therefore, runs a risk through lack of security that materials that are highly dangerous would leave their laboratory.

Mr. UPTON. Okay. We are going to take a brief recess. Well, the brief is now over.

I pass the baton to Mr. Burr. I know other members are on their way back. Thank you.

Mr. BURR. [presiding] I didn't hear anybody clap when he said that.

Let me go back to CDC for a second. I would like you to walk me through. How quickly would the CDC know whether there was a missing shipment?

Mr. OSTROFF. Again, the receiving facility is supposed to notify us within 72 hours that the material has been received.

Mr. BURR. How are they notified that shipment took place?

Mr. OSTROFF. Excuse me?

Mr. BURR. How are they notified that the shipment took place?

Mr. OSTROFF. The shipping facility must notify both CDC, as well as the recipient, of the intent to ship.

Mr. BURR. And the recipient, if they don't receive it in 72 hours, is bound to contact CDC?

Mr. OSTROFF. Correct.

Mr. BURR. What happens if they don't contact you? In other words, let me ask one question in between. Are they required to contact you to tell you that they did get the shipment?

Mr. OSTROFF. Yes.

Mr. BURR. Or just didn't get the shipment?

Mr. OSTROFF. No, did. Again, since we receive notification from the shipper that a shipment is en route; if we then did not receive something from the recipient indicating that it had been received, we would follow-up on that.

Mr. BURR. Now, if they didn't contact you, what would happen?

Mr. OSTROFF. We would contact them.

Mr. BURR. If they didn't get the shipment, what would happen?

Mr. OSTROFF. Several things would happen. There would be an attempt to try to track it. We would also notify the appropriate law enforcement authorities.

Mr. BURR. That would be?

Mr. OSTROFF. Most likely, the FBI.

Mr. BURR. Is there a specific division within the FBI that everybody in that particular area of CDC know who the contact is, and this is the telephone number?

Mr. OSTROFF. I believe so.

Mr. BURR. That is a written policy with the CDC?

Mr. OSTROFF. Correct.

Mr. BURR. Is there a policy at the FBI if you get a call from the CDC relative to a shipment that is missing?

Mr. BURNHAM. Absolutely. In fact it would come into our weapons of mass destruction unit. If we received notification of a shipment like that, we would contact the appropriate field office, do a threat assessment, and respond accordingly.

Mr. BURR. Has it ever happened?

Mr. BURNHAM. No.

Mr. BURR. Has a shipment ever not made it?

Mr. OSTROFF. No. There was one episode, that I am aware of, where the paperwork got lost, but the shipment had actually been received. That was promptly dealt with. It was just a matter of the paperwork not following the material.

Mr. BURR. What is the FBI's general sense of the security of the laboratories and facilities that were shipping biologics? Have they ever made any assessment?

Mr. BURNHAM. No. I think that I stated that earlier. We haven't made any site assessments. We haven't done any vulnerability assessments with threat analysis. So, to answer your question—no.

Mr. BURR. What is your sense of the coverage of the select agent list? Have you assessed that list?

Mr. BURNHAM. No.

Mr. BURR. So we don't really know today whether we are capturing everything we should be targeting?

Mr. BURNHAM. Again, I am not a scientist and I am not expert in this; but I do know that it is constantly changing—you know, genetic engineering and stuff like that.

Mr. BURR. Whose responsibility is it?

Mr. BURNHAM. I would suppose it would be CDC's.

Mr. BURR. There is nobody in law enforcement that goes through an evaluation of those agents that might risks? If they find one, are they double-checking to make sure CDC has it on an agents list?

We are not here to try to pick apart. We are here to try to raise our comfort level, or possibly raise some questions on some things we haven't thought of—some areas that haven't been addressed. There is a requirement here. I think Mr. Stupak got to it.

One, is CDC the appropriate place? I don't think we are here to judge that. We are here to ask questions so that there is an assurance that the choice is correct. If so, do you have the resources? If you have the resources, do we have the structure of how everything works where everybody understands it? Does Mr. Reynolds and the Department of Justice understand it? Does the FBI understand it? Does HHS understand it? So that on your side of it, everything runs smooth; Mr. Reynolds' side, everything runs smooth.

I have to be totally honest with you. I don't think that you have all the answers. I am not sure, yet, that you have all the questions. I think that, hopefully, if you garnish anything out of this hearing it will stimulate the need for some more questions to be asked.

What does the law enforcement community think about the current exemptions to CDC regulations?

Mr. REYNOLDS. This would relate to, for instance, shipment overseas——

Mr. BURR. Clinical labs.

Mr. REYNOLDS. Again, we are going to defer to CDC on that. We don't have an independent basis for assessment at this point. We remain concerned that we have a sufficiently secure system. To back this issue back one step, we are concerned right now of even having the statutory jurisdiction to deal, in the way of a prosecution, if in fact CDC came to us with a violation.

Right now you have misdemeanor enforcement of their transfer regulation. For example, if you had a theft from the shipment, there is a real question to be addressed.

Mr. BURR. Clearly, your belief is that the administration in their crime bill will try to tie these loose ends up, so that the enforcement side and the prosecution side exist.

Mr. REYNOLDS. That is exactly right. That is what this is about. It is an attempt to tie these loose ends up.

Mr. BURR. I hope you understand my concern that if, today, law enforcement does not have a position on the question of exemptions—clinical labs and other things—that is in the statute, then I have to wonder how closely we looked at the whole process. I get the impression that you have looked at your piece; and you have looked at your piece. Somewhere, there is hopefully somebody that is coordinating this whole thing to ultimately make all the pieces fit.

Mr. REYNOLDS. This was looked at, at one point. But the time at which law enforcement participated in the examination was the time of the development of what became the HHS regulations.

Those regulations were designed as part of an interagency group. The Department of Justice and FBI participated, as did a number of other agencies. It would be fair to say there was give and take as far as the comprehensiveness of those regulations. But at that time, we were satisfied that those regulations represented a very productive step forward.

I think they did, at that time. There is a valid question, now, in light of the experience in the last 3 years, whether they should be tightened. We believe they certainly should be tightened, or there should be a new statutory structure to cover possession. I think you were out of the room at the time, but we talked in terms of these regulations covering transfer to a facility. If the facility wants to transfer the select agent out later, then the regs pick it back up. The regs don't deal with it while it is at the facility, which is a concern to us and would be addressed under this legislation.

Mr. BURR. Let me bring one fact to light and ask you if it, in any way, raises your sense of urgency on clinical labs. There are 150,000 clinical labs. Am I correct? So particularly for that one slice there are 150,000 possible exemptions. Is that a comfort for law enforcement? I will leave that as an open-ended.

Mr. REYNOLDS. Let me just say that in that regard, obviously, as law enforcement people and prosecutors, our educational background and experience is in investigating, law, and in prosecution. So we are dependent upon seeking expert scientific advice, as we do. We look to HHS; we look to CDC to provide that advice. We don't have a good independent basis.

Mr. BURR. Would you disagree that the policy should be a balance between deterrent and the ability to enforce law?

Mr. REYNOLDS. That is absolutely correct.

Mr. BURR. You are right. Based upon the structure, CDC has the ability to say, "Even with 150,000 clinical labs, we still think they should be exempt." I hope that the law enforcement side is saying, "Tell us why. Make the case to us; because we see 150,000 uncontrolled clinics as a potential high-risk area." Hopefully, if that exchange hasn't taken place, you will ask that question. This side will provide that answer. If it is not sufficient for law enforcement, we might go back to the table and look at that a little bit further.

Let me just ask a couple more questions, because Mr. Stupak is back. Mr. Reynolds, in your testimony you stated that under current law, by the time the biologic weapons or devices had been created, or were under development, it may be too late to undertake action to prevent the attack. I think that is a pretty important point. I wanted to ask you to describe a little more about it. Is there a particular case that you could provide any more detail on, for the committee?

Mr. REYNOLDS. Well, some of the cases were discussed in Mr. Burnham's testimony. Let me focus on the specific aspects and start with the most difficult. That is, where the weaponization is simply the use of the biological agent to place on the salad bar, as occurred in Antelope, Oregon, in 1985. About a couple hundred people became seriously ill.

Another situation occurred, more recently in Dallas, Texas, where the biological agent was placed on doughnuts. I think 18 or 19 people became ill. The weaponization, in that situation, is not

concoction of a device, per se; but simply the taking of the biological agent and physically placing it on the food supply.

Mr. BURR. Let me see if I understand you. If, in fact, a shipment is diverted or stolen, at some point soon after then, our concern or risk never gets higher. Once they have the biological agent, they don't necessarily have to have the attack planned, or the device made; but our risk is every bit as great.

Mr. REYNOLDS. There is a risk that is there from the start. Let me distinguish between two things for you. The regulations that exist right now relate to select agents, of which there are approximately 40 on the list. There are many other biological substances, obviously. The ones that were used in Antelope, Oregon, and Dallas, Texas, which made people sick were salmonella and shigella, neither of which is on the select agent list. There is the potential for vast damage to be done with agents that are not a part of that select agent list, or the CDC regulatory process—absent the placing of them on the select agent list.

Mr. BURR. Let me ask you one last question. You can elect not to answer it if you want to. Even under the administration's new crime bill proposal, would you say that our regulations on guns in this country is stricter than the proposal that we have made on biological agents?

Mr. REYNOLDS. That is a difficult question to answer. The biological weapons legislation that has been developed, is developed to focus on biological agents, and the specific aspects of biological agents. It is, in many ways, very different. There is some analogies that can be drawn, but it is really very different.

It includes an unsafe handling provision. I suppose you could analogize in firearms law to what is being discussed right now in the way of safety locks. But the unsafe handling provision on the biological side, obviously, is more extensive than the safety lock proposal.

There are some aspects as relates to restricted persons that might be analogous, depending on the final shape of this bill. Unjustified possession is extraordinarily important to us. If the FedEx employee steals the material out of the interstate shipment, what is our Federal violation to deal with that right now. We are in a very difficult position. Theft from interstate shipment requires a certain threshold of monetary value before we have jurisdiction.

Mr. BURR. If a felon has a handgun, there is a law, isn't there?

Mr. REYNOLDS. If a felon has a handgun, there is a law. That is correct.

Mr. BURR. I only raised the question, not to have you comment on our gun laws; but to point out the fact that we spend a tremendous amount of time trying to find the right balance there and debating what the right balance is. We address it very quickly when we have a situation that arises. I am sure that we will have further debates based upon this morning's current conflict. Biologic agents are every bit the threat—if not more—and much tougher for us to maybe set a structure that we feel confident works. I am not sure that we spend quite the same amount of time trying to get it right. At least to this point, we have not, as we do in gun enforcement.

The Chair would yield to the gentleman from Michigan, for 10 minutes, if he needs it.

Mr. STUPAK. Thank you. Dr. Raub, how many people die each year from infectious diseases?

Mr. RAUB. I don't know off-hand, sir.

Mr. STUPAK. Does 17 million, sound right, worldwide?

Mr. RAUB. Worldwide, that is possible, yes.

Mr. STUPAK. How many die from bioterrorism attacks?

Mr. RAUB. I am not aware of any, sir.

Mr. STUPAK. Okay. So when we start talking about biological weapons, people get scared. They get very scared, even though these biological agents have been amongst us, in the world, for centuries. Once we start saying that these agents can, theoretically—and I want to emphasize theoretically—be weaponized, aren't we demanding an extremely high level of security, then, in all aspects of handling these materials?

Mr. RAUB. In the antibioterrorism initiative we have proposed, we have tried to distinguish between the organisms that are potentially weapons of mass destruction—that is, that could be used on an area as broad as a municipality—as distinct from some that could be used in a harmful way, but in much more limited circumstances. So we have tried to make that measure and distinction.

Mr. STUPAK. Give me an example of what you are talking about.

Mr. RAUB. Well, for example, high on our list as an agent of concern for bioterrorism is anthrax.

Mr. STUPAK. Anthrax, okay.

Mr. RAUB. It is based on the characteristics of the organism. It has a spore form as part of its natural life-cycle, which lends it to being weaponized. Moreover, in previous decades, a number of nations worked with weaponizing this material. So there is some basis of experience out there.

The spores, relatively speaking, are easily aerosolized. It can be released into the air, and create a broader threat than would be true than with, say, salmonella or other agents that might be in food.

Mr. STUPAK. Salmonella is not one of these 40 agents.

Mr. RAUB. That is correct. It is not.

Mr. STUPAK. So it wouldn't be fair to put salmonella in that.

Mr. RAUB. No, I was making the contrast that you asked for, sir.

Mr. STUPAK. So when we are dealing with anthrax or these 40 special agents, are you then asking us to put in extremely high levels of security in all aspects of handling things like anthrax?

Mr. RAUB. No, sir, we aren't. I believe that, when the crime bill proposal comes forward, it will capture a balance between promoting additional attention to security and safety; but still within the kinds of guidelines that we have. While putting some additional requirement on the research, laboratory and public health communities, it will be balanced by related provisions, such as those Mr. Reynolds was describing, having to do with additional criminal authorities with respect to inappropriate possession, reckless handling, and so on. It is the balance of those that will be important in the bill.

Mr. STUPAK. Reckless handling and all that. That is a crime and no problem with that stuff. That should be in a crime bill. Again, our jurisdiction here is the labs. I guess what I am trying to get

at is that if you have these 40 agents that we have theorized that mass destruction and everything else is going to happen, can someone explain to me what are your procedures? What are your regulations you are proposing for these labs?

We have 11 CDC labs. We have 1,500, I think Mr. Burr said, other labs. How are you going to safeguard? What are your policies? What are your regulations? What are your inspections? What are we talking about here? What do you want us to implement? Can anyone answer that—Dr. Raub or Mr. Reynolds?

Mr. RAUB. From the laboratory side, I can say only that until the decisions are made about what the specific content of the legislative proposal will be, we won't be able to——

Mr. STUPAK. Well, you just said that I would probably see a nice balance here.

Mr. RAUB. That is certainly the intention, sir.

Mr. STUPAK. Well, tell me this nice balance that may be coming.

Mr. RAUB. I think, as in my statement and in Mr. Reynolds', we have identified the areas that need to be addressed. What I was emphasizing there is that if all those areas are addressed simultaneously and in relation to each other, it will constitute a balance that will not put an undue on weight on any part of this.

The stated concern on the part of the Attorney General is not to chill important research and laboratory work. That is certainly a concern of ours. I am hopeful of that.

Mr. BURR. Will the gentleman from Michigan yield for one question?

Mr. STUPAK. Yes, sure.

Mr. BURR. Let me ask any of you: how many labs that handle nuclear material go unregistered?

Mr. REYNOLDS. They are regulated by the NRC, as you probably well know.

Mr. BURR. All of them?

Mr. REYNOLDS. If they handle nuclear material. As far as I am aware, it is a highly regulated system.

Mr. BURR. Is there a significant difference between the threat in nuclear material and biological agents?

Mr. REYNOLDS. It depends on the threat that one is talking about. If you are talking about a threat in the immediate area, it may be that the nuclear threat is greater to those immediately surrounding the area. If you are talking about the potential for use by a terrorist, it may be that the biological substance is the most pervasive challenge that we face in the terrorism area.

Mr. BURR. I thank you. I thank the gentleman for yielding.

Mr. STUPAK. Going back to our questions there. You mention the Attorney General; you mention your testimony, and if we would implement these things that are in here. But what I see in all the testimony, and what I have heard, thus far, is talking about the 21st century crime bill, which will strengthen our efforts to combat international crime and terrorism. The threat of weapons of mass destruction is real and increasing in the age of technological change and open borders. The bill will make it a Federal crime to possess these agents. I agree with all that, okay?

Possession of biological agents not justified, I agree with you. Unsafe handling, I agree with you. Unregistered possession, I agree.

Knowingly perpetrating a hoax regarding biological agents, I agree. Possession of select agents by restricted individuals—agree. Those are crimes. They could file them in title 18 of U.S. Code, probably.

But let us get back to these labs, these 11 labs. You can pass these crimes; but once they get out there, what are you asking these labs to do? I am afraid that what is going on here is that we are looking at the crime aspect. But where they are developed; where they are moved; where they are transferred, and where there is access or they are readily accessible, there is not the physical nor the internal security that would be needed to prevent the unauthorized use or things that you see which could promote weapons of mass destruction.

So what do you see in these registrations and inspections of these labs? How do you handle it when you pass your crime bill?

Mr. RAUB. The answer is, not having the specifics of the bill, I am not able to address that.

Mr. STUPAK. It is not necessarily the specifics of the bill. Aren't you concerned—the cost? We have $1 million, based on one regulation, and that was just right at the labs. There is also a deep concern that the independent scientific credibility of the CDC will be seriously weakened by the recognition that, if you put it on CDC are they now going to be responsible for policing the external organizations, institutions, and individuals that they are trying to develop working with relationships with to wipe out diseases and other problems that develop up, worldwide? I don't think CDC wants to be targeted agency, or law enforcement activity. Have you guys given any thought to that?

Mr. RAUB. Sir, again, I don't believe anybody involved wants to compromise the CDC's pursuit of its mission, as the price of making the needed improvements here.

Mr. STUPAK. Okay.

Mr. RAUB. On the other hand, I think we all recognize that the Department of Health and Human Services must be part of the solution to this. We need to be effective partners with the Department of Justice and with other parts of the administration. We will do our best at that.

Mr. STUPAK. Do you want HHS to do the inspections, then, of labs?

Mr. RAUB. That is still under discussion, sir.

Mr. STUPAK. Can you give me any drift of where you guys are going? Are still drifting out there? I have heard of all these discussions. There has been testimony about the administration having discussions and trying to formulate. Well, tell us what you are trying to formulate. Maybe we can help. We don't want to be adversarial here. This is a serious matter. We would like to help out.

We have made comparisons, now, to gun laws; to nuclear weapons; to weapons of mass destruction by bioagents, even to salmonella. We are all over the map here. Focus us in. What are you trying to accomplish here? How are you going to do it? Give us some idea so we can help.

Mr. REYNOLDS. Can I address that from a law enforcement perspective? Do we have the time?

A key factor in the legislation that we anticipate will be sent to the Hill is to give law enforcement the opportunity to move into the

investigation at an earlier period of time. The statutes that we have right now were a good first step when enacted, but they require that we develop some evidence of intent, or weaponization, which puts us well down the line in preventing the terrorist act. The statutes that we would anticipate, or the legislation we would anticipate sending up, on justifiable possession, reckless handling, and possession, all give us a basis to move into an investigation at an earlier time in an effort to avoid the catastrophe that could occur.

Mr. STUPAK. I don't disagree with any of that. Having been a cop for 12 years, I agree totally. But then, we should leave the labs alone. Give it to the FBI and Justice. Let them do their job; and not put all kinds of regulations on labs that we can't even have a knowledge of what we are going to do, or how we are going to enforce it. Let CDC do their job. Give the FBI or Justice whatever they need to do their job.

If we have to tighten up some criminal laws, I am all for it. I will be happy to help you. It would be outside the scope of this committee. With that, Mr. Chairman, I yield back to you.

Mr. UPTON. [presiding] Thank you, Mr. Stupak. Mr. Burr, do you have further questions?

Panel, we thank you very much for your testimony this morning. We look forward to seeing the recommendations from the President, and working with all parties to try to close the loopholes that have been identified this morning. Thank you. You are excused.

Panel two. Panel, as you heard from panel one, we have a long tradition of swearing witnesses under oath. Do you have any problem with that? Do any of you want counsel, or have provided counsel? Okay. If you would stand and raise your right hand.

[Witnesses sworn.]

You are now sworn, under oath. People go to jail for doing otherwise, sometimes—hopefully, most of the time—hopefully, all the time.

As I indicated before, we would like you to keep your comments to 5 minutes. All of your statement will be made part of the record. If you would like to summarize it, if is longer than that, that is fine.

Dr. Atlas, we will start with you. Thank you.

TESTIMONY OF RONALD M. ATLAS, CO-CHAIR, TASK FORCE ON BIOLOGICAL WEAPONS CONTROL, AMERICAN SOCIETY FOR MICROBIOLOGY; DOROTHY B. PRESLAR, WASHINGTON PROJECT OFFICER, BIOLOGICAL WEAPONS VERIFICATION PROJECT, FEDERATION OF AMERICAN SCIENTISTS; AND NANCY D. CONNELL, ASSOCIATE PROFESSOR OF MICROBIOLOGY AND MOLECULAR GENETICS, DEPARTMENT OF MICROBIOLOGY, UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

Mr. ATLAS. Thank you, Mr. Chairman. My testimony is presented on behalf of the American Society for Microbiology, which is the largest life science organization in the world. It has a membership of 43,000. The ASM appreciates the opportunity to testify today, and has submitted the longer statement for the record. I am just going to summarize some of the points.

The ASM is acutely aware of the threat posed by the possible misuse of microbial agents as weapons of terror. Indeed, in the past, the ASM has assisted in the development of sound and effective public policies for the control of select agents, while avoiding undue inhibitions on scientific research. To this end, ASM has been an advocate for placing responsibility for the safe transfer of select microbial agents at the level of individual institutions; supported by Government oversight and monitoring to minimize risks, without inhibiting scientific inquiry and clinical diagnosis of disease.

ASM contributed to the passage of section 511(d) of the Antiterrorism and Effective Death Penalty Act of 1996, which was intended to protect the dual public interests of safety and free and open scientific research through promulgation of rules that would implement a program of registration of institutions engaged in transfer of select agents. It is in the same spirit of recognizing and dealing with the threat of bioterrorism, while protecting essential research, that ASM testifies today.

We have a couple of principles that we would like to put forward. First, we cannot discount the possibility that, as unfathomable as it may be to the civilized mind, terrorism may take the form of bioterrorism. Most certainly, therefore, Government and scientific communities are duty-bound to take every reasonable precaution to minimize any risks of terrorist use of select microbial agents.

Second, even as we strive to prevent bioterrorism, we must candidly recognize that no set of regulations can provide absolute assurance that no act of bioterrorism will ever occur. Therefore, as we strive to prevent such acts, we must have a duty to pursue research aimed at developing the most effective possible responses to such bioterrorism acts. Research and public health responses related to effectively combatting an act of terror are a critical component of the public policy response to the threat of bioterrorism.

Third, while the possibility of a future act of biological terrorism is a terrible threat, scourge of infectious diseases is a terrible reality that daily takes the lives of thousands of Americans, and tens of thousands around the world. Infectious diseases are now the third leading cause of death in the United States, and the leading cause of death in the world. Responding to the threat of terror, therefore, we must minimize any adverse impact on basic bioclinical and diagnostic research related to infectious diseases.

Past legislation, certainly, has recognized the need for balancing these concerns. Congress and Federal agencies have appreciated these competing considerations, and have sought to minimize interference with research and the transfer of clinical specimens for patient diagnosis through measures recognizing the appropriate exemptions in regulating the handling of infectious microorganisms. We know that such balancing will continue. The ASM is committed to providing the available assistance in achieving balance and effective policy.

The ASM supports measures to prohibit possession of listed biological agents, unless they are held for purposes that are in the public interest, and the cultures are maintained under appropriate biosafety conditions. Accordingly, the ASM supports extending the current CDC regulations covering the shipment of listed agents to

include possessions of cultures of those agents, following the principles that are outlined.

First, governmental responsibility for establishing, implementing, and monitoring programs related to biosafety should remain with the Department of Health and Human Services, and the CDC. The DHHS and CDC possess institutional knowledge and expertise related to issues of biosafety, and the designation, transportation, storage and use of select agents. The CDC is well-qualified to balance the need for biosafety regulation; the critical need for scientific research, and clinical and public health activities directed at the prevention, treatment, and cure of infectious diseases.

Any expansion, though, of existing duties will require additional financial and other resources by the CDC. Based on surveys that we have performed, we estimate that there are approximately 300 institutions possessing select agents. Approximately half of those institutions are currently registered with the CDC, pursuant to existing law. Registration of additional institutions would impose new expense and resource burdens on the CDC.

Second, focus must be maintained on the legitimate important and fundamental issues related to biosafety. As in other areas concerning biological, chemical and radiological safety, focus for ensuring safety should be on the institution.

Third, we must recognize that we are dealing with naturally occurring organisms, and that cause of these diseases will be found with organisms that occur in nature. We want to make sure that possession does not extend to individuals who become ill from disease, or to those who are involved in the isolation for organisms for diagnostic purposes.

In conclusion, Congress should recognize the need to deal with the threat of biological terrorism will be an on-going duty for the indefinite future, and will continue to require balancing competing considerations. Congress, acting through the DHSS and CDC, should provide for continuing consultation with the scientific community regarding the substance and procedures and regulations governing select agents. ASM is committed to working with the Congress and the Federal agencies to protect the public against the threat of bioterrorism, while engaging in rigorous research aimed at improving biomedical knowledge of disease and our clinical diagnosis and treatment of those diseases. Thank you, Mr. Chairman.

[The prepared statement of Ronald M. Atlas follows:]

PREPARED STATEMENT OF RONALD M. ATLAS, CO-CHAIR, TASK FORCE ON BIOLOGICAL WEAPONS CONTROL, AMERICAN SOCIETY FOR MICROBIOLOGY

Thank you for inviting the American Society for Microbiology (ASM) to discuss issues related to the adequacy of federal law relating to dangerous biological agents. The ASM is the largest single life science society in the world with a membership of 42,000, and represents a broad spectrum of subdisciplines, including medical microbiology, applied and environmental microbiology, virology, immunology and clinical and public health microbiology. The Society's mission is to enhance microbiology worldwide to gain a better understanding of basic life processes and to promote the application of this knowledge for improved health, economic and environmental well-being.

The ASM has a long history of bringing scientific, educational and technical expertise to bear on the safe study, handling and exchange of pathogenic microorganisms. The exchange of scientific information, including microbial strains and cultures, among scientists is absolutely essential to progress in all areas of research in microbiology. The ASM understands the unique nature of microbiology labora-

tories, the need for safety precautions in research with infectious agents and the absolute necessity for maintaining the highest qualifications for trained laboratory personnel. The ASM conducts education and training programs, as well as publication of material related to shipping and handling of human pathogens. Through its Public and Scientific Affairs Board, the ASM provides advice to government agencies and to Congress concerning technical and policy issues arising from control of biological weapons. The Society's Task Force on Biological Weapons Control assists the government on scientific issues related to the verification of the Biological Weapons Convention (BWC).

The ASM is acutely aware of the threat posed by the possible misuse of microbial agents as weapons of terror. Concerns that bioterrorists will acquire and misuse microorganisms as weapons have resulted in stricter controls on the possession, transfer and use of biological agents to restrict access to only legitimate and qualified institutions, laboratories and scientists. Over the past 10 years, the ASM has worked with the Department of Health and Human Services (DHHS), the Centers for Disease Control and Prevention (CDC), the Department of Agriculture (USDA) and Congress to develop and establish legislation and regulations that are based on the key principle of ensuring protection of public safety without encumbering legitimate scientific and medical research or clinical and diagnostic medicine for the diagnosis and treatment of infectious diseases. The ASM has been an advocate of placing responsibility for the safe transfer of select agents at the level of individual institutions supported by government oversight and monitoring to minimize risks without inhibiting scientific research.

The ASM notes that national security efforts to control biological weapons require that the United States increase biodefense and public health capabilities at the same time that it tries to develop safeguards to prevent the misuse of biological agents to harm the public health. Limiting the threat of bioterrorism includes reducing access to biological agents that might be used as weapons; however, combating infectious diseases and increasing medical preparedness against bioterrorism necessitates increasing biodefense, biomedical and other life sciences research, including work on the same "threat" agents that could be used as biological weapons. As safeguards are developed, we must ensure that biomedical research, public health and clinical diagnostic activities are not inhibited or we risk jeopardizing the public's health and welfare.

Legal and Regulatory Protections have been Established

Congress already has established a legal and regulatory framework to prevent the illegitimate use of toxins and infectious agents, outlawing virtually every step that would be necessary for the production and use of biological weapons. In doing so it has balanced assuring the availability of materials to the scientific and medical community for legitimate research purposes with preventing access to these agents for bioterrorism. For instance, the 1989 Biological Weapons Act authorizes the government to apply for a warrant to seize any biological agent, toxin, or delivery system that has no apparent justification for peaceful purposes, but exempts agents used for prophylactic, protective, or other peaceful purposes. Prosecution under this statute requires the government to prove that an individual did not intend to use the biological agents or toxins in a peaceful manner. The law also enables federal officials to intervene rapidly in cases of suspected violations, thereby decreasing the likelihood of bioterrorism while protecting legitimate scientific endeavors, such as biomedical research and diagnosis of infectious diseases.

The Antiterrorism and Effective Death Penalty Act of 1996 (the Act) broadens penalties for development of biological weapons and illegitimate uses of microorganisms to spread disease. ASM testified before the 104th Congress with respect to the control of the transfer of select agents that "have the potential to pose a severe threat to public health and safety . . ." and contributed to the passage of Section 511(d) of the Act. The Act was intended to protect dual public interests of safety and free and open scientific research through promulgation of rules that would implement a program of registration of institutions engaging in the transfer of select agents. The transport of clinical specimens for diagnostic and verification purposes are exempt, although isolates of agents from clinical specimens must be destroyed or sent to an approved repository after diagnostic procedures are completed. The CDC is responsible for controlling shipment of those pathogens and toxins that are determined to be most likely for potential misuse as biological weapons. The ASM believes the CDC regulatory controls provide a sound approach to safeguard select agents from inappropriate use and should serve as a worldwide model for regulating shipment of these agents.

In April 22, 1998 testimony before the Senate Subcommittee on Technology, Terrorism and Government Information Committee on the Judiciary and Select Com-

mittee on Intelligence, Attorney General Janet Reno stated that "mere possession of a biological agent is not a crime under federal law unless there is proof of its intended use as a weapon, notwithstanding the existence of factors, such as lack of scientific training, felony record, or mental instability, which raise significant questions concerning the individual's ultimate reason for possessing the agent." She, like other law enforcement officials, are troubled by the fact that someone can possess a biological agent that could be used as a weapon and not be in violation of a law unless one can establish intent. It is our understanding that the Department of Justice and other federal agencies have reviewed federal criminal statutes that could be expanded to make possession of certain biological agents illegal.

Safety and Security Measures Must be Balanced to Protect Biomedical Research and Clinical Diagnostic Programs

The ASM agrees that enhancing security and safety is a critical necessity when bioterrorism poses a credible threat to society. However, proposals intended to promote safety should not pose a threat to biomedical or other life sciences research and clinical diagnostic activities that are essential for public health. Unintended consequences could stifle the free exchange of microbial cultures among members of the scientific community and could even drive some microbiologists away from important areas of research. Ironically, extreme control measures to prevent bioterrorism, instead of enhancing global security, could prove detrimental to that goal if scientists can no longer obtain authenticated cultures. A key point is that natural infectious diseases are a greater threat than bioterrorism. Infectious diseases remain the major cause of death in the world, responsible for 17 million deaths each year. Microbiologists and other researchers depend upon obtaining authenticated reference cultures as they work to reduce the incidence of and deaths due to infectious diseases.

Dealing with the threatened misuse of microorganisms, therefore, will require thoughtful consideration and careful balancing of three compelling public policy interests.

First, we must acknowledge the terrible reality of terrorism within the United States and abroad from both foreign and United States origins. We cannot discount the possibility that, as unfathomable as it may be to the civilized mind, terrorism may take the form of bioterrorism. Most certainly, therefore, the government and scientific communities are duty bound to take every reasonable precaution to minimize any risk of terrorist use of microorganisms. The ASM is taking a proactive role in this regard.

Second, even as we strive to prevent bioterrorism, we must candidly recognize that no set of regulations can provide absolute assurance that no act of bioterrorism will ever occur. Therefore, as we strive to prevent such acts, we also have a duty to pursue research and public health improvements aimed at developing the most effective possible responses to acts of biological terror. Research and public health responses related to effectively combating an act of terror are a critical component of the public policy response to the threat that exists.

Third, while the possibility of a future act of biological terrorism is a terrible threat with which we must and will deal, the scourge of infectious diseases is a terrible reality that daily takes the lives of thousands of Americans and tens of thousands around the world. Infectious diseases are now the third leading cause of death in the United States. Research on the prevention and treatment of such diseases is critical to the well being of our entire population. In responding to the threat of terror, therefore, we must minimize any adverse impact upon vital clinical and diagnostic research related to infectious diseases.

Congress and federal agencies have appreciated these competing considerations and have sought to minimize interference with research through such measures as recognizing appropriate exemptions in regulating the handling of pathogenic microorganisms. As we have stated, past legislation has recognized the need for balancing these concerns. We know that such balancing will continue, and the ASM is committed to providing all available assistance in achieving balanced and effective responses to the threat to the public welfare.

ASM Supports Measures to Increase Safeguards Against Biological Terrorism

The ASM supports making it more difficult for bioterrorists to acquire agents that could be used as biological weapons and to make it easier for law enforcement officials to apprehend and to prosecute those who would misuse microorganisms and the science of microbiology. The ASM code of conduct specifies that microorganisms and the science of microbiology should be used only for purposes that benefit humankind and bioterrorism certainly is inimical to the aims of the ASM and its members. The ASM established its Task Force on Biological Weapons to assist the gov-

ernment and the scientific and biomedical communities in taking responsible actions that would lower the risks of biological warfare and bioterrorism.

The ASM supports measures to prohibit possession of listed biological agents or listed toxins unless they are held for legitimate purposes and maintained under appropriate biosafety conditions. Accordingly, the ASM supports extending the current regulations implemented by the CDC to oversee the shipment of listed agents to include possession of cultures of those agents.

Although the ASM will not offer specific proposals today, we do think it will be useful to outline certain basic principles that we believe should be considered:

First, governmental responsibility for establishing, implementing, and monitoring programs related to biosafety should remain with the Department of Health and Human Services and CDC for human health and the USDA for animal and plant health. The CDC possesses institutional knowledge and expertise related to issues of biosafety and the designation, transportation, storage and use of select agents. The CDC is well qualified to balance the real need for biosafety regulation with the critical need for scientific research, especially clinical and diagnostic research for the prevention, treatment and cure of infectious diseases.

The CDC's responsibilities should include the duties to:

1. Continue to establish and periodically revise the list of select agents; and
2. In accord with proper administrative procedures, promulgate any additional regulatory measures related to registration of facilities, establishment of biosafety requirements, institution of requirements for safe transportation, handling, storage, usage, and disposal of select agents, and the auditing, monitoring, and inspection of registered facilities.
3. The CDC should notify the Department of Justice about any concerns that it may have about institutions that possess select agents.

Congress and the Administration must recognize that any expansion of existing regulations will require additional financial and other resources by the CDC. Based upon surveys that ASM has performed, we estimate that approximately 300 institutions possess select agents. Approximately half of those institutions are currently registered with the CDC pursuant to existing law. Registration of an additional 150 institutions, therefore, would impose additional expense and resource burdens upon the CDC that should be recognized and funded to ensure the timely and complete fulfillment of the CDC's critical mission.

Second, Congress, the CDC, and any other relevant governmental agencies must maintain their focus on the legitimate, important, and fundamental issues related to biosafety. In this regard, biosafety initiatives should be directed toward, and focused on institutions that utilize select agents for scientific purposes, regardless whether such institutions are in the academic, commercial, or governmental sectors. As in other areas concerning biological, chemical, and radiological safety, the focus for ensuring safety should be on the institution. The institution rather than any individual scientist should be responsible for registering possession and maintaining the proper biosafety conditions for storage and usage of the agent.

In this context, ASM supports registration with the CDC of every institution that possesses and retains viable cultures (preserved and actively growing) of select agents along with the concomitant duty to follow all regulatory requirements related to such possession and usage. Institutions and individuals, thus, would be prohibited from possessing cultures of select agents unless the agents are maintained under appropriate biosafety conditions.

The DHHS/CDC, acting in cooperation with the scientific and biomedical communities, and with public notice and input, should establish the rules and provide for governmental monitoring. However, the registered institution must be responsible for assuring compliance with mandatory procedures and for assuring fully appropriate biosafety mechanisms, including appointment of a responsible official to oversee institutional compliance with biosafety requirements.

These institutional responsibilities include assuring safety through proper procedures and equipment and through training of personnel. Thus, the institution would bear the responsibility for training employees regarding the biosafety requirements, including the absolute necessity for following those requirements, and such duties as reporting isolation of select agents or any breach in a biosafety protocol.

As institutions comply with appropriate safeguards, scientists may undertake their research with knowledge of clear procedures and with assurance that compliance with such procedures will fulfill all governmental requirements related to select agents. The institutions would be required to maintain records of authorized users and to ensure that they are properly trained as is currently the case for work with radioisotopes. Intentional removal of select agents from a registered facility would subject the individual to criminal sanctions.

Third, Congress and the CDC must balance the public interests of minimizing the threat of bioterrorism and assuring vigorous scientific research, especially research relating to clinical and diagnostic methods and to protecting the nation's food supply. We must recognize that we are dealing with naturally occurring organisms that cause natural diseases. The focus should be on cultures of biological agents and quantities of toxins on the CDC select agent list in order to address any problem arising from an individual who may unknowingly pick up a dead deer mouse with Hantavirus, a handful of soil with *Bacillus anthracis,* a jar of honey with *Clostridium botulinum,* or contract an infectious disease with one of the select agents, and who could be in technical violation of a law prohibiting possession. Because microorganisms, including listed agents, are invisible and widely distributed, there is no way of knowing what you might possess unless you culture the organisms or use sophisticated molecular diagnostic procedures.

The CDC, working with the scientific community, should develop a comprehensive definition of a culture of a biological agent that would include microorganisms growing in artificial media, animal cells, and preserved viable materials from such cultures, which are the materials of concern.

Fourth, Congress should recognize that the need to deal with the threat of biological terrorism will be an ongoing duty for the indefinite future and will continually require balancing competing considerations as discussed in our earlier testimony. Therefore, Congress, acting through the DHHS and CDC, should provide for continuing consultation with the scientific and biomedical communities regarding the substance and procedures of regulations governing select agents. The CDC should be empowered to act swiftly to adjust definitions, substantive duties, and procedural requirements to the inevitable changes resulting from scientific research. ASM is committed to working with Congress and the DHHS and CDC to protect against threats of terrorism while engaging in vigorous research for the betterment of humankind.

Mr. UPTON. Thank you.

Ms. Preslar.

TESTIMONY OF DOROTHY B. PRESLAR

Ms. PRESLAR. Thank you, Mr. Chairman, and members of this committee. On behalf of the Federation of American Scientists, I am pleased to be here today, and hope that the testimony I bring will assist your efforts to control the possession and transfer of certain highly pathogenic and toxic agents.

For any of you who may not be familiar with the Federation of American Scientists, it was founded in 1945 by Manhattan Project Scientists to promote the peaceful and humanitarian uses of the nuclear technology. Over the past half-century, we have addressed many arms control issues. In the last decade, we have started initiatives in other areas of global security, such as the threat of infectious disease, food production, energy, and the environment.

Today I speak in my statement for the FAS working group on biological weapons. This group has spent 10 years studying means to prevent the use of biologicals as weapons. I will speak, also, for myself as may be appropriate in a question and answer period.

FAS supports efforts to raise the level of accountability for handling deadly pathogens and toxins. It is clear that both national security and public health will be served if these agents remain in secure environments at all times; and if facilities that work with them are held strictly responsible for their safe storage, proper handling, restricted access and closely monitored transfer.

Our working group suggests to you the following measures that may assist in this work. One, extend the rules for registration to facilities that possess these select agents. Two, impose strict controls on possession by individuals, of any amount, of a select agent outside the confines of a registered facility, or any laboratory.

Three, amend the exemption for select agents that are part of clinical specimens to require that clinical samples received for diagnostic reference or verification purposes, and any cultures derived from them, after the specific task has been accomplished must be disposed of properly in their entirety, or transferred in their entirety to a designated facility.

Four, modify the CLIA exemption to require notification of CDC, or other Federal authority as appropriate in the future, when select agents are diagnosed from chemical samples. This would serve a dual purpose, serving as a sentinel system for outbreaks of diseases caused by these agents. Five, conduct an intensive education campaign aimed at research and laboratory personnel. We believe that greater accountability can be achieved by explaining the importance of regulations, and appealing to the civic responsibility of the scientific community. Appropriate education means include presentations and information booths at scientific conferences; mailings to institutions; notices in scientific publications, and inclusion in medical and science ethics courses at our colleges and universities.

Six, we also would suggest that you address the potential for attack on the food production resources of the United States by terrorists. These might be political terrorists, or they might be economic terrorists, using animal and plant pathogens. In recent weeks, as you may know, the USDA officials have sounded a warning saying that such targeting is inevitable, in the long term. A number of animal pathogens are already on the select agent list, because they are zoonoses, or diseases that affect both animals and humans. Considering the possible impact on food production, and also our food trade globally, that could result from synchronized attacks on cattle, poultry, pigs, corn, wheat, and soybeans, in the short term; our food export industry could be seriously affected. There might be shortages, also, in the United States. More importantly, in some ways, is that long-term fear can be created in these incidences.

Last, develop and implement technologies for detection for proactive intervention, so as not to rely solely on regulations and criminal statutes to prevent unauthorized possession of select agents. Thank you.

[The prepared statement of Dorothy B. Preslar follows:]

PREPARED STATEMENT OF DOROTHY B. PRESLAR, FEDERATION OF AMERICAN SCIENTISTS

Good morning. On behalf of the Federation of American Scientists, I am pleased to be here today and hope that the testimony that I bring will assist your efforts to control the possession and transfer of certain highly pathogenic and toxic agents.

My name is Dorothy Braddock Preslar. Since 1994 I have served as the Washington project officer for our Biological Weapons Verification project and, since 1995, have directed a project to promote surveillance of animal diseases, particularly in developing countries. For any among you who may not be familiar with the Federation, it was founded in 1945 by Manhattan Project scientists to promote peaceful and humanitarian uses of the new nuclear technology. Our organization, sponsored by some 55 American Nobel Laureates, has addressed arms control issues for over a half century and has in the past decade undertaken initiatives on global security issues such as the threat of infectious diseases, food production, energy and the environment.

Today, I will speak for the FAS Working Group on Biological Weapons, which has spent ten years studying means for preventing the use of biological agents as weapons, as well as for myself, as may be appropriate in the question period.

FAS supports efforts to raise the level of accountability for handling deadly pathogens and toxins. It is clear that both national security and public health will be served if these agents remain in secure environments at all times and if facilities that work with them are held strictly responsible for their safe storage, proper handling, restricted access and closely monitored transfer.

Our Working Group on Biological Weapons suggests the following measures:

1. Extend the rules for registration of facilities that transfer or receive specified agents to include the registration of all facilities that possess them.

2. Impose strict controls on possession by individuals of any amount of a select agent outside the confines of a registered facility, or any laboratory.

3. Amend the exemption for select agents that are part of a clinical specimen to require that clinical samples received for diagnostic, reference or verification purposes, and any cultures derived from them, must after the specific task has been accomplished be disposed of properly in their entirety, or transferred in their entirety to a designated facility.

4. Modify the CLIA exemption to require notification of CDC, and other federal authority as appropriate, when select agents are diagnosed from clinical samples. This would serve a dual purpose, serving as a sentinel system for outbreaks of diseases caused by these agents.

5. Conduct an intensive education campaign aimed at research and laboratory personnel. We believe that greater accountability can be achieved by explaining the importance of the regulations and appealing to the civic responsibility of the scientific community. Appropriate educational means include presentations and information booths at scientific conferences, mailings to institutions, notices in scientific publications, and inclusion in medical and science ethics courses.

6. Address the potential for attack on the food production resources of the U. S. by terrorists using animal and plant pathogens. In recent days, as you may know, USDA officials have sounded a warning, saying that such targeting is inevitable. A number of animal pathogens are already on the select agent list because they are zoonoses (diseases that affect both animals and humans). Considering, however, the possible impact on food production that could result from synchronized attacks on cattle, poultry, pigs, corn, wheat, and soya beans, in the short term our food export industry could be seriously affected and long-term fear could be created.

7. Develop and implement detection technologies for pro-active intervention, so as not to rely solely on regulations and criminal statutes to prevent unauthorized possession of select agents.

Thank you.

Mr. UPTON. Thank you.

Dr. Connell. If you could just move that mike a little bit closer, that would be perfect.

TESTIMONY OF NANCY D. CONNELL

Ms. CONNELL. I am assistant professor of microbiology at the University of Medicine and Dentistry, New Jersey Medical School, in Newark. I received my Ph.D. at Harvard Medical School. I am director of molecular microbacteriology at the New Jersey Medical School National TB Center. I have an appointment on my institution's biosafety committee.

I am also a member of the ASM and FAS, but I come here today as a researcher in the front lines; someone who works with agents that, while are not directly listed—I work with multi-drug-resistant tuberculosis—many of the processes that we use in ensuring the safety and security of our TB strain, are applicable.

My involvement in the topic of possession and control of pathogenic organisms and deadly toxins is, thus, a direct result of the work that I do. In addition, I have a longstanding interest and commitment to the development of the Biological Weapons Convention of 1972. I believe that the new climate of bioterrorist global threat demands a preventive role that bioscientists can now play. This is imperative.

Our performing experiments with an airborne pathogens, such as multi-drug-resistant TB, has familiarized me with the kinds of security issues that we are dealing with today. For example, all exchanges of MTB strains, as well as biological products derived from them—proteins, DNA, and so forth—are subject to shipping codes that are established by the public health service regulations of etiologic agents. These practices, I should say, were easily incorporated into the smooth running of my own laboratory.

Currently, there are a wide variety of Government regulations that dictate health and safety standards in scientific research institutions. These standards have greatly improved working conditions with respect to health and safety within academic research institutions. As a result of the combination of these oversight mechanisms, much of the groundwork required for the kinds of control we are discussing today, I think, are already in place.

Now I appreciate section 511 regulations, the regulations established by CDC, with respect to the act; but would support—as my colleagues do—some broadening of their terms. I think we have actually touched on the same, so I will shorten presentation of my list.

Certain facility exemptions. Before 1996, any facility that possesses these agents should be registered. There is no questions about that in my mind. Compliance. How can we ensure that all facilities comply? It is an important question. How can we interview, find out, or inspect all the facilities actually in the country to see whether they possess agents?

As far as clinical laboratory exemptions—this is a contentious issue, of course. One-hundred-fifty-thousand new registrants would be very difficult to do. I think it is unworkable. But I do agree that the identification of a listed agent in any of these clinical labs should be immediately reported to CDC; and transferred, if necessary for further study, to a registered institution.

And finally, individual possession. Of course that remains, as we have all been saying, outside the scope of the final rule. But individuals with access to these agents may well be the first link in the scenario that we are trying to prevent from occurring. Inappropriate transfer or possession of a listed agent would probably be the first event.

Certainly, there is a long tradition of exchange of scientific materials between and among scientists—carrying a strain in your briefcase, for example. But the world is different now. Individuals who must carry these agents on their person must carry authorization—strict authorization—in writing.

Responsibility of individual scientists. A recent survey of academic scientific research institutions carried out by Dr. Atlas revealed that two-thirds of academic institutions had no knowledge of the Biological Weapons Convention. I ask my medical students every year, "How many of you have heard of Biological Weapons treaty?" I call it a treaty so they know what it is. The numbers are slowly increasing.

One might infer from this that many scientists are under-informed with respect to issues to biological weapons, such as transfer, security, and disposal. Biological agents security issues should be included in existing ethics courses in all medical and graduate

schools. Many such ethics courses, as you already know, are mandated by the NIH. So in addition, the topic should be incorporated into OSHA training. This is a way of distributing some of these responsibilities.

I see some implications in addition to the purpose of the act. The public health sector communities in which these kinds of research facilities are located will be enhanced by stricter control of the whereabouts of these agents. Many of the organisms listed are among the growing list of emerging pathogens, which is a major global health problem. This tracking system will aid in CDC's efforts to track these kinds of outbreaks.

Finally, the President has recently stressed the importance of the current negotiations to strengthen the 140-member Biological Weapons Convention. These negotiations should benefit from the demonstration of U.S. research facilities' and scientists' willingness to make accurate and timely declarations regarding these biological agents. Thank you, very much.

[The prepared statement of Nancy D. Connell follows:]

PREPARED STATEMENT OF NANCY D. CONNELL, ASSISTANT PROFESSOR OF MICROBIOLOGY AND MOLECULAR GENETICS, UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, NEW JERSEY MEDICAL SCHOOL, NEW JERSEY MEDICAL SCHOOL NATIONAL TUBERCULOSIS CENTER

My name is Nancy Connell and I am an Assistant Professor of Microbiology at the University of Medicine and Dentistry-New Jersey Medical School in Newark, NJ. I received my Ph.D. at Harvard Medical School and my Postdoctoral training at Albert Einstein College of Medicine. UMDNJ is the largest public health sciences university in the nation, with three medical schools and schools of dentistry, nursing, health related professions, public health and graduate biomedical sciences. In addition, UMDNJ comprises a University-owned acute-care hospital, three core teaching hospitals, and a statewide system for managed care and over 100 health care and educational institutions state-wide. UMDNJ is home to the newly established International Center for Public Health, a strategic initiative that will create a world-class infectious disease research and treatment complex at the University Heights Science Park in Newark, NJ. I am also Director of Molecular Mycobacteriology at the New Jersey Medical School National Tuberculosis Center, and a member of ASM. The focus of my research is the molecular genetics *Mycobacterium tuberculosis,* the organism that causes tuberculosis. My laboratory studies the molecular basis of pathogenicity and analyzes the genetic basis of drug resistance in this organism. My research program is supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIAID 2R21AI3443606A1). Crucial steps of my work must be performed in a Biosafety Level Three laboratory, often with multidrug resistant strains.

My involvement in the topic of possession and control of pathogenic organisms and deadly toxins is a direct result of the work that I do. In addition, I have a long standing interest and concern in the development of the Biological Weapons Convention of 1972. In 1991, I traveled to the United Nations in Geneva and presented to the States Parties of the Convention a petition signed by several thousand signatures of scientists from around the globe. These scientists pledged not to engage in research that would knowingly result in the development of biological weapons. Thus, the role of scientists in preventing the use of biological weapons in a central theme in my professional activities.

Background.

The possibility that certain biological and toxin agents could be used in domestic acts of terror has come under scrutiny in the wake of several national and international events, by now well known to you all. Many of these potential weapons agents are the focus of, or are used in, vital research programs. Section 511 of the Act (Public Law 104-132) stipulates that the Department of Health and Human Services regulate the transfer of a number of such agents. The final version of these regulations, compiled by CDC (42 CFR 72.6—"Additional requirements for facilities transferring or receiving select agents") went into effect April 15, 1997. All facilities either transferring or receiving organisms or toxins from among a list of 36 biologi-

cal agents (species, genera or toxins) must register with the Select Agent Transfer Program administered by CDC. The regulations were originally designed to balance the protection of public safety without burdening biomedical research with excessive administrative and regulatory restrictions.

Scientific institutions have been slow to enforce the stringent workplace safety standards adopted by industry. Currently, there are a wide variety of government regulations dictating health and safety standards in scientific research institutions. Among recent regulations impacting scientific research institutions are OSHA's "Bloodborne Pathogens Standard" and "Occupational Exposure to Hazardous Chemicals in Laboratories Rule" (also known as the Lab Standard). These standards have greatly improved working conditions with respect to health and safety within academic research laboratories. Federal, state and local agencies superintend the standards. As a result of these oversight mechanisms, much of the information required for the kinds of control we are discussing are already available within institutional biosafety and/or environmental health and safety offices.

Addressing biological hazards directly are the joint CDC/NIH guidelines, outlining safe techniques for the storage, transport, manipulation and destruction of hazardous organisms in the laboratory. The descriptions of biosafety containment levels (BSL 1-4) found in the joint CDC/NIH guidelines parallel those found in a another oversight system, the NIH recombinant DNA (RDNA) guidelines. The NIH reserves the right to withhold funding from those institutions found not to be in reasonable compliance with the RDNA guidelines.

These levels of control, monitoring and tracking are administered at each institution by the appropriate committee, such as the biosafety committee. In addition, most institutions have strict intellectual property laws that require accurate record of each and every unique biological construct (new strains of bacteria, viruses and cell lines; transgenic animals; specific pieces of DNA, etc.) that leaves or enters the laboratories. Finally, most institutions have risk management offices that are concerned with protection against litigation, which is a strong motivator for strict compliance with applicable regulations and guidelines.

The current regulations established by CDC have been designed to ensure safe packaging, labeling and transport of infectious agents and to enable the tracking of these agents as they are transferred from facility to facility. These regulations do not impose undue burdens on the facilities or the investigators involved.

I have some observations and suggested revisions for improving the regulations.

1. Compliance. How can we ensure that all facilities comply if eligible? According to estimates made by the Federations of American Scientists, there are approximately 685 U.S. facilities working with agents currently listed by the Biological Weapons Convention (Federation of American Scientists, 1998). (There are a number of differences between the CDC list and the agents listed in the negotiations for a protocol for the BWC) I suggest that all research facilities should be recontacted on a biannual basis to ensure that there has been no change in status.

2. Facility exemptions. Facilities not involved in actual transfer of listed agents are considered exempt. In other word, if a listed agent has been stored in a facility before April 15, 1997, registration is not required, until the agent is transferred out of the facility. Transfers of agents within single facilities are not subject to the regulations. Should these facilities not also be registered? There are obvious security breaches involved in any kind of transport of agents outside containment laboratories. I suggest that institutions currently possessing agents should be required to register, not only those engaged in transfer of listed agents. The security of listed agents must be enforced at all institutions, not just those shipping or receiving them.

3. Clinical laboratory exemptions. In view of the huge numbers of clinical (i.e. nonresearch) laboratories engaged in diagnosis, reference and/or verification (estimated to be well over 100,000), registration of all these facilities would be an unworkable proposition. However, clinical samples are often the source of our most interesting isolates for basic research. These isolates may be transferred to already registered research facilities for further experimentation. Can these types of transfers be monitored without actually requiring regulation of the clinical lab that identified the agent? I propose that clinical labs should remain exempt but clear provisions should be included to ensure that upon diagnosis/identification of select agents in a clinical sample, the lab must notify CDC. Isolates can still be sent out to an appropriate registered institution for expansion of culture, further examination, storage or appropriate disposal.

4. Individual possession. Possession remains outside the scope of the final rule. But individuals with access to these agents may well be the first link in the scenario we are trying to prevent from occurring: inappropriate transfer/possession of a listed agent. Certainly there is a long tradition of exchange of scientific material among

scientists. But the world is different now. Scientists and those working with them must learn to behave responsibly. On occasions when individual possession (i.e. by a worker) is necessary, that individual should be authorized in writing by the registered facilities sending and receiving the agent.

5. Responsibility of individual scientists. A recent survey of academic scientific research institutions revealed that two-thirds of academic institutions had no knowledge of the Biological weapons Convention (Weller et al., 1998). One might infer from this that many scientists are underinformed with respect to the issues related to biological weapons such as transfer, security and disposal. Education: Biological weapons issues must be included in ethics courses in currently existing graduate programs and medical schools. The NIH mandates ethics course for students involved in NIH-funded training programs. In our Institution, for example, all students are required to take this ethics course. Biological and toxin weapons and their control should be among the required topics. In addition, the topic should be mandated to be part of biosafety/OSHA training.

Implications.

The above comments are respectfully put forward as topics for discussion. In addition to the direct application of these issues to the problem of bioterrorism, there are several beneficial aspects that would accompany the strengthening of the Select Agent Transfer Program. First, the public health of the communities in which research facilities are located will be safeguarded by stricter control of the whereabouts of these agents. Second, many of the organisms listed are among the growing list of emerging pathogens. Endemic pathogens on the list may cause diseases not yet found on individual State Department's "reportable diseases", and this tracking system would assist CDC to monitor outbreaks. Finally, the President has recently stressed the importance of the current negotiations to strengthen the 140-member Biological Weapons Convention. These negotiations will benefit from demonstration of US research facilities' and scientists' willingness to make accurate and timely declarations regarding thee biological agents.

Conclusions.

Biomedical research has performed marvels for human health. Now it needs to do a simple thing: keep track of the whereabouts of disease-causing microbes (microbial pathogens) studied in research laboratories and make sure that they are handled safely and securely stored. In general, these measures are carried out by professional safety officers and no undue burden need be placed on the researchers themselves. But for scientists who have chosen to devote their lives to the study and control of pathogenic microbes, preventing their spread in every way possible is just part of the job. This is clearly the critical moment for us and our research institutions to make sure that our houses are in order.

Acknowidegements.

I would like to acknowledge the contributions of Mitchell Gayer, Paul Rubock, Theodore, Myatt, and Len Cole in the preparation of this testimony.

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Mr. UPTON. Thank you. You know the procedure for us up here. I will start my 5 minutes.

I heard all of you say, both in your testimony and verbally, that there really is never a legitimate reason to possess biological agents outside of an improved, secure lab environment. Such possession really should be unlawful, is the bottom line. Ms. Preslar, what is your sense on the research community's compliance with the current CDC transfer regulations? Do you think there is 100 percent compliance, 50 percent? What are your thoughts?

Ms. PRESLAR. That is very difficult for me to assess. I do think that there have been successes in this. I think there have been more successes after the dropping of the fee, because $13,000 is quite high for an academic lab to cough up if they want to send

a vial of something to a colleague in Oregon. Maybe that is not the right place to send it.

I think there will continue to exist individual transfers to colleagues working on the same agents, both domestically and internationally, until such time as either the scientists are frightened to death of criminal prosecution; or frightened of losing their jobs at the institutions; or until they simply recognize that they have a responsibility to cooperate.

Mr. UPTON. Dr. Atlas you wrote in ASM News last year, and I quote here, "The majority of microorganisms that could be used as biological warfare agents are freely circulated among scientists, and ordinarily may be obtained through these non-documented, non-authenticated sources." Is that still your sense?

Mr. ATLAS. I think that if we talk about an organism that can cause disease, not a weapon of mass terror, then that is correct. We have the salmonellas—any number of organisms—that are freely transferred and are not regulated. I have no sense that anyone is violating the current statutory regulations for registration of shipment of listed agents. My conversations in the scientific community indicate, in fact, what has happened is that a number of individuals are simply not shipping. They are not exchanging.

I think the point in the article that I wrote is that if you wanted to be a bioterrorist, you could find the materials freely in nature. You could obtain them. You would not have to register. You could, in fact, possess them. I think that the current discussion of how to tighten up the regulations would, in fact, potentially make it a crime to possess such agents outside duly authorized and appropriate institutions. I think that is really the critical thrust of where things seem to be going.

Mr. UPTON. So you would be very supportive, particularly of the first panel that was here and the movement that is being made along those lines?

Mr. ATLAS. I think I am very supportive of the movement toward the regulation of possession. Not having seen the administration's legislative proposal, however, the devil may be in the details. So I think I, and my colleagues, remain concerned, since we have not been at the table with respect to the details of that proposed legislation. We certainly have been consulted in general terms. I think we are comfortable with much of what is being discussed, generally. Although, again, we get very concerned when we get to the point of who really, legitimately can have access to a laboratory where agents are being employed.

Mr. UPTON. Okay. Thanks. We will have a second round here. Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman. If I may pick up on Dr. Atlas and Ms. Preslar, have your organizations been consulted by the administration in preparing their so-called package?

Mr. ATLAS. Informally we have had some discussions with individuals, from HHS in particular, who have been involved in those discussions. However, we have not been brought to the table for the actual discussions. We think that is a very important and missing step.

Mr. STUPAK. So you feel you should be consulted?

Mr. ATLAS. Yes.

Mr. STUPAK. Ms. Preslar?

Ms. PRESLAR. Our organization has not; but then our organization was not consulted in the 1997 rule, either.

Mr. STUPAK. Okay. Do any of you in your own research work, work with special biological agents? Shaking of heads—that means "no"? No one does.

Ms. CONNELL. No.

Mr. STUPAK. Do any of you represent any institutions or companies that actually own laboratory facilities?

Ms. CONNELL. No.

Mr. ATLAS. No.

Mr. STUPAK. Okay.

Mr. STUPAK. Ms. Preslar, you proposed there be strict controls, you said, on possession by individuals of any amount of select biological agents outside the confines of a registered facility, correct?

Ms. PRESLAR. Right.

Mr. STUPAK. So then what is your opinion of possession of the agents by commercial courier: UPS, FedEx or mail system employees during shipping?

Ms. PRESLAR. I think there ought to be closer monitoring. I think the tracking system ought to be special for these things. Although, I understand from the prior testimony when you do that, then you may indeed signal what the contents are of a package. I don't think we want to do that. One never knows who is coming across this package.

You are absolutely right, from the prior panel, to suggest that after it leaves the doorway of lab and before it reaches the doorway of a second lab, anything can happen to it. It can be stolen. It can be lost. It can be damaged. The safe packaging—I am not sure if that was described. There are containers that are very resistant to tampering, and so forth.

Mr. STUPAK. Dr. Atlas, I think you testified that the Society of Microbiology worked on those transfer and shipping rules, and think they are adequate. But do you think that special biological agents should have less protection than the transferring or shipping of money?

Mr. ATLAS. Yes, in some ways. When you have a patient in a clinical situation and you isolate pathogen, it is of the utmost importance that we get that diagnostic specimen to an appropriate laboratory for diagnosis. If we are going to ever have a bioterrorist attack, what is going to be critical is that we carry-out the diagnosis.

Mr. STUPAK. You are talking about a clinical laboratory sample, right? We are not talking about special biological agents here, are we?

Mr. ATLAS. Well, but we are. In other words, if you have a patient who, in fact, is diagnosed with a disease. You have an envelope, as the FBI has brought to our hospital, with suspected spores of anthrax in it. One has to take appropriate quick steps to move that specimen.

Mr. STUPAK. That is for diagnosis and when you don't know what it is, right? I am talking about special biological agents that you do know what it is.

Mr. ATLAS. I guess what I am saying is that it is very hard in many situations to make that distinction between the clinical specimen and the biomedical research material. What has been critical to us is really the biosafety aspects of shipment.

Mr. STUPAK. You spoke in your testimony, again, about that natural infectious disease kills 17 million every year in the world, and are a much greater threat than future bioterrorism scenarios. I think where we are going—and I guess, where we are all trying to go—in very practical terms, at what point does Government regulation encumber the diagnosis and treatment effort?

Mr. ATLAS. If one had to, for example, pause for 24 hours while one obtained permits to make the shipment it would clearly inhibit the diagnosis. I don't think anyone wants to that. This is why there has been this exemption on the clinical isolation.

With regard to other shipments, I think the broader issue, which has been touched upon by the first panel, and which ASM would support, is some greater consideration to the security aspect related to biosafety. We have been very concerned with avoiding exposures to individuals working with the organisms to anyone else in the public. With these select agents, it is appropriate for the CDC and other HHS organizations to work with the scientific community to better define the security arrangements, including the shipment aspects.

Mr. STUPAK. Are your comments more toward protection of the workers who are dealing with these in the labs?

Mr. ATLAS. I think it goes beyond that. It starts—and where it currently is at—is in the protection of the workers. I think there needs to be some additional consideration here given to maintaining the appropriate security of both the laboratory and the shipment.

Mr. STUPAK. Thank you.

Mr. UPTON. Thank you. Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman. Let me also take this opportunity to thank Dr. Ostroff and Dr. Raub for sticking around. I would just be curious—is there anybody here from the Department of Justice? Thank you. How about from the FBI, specifically? I know it is under your purview. My only concern is that they are not as interested to be here to hear the continuation of panel two. I think there has been some good information.

I would also like to welcome Ms. Preslar. I notice that you are a Wake Forest graduate. I am always tickled to death to have those up here. I thought maybe our paths had crossed until I saw the cum laude and Phi Beta Kappa.

I realized the chances were very slim.

Ms. PRESLAR. I did tutor a lot of football players.

Mr. UPTON. It is even slimmer, yet.

Mr. BURR. He is the wrong one to engage in something like this. Let me ask all three of you. I will assure you that this committee is not attempting to over burden the research community. We are not here to determine which agency is the right one, and what balance of law enforcement versus science should drive the decision.

I have a tremendous amount of confidence in the CDC on just about everything. But I think it is legitimate for this committee to ask if we have given them an assignment that is acheiveable? So

I would ask you. Have we given them, in this case, a task to carry out that you feel this is the most appropriate place for it to come from?

Mr. ATLAS. Simply, yes. I think that the overall mission of the CDC is to protect human health. That involves ensuring biosafety. In this case, it extends to deterrents of bioterrorism.

Mr. BURR. Ms. Preslar?

Ms. PRESLAR. Not entirely. I think that the ideal situation would be if you had an inter-agency situation. CDC is not equipped to do law enforcement, as was brought up in the last panel. Law enforcement is not able to have the sensibilities toward research work and know, actually, what they are dealing with half the time, unless they are trained well. So I would say that you would need input. You need OSHA input. You need academic laboratory input. You need industry input.

My suggestion would be, if the United States is going down this path, that some thought be given to creating—not an NRC—but a minuscule "BRC," perhaps.

Mr. BURR. Well, I have actually had two instances in the past several months in North Carolina of anthrax scares. One was an abortion clinic in Asheville, and another was a facility in Roanoke, Virginia. In both cases, the FBI did not call the CDC. They called a special operations medical team in Winston-Salem, where a team went out to determine whether it was a valid threat. That sort of stimulates my questions, to some degree. Dr. Connell?

Ms. CONNELL. I would say CDC, with input.

Mr. BURR. With input from the agencies.

Ms. CONNELL. That looks like that is happening.

Mr. BURR. Ms. Preslar, in staff interviews you mentioned your concern that security and accountability is a significant problem at many labs, particularly hospitals and other academic labs, less so with pharmaceutical companies. Would you like to expand on that at all?

Ms. PRESLAR. Academic labs and some institutional labs simply do not have the funds to provide total security. We know that. Also in academic labs there is, probably, a more relaxed atmosphere when dealing with these things. It is because these environments have been, in some ways, rather sacrosanct. These people have not had to worry about bioterrorism.

Mr. BURR. Would they know if there was a theft?

Ms. PRESLAR. Possibly no. It depends on the inventory control aspects the place.

Mr. BURR. Dr. Connell, you stated in your testimony that academia has not done as good a job as private commercial labs, with respect to safety and security. Can you expand on that?

Ms. CONNELL. I think there has been a lag in the implementation of a lot these kinds of things. This is a different issue. We are talking about safety.

Mr. BURR. Let me just say, before you answer, I think it gets at the heart of the thought process that they put into it. Because safety, to some degree, is prerequisite to security.

Ms. CONNELL. That is true. So I do think there has been a lag, but I do think they are catching up. I think that now academic in-

stitutions are actually slapped with fines for noncompliance in various areas of safety, certainly by the NRC, by OSHA, and so forth.

Mr. BURR. Does that encourage or discourage additional research?

Ms. CONNELL. I think it is irrelevant. This is a point that I would like to make. I think that a committed principal investigator who wants to work on an organism will work on the organism, and will go through the necessary paperwork that is required.

Mr. BURR. How many times would an academic lab be fined before they might restrict what their researchers have access to?

Ms. CONNELL. Fined by what?

Mr. BURR. You mentioned the fines.

Ms. CONNELL. NRC fine, for example. A security violation for the NRC for leaving a small vial of P32 unattended——

Mr. BURR. We are at a disadvantage because we don't know what will be in the crime bill. There might be some monetary approaches that they take toward lack of security of safety. I thought that might have been what you were suggesting.

Ms. CONNELL. Yes. There is definitely been a response. NRC has been able to implement these strict security guidelines over the past 5 years that have been very carefully followed. Yes, the institutions have been fined.

Mr. BURR. Dr. Atlas, you have written that security should be increased at laboratories that legitimately use and store potentially dangerous microbial agents. Can you be more specific about what types of measures your are talking about, and what types of deficiencies you have observed that lead up to this suggestion?

Mr. ATLAS. I think there is a need, first, for educational awareness that security is necessary with these agents. Locked laboratories; limited access to laboratories; knowing who enters and has access to materials, I see as part of a biosafety requirement. It then extends to the security issue.

To date, in academia at least, we have left our laboratories largely open, regardless of the organisms that we have in them. We have common refrigerators and storerooms where, if it is frozen and sealed in a vial, it is concerned safe. Anyone may have access to it.

We do not have centralized inventories at most academic institutions that would allow a biosafety officer—many academic institutions don't have biosafety officers. All those, I think, can be strengthened and should be strengthened. I think that the actions of this committee in bringing this to greater attention will help universities focus their attention where it needs to be.

Mr. BURR. Let me just make one last comment. It gets at the heart of, I think, what Mr. Stupak was at. Am I off base in seeing a distinct difference between the diagnosis of an illness, or the exposure versus the research of biologic agents? Are they not two, distinctly different things?

Mr. ATLAS. They are two distinct processes, but in both you wind up with possession of the organism.

Mr. BURR. I would suggest that with the diagnosis side, there is a way within the CDC and HHS that we can address the immediate access needs to that; but treat the research side with somewhat different controls that are not as time-sensitive.

Mr. ATLAS. That is correct.

Mr. BURR. I thank this panel. I thank you, Mr. Chairman for you leniency on that quick clock. I know you shorted me some time because of your bad eyesight.

I yield back.

Mr. UPTON. I just have a couple of follow-up questions. Dr. Atlas, you said in your statement that actually a vast majority of labs don't keep track of their inventory. Is that correct—in the study?

Mr. ATLAS. A vast majority of academic institutions report that they have no centralized inventory. They don't know what they have. Anecdotally, I was chairing a department at our medical school and I can tell you, I didn't know what existed in our department.

Mr. UPTON. I take it based on that conclusion that you believe we ought to have some inventory checks or some way to gauge exactly what is there. Should the CDC be the ones to keep track of that? What recommendation would you make?

Mr. ATLAS. I think that institutional responsibility is critical. I think that what needs to happen, if we move toward possession as opposed to just shipment, is that we place the responsibility on the institution for maintaining the appropriate biosafety. That will include knowing what they have; where it is; who is using it, and those records could certainly be made available to CDC on inspections. That would be an extension of the current inspections. As Dr. Richmond indicated, there will be instances on a CDC inspection, they decide that a given laboratory is not meeting the appropriate requirements. I think it has to be institutional responsibility to maintain those standards.

Mr. UPTON. Dr. Connell.

Ms. CONNELL. If I could make a comment. It is my understanding that the NIH Recombinant DNA Advisory Committee mandated that any institution using recombinant DNA have a biosafety officer; and have a record in each lab of what recombinant molecules are being produced, and so forth. So yes, straight organisms don't fall under that purview and I think it should be extended.

Mr. UPTON. What about background checks? You think the institution should require a background check in terms of past felony convictions, or something along that line, for folks handling these things?

Mr. ATLAS. I think that is where I have a problem, as a scientist, saying what the appropriate place for background checks is.

Mr. UPTON. Maybe you could ask if they have a firearm. If they have a firearm, they are supposed to have had that, right? At least when the Senate is done this week.

Mr. ATLAS. I guess where I have my problem is that I don't see that it is ever appropriate for individuals to really possess. I think institutions possess. Individuals have access and use within the facilities of an institution. It will be a major burden, I suspect, depending on the sort of background check. It may be very difficult in various States and institutions to deny employment for individuals in our universities and other facilities.

Again, not knowing what is being proposed or even discussed, it seems to change in rumor each day as to what the legislation may or may not include. It is very difficult to comment on how that real-

ly would impact, or how workable that would be. I have concerns. On the other hand, no, I don't want someone with access to pathogens who has a propensity for misusing.

Mr. UPTON. I would just like to say as I wind up my time, when we do see this proposal, my sense is that our committee will get a piece of the referral of that legislation. I certainly would like to stay in touch with the three of you and get your comments once we see that in written form. If you wouldn't mind doing that, that would be terrific. With that, Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman. Let me just ask some questions along those lines that the Chairman was asking.

The President's proposal—one of them—said that it would ban violent felons and fugitives from possessing these agents. Any of you know of violent felons or fugitives working in the labs? I mean, not currently, but in the past.

Ms. PRESLAR. Well, I don't think that is the question. I think the question is how can you tell they are violent felons?

Mr. STUPAK. Exactly right. The violent felons, of course, we have title I crimes, which are considered violent. I guess that is the definition. But the point I am trying to make is that while the proposal sounds real good and everyone says, "Yeah, let's do it," you just don't have fugitives and violent felons working in labs.

Ms. PRESLAR. You could have. It is possible.

Mr. STUPAK. Okay. Then we should do some background checks on everyone. Is that what you are saying?

Ms. PRESLAR. I am not expert on employment law, or labor law. But is it not still acceptable on an application to ask if you have ever been convicted of a felony?

Mr. STUPAK. You have to be careful there.

Ms. PRESLAR. You can no longer ask?

Mr. STUPAK. You can ask if you have been convicted.

Ms. PRESLAR. Not arrested, but convicted.

Mr. STUPAK. Yes. So are you saying the institution should have that responsibility?

Ms. PRESLAR. I think the institution should ask the question. I think that puts people on notice regarding their obligation.

Mr. STUPAK. Dr. Atlas, would you agree with those?

Mr. ATLAS. I don't know. I really am not sure what the institutional responsibility ought to be in that instant. In part, that comes from my lack of knowledge of labor law and how institutions operate.

Mr. STUPAK. I believe the FBI had actually suggested, too, along these lines: mental instability; drug and alcohol problems; financial problems. These would be incentives, if you will, have people put these agents out or monetarily gain from them because of some deficiency in their own character. Should we do background checks on folks who work there to make sure they don't have financial difficulties, instabilities, or alcohol or drug problems?

Mr. ATLAS. Now you are raising the issues where, as I said, the devil is in the details, and where my concerns are. We have also heard that people have marital problems of various types may be excluded from the labs.

There are endless rumors. I don't know how to respond to those rumors other than to say that I am concerned. When the actual

legislation comes forward we would welcome the opportunity to comment back to the appropriate committees as to what the likely impact would be.

Mr. STUPAK. Should all foreign nationals be banned from the labs? Should they undergo background checks and things like that?

Mr. ATLAS. I think that is the one we have heard that gives me the biggest problem in that I believe that 25-30 percent of our graduate students working in labs are foreign nationals that we continuously recruit. I understand there are security concerns. But in many cases, a number of these agents are exotic diseases to the United States. We are carrying out research to help in Africa or elsewhere. It behooves us, then, to have researchers from those countries who will bear the burden of carrying forth on that to come to our labs, be it the CDC or elsewhere, and work with our scientists. I would not want to ban them from research on the agents that are really their concern more than ours.

Mr. STUPAK. Let me ask this. Let me ask in a series of questions, if I may, and try to wrap it up here.

I am still struggling with what kind of security to we want at these labs with special biological agents. I am talking about special biological agents, not biosafety measures. I am talking about physical security.

Should new labs be built on a much higher level of physical security, similar to our nuclear weapons? Should all these labs have 24-hour armed, trained guards and surveillance cameras? Should all persons with access to the labs undergo checks for their criminal records; mental stability; drug, alcohol, gaming addictions, credit cards, political activities, intelligence—I mean, we could go on and on?

What kind of security would you be comfortable with? What do you think we could do and still balance the research that you are trying to do to stop the death of 17 million people a year?

Saved by the bell. I know I threw a lot of things out there. But, where do we go with this stuff?

Mr. ATLAS. The answer is, I think, in part both from the biosafety and the security issue that having a more limited access to a number of laboratories where they are not common, shared facilities is appropriate. Armed guards seems excessive. I say that, in part, because you have to recognize that for most of these agents, you always go and obtain them from nature.

So the question becomes one of balance. How far do you go in locking the doors and simply forcing them out into a field to isolate the organism?

Mr. STUPAK. See, my concern is that what we have heard thus far from the panels, I think, has been like if we make it crime, let's make it a crime. Then we have control of the situation. It doesn't work. It is not just making it a crime, as you said. They can grow it. They can do other things to obtain it. I am trying to get the safety measures, internally, so that it doesn't get out. I agree with you that there are some problems there. But you can't simply make something a crime and it goes away. If you make it a crime, then we have law enforcement running labs, not scientists.

Ms. CONNELL. Most of the agents have worked with inside biosafety level three and above—containment facilities which are totally contained.

Ms. PRESLAR. I just wanted to say that I think that the biosafety and the bioterrorism aspects of this are intertwined. The more we talk about bioterrorism, the more we indicate that there is a terrorist standing on every street corner, or a potential terrorist, the more important it is to prevent accidental release of any of these select agents. Because, even if you have a unnatural outbreak from an accidental release, the terrorist aspects of that in terms of the population increases exponentially.

Mr. STUPAK. Thank you.

Mr. UPTON. Well, again we thank you for testimony. We look forward to hearing back from you once we see the administration proposal. We thank you very, very much for spending the time with us today. We are all excused.

[Whereupon, at 12:21 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

RESPONSES TO QUESTIONS FOR THE RECORD FROM REP. HENRY WAXMAN BY STEPHEN M. OSTROFF, M.D.

Question 1. Dr. Ostroff's supervisor, Dr. James Hughes, testified on April 20 in the Senate on bioterrorism. He identified four CDC priorities to which $41 million are being allocated: 1) detection of unusual events, 2) investigation and containment of outbreaks, 3) laboratory diagnosis, and 4) communication.

These four priorities are consistent with CDC's traditional functions and mission. Aren't new regulatory responsibilities, such as background checks and laboratory inspections, at odds with CDC's existing priorities for strengthening the national public health infrastructure? Wouldn't such new responsibilities threaten to divert CDC resources and staff from these priorities?

Answer 1. A primary role of CDC is prompt recognition of disease threats whether they are naturally occurring or intentional. This requires careful monitoring by effective disease surveillance systems, backed by the capacity to investigate and control outbreaks of a variety of health problems in a timely manner. As the nation's disease prevention and control agency, it is CDC's responsibility to provide national leadership in the public health and medical communities in a concerted effort to detect, diagnose, respond to, and prevent illnesses, including those that occur as a result of a deliberate release of biological or chemical agents. This task is an integral part of CDC's overall mission to monitor the health of the U.S. population.

When considering whether to add law enforcement duties to an agency such as CDC, several issues should be considered. First, CDC is a not a law enforcement agency, and such responsibilities are considerably beyond CDC's expertise and mission. Second, CDC does not have an infrastructure to efficiently implement and administer such requirements. Such requirements would divert expertise from our more traditional high priority tasks such as surveillance and outbreak investigation. Third, such activities could jeopardize the independent scientific credibility of CDC when it is recognized that CDC is policing external organizations, institutions and individuals. The same non-governmental researchers that we must collaborate with on a voluntary basis in order to solve complex scientific issues, whether they pertain to bioterrorism or to a naturally occurring disease outbreak, will be targeted by these law enforcement activities. CDC clearly has had, and will continue to have, a responsibility to provide technical assistance and advice to the law enforcement community at both the federal and the state level. Nevertheless, CDC cannot function effectively while administering a primary law enforcement/regulatory function that is beyond, and in many respects contrary to, its mission, staffing, and expertise.

Question 2. This year, the National Academy of Science issued a report entitled, "Chemical and Biological Terrorism." Their fourth recommendation was: "Improvements in CDC, state and local surveillance and epidemiology infrastructure must be undertaken immediately and supported on a long term basis."

Wouldn't charging CDC with new regulatory and law enforcement responsibilities, such as background checks and laboratory inspections, be inconsistent with the NAS recommendation?

Answer 2. As indicated above, additional regulatory responsibilities would impede CDC's traditional mission-related tasks which are critical to the nations' bioterrorism efforts. In the overall context of responding to bioterrorist threats, there are a number of areas where further work is needed to develop appropriate safeguards against the treats to public health and safety presented by biological agents, and toxins. These include effective surveillance and epidemiologic investigations, enhanced laboratory capacity, improved communication networks, and development of a pharmaceutical stockpile of essential drugs and biologics for use in civilian emergencies. These activities fall within the traditional purview of CDC, and using FY 99 resources, CDC is moving aggressively to build capacity in the public health community in each priority area. CDC believes regulatory and law enforcement responsibilities have the potential to conflict with building the public health component of our bioterrorism response capacity.

In December 1998, CDC established the Bioterrorism Preparedness and Response Activity (BPRA), to lead an agency-wide effort to prepare for and respond to acts of terrorism that involve actual, threatened, or suspected uses of biological or chemical agents. BPRA is charged with the coordination of CDC's epidemiological and laboratory response following a suspected or actual attack and response to health threats from unknown biological or chemical agents.

In February, in an effort to provide support and assistance to State and large metropolitan health departments in enhancing their ability to be prepared for and respond to a terrorist attack that involves a biological or chemical agent, CDC announced the availability of nearly $41,000,000 in Public Health Preparedness and Response to Bioterrorism cooperative agreement funds. This announcement, along with other extramural and intramural strategies, focuses on strengthening the public health infrastructure to improve the national capacity to address biological and chemical terrorism.

CDC appreciates the need to craft appropriate restrictions and sanctions for improper possession and handling of these select agents. However, we believe that any safeguards be carefully balanced against other important societal concerns, notably the need to support and encourage legitimate and important research involving these substances. Federal Government agencies are actively collaborating with the private sector on a wide range of research efforts addressing the bioterrorism threat and these efforts need to be expanded. We must bring the best and brightest minds to bear on the development of vaccines, antivirals, antibiotics, and other therapies for exposure or illness due to biologic agents; to develop and test protective equipment; and to develop reliable, rapid assays capable of detecting minute concentrations of biologic agents.

To do so, we need to ensure that current or contemplated restrictions and sanctions on possession or handling of biologic agents do not have a chilling effect on the availability and willingness of scientists and research establishments to take part. Such could well be the effect of ill-advised and overbroad provisions of law that, for example, place unnecessary restrictions on categories of individuals permitted access to biologic agents, or require research laboratories to perform law enforcement functions with regard to their employees. In the ongoing exploration of this issue, HHS is committed to consulting closely with law enforcement agencies and the medical and scientific research community to develop safeguards on possession and handling without creating disincentives that would impede this critically needed research work.

PREPARED STATEMENT OF ALAN F. HOLMER, PRESIDENT, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Mr. Chairman and Members of the Subcommittee: On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am pleased to present recommendations for inclusion in the Subcommittee record on the adequacy of federal law relating to biological agents. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which will invest more than $24 billion this year alone in discovering and developing new medicines to help and heal patients. PhRMA companies are leading the way in the search for new cures and treatments. Currently, there are 136 new medicines in development to treat or prevent infectious diseases, humankind's oldest and most persistent enemy.[1]

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[1] Pharmaceutical Research and Manufacturers of America. New Medicines in Development for Infectious Diseases. Washington, D.C. 1998.

PhRMA recognizes that concerns have been expressed about the threat of bioterrorism and believes that these concerns should be carefully addressed. We will continue to work with the Commerce Committee and the Administration to find ways to minimize the threat of misuse of biologic agents at home and abroad. However, without diminishing these concerns, we caution that natural occurrences of infectious diseases are a far greater threat to human life and public health than biological agents are. The Center for Disease Control and Prevention's (CDC) 1998 document "Preventing Emerging Infectious Diseases"[2] reports that, without a strong and vigilant public health system, we can expect to see a continued reemergence of infectious diseases. Infectious diseases will claim more than 100,000 American lives this year and cost more than $30 billion in direct treatment expenses alone.[3]

The 136 medicines and vaccines currently being developed by America's pharmaceutical companies provide our best hope of reducing that toll. Therefore, any regulation or legislation regarding the possession and transfer of select biological agents must take great care not to obstruct legitimate research that helps patients.

We believe the CDC regulatory controls on the transfer of select biological agents and other infectious agents establish strong and sufficient protections against related criminal bioterrorist activity, while allowing important research and disease surveillance activities to go forward. However, any new legislation or regulation should:

- **be carefully drafted so that it is not unduly broad.** For example, any new legislation or regulation should not cover biological agents in clinical specimens, or naturally occurring biological agents (e.g., *Bacillus anthracis* in soil).
- **not put undue burdens on the exchange of microbial strains and cultures**—including, sample collections which are not fully characterized—among biomedical research scientists. Such burdens may discourage or delay legitimate and important research into ways of combating infectious disease and complicate the operation of surveillance programs (potentially without having a great effect on those intent on illegitimate bioweapons research).
- **take into account the legislation and regulation which already exist for the use of infectious agents.** For example, agent risk group classifications and procedures for handling certain infectious agents are given in the National Institutes of Health document "Guidelines for Research Involving Recombinant DNA Molecules" (61 Fed. Reg. 1481-1490). The use of Human Immunodeficiency Virus (HIV), Hepatitis B Virus and 13 other microorganisms are regulated under "Occupational Exposure to Bloodborne Pathogens" (56 Fed. Reg. 64175-64182). CDC, the Department of Agriculture, and the Department of Commerce control the import and export of microorganisms. Airline transportation rules also play a role in ensuring the safety of shipments of biological agents. Thus, multiple regulations are already in place.

We thank you for the opportunity to submit these comments. PhRMA applauds the Committee's efforts to combat terrorism and we look forward to working with you on this important issue.

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[2] Centers for Disease Control and Prevention. Preventing Emerging Infectious Diseases: A Strategy for the 21st Century. Atlanta, Georgia: U.S. Department of Health and Human Services, 1998.

[3] Pharmaceutical Research and Manufacturers of America. New Medicines in Development for Infectious Diseases. Washington, D.C. 1998.