

**GERMS, TOXINS AND TERROR: THE NEW THREAT
TO AMERICA**

HEARING

BEFORE THE

SUBCOMMITTEE ON TECHNOLOGY, TERRORISM,
AND GOVERNMENT INFORMATION

OF THE

**COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE**

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

NOVEMBER 6, 2001

Serial No. J-107-46

Printed for the use of the Committee on the Judiciary



U.S. GOVERNMENT PRINTING OFFICE

81-677 PDF

WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
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GERMS, TOXINS AND TERROR: THE NEW THREAT TO AMERICA

TUESDAY, NOVEMBER 6, 2001

SUBCOMMITTEE ON TECHNOLOGY,
TERRORISM AND GOVERNMENT INFORMATION,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The Subcommittee met, pursuant to notice, at 10:07 a.m., in Room SD-226, Dirksen Senate Office Building, Hon. Dianne Feinstein, [Chairman of the Subcommittee] presiding.

Present: Senators Feinstein, Edwards, Kyl, and McConnell.

OPENING STATEMENT OF HON. DIANNE FEINSTEIN, A U.S. SENATOR FROM THE STATE OF CALIFORNIA

Chairperson FEINSTEIN. I would like to call this hearing together and say good morning and welcome, all of you. This is the Judiciary Subcommittee on Technology, Terrorism and Government Information.

A little over two months ago Robert Stevens, a photo editor at American Media Incorporated in Boca Raton, Florida, was diagnosed with inhalation anthrax. He died two days later. The event began a second wave of terrorist attacks across our country. In the past month an unknown number of deadly anthrax packages have coursed through our domestic mail delivery system. So far, 17 individuals have confirmed anthrax infections. Four of those have died from inhalation anthrax.

Beyond the individual infections, communities have contended with the disruption of the mail, the overflow of public health clinics, the closing of buildings, and the dislocation of commerce. Our own offices in the Hart Senate Building remain closed because of anthrax contamination.

Our nation has little experience with anthrax. In the past century only 18 cases of inhaled anthrax have occurred, the most recent in 1976. Nor is our country familiar with bioterrorist attacks. The only major documented bioterror attack against an American population in the past century occurred when an Oregon cult contaminated local salad bars with Salmonella, poisoning 750 people.

The new bioterror threat, though, is unlike any other threat our nation has encountered. It is different because attacks do not come with a visible bang but are only recognized after the fact by doctors or nurses in emergency rooms. Antibiotics, not tanks and anti-missile systems, provide the best defenses. So while we cannot stop bioterrorism, I believe we can reduce the threat.

This hearing will assess our existing protections against bioterror in light of the recent anthrax attacks. It will also review the security and prevention measures the United States government can institute to further deter terrorist attacks.

I believe that this Congress can and should take concrete actions today to reduce the bioterror threat and I hope this hearing will shed some light on how best to proceed. For example, I believe that we should toughen federal laws resulting in the possession of specimens of anthrax, smallpox and other highly toxic biological agents. Amazingly, until the passage of comprehensive terrorism legislation several weeks ago, the law actually did not prohibit any ordinary citizen from building his own personal cache of anthrax. Even with the new law, individuals can possess dangerous pathogens with very few restrictions. It is actually up to the prosecutor in a case to show why the individual should not possess these deadly pathogens.

So I do not think we can afford to treat these weapons of mass destruction so casually. Last week I announced legislation to tighten controls over the possession of 32 different biological agents, all of them deadly, and I am working with a bipartisan coalition of senators, including Senator Kennedy and Senator Frist and I hope Senator Kyl on my right, on a comprehensive bioterrorism package to eliminate these loopholes. My proposal would make it illegal for individuals to possess personal stockpiles of dangerous biological agents like anthrax or ricin. I can think of no legitimate reason why ordinary people on the street need to possess these pathogens, whether they be anthrax, smallpox or the Ebola virus specimen.

Under the bill, only labs certified by the Secretary of Health and Human Services would be able to possess these substances and only if they have a legitimate research purpose. Therefore, only somebody working for a lab, certified with a legitimate research purpose would be able to possess these 32 toxins and pathogens. Current law does not require labs to register their possession of these agents. Thus, nobody knows how many labs actually have them.

The legislation would require any researchers handling these dangerous biological materials to pass background checks. School bus drivers must pass criminal background checks. Drivers of hazardous waste vehicles need to pass criminal background checks. School employees in some states must pass background checks and so should researchers who handle these most lethal of agents.

Legislation should also allow for civil and criminal penalties to be imposed on individuals who handle these dangerous agents in a manner that threatens the public health.

I propose these new restrictions because quite simply, these microbes are too dangerous to be handled without adequate security. In the wrong hands, as we have seen, they can be converted into weapons of substantial destruction.

Even according to the calculations of some experts, biological weapons are, pound for pound, potentially more lethal even than thermonuclear weapons. The Office of Technology Assessment calculated that 100 kilograms of anthrax spread over Washington would kill from 1 to 3 million people under the right conditions. In

contrast, a 1-megaton nuclear warhead would kill from 750,000 to 1.9 million people.

I am not going to go into any more of that because I think it is extraordinarily depressing, to say the least, but one thing is clear. We should toughen our laws and we should see that whether they are thermonuclear weapons or these 32 toxins and pathogens, only the most certified labs and the people working for these labs who have been cleared to handle these pathogens and toxins should have possession of them.

We need to explore how the federal government can encourage private sector companies to develop technologies to scan and detect these agents. We need to examine the commercial sale of equipment—aerosol sprayers, for example—used to disperse and aerosolize these agents. We need to beef up needed stockpiles of vaccines and better educate public health personnel. As a matter of fact, the testimony that we have had today indicates that the weakest link in our chain are local and state public health offices.

So we have many initiatives that are needed and they can help save life.

Before turning to the ranking member I want just very quickly to state that the first panel will contain government witnesses, including Jim Reynolds, the chief of the Terrorism and Violent Crime Section of the Department of Justice, and Mr. J.T. Caruso, the department assistant director of the FBI.

Deputy Secretary Claude Allen intended to testify but I understand he has suddenly been taken ill. Apparently this is the first time he has missed a day of work in seven years so we're very sorry that he is not here. But our second panel will include John Parachini of RAND Corporation, Dr. Michael Drake, vice president of health affairs of the University of California, Ronald Atlas, the national president of the American Society of Microbiology, and Senator McConnell has asked to introduce him, and Steven Abrams, the mayor of Boca Raton, Florida, where the first outbreak took place.

[The press release of Senator Feinstein and information regarding legislation follows:]

SENATOR FEINSTEIN URGES BAN ON INDIVIDUAL POSSESSION OF ANTHRAX, OTHER PATHOGENS AND STRICT NEW CERTIFICATION OF LABS

WASHINGTON, D.C.—Concerned that dangerous pathogens and toxins capable of being used as biological terror weapons are too readily available, U.S. Senator Dianne Feinstein (D-Calif.) today announced legislation to ban individual possession of these hazardous agents and establish strict new certification requirements for labs.

"With the spread of anthrax through the mail, our nation is facing an unprecedented biological attack," Senator Feinstein said. "Yet amazingly, under current law, individuals can possess anthrax bacteria, smallpox virus or other dangerous pathogens with very few restrictions. Labs are not even required to report this information to Federal authorities unless they plan to transfer or move the pathogens. We are a nation at risk and strict new safeguards are needed."

Feinstein provided details of her legislation at a hearing of the Judiciary Subcommittee on Terrorism, Technology and Government Information, which she chairs.

Under her proposed bill, labs seeking to possess and work with a specific list of biological agents would be required to be certified by the Secretary of Health and Human Services as a legitimate research facility and they would be required to demonstrate that possession is required for legitimate research purposes.

The lab must also show that it can safely and securely handle the pathogens and toxins by:

- demonstrating proper training and skills to handle such agents;
- possessing proper facilities to dispose of the agents;
- implementing security safeguards at its facilities to prevent criminal and terrorist access to such agents.

Also, any individual handling the materials within the lab must pass a background check and be registered with the Health and Human Services Department or the Center for Disease Control for the specific research project (or projects) requiring their use of the agents. A lab that permits restricted individuals to handle the agents is subject to decertification and civil penalties up to \$500,000. Supervisory personnel at labs where such violations occur would be subject to civil and criminal penalties (one year in jail, civil fine up to \$250,000).

The antiterrorism bill signed into law last week by President Bush prohibited individuals from possessing pathogens unless they can demonstrate they are using it for research and/or other peaceful purposes. It also barred possession by convicted felons, illegal aliens or other similarly restricted individuals. However, Senator Feinstein's proposed legislation would go further and ban any individual possession outside a government certified lab. Violators would face five years in prison.

The legislation would also require the Secretary of Health and Human Services to review, and if necessary, revise the existing list of dangerous biological agents and toxins in consultation with the Secretary of Defense, the Attorney General, the Director of the Center for Disease Control and other appropriate agencies.

The current CDC list of select biological pathogens and toxins includes:

Viruses	Brucella abortus
Ebola virus	Francisella tularensis
Smallpox	Yersinia pesos
Marburg virus	Rickettsiae and fungi
Eastern equine encephalitis virus	Coxiella burnetti
Rift valley fever	Rickettsia prowazekii
Lassa fever virus	Rickettsia rickettsii
Equine morbillivirus	Coccidioides immitis
Crimean-Congo haemorrhagic fever	Toxins
Tick-borne encephalitis	Abrin
South American haemorrhagic fever	Aflatoxins
Venezuelan equine encephalitis	Botulinum
Hantavirus pulmonary	Clostridium perfringens
Yellow fever	epsilon
Bacteria	Conotoxins
Anthrax	Diacetoxyscirpenol
Clostridium botulinum	Ricin
Francisella tularensis	Saxitoxin
Burkholderia	Shigatoxin
Bacteria	Staphylococcal enterotoxins
Anthrax	Tetrodotoxin
Clostridium botulinum	T-2 toxin
Francisella tularensis	Abrin
Burkholderia	Aflatoxins
Brucella abortus	Botulinum
Francisella tularensis	Clostridium perfringens
Yersinia pesos	epsilon
Rickettsiae and fungi	Conotoxins
Coxiella burnetti	Diacetoxyscirpenol
Rickettsia prowazekii	Ricin
Rickettsia rickettsii	Saxitoxin
Coccidioides immitis	Shigatoxin
Toxins	Staphylococcal enterotoxins
Rickettsiae and fungi	Tetrodotoxin
Coxiella burnetti	T-2 toxin
Rickettsia prowazekii	Abrin
Rickettsia rickettsii	Aflatoxins
Coccidioides immitis	Botulinum
Toxins	Clostridium perfringens
	epsilon
	Conotoxins

Diacetoxyscirpenol	Staphylococcal enterotoxins
Ricin	Tetrodotoxin
Saxitoxin	T-2 toxin
Shigatoxin	
Toxins	Diacetoxyscirpenol
Abrin	Ricin
Aflatoxins	Saxitoxin
Botulinum	Shigatoxin
Clostridium perfringens	Staphylococcal enterotoxins
epsilon	Tetrodotoxin
Conotoxins	T-2 toxin

SUMMARY OF FEINSTEIN BIOTERRORISM PROTECTION LEGISLATION:

Individual Possession—Prohibits any individual from possessing a dangerous biological agent like anthrax or small pox under any circumstances. The penalty would be five years in jail.

Lab/Medical Possession—Requires prior certification for any lab or other organization wishing to possess anthrax or other dangerous biological agents.

A lab would only be allowed to possess these agents if:

1. The lab is first certified by the Secretary of HHS as a legitimate research, health or other entity;
2. The lab is separately certified to possess these agents for legitimate research, medical, or other legitimate, peaceful purposes;
3. The lab agrees to submit to periodic site inspections;
4. The lab can demonstrate proper training and skills to handle such agents;
5. The lab possesses the proper facilities to dispose of the agents;
6. The lab implements security safeguards at its facilities to prevent criminal and terrorist access to such agents;
7. Any individuals handling materials within the facility must pass a background check and be registered with the CDC for the specific research project (or projects) requiring their use of the agents.

List of Restricted Biological Agents or Toxins—Requires the Secretary of HHS to review, and if necessary, revise the existing list of dangerous biological agents and toxins in consultation with the Secretary of Defense, the Attorney General, the Director of the CDC, and other appropriate agencies.

Transfer to Unregistered Facilities—The legislation would prohibit the transfer of dangerous biological agents or toxins to uncertified labs or to individuals, and subjects violators to civil or criminal penalties (up to \$500,000 and/or 1 year).

Unsafe handling—Individuals who handle biological agents or toxins in a manner that endangers the public would also be subject to civil and criminal penalties.

Current CDC List of Biological Pathogens and Toxins

Viruses	Bacteria	Rickettsiae and Fungi	Toxins
1. Crimean-Congo haemorrhagic fever	1. Anthrax	1. Coxiella burnetti	1. Abrin .
2. Eastern Equine Encephalitis Virus	2. Brucella abortus, B. melitensis, B. suis .	2. Rickettsia prowazekii	2. Aflatoxins .
3. Ebola virus	3. Burkholderia (Pseudomonas) mallei .	3. Rickettsia rickettsii	3. Botulinum toxins .
4. Equine Morbillivirus	4. Burkholderia (Pseudomonas) pseudomallei .	4. Coccidioides immitis (fungi) .	4. Clostridium perfringens epsilon toxin .
5. Lassa Fever virus	5. Clostridium botulinum	5. Conotoxins .
6. Marburg virus	6. Francisella tularensis	6. Diacetoxyscirpenol .
7. Rift valley fever	7. Yersinia pestis	7. Ricin .
8. South American haemorrhagic Fever	8. Saxitoxin .
9. Tick-borne encephalitis	9. Shigatoxin .
10. Smallpox (Variola Major virus)	10. Staphylococcal enterotoxins .
11. Venezuelan Equine Encephalitis	11. Tetrodotoxin .

Current CDC List of Biological Pathogens and Toxins—Continued

Viruses	Bacteria	Rickettsiae and Fungi	Toxins
12. Viruses causing hantavirus pulmonary 13. Yellow Fever	12. T-2 toxin .

I would now like to turn to Senator Kyl and I want to thank you for your effort and help and leadership, Senator. And welcome to this hearing.

**STATEMENT OF HON. JON KYL, A U.S. SENATOR FROM THE
STATE OF ARIZONA**

Senator KYL. Thank you, Senator Feinstein, and thank you for holding this hearing at a most propitious time. Preparing for this, my staff went back through some of the transcripts and files from previous hearings that the two of us have held over the last seven and a half years on this Terrorism Technology Subcommittee and it was interesting to track back. Two and a half years ago we held a hearing and talked about the threat of anthrax in the bioterrorism context, issued some warnings at that time. We have done the same for some other threats that face us and it is no solace to me that there is now a reality to the threats that we were projecting back at that time. But this hearing today will certainly help us understand if there are areas in which we need to make improvements with regard to the control and the production of these kinds of agents, what they need to be and how we can be useful in doing that.

I would also like, though, to throw out another possibility here that I hope we can deal with in the future. The question, of course, has been asked, what if there had been a wider spreading of the anthrax that was mailed? And we have all contemplated how much difficult a challenge that would have been for our responders and how many more casualties undoubtedly would have resulted.

There is an additional threat which I would like to simply note this morning and perhaps ask our witnesses to relate to in their response to our questions. It is suggested by, whether it was inadvertent or advertent, the use of aircraft by the terrorists on September 11. I do not know that they fully appreciated the extent to which the ripple effect of the use of aircraft would damage our economy and affect so many other areas of our society that were seemingly unrelated to the specific subject of the attacks.

But contemplate that in our society where we are so interdependent on high technology, among other things, that we have a few very critical nodes of information, of vulnerability—let me put it that way—a few places in our country where an attack can have a very significant ripple effect on other aspects of our society, our government, our economy. And if there were a biological or chemical terrorism event directed at the people or the place of that critical part of our infrastructure, the effect could be dramatic in our entire society, in effect creating a domino effect, a downward spiraling of our ability to handle crises.

So because our society has these kinds of vulnerabilities I think it is important for us as a Committee and for the new Homeland

Defense director to examine those points of vulnerability for all of the various kinds of threats. We have focussed on cyber threats in the past but certainly an anthrax threat to a very critical node in our society could have a dramatic impact on us all.

And I also think that, in addition to the kind of nuclear weapon that Senator Feinstein talked about, we need to look at the need for protection against the radiological weapon, the weapon that is made out of conventional explosive that has a significant amount of highly radioactive material imbedded in it in such a way that upon explosion it spreads that radioactivity over a larger area. It is important for us to think about protecting spent fuel deposits and other areas.

So while we are focussed here directly this morning on a slightly more narrow aspect of the problem, I think we will probably have to enlarge our inquiry into all of the areas in which our society will need to be protected.

So again I would just ask the witnesses, if not today, to at least think about how they could respond to the obvious question, which is what about other threats? Are there laws that need to be passed? Are there loopholes in the way that our government deals with these things? Any suggestions you could make to us for congressional action would be very much appreciated because our goal obviously is to find out where the problems are so that we can respond to that legislatively or support the administration in its administrative or executive actions with regard to these threats.

Again I thank Senator Feinstein for holding this hearing and look forward to obviously cooperating with her as time goes on to do our part in defeating the terrorists and fighting this war on terrorism. Thank you.

[The press release of Senator Kyl follows:]

KYL TO SEEK ANSWERS ON BIOTERRORISM

FEINSTEIN-KYL HEARING WILL EXAMINE WAYS TO SAFEGUARD BIOHAZARDOUS MATERIALS

WASHINGTON, D.C.—U.S. Senator Jon Kyl (R-A7), Ranking Member of the Judiciary Committee's Subcommittee on Technology, Terrorism, and Government Information, today welcomed administration officials and other bioterrorism experts before the subcommittee, saying the American people need reassurance on the state of U.S. bioterror preparedness.

"Bioterrorism is not a novel subject for this subcommittee, as we've heard repeated warnings from experts on the dangers of a bioterror attack," said Kyl. "As far back as 1998, for example, we called for a more coordinated, integrated approach to the detection and tracking of bioterror threats within the United States such as anthrax—and ways to enhance our ability to manage and treat outbreaks.

"It is important that Congress examine how we can be better prepared for future outbreaks, what the greatest dangers posed to Americans are, and whether we are ready to respond to serious health emergencies."

Expected to testify before the subcommittee today are representatives from the FBI, Jim Reynolds, Chief of Terrorism and Violent Crimes Section of the Department of Justice, and Claude Allen, Deputy Secretary, Department of Health and Human Services. Additionally, the subcommittee is expected to hear from many experts on bioterrorism from the private sector.

"We will have to live with the threat of bioterrorism for the foreseeable future, and we need to give the administration all the assistance it may require in securing our homeland from bioterror attacks," said Kyl. "I welcome the opportunity to explore ways to keep biohazardous materials from those who mean Americans harm.

Chairperson FEINSTEIN. Thanks very much, Senator Kyl.

We will begin with the first witness. Mr. James Caruso was reassigned to the Intelligence Division at the FBI as the bureau's chief of Russian counterintelligence in 1990. He served in several assignments for the Intelligence Division—from 1994 to 1997 was an assistant special agent in charge of the New York Field Office, then reported to FBI headquarters as the section chief of the Eurasian Division, National Security Division.

He was promoted to special agent in charge of the National Security Division, the Washington Field Office in February of 1999. In 2001 he was designated deputy assistant director of the Counterterrorism Division at the FBI headquarters.

And before you begin, Mr. Caruso, I would like to acknowledge here someone that we had asked to testify today but she declined because she is a journalist. I have worked with her in the Aspen Strategy Institute and so I am delighted that Judith Miller of the New York Times, the author of the best-selling book "Germs," is in the audience. As a matter of fact, I just noticed that it had gone to the top of the New York Times Bestseller list this Sunday. So welcome, Judith. We are delighted to have you here.

Go, Mr. Caruso.

STATEMENT OF JAMES T. CARUSO, DEPUTY ASSISTANT DIRECTOR, COUNTERTERRORISM DIVISION, FEDERAL BUREAU OF INVESTIGATION, WASHINGTON, D.C.

Mr. CARUSO. Good morning, Madam Chairwoman and Senator Kyl. Director Mueller was unable to attend and sends his regrets.

I appreciate the opportunity to appear before you today to discuss law enforcement response to bioterrorism. The bioterrorism threat has risen to a new unprecedented level. The federal government, in partnership with state and local law enforcement agencies, has over recent years taken the threat concerning the intentional release of a biological agent seriously. Although the federal government and state and local responders undertook training and coordination exercises in recent years to hone their response to weapons of mass destruction like biological agents, none faced an actual release of anthrax.

The intentional introduction of bacillus anthracis into the infrastructure of American lives has resulted in significant national alarm concerning our health and safety. Today I would like to comment on the manner in which the law enforcement community responds to a suspected act of terrorism involving biological agents and thereby demonstrate the cooperation which exists between the federal government and the many first responders who provide guidance, assistance and expertise.

The law enforcement response to a potential bioterrorist threat is different, depending on how the biological agent is introduced—whether it is an overt release or a covert release. Regardless of whether a biological release is overt or covert, the primary mission of law enforcement and the public health community is saving lives. May I repeat? When the potential for a biological release exists, the primary mission of law enforcement and the public health community is saving lives.

An overt use of a biological agent involves the announced release of an agent, often with some type of articulated threat. An example

of this would be the receipt of a letter containing a powder and a note indicating that the recipient has been exposed to a biological agent, such as anthrax. This type of situation would prompt an immediate law enforcement response, to include local police, fire, and emergency medical service personnel. Each FBI field office is staffed with a weapons of mass destruction coordinator whose responsibilities include liaison with first responders in the community.

Due to this established relationship with first responders, the local FBI WMD coordinator would be notified and also respond to the scene. The articulated threat involving a biological agent and the authority given to the FBI by statute and Presidential Decision Directives 39 and 62 direct the FBI to investigate these matters. The response protocol would involve security the crime scene and initiating the FBI's interagency threat assessment process. The FBI's Counterterrorism Division at FBI headquarters coordinates this threat assessment process, which determines the credibility of the threat received, the immediate concerns involving health and safety of all responding personnel, and the requisite level of response warranted by the federal government. These directives are based upon the detailed information received from the on-scene personnel and input from other federal agencies with an interest in the particular incident.

In a biological event, representatives from the Centers for Disease Control and Prevention, the Department of Health and Human Services, the United States Department of Agriculture, and the Food and Drug Administration are the key agencies called upon in assessing the particular threat. Based upon that assessment, a determination is made as to the level of response necessary to adequately address the particular threat, which could range from a full federal response if the threat is deemed credible to collection of the material in an effort to rule out the presence of any biological material if the threat is deemed noncredible.

The method of collecting suspect material is established by protocol set forth by the FBI's Hazardous Material Response Unit. These protocols, recognized and followed by state and local hazmat teams, are necessary to ensure that sufficient evidentiary samples are collected, screened and overpacked according to scientific safety guidelines for transportation to appropriate testing facilities.

Over 85 state health laboratories perform testing on behalf of the CDC and belong to a coordinated collection of facilities known as the Laboratory Response Network. Once the testing has been completed, the results of the analysis are then disseminated to the exposed person or persons, local first responders, and to the local public health department. Additionally, results will be forwarded to the Centers for Disease Control and Prevention in Atlanta, Georgia and all other agencies involved in the assessment.

A covert release of a biological agent invokes a different type of response, this time driven by the public health community. By its nature, a covert introduction is not accompanied by an articulated or known threat. The presence of the disease is discovered through the presentation of unusual signs and/or symptoms in individuals reporting to local hospitals or physician clinics. In this situation there is initially no crime scene for law enforcement personnel to

respond to. The criminal act may not be revealed until days have elapsed following the agent identification and preliminary results obtained from the epidemiological inquiry conducted by the public health sectors.

Contrary to an overt act where the law enforcement community makes the necessary notifications to the public health, in a covert release notification to law enforcement is made by the public health sector. The early notification of law enforcement in this process encourages the sharing of information between criminal and epidemiological investigators. Once an indication of the criminal act utilizing a biological agent is suspected, the FBI assumes primary authority in conducting the criminal investigation while the public health maintains responsibility for the health and welfare of the citizens.

The initial response of first responders, the FBI, our federal partners, and the professional health community to an actual threat or one that is later determined not credible or a hoax is indistinguishable. The response to an actual threat or a hoax tolls significant costs. All participants from the responders to the potential victims and their communities can be significantly and adversely affected.

The first responders, the FBI, the victims and the communities in which they live must treat each incident as a real event until scientific analysis proves that the material is not a biological agent. Both the responding entities and the potentially exposed victims pay a heavy price when it appears a biological agent is present. As a result, hoaxes suggesting a biological agent is present in a package, letter or location are particularly pernicious. Individuals perpetuating hoaxes dealing with weapons of mass destruction must be held accountable for their actions.

In 1999 the FBI testified before the House Energy and Commerce Subcommittee on Oversight and Investigations, discussing the need for improved federal statutes which address the threatened use and possession of biological agents. During this testimony it was reported that in 1998 the FBI opened 181 cases related to weapons of mass destruction events, of which 112 were biological in nature. The number of cases has increased since then to 267 in 1999 and 257 in 2000. The vast majority of these instances were hoaxes.

As the Committee will quickly note by my upcoming testimony, the number of FBI cases relating to alleged biological agents initiated since mid-September of this year went off the charts. Prior to the events of September 11, 2001, the number of cases initiated for the first eight and a half months of 2001 was 100, of which 67 were biological. A large percentage of these cases involved the threatened release of anthrax, necessitating a law enforcement response. Here again the vast majority of these instances were hoaxes.

The combined terrorist attacks on the World Trade Center and the Pentagon, the subsequent publicity afforded to a handful of anthrax letters, and the traffic death of four persons have resulted in a dramatic increase in calls for help from the public. And, as it should be, the law enforcement communities and first responder communities—fire, police, and emergency medical personnel—and the public health communities have responded.

Since mid-September the FBI has responded to approximately 7,089 suspicious anthrax letters, 950 incidents involving other WMD matters, such as bomb threats, and an estimated 29,331 telephone calls from the public about suspicious packages. The vast majority of these responses were not actual incidents. Resources made available by law enforcement in responding to the alleged threats and the resources made available by the public health laboratories in testing suspicious materials for the presence of biological agents are strained and stretched to capacity.

As part of a terrorism-related legislative package which the president signed into law, Congress recently passed a modification of Title 18, U.S.C. Section 175, which criminalizes the possession of biological material except for medical or clinical purposes or bona fide research. Prior to this modification, the government had the burden of proof that possession of a specific biological agent was for illegal purposes or evil intent. This was a significant burden on the law enforcement community to provide sufficient proof that a biological agent was intended to be used as a weapon.

Congress's modification will be a significant benefit in addressing the need to apprehend and prosecute those individuals who are capable of and intent upon creating a biological weapon to harm and terrorize the American people. It will allow for early apprehension of the responsible party and the prevention of any release of biological material.

Under the leadership of the Attorney General John Ashcroft and FBI Director Mueller, we are prosecuting noncredible threats, hoaxes, to the fullest extent of the law. In fact, nearly a dozen investigations, complaints or indictments have been issued by the United States Attorneys Offices throughout the country for persons threatening the release of anthrax. Utilizing the statutory guidelines which became effective November 1, 2001, these individuals face a possible five-year mandatory minimum prison sentence.

Attorney General Ashcroft and Director Mueller are sending a clear and unambiguous signal across America. Hoaxes concerning biological agents, hoaxes concerning weapons of mass destruction, will be aggressively investigated by the FBI and vigorously prosecuted by the Department of State. Thank you, Madam Chairwoman.

[The prepared statement of Mr. Caruso follows:]

STATEMENT OF JAMES T. CARUSO, DEPUTY ASSISTANT DIRECTOR, FEDERAL BUREAU OF INVESTIGATION, COUNTERTERRORISM DIVISION

Good morning Madame Chairwoman, Senator Kyl and members of the Subcommittee. I appreciate the opportunity to appear before you today to discuss the law enforcement response to Bioterrorism.

The Bioterrorism threat has risen to a new level. The Federal Government, in partnership with State and local law enforcement agencies, has over recent years taken the threat concerning the intentional release of a biological agent seriously. However, until recently, neither the Federal Government nor State and local responders have been required to utilize their assets to coordinate a response to an actual release of anthrax. The intentional introduction of bacillus anthracis into the infrastructure of American lives has resulted in significant alarm concerning our health and safety. Today, I would like to comment on the manner in which the law enforcement community responds to a suspected act of terrorism involving biological agents, and reinforce the cooperative effort that is in place between the Federal Government and the myriad of first responders who provide guidance, assistance and expertise.

The response to a potential bioterrorist threat can be broken down into two different scenarios: overt and covert releases. The distinction between the two involves the manner in which the biological threat agent is introduced into the community and the nature of the response. Regardless of whether a biological release is overt or covert, the primary mission of law enforcement and the public health community is saving lives.

An overt scenario involves the announced release of an agent, often with some type of articulated threat. An example of this would be the receipt of a letter containing a powder and a note indicating that the recipient has been exposed to anthrax. This type of situation would prompt an immediate law enforcement response, to include local police, fire and emergency medical service (EMS) personnel. Each FBI field office is staffed with a Weapons of Mass Destruction (WMD) Coordinator whose responsibilities include liaison with first responders in the community. Due to this established relationship with first responders, the local FBI WMD Coordinator would be notified and dispatched to the scene. The articulated threat involving a biological agent and the authority given to the FBI by statute and Presidential Decision Directives 39 and 62, directs the FBI to investigate these matters. The response protocol would involve securing the crime scene and initiating the FBI's interagency threat assessment process.

The FBI's Counterterrorism Division at FBI Headquarters, coordinates this threat assessment which determines the credibility of the threat received, the immediate concerns involving health and safety of the responding personnel, and the requisite level of response warranted by the Federal Government. These directives are based upon the detailed information received from the on-scene personnel and input from the necessary Federal agencies with an interest in the particular incident. In a biological event, representatives from Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS), United States Department of Agriculture (USDA) and Food and Drug Administration (FDA) are the key agencies called upon to assist FBI personnel in assessing the particular threat. Based upon the assessment, a determination is made as to the level of response necessary to adequately address the particular threat, which could range from a full Federal response if the threat is deemed credible, to collection of the material in an effort to rule out the presence of any biological material if the threat is deemed not credible.

The method of collecting suspect material is established by protocols set forth by the FBI's Hazardous Material Response Unit (HMRU). These protocols, recognized and followed by state and local Hazmat teams, are necessary to ensure that sufficient evidentiary samples are collected, screened and over-packed according to scientific safety guidelines for transportation to the appropriate testing facility. More than 85 State Health Laboratories perform this analysis on behalf of CDC and belong to a coordinated collection of facilities known as the Laboratory Response Network (LRN). Once the testing has been completed, results are provided to the FBI for dissemination in the appropriate manner. The results of the analysis are then disseminated to the exposed person or persons, local first responders and to the local public health department. Additionally, results will be forwarded to the Centers for Disease Control and Prevention (CDC) in Atlanta, GA.

A covert release of a biological agent invokes a different type of response, driven by the public health community. By its nature, a covert introduction is not accompanied by any articulated or known threat. The presence of the disease is discovered through the presentation of unusual signs and/or symptoms in individuals reporting to local hospitals or physician clinics. In this situation, there is initially no crime scene for law enforcement personnel to respond to. The criminal act may not be revealed until days have elapsed, following the agent identification and preliminary results obtained from the epidemiological inquiry conducted by the public health sector. Contrary to an overt act where law enforcement makes the necessary notification to Public Health, in a covert release, notification to law enforcement is made by the Public Health sector. The early notification of law enforcement in this process encourages the sharing of information between criminal and epidemiological investigators. Once an indication of a criminal act utilizing a biological agent is suspected, the FBI assumes primary authority in conducting the criminal investigation, while Public Health maintains responsibility for the health and welfare of the citizens. At the local level, involving the BI WMD Coordinator and the State or local public health department, and at the national level between FBI Headquarters and the CDC, effective coordination has been accomplished to address the requisite roles and responsibilities of each agency.

The response to an actual threat or one that is later determined to be not credible, or a hoax, is indistinguishable. This includes deployment of a Hazmat team, thorough examination of the potentially contaminated area (in situations where a tele-

phonic reporting is received) and the disruption of the normal operations of the affected entity. Additionally, the individuals potentially exposed to the WMD may experience extreme anxiety/fear due to the reported release. Potential victims may have to be decontaminated or transported to a medical facility. The first responders must treat each incident as a real event until scientific analysis proves that the material is not a biological agent. To both the responding entities and the potentially exposed victims, the presence of a powder threatening the presence of anthrax is not a "hoax," or something to be taken lightly. The individuals perpetrating such an activity must be held accountable for their actions.

In 1999, the FBI testified before the House Energy and Commerce Subcommittee on Oversight and Investigations, discussing the need for improved Federal statutes which address the threatened use and possession of biological agents. During this testimony, it was reported that in 1998, the FBI opened 181 cases related to WMD events, of which 112 were biological in nature. The number of cases has increased since then, with 267 in 1999, and 257 in 2000 (threatened biological releases accounted for 187 and 115 respectively).

Prior to the events of September 11, 2001 and the subsequent release of anthrax along the East Coast, the number of cases initiated for 2001 was 100, of which 67 were biological. A large percentage of these cases involved the threatened release of anthrax, necessitating a law enforcement response. The combined terrorist attacks on the World Trade Center and Pentagon, the subsequent publicity afforded to a handful anthrax threats, and the tragic death of four persons, have resulted in a dramatic increase in calls for help from the public. The law enforcement communities and first responder communities (fire, police and emergency medical services) have responded.

Since mid-September, the FBI has responded to approximately 7,089 suspicious anthrax letters, 950 incidents involving other WMD matters (bomb threats, etc.), and an estimated 29,331 telephonic calls from the public about suspicious packages. Resources available to law enforcement for responding to the alleged threats and public health laboratories in testing suspicious material for the presence of biological agents are strained and stretched to capacity.

As part of the USA PATRIOT ACT which the President signed into law on October 26, 2001, Congress recently approved a modification to Title 18, USC, Section 175 which criminalizes the possession of certain biological material except in instances which are reasonably justified by a prophylactic, protective bona fide research or other peaceful purpose. Prior to this modification, the government bore the burden of proof that specific possession of a biological agent was for illegal purposes or evil intent. This created a significant burden on the law enforcement community to provide sufficient proof that the biological agent was intended to be used as a weapon. The recently provided modification of Title 18, USC, Section 175 will be of significant benefit in addressing the need to apprehend and prosecute those individuals who are capable of and intent upon creating a biological weapon to harm and terrorize the American people. It will allow for early apprehension of the responsible party and the prevention of any release of the biological material.

Under the direction of AG Ashcroft and FBI Director Mueller, the Federal government is now prosecuting non-credible threats, or hoaxes, within the full extent of the law. In fact, 11 indictments or complaints have been issued by United States Attorney's Offices throughout the country, threatening the release of anthrax. Utilizing the statutory guidelines which became effective November 1, 2001, these individuals face a possible 5-year mandatory minimum incarceration.

As the FBI strives to meet new challenges, we will continue to stress coordination with state and local law enforcement agencies and emergency responders through Joint Terrorism Task Forces (JTTFs), Regional Terrorism Task Forces (RTTFs) and WMD Coordinators.

This concludes my prepared remarks. I would like to respond to any questions of the Subcommittee.

Chairperson FEINSTEIN. Thank you very much, Mr. Caruso.

I neglected to ask everybody to please try to confine your remarks to five minutes so that we can have some questions and discussion. And I am going to change the order of witnesses slightly because I think with what you said, Mr. Caruso, it would be very important to have the mayor of Boca Raton come to the table right now and if you could take your place at that end, that is fine.

The mayor is Steven Abrams. He is from the city of Boca Raton. He is past president and board member of the Palm Beach County

League of Cities. He has served as a member of the board of directors of the Florida League of Cities. He was a member of the Treasure Coast Regional Planning Council, was appointed by the president of the Senate to the Florida Commission on Local Government.

He is a practicing lawyer. He is a graduate of Harvard, received his law degree from George Washington University, born in Des Moines, Iowa and grew up in Philadelphia and found his way to Boca Raton.

Mr. Mayor, we welcome you. As a former mayor, I would be very interested in your comments on how you believe the government reaction to your plight was, where there are problems and how we might correct them.

STATEMENT OF HON. STEVEN ABRAMS, MAYOR, BOCA RATON, FLORIDA

Mayor ABRAMS. Thank you, Madam Chairman. Unfortunately, Boca Raton was the first city, as you noted, in America to have to deal with a bioterrorism incident. I am glad to say though as mayor that we fully recovered, we are back to normal, the quality of life that Boca Raton is known for, people are enjoying, but I do want to thank the Subcommittee for the opportunity to share our lessons with you.

As the president has said several times since September 11, cities are the first line of defense against potential terrorist threats. And I would add to that that city officials are the first point of contact for residents who are seeking reassurance and seeking information.

We do not need, as local officials, to know when the ground troops are going into Afghanistan but we do need to be aware of information affecting the health and safety of our residents. And we also need to know as soon as possible about decisions that affect city operations. I mentioned in the testimony that I prepared, which I ask be included in the record, certain examples, one of which was when the post offices in Boca Raton were involved. Remember these were the first post offices in the United States to be affected by anthrax, the trail leading from the AMI building in Boca Raton. We at the city level had been hearing rumors that the post offices were going to be shut down, that people were going to be evacuated, as they had been at the AMI building, and that was significant for us because one of our post offices was not the typical stand-alone building but was integrated into a low-rise office building housing about 4,000 private sector employees.

Now the FBI and the CDC were very helpful in confirming these secondhand reports but certainly a more proactive effort can be undertaken in the future. And I am certainly not here to point fingers at anyone because I have been working now with the law enforcement and the public health professionals and they are working around the clock to ensure our safety and we are very grateful for their efforts.

In fact, I want to show my confidence in the public health professionals. I was in, for example, the postal facility speaking to the very worried workers and in the perimeter of the AMI building talking to our police officers and our firefighters who were securing

the site and I have not been tested for anthrax; I am not taking antibiotics because, as a public official, I feel it is important for me to show confidence in the assurances that are given by our public health professionals.

But certainly steps though can be taken to improve the lines of communication. I am suggesting several things. First is that there be a point person or a single agency to take responsibility for coordinating the investigation. This is difficult. As has been pointed out, bioterrorism incidents, by definition, have a criminal aspect to them and have a public health aspect to them so there is a lot of responsibility across the board. But to the extent that one agency or one person can be the point person, that would be very useful.

Also, the affected city should be included fully in the command that is established. There should be a central information command for the dissemination of public information so that it is coming from one source.

I guess I would say in closing—

Chairperson FEINSTEIN. Did you set up a command post immediately?

Mayor ABRAMS. Yes, Palm Beach County set up its emergency operations center because health issues are not within the jurisdiction of the city but within the jurisdiction of the county and the state of Florida. So the county immediately set up its emergency operations center but that was one agency.

I would say in closing, in illustrating this, that believe it or not I now subscribe to the National Enquirer which, as you know, is published by AMI. During the course of the investigation they had felt at times that they were not quite in the information loop so were developing their own sources and their own back channels of information, which actually proved quite reliable, but that is not the solution, obviously, although I am sure my friend the CEO of AMI would tell you that it is the solution, that everyone should subscribe to his publications. But obviously it is not and we had to set up our own back channels, as well.

The answer is to consider some of these suggestions that I have made, that others have made. Mayor Giuliani has had the same frustrations. He has indicated and has offered suggestions and recommendations so that we can make the system work better in the future for everyone. And I would be glad to answer any questions that you or Senator Kyl might have.

[The prepared statement of Mayor Abrams follows:]

STATEMENT OF HON. STEVEN L. ABRAMS, MAYOR, CITY OF BOCA RATON, FLORIDA

Thank you, Madam Chairman, Members of the Subcommittee. My name is Steven Abrams, the Mayor of Boca Raton, Florida.

Unfortunately, Boca Raton was the first city in America to have to deal with a bioterrorism incident. I appreciate this timely opportunity to share the lessons that we learned to help other cities that are facing this challenge now and that may face it in the future.

Those who attacked the American Media, Inc. building in Boca Raton with anthrax could not have picked a safer city. Boca Raton has always had an international reputation as a safe and secure city. In fact, we are an even safer and more secure city in the aftermath of this incident.

Our Fire-Rescue Department's hazardous materials team has won international competitions. Our Police Department is outstanding. They responded in exemplary fashion to the anthrax incident.

But we could not do it alone. I want to thank the federal, state, and county agencies that assisted us. Our Governor, Jeb Bush, was there for us. In addition, I want to thank Senator Nelson, who also came to Boca Raton and offered the city his assistance.

Madam Chairman, the assistance that cities need is in establishing and maintaining effective lines of communication with all of the different agencies.

The President has stated on more than one occasion since September 11 that cities are the first line of defense against terrorist threats.

City officials are also the first point of contact for our residents who are understandably worried about the potential health and criminal threats posed by bioterrorism.

But reliable information was frequently lacking. In fact, I was surprised to hear that even the Mayor of New York had the same concerns. Anything that would affect the safety and security of the people of the city I need to know, and I need to know it now.

The division of responsibilities among the agencies themselves also proved to be a problem early on. I hasten to add the caveat that all of us were covering new ground here. But the Subcommittee has asked us to illustrate the gaps for future planning purposes.

Our police chief was first notified by the F.B.I. that the AMI building would be tested for anthrax on the Friday after the case was revealed concerning Robert Stevens, the AMI employee who eventually died. But then that Sunday, the Chairman of the Palm Beach County Commission was the one who contacted the city on behalf of the county health department (which to add to the confusion happens to be a state agency) to advise that the anthrax was discovered in the building and that the city would be involved in securing the site (and later decontaminating the investigators). The responsibility had shifted between the criminal and the public health sides of the investigation.

Then the following Tuesday night, I watched on television, by pure chance, a national press conference being held in Boca Raton to announce that the third person in America had been exposed to anthrax and that the incident was now being handled as a criminal investigation.

I rushed over to the hotel and met face to face in the lobby with the Acting U.S. Attorney and the F.B.I.'s Special Agent in Charge to let them know in plain terms the necessity for better communications between their agencies and the city. To their credit, they have kept the city much better informed about the case from their side of it.

We don't need to know when ground troops are going into Afghanistan, but we do need to be aware of information that affects the health and safety of our residents, as well as know about developments that will have a bearing on city operations.

It behooves the agencies to do this, Senators. The local governments understand that the Federal agencies are leading the investigation. However, making cities an integral and timely part of the information loop will go a long way toward helping us to reassure the public that the utmost is being done by the agencies to protect our constituents, as well as toward dispelling misinformation that might hinder the investigation.

I will give you another illustration. When the anthrax trail led to the two post office facilities in Boca Raton, the lack of close coordination persisted.

Our city manager, police chief, and I spent an entire morning trying to track down rumors that one or more of our post offices were contaminated and going to be shut down. This was significant for us because one of the postal facilities is not a stand-alone building, but is integrated into a low-rise office building housing some 4,000 employees of several private companies. We did not know if they were going to have to be evacuated or tested. Even if they were not going to be evacuated, we did not know what their reactions would be. We needed to determine what our response would be.

Remember, these were the very first post offices to be contaminated in the United States, and so we were in uncharted waters.

The F.B.I. and Center for Disease Control were helpful in responding to our telephone calls for confirmation of reports we were hearing secondhand. But this is simply not adequate. Indeed, public statements were being made by members of our Congressional delegation that communication with local governments and residents was insufficient.

Mayors are the ones on the front lines-literally. We are standing next to the crime scene tape that is cordoning off the site. We are surrounded by the camped-out national media. Because of this, local officials can build up a level of trust and confidence with the media and their viewers and readers. It would have been easy for

me to join in the chorus of criticism, but I refrained. I want to join hands, not point fingers.

So, for instance, even though I went inside the perimeter of the AMI building to speak with our police officers and firefighters and into one of the decontaminated postal facilities to answer questions from worried workers, I will not get tested for anthrax nor take antibiotics. I believe it is important for me as an elected official to show confidence in the assurances given by our public health officials.

But please help give me a full measure of confidence, Senators. There are improvements that can be made to the system.

These are my recommendations:

Establish at the outset one agency—with one authoritative point person—to take responsibility for coordinating the investigation. This is a designation, or even a direct role, that could be determined by the new Office of Homeland Security. Admittedly, this is difficult to do in bioterrorism investigations that have both criminal and public health aspects, but it must be done.

Second, an affected city should be fully included in any joint command.

Third, a central information command should be set up so that all of the public information that is released by the various agencies is coordinated and comes from one source.

Finally, keep in mind that communications issues do not end when the television cameras leave. I have just written to the Postal Service to remind them that the city wants to know if further testing will be done at Boca Raton's postal facilities and to tell us when we can expect irradiation equipment to be installed to guard against a possible second wave.

The Environmental Protection Agency is now cleaning up the AMI site and will also have to be reminded that the City of Boca Raton should not have to read about their findings in the newspaper, that we need to be ahead of the curve to be able to calmly explain the results to a still-anxious public.

So these are examples of additional Federal agencies that have been brought into the case as it has progressed that do not appear to be under any central command.

In closing, believe it or not, I just began a subscription to *The National Enquirer*, which is published by American Media, Inc., so I can keep up to date. When AMI felt that they themselves were being left out of the loop, they, as investigative writers, developed their own sources of information, which proved very reliable. I would speak with AMI officials and, lo and behold, the information they gave me would turn out exactly as they had recited. Similarly, I also was able to effectively develop my own back channels of information.

But obviously this should not be the solution. I urge the Subcommittee to focus on the "government information" part of your name. Bioterrorism is terrible enough without the problem being compounded by the potential for a mistake or needless panic because local governments were lacking some piece of critical information.

Please know that my comments are meant to be constructive. These bioterrorist attacks are a completely novel situation for all of us, and indeed we were the first case. Dealing with bioterrorism is by definition a complex multi-jurisdictional effort. All of our law enforcement and public health professionals are working around the clock to protect our safety. We are grateful.

Thank you again, Madam Chairman and Members of the Subcommittee, for the opportunity to be heard today.

Chairperson FEINSTEIN. Thanks very much, Mr. Abrams.

We are joined by Senator Edwards. Welcome, Senator. If it is agreeable with you we will hear the next witness and then if you have some comments you might like to make—

Senator EDWARDS. That would be terrific. Thank you.

Chairperson FEINSTEIN. Excellent.

Mr. Reynolds was appointed chief of the Terrorism and Violent Crimes Section when the section was created in 1991. He continues to serve in that position. He has been affiliated with the Department of Justice since 1968, served there consistently since 1973. In 1978 he was appointed deputy chief of the Criminal Division's Special Litigation Section. From 1979 to 1990 he served as principal deputy chief of the division's General Litigation and Legal Advice Section. That section had responsibility for a wide variety of federal

criminal offenses, including international terrorism cases, domestic violence crimes, property offenses, and most regulatory violations. In 1990 he became acting chief of that section.

Mr. Reynolds, welcome.

STATEMENT OF JAMES S. REYNOLDS, CHIEF, TERRORISM AND VIOLENT CRIMES SECTION, CRIMINAL DIVISION, DEPARTMENT OF JUSTICE, WASHINGTON, D.C.

Mr. REYNOLDS. Thank you, Madam Chair, Senator Kyl, Senator Edwards. Let me just submit my prepared statement and limit my comments to just a couple of points so that we can move on quickly to questions.

Chairperson FEINSTEIN. Excellent. We appreciate that.

Mr. REYNOLDS. I would note that as we interrelate with public health providers, with our colleagues at HHS, and with law enforcement there has been a growing consensus over the last several years that the most severe threat that we face is the bioterrorism threat.

In that context, I know we have testified before your Committee, Senator Kyl, and let me reference the testimony of Dr. Margaret Hamburg, who was an assistant secretary previously at HHS. In speaking of bioterrorism events she indicated in her words that they differ from any other of terrorism in their potential to precipitate mass behavioral responses, civil disorder, pandemonium.

The government has devoted a lot of funds, as well we should, to preparing to respond to bioterrorism incidents but as Dr. Hamburg said in her testimony in 1999 before a congressional Committee, measures that will deter or prevent bioterrorism will be far and away the most cost-effective means of countering threats to public health and social order that flow from bioterrorism events. The consequences of the current anthrax releases underscored the imperative of prevention and let me just make a couple of comments on what we have perceived for some time to be that imperative.

Federal law, as Tim Caruso referenced, had been tied to the weaponization or the nexus between the possession of a biological substance and its use as a weapon. That has fortunately been altered in the recently enacted October 26 terrorism bill and now under 18 U.S.C. 175, the possession of a dangerous biological substance in an amount and of a type that is not reasonably justifiable for a peaceful purpose now becomes illegal. That will be a significant benefit to law enforcement as we move forward with the effort of preventing biological incidents.

The importance of that statute for prevention flows from the need to be able to have the FBI intervene at the earliest possible time when we become aware that an individual is in possession without justification of a dangerous biological substance. If we wait until it is weaponized we may well wait too late.

Let me mention just one other issue and that is as we look as to whether there is a need for any further legislation we, of course, know that HHS has submitted legislation and we look forward to working with them and with Congress on that legislation.

As far as other legislation, certainly it leaps out that there is an issue of hoaxes. There are, as Mr. Caruso indicated, presently out

of control. They utilize scarce law enforcement and public health resources. But well beyond that, they exact a very substantial psychological toll on people who are placed in a position of believing that their life or their health is seriously threatened and they are left to wait for laboratory results, which are necessary, before they can be relieved of that concern. Often those results take two, three, four days to get.

So under the imperative of prevention I think that we should add as legislation is considered the imperative of preventing hoaxes, people making statements knowing that their statements have no basis in fact, leading then to the devotion of a tremendous amount of public health and law enforcement resources and to exacting a very substantial toll on members of the public. Thank you.

[The prepared statement of Mr. Reynolds follows:]

STATEMENT OF JAMES S. REYNOLDS, CHIEF, TERRORISM AND VIOLENT CRIMES
SECTION, CRIMINAL DIVISION, DEPARTMENT OF JUSTICE

Madam Chair and Members of the Subcommittee, thank you for the opportunity to appear before you today. I am James S. Reynolds, Chief of the Terrorism and Violent Crime Section of the Criminal Division, United States Department of Justice. I appreciate the opportunity to appear before you today to discuss the existing federal statutes relating to dangerous biological agents and toxins.

In recent years 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, and is reinforced by the pervasive consequences currently being confronted by our nation as a result of the recent criminal dissemination of anthrax.

For example, Dr. D.A. Henderson, who has been appointed the Director of the Office of Public Health Preparedness in the Department of Health and Human Services, and who was formerly Director of the Johns Hopkins Center for Civilian Biodefense Studies, 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, and Education of the Senate Committee on Appropriations, Hearing on Bioterrorism (March 16, 1999).

Similarly, Dr. Margaret A. Hamburg, former Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services 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).

In recent years, the Department of Justice has noted that there is increasing telligence of interest by terrorists in the use of biological weapons both in the United States and abroad. Five-Year Interagency Counter-Terrorism and Technology Crime Plan submitted by the Attorney General to Congress on December 31, 1998. 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 several years involving biological agents and toxins, including hoaxes and threats involving such materials. Most recently, the United States and its citizens have been the subject of anthrax disseminations which have resulted in deaths and illness, and the interruption of governmental processes.

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. As Dr. Hamburg noted in her March 25, 1999, congressional testimony, "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." The consequences of the current anthrax incidents serve to underscore the importance of prevention.

To facilitate that paramount objective, improvements were recently made to existing federal criminal statutes. Prior to the amendments of October 26, 2001 (the USA PATRIOT Act, Pub. L. 107-56), the key federal statutes pertinent to bioterrorism have been 18 U.S.C. 175 and 2332a. 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. 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.

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

On October 26, 2001, 18 USC 175 was amended. Among the changes was the insertion of a provision that makes the knowing possession of any biological agent or toxin a crime if the agent is of a type or in a quantity that, under the circumstances, is not reasonably justified by a "prophylactic, protective, bona fide research, or other peaceful purpose." Additionally, the amendment creates a category of restricted persons who are barred from possessing any biological agent that has been designated under the Code of Federal Regulations as a "select agent." These are biological agents and toxins that have the potential to pose a severe threat to the public health and safety. The term "restricted person" includes individuals under indictment for a felony or who have been convicted of a felony, unlawful users of controlled substances, illegal aliens, and persons who have been adjudicated as a mental defective or who have been committed to a mental institution. Knowing possession of a select agent by any restricted person constitutes a felony.

These recent amendments to the federal biological terrorism statutes will be of assistance to federal law enforcement in pursuing action designed to prevent potentially tragic bioterrorism acts. For example, if probable cause is developed that a person possesses a biological agent and such possession is not reasonably related to a peaceful purpose, an arrest warrant can be sought for the purpose of arresting the individual before the biological agent is used in a manner that endangers the public. Previously, action could not be taken against the possessor of the agent absent proof that he possessed the agent for use as a weapon. Similarly, if probable cause is developed that a restricted person, such as a felon, is in possession of a select agent (i.e., any one of a group of particularly deadly biological agents), law enforcement can take action against that individual without delay.

In light of the recent anthrax incidents, there is a need for additional changes in federal law relating to biological terrorism. For example, and as Secretary Allen notes in his testimony, the Department of Health and Human Services recently submitted a package of such changes to Congress for its consideration.

Another area of legislation that merits consideration relates to the creation of a statute that specifically addresses hoaxes which involve purported biological substances. Such a statute could also address hoaxes involving chemical, nuclear, and radiological substances. Persons who convey information, knowing it to be false, indicating the existence of a hazard involving a biological substance, cause a public safety response that drains governmental resources and diminishes the capability to respond to actual hazardous material incidents. Moreover, such hoaxes inconvenience the public and often exact a significant psychological toll from victimized members of the public who are placed in the position of fearing that their health or life is endangered.

Madam Chair, that concludes my prepared remarks. I will be happy to respond to any questions that you or other Members of the Subcommittee may have at this time.

Chairperson FEINSTEIN. Thank you very much.

Senator Edwards, would you like to make a quick statement before we proceed to questions?

**STATEMENT OF HON. JOHN EDWARDS, A U.S. SENATOR FROM
THE STATE OF NORTH CAROLINA**

Senator EDWARDS. Just very briefly, Madam Chairwoman.

Let me first thank you for having this hearing on such an important issue and before Senator Kyl leaves, thank you and Senator Kyl for all the work you have done on this issue for so many years. The both of you have been ahead of the curve on this and you have shown real leadership and we thank you for that.

The purpose of this hearing and the subject matter of this hearing is very important and I want to ask questions about that later and comment on it. Before I get to that I want to update my colleagues on the work we have been doing on the issue of preparedness. I know Senator Feinstein made a comment about that earlier.

Several weeks ago Senator Hagel and I introduced legislation before the anthrax attacks began dealing with the issue of preparedness for a possible biological attack. Both of us believe very strongly that there were some critical things that need to be done and it basically fell in three different categories: first, making sure that the people on the front lines were ready to respond to a biological attack if one occurred, which meant getting money out of Washington to the local and state authorities, the people who, in fact, would have to respond—local health care providers, local emergency rooms, members of the public health system—and making sure that all the folks who would be responsible for first identifying that a biological attack had occurred and responding to it were prepared.

Secondly, making sure that we had adequate stockpiles of vaccine and antibiotics, which we all now know, the American people now know we do not presently have.

And third, making sure both our crop supply and our food supply were better protected. Those were the three components of our legislation.

We have been working with Senators Kennedy and Frist over the past several weeks. We are very close to having an agreement to introduce a comprehensive piece of bipartisan legislation. I expect that legislation to be introduced sometime in the next day or so. It will incorporate the three major components of the work that Senator Hagel and I have done and I think will go a long way toward getting this country adequately prepared to respond to a serious biological attack.

I also want to say on the subject matter of this particular hearing, and I am interested in the comments of the witnesses, that we obviously need to be prepared to deal with this issue of hoaxes and I think they need to be taken seriously and treated seriously from a criminal prosecution perspective. The questions I have, which I will address later after my colleagues have had a chance to ask questions, are number one, is existing law adequate to prosecute this particular behavior? And number two, if it is not, what does the law need to contain substantively? And I am more specifically interested in any comments that any of you would have about what the mens rea requirement should be, the criminal intent requirement, in any kind of statute that we might enact.

So Madam Chairwoman, thank you for letting me make those comments and I have some questions when you and my colleagues have finished.

Chairperson FEINSTEIN. Good. Thank you very much, Senator.

I have just two questions in this round. The first is really for Mr. Caruso.

I have been very surprised the FBI has not made more progress and I would assume by now all labs have been checked. I'm talking about the derivation of the anthrax, particularly that that was in the Daschle letter, which is highly pure, is coated with something,

aerosolizes easily. It seems to me that within this country there are limited places where that kind of anthrax would be available and that you could have early on established the DNA and made that contact.

Is it fair to say then that that anthrax did not come from one of these major laboratories?

Mr. CARUSO. Senator, the answer to that is we are still searching for that answer. With close partnership with the CDC and USAMRID and other institutions, we are learning more about the various characteristics of anthrax and with that, we are positioning ourselves to ask smarter questions and get better answers.

Chairperson FEINSTEIN. How many labs handle anthrax in it United States?

Mr. CARUSO. We do not know that at this time.

Chairperson FEINSTEIN. You do not know that?

Mr. CARUSO. No, we do not. We are pressing hard to determine that.

Chairperson FEINSTEIN. Could you possibly tell me why you do not know that?

Mr. CARUSO. The research capabilities of thousands of researchers is something that we are just continuing to run down. I know it is an unsatisfactory answer and unsatisfying to us, as well.

Chairperson FEINSTEIN. So is what you are saying that anthrax is actually in the hands of thousands of researchers all across this country?

Mr. CARUSO. No. What I am saying is that it appears to us that there are many, many people who have been educated in the United States over the years that possess the capabilities, the intellectual knowledge to be able to produce various kinds of pathogens. The question then after that also is do they have the kind of laboratory access and equipment to be able to actually produce something that would be harmful. That is also a question that we are pursuing.

Chairperson FEINSTEIN. Have you nailed down the number of labs that are capable of producing this quality anthrax?

Mr. CARUSO. We do not know that at this time.

Chairperson FEINSTEIN. So you do not know how many labs produce it, how many labs produce this quality. What do you know?

Mr. CARUSO. If I may, we could submit to you for your review a detailed answer with reference to that. Some of the information that I could provide you at this time in a public forum would not be necessarily beneficial to the investigation and the kind of work that we are doing. We would look forward to providing that to you in a different forum than this.

Chairperson FEINSTEIN. Okay, I would be happy to set that up for the Committee.

How many people do you have working on this at this time?

Mr. CARUSO. For the past seven or eight weeks since the attack we have about 4,000 special agents and about 3,000 individuals across the country and around the world that are working on this, as well as in partnership with other foreign governments and services.

Chairperson FEINSTEIN. And I trust you do not want to discuss what foreign partnerships you have at this time, or is it possible for you to tell us that?

Mr. CARUSO. I would prefer to do that in a different forum. We have about 44 legal attaches around the world, each in a different country, and all of those countries have been helpful to us in this effort, ranging from traditional partners in Europe all the way through the Middle East, where we do have legal attaches, legal representation, as well as into Southeast Asia.

Chairperson FEINSTEIN. Have you made any judgments whether this could have been produced in other countries and, if so, where?

Mr. CARUSO. We have not come to any final judgments.

Chairperson FEINSTEIN. Okay. Can you summarize what seems to be delaying the investigation? Is it the fact that it is so diffuse, that there are so many sources of anthrax? This has been a big puzzle to me. I would have thought this was an investigation, that there was a limited amount of this quality out there, that it would be fairly easy to determine the number of sources, go directly to them, get lists of everybody that has handled them, run it down and come up with some conclusions.

Mr. CARUSO. I just follow up on some of the comments you made earlier in your opening statement to us that the kind of background investigations that are required for people in other walks of life are not necessarily required for individuals who are doing the kind of research that could produce very deadly pathogens and that, I think, is a really good example as to how widespread and diffuse the knowledge is to produce this.

The second aspect of that is—

Chairperson FEINSTEIN. So you are corroborating that, in essence, that there are many people handling this stuff that should not be.

Mr. CARUSO. We think that there are many people that have the potential, that have the knowledge to be able to produce deadly biological agents. The question then is do they have the actual facilities and laboratory to do it? That is an important piece to that. But we are a rich and diverse country and people from all over the world have flocked here for education and training. There are many, many people that pass through the ivory halls of our universities and colleges and have now left the United States and some remain here. It is a very, very big population and universe to look at.

Chairperson FEINSTEIN. Thank you very much.

One quick question, Mayor Abrams. Mr. Mayor, I want to go back to the command center and you seem to indicate that this was a health problem, therefore in the country jurisdiction, I guess, not in your city jurisdiction.

Do you have an emergency command center where if you have a major event all relevant departments report forthwith and was that activated?

Mayor ABRAMS. Yes. One of the features of living in South Florida is that we do have very good emergency preparedness plans that are obviously geared more toward natural disasters. We just missed a hurricane last week.

Chairperson FEINSTEIN. Right.

Mayor ABRAMS. So we have very sophisticated equipment. The city of Boca Raton, even though we are 75,000 people, has our own emergency operation center and can staff it fully with the most up-to-date equipment, as well as Palm Beach County.

So yes, we have the capability and, in fact, as I said, the county did activate its command center. But the problem did not occur in terms of being able to establish that but when you have so many different jurisdictions because we are just discussing the public health side which yes, is county but actually is controlled by the state of Florida the way it is set up in Florida, but also then the law enforcement side—the FBI, the U.S. Attorney's Office.

Then, after the incident occurs, we have other federal agencies involved. Right now the AMI building is still being cleaned up by the Environmental Protection Agency. We now, of course, have the Postal Service involved. So there are a myriad of agencies, both federal, state and local, that are involved and they need to be not just physically brought together but have one spokesperson and have one agency that is clearly held accountable.

When this incident broke the city was first notified by the FDA through our police department and that was fine. Then when several days later it was determined that the AMI building was going to be evacuated, the city was notified by—we received a call from our county commissioner that this was occurring. The responsibility had shifted somewhere along the line from the law enforcement side to the public health side and while we were able to scramble and mobilize our people, it would have been much more helpful to us if there had been a central point person.

Chairperson FEINSTEIN. Appointed by?

Mayor ABRAMS. Well, maybe that is a good task for the Office of Homeland Security. The responsibility is among types of—

Chairperson FEINSTEIN. So you are talking about a federal person that would be in charge, as opposed to your just taking the bull by the horns and saying—one of the things I found in emergencies, just do it. Just say so-and-so is in charge and they say, "Who said?" "I said." Then if they do not like it, they lump it but it is done.

Mayor ABRAMS. That is true and that is, in fact, what has to happen, especially at the local level because, as we have seen in other cities where we have had incidents, people look to their mayor and you know that better than anyone, and so you automatically become a point person. And maybe it is the mayor of a city who is the point person but there has to be some, it would seem to me, some sort of process and procedure in place so that there is not that appointment by default by someone who can step up to the forefront and have the information and have the knowledge to impart to the people.

Chairperson FEINSTEIN. Thank you very much.

Senator KYL?

Senator KYL. Thank you, Madam Chairman.

First let me ask some questions to you, Mr. Reynolds. And I wish Mr. Allen were here because some of my questions are taken from his testimony. We will perhaps talk to him later.

Is it your understanding that most of the regulations that were promulgated in 1997 pursuant to the 1996 act related to the shipment of these kinds of materials?

Mr. REYNOLDS. That is correct and I think it is an important point to pick up on because I do not want to leave the impression, Senator Feinstein, from the testimony here that we have no idea where anthrax is. Anthrax is a select agent under the transfer reg put in place in 1997. The shipment of anthrax from one laboratory facility to another must be done pursuant to the regulation. There must be a documentation of that.

So we have and we are following very closely the shipments of anthrax and identifying the laboratories that received or shipped anthrax.

Additionally, it takes a laboratory of a certain level. The microbiologists here can correct me if I am wrong but I believe it is at least a level 3 to deal with anthrax. Again HHS CDC is advising us concerning level 3, level 4 laboratories.

So there is a very systematic effort to try to identify where anthrax is and I do not want to leave you with the impression that somehow we do not have a way of trying to track that down. It is not a perfect way.

Senator KYL. But I gather there are a fair number. Can you quantify in any general sense the number of places where shipments have come from or gone to that might be of interest considering their level of expertise?

Mr. REYNOLDS. That is part of the investigation that is being pursued right now. We do have the transfer records from CDC and it is being pursued. I would be premature to comment on or to quantify the numbers.

Senator KYL. Okay. Now regarding the 1997 regs, were those limited by the legislation to transportation or were the other aspects with regard to law enforcement clear enough? Or do we need to go beyond the shipment and transfer in legislation that we consider?

Mr. REYNOLDS. Well, my understanding of the HHS bill is that it would require under a regulatory process that would—

Senator KYL. This is the proposed HHS bill.

Mr. REYNOLDS. The proposed HHS bill. It would create a new regulatory process, which would subsume the one from 1997 and add to it and the added provisions would involve some degree of requirement of registration—that may not be the right term but identification of ones possession of certain of the select agents.

Senator KYL. So without speaking for Secretary Thompson, would it be your understanding that the proposal that he has offered would represent the administration's view as to the additional authorities or requirements that would be necessary in this area, possibly excepting new legislation regarding hoaxes?

Mr. REYNOLDS. I think that is a point at which we will need to come back at a policy level as to whether there are other areas.

Senator KYL. This gets right to Senator Edwards's question, the same question I had, and that is we need from the administration, from the FBI, from HHS, from the Justice Department and anybody else any other authorities that you think the administration should have, any other procedures that we need to legislate, any other assistance, whether it be financial or otherwise, that we need to provide. And I would invite you at this time to take that back to the attorney general and to the others in the administration and

we will communicate with Secretary Thompson, as well. But there will be some cross-committee jurisdiction here. Part of his legislation probably would go to a different Committee than ours but with respect to the legal part of it, we would certainly consider that. So we need to know as soon as possible what other recommendations the administration would have to deal with this.

Now let me get specifically to the area of hoaxes and probably either Mr. Caruso or you could answer this. Do you think we need some additional legislation making various kinds of hoax actions criminal and/or increasing the penalties for them?

Mr. REYNOLDS. Yes.

Senator KYL. And if so, would you be willing to communicate with us about how you would propose that to be written?

Mr. REYNOLDS. We would be happy to work with staff to prepare drafts. We have had some communications with staff. There are a variety of hoax statutes, none of which are biological hoaxes but a number of hoax statutes in the federal criminal code. They are written in numerous different ways. They have different intent elements.

Senator KYL. Could you maybe try then to go back and conform those as best as possible with a set of recommendations that we could then take to the full Judiciary Committee and improve that area?

Mr. REYNOLDS. Yes.

Senator KYL. Just two other quick questions here. I got the impression from the last answer to Senator Feinstein's question that not only is the number of people scientifically capable of dealing with anthrax fairly large in number but the facilities are relatively ubiquitous, as well, and that might even include facilities capable of producing the kind of spores that we are aware of in recent weeks. Is that generally true?

Mr. REYNOLDS. I would prefer, if you could, that you ask that to one of the microbiologists who will testify in the next panel. You will get a more authoritative answer.

Senator KYL. And finally, with regard to my earlier question about—well, it is two parts. One, radiological material, that is probably not included within a definition of bioterrorism materials but would it not be important to ensure that as we are drafting these statutes, to include radiological materials, as well as biological materials if they are not covered in some other statute?

Mr. REYNOLDS. Yes, I think we should consider, for instance, in a hoax statute covering not only biological but chemical, nuclear and radiological. All of those areas or at least all but the chemical aspect of those four areas that I mentioned are currently covered in the weapons of mass destruction statute, 18 U.S.C. 2332(a). However, it does not have a hoax provision.

Senator KYL. Okay. But also, not just with respect to hoaxes but also the identification of people who handle the material, how it is shipped. In other words, the same kind of requirements that would pertain to something like anthrax should also pertain to radiological material of a certain level of danger or radioactivity; would you not agree?

Mr. REYNOLDS. Again I am not an expert in that area. There is both the Department of Energy and the Nuclear Regulatory Com-

mission. My sense from looking at this when we worked on biological legislation after testifying before you, Senator Kyl, in I think April of 1998, we did look extensively at the nuclear and radiological pattern.

My sense is it is a highly regulated industry. There are a lot of restrictions and we would need to look at that.

Senator KYL. We will add that as a question to ask various people at the department and we will ask the question of others, as well. Thank you.

Mayor, I do not have any questions of you but it was a fascinating bit of testimony that you provided our Committee and I thank you for being here, as well.

Mayor ABRAMS. Thank you, Senator.

Chairperson FEINSTEIN. I have one follow-up question I want to ask. I am really sorry Mr. Allen is not here because this leaves me very confused.

It is my understanding that one exemption in current CDC regulation concerns so-called CLIA labs or labs that meet certain certification requirements set forth under the Clinical Laboratory Improvement Amendment of 1988. These labs, I am told, are not required to register with the CDC if they transfer or receive anthrax or other biological agents or toxins.

Does anybody here know how many labs are currently certified as CLIA labs?

Mr. REYNOLDS. I have heard the number. It is a large number. I would not want to venture the specific figure.

Chairperson FEINSTEIN. Does anybody know how many of these labs are working with select biological agents?

[No response.]

Chairperson FEINSTEIN. Do these labs that work with select biological agents submit any kind of registration to any government agency indicating that they are working with these biological products?

Mr. CARUSO. According to federal regulation there are about 100 laboratories that have registered and I can get you some additional information about that that are required by federal law 42 CFR 76 to register. I can get you some additional information on that.

Chairperson FEINSTEIN. Right, because I would appreciate it. I am also going to send you questions in writing to everybody because the way it appears to me, members, and I hope I am wrong, this is one more area of intense sloppiness where there are all these entities functioning out there, handling these materials, and no one knows who they are, at least no one in the federal government knows. And as the delay goes on and we are unable to really come to grips with this thing from a law enforcement point of view, the more I suspect how wide the field is. I hope I am wrong but I think this Committee is entitled to know some of this information, so I would hope that when you get these questions, gentlemen, that you will give it your highest priority.

Chairperson FEINSTEIN. Any other questions of this panel?

Senator EDWARDS. Yes.

Chairperson FEINSTEIN. Go ahead.

Senator EDWARDS. Thank you.

Mr. Caruso, you know as well as all of us do, that the American people are very concerned about where we are today with respect to determining the origins of this anthrax and where it came from. I just want to ask you some basic questions.

As of now, as you sit here now, do you know where the anthrax came from?

Mr. CARUSO. We do not know at this time.

Senator EDWARDS. Secondly, the anthrax has been tested. The anthrax that has been sent through the mail to Senator Daschle and others, do you know how many people in this country have access to that anthrax as you sit here today?

Mr. CARUSO. No, I do not know that at this time.

Senator EDWARDS. It is my understanding that the Daschle letter contained what is known as the Ames strain of anthrax. First of all, have you identified every person in the country who has access to the Ames strain of anthrax?

Mr. CARUSO. I do not believe we have had the ability to do that. My understanding is, and I will defer to the scientists to give you a better answer, the Ames strain goes back nearly 50 years and there might be a whole variety of people over time.

Senator EDWARDS. The bottom line is you do not know who has it.

Mr. CARUSO. No, we do not know. It is too diverse a population at this time.

Senator EDWARDS. Have you made any effort to go to the places that you are aware of that have the Ames strain to make sure that they have it under control, their supply under control?

Mr. CARUSO. We have FBI agents out over the country talking to people in laboratories, as well as the laboratories that we know of and following up leads that we may be given to other places in the country.

Senator EDWARDS. The bottom line is this. As of now you do not now where the anthrax came from and you have not been able to identify all the people who may have access to it. Is that fair?

Mr. CARUSO. That is correct.

Senator EDWARDS. Let me ask you a follow-up question to that. If at some point in the future there were another attack in some other part of the country using another biological agent, given the time that it has taken to get to the place you are now with respect to these anthrax attacks and obviously tremendous amount of work left to be done to figure out what happened and how to prevent it from happening again, are you prepared to fight a two-front war?

In other words, if another attack occurs or a third attack occurs, are we ready to investigate and respond to those attacks?

Mr. CARUSO. Senator, we have a tremendous amount of individuals that are working this particular case and we would apply other individuals to work on a second front. There is no other alternative. The American people expect us to do that and we will do that.

Senator EDWARDS. My question is are you ready to do that?

Mr. CARUSO. We are ready to do that and I think the kind of excruciating and painless experience that we all have suffered through this and we have learned from this has solidified and made seamless the kind of partnerships that we have with the fed-

eral and other state and local agencies. This is a war that we are all fighting and like in every war, there is a certain amount of fog but we are learning and we have learned from it and we have no choice.

Senator EDWARDS. Now my understanding is there are literally millions of letters that have piled up yet to be decontaminated. Can you tell me where we are in that process? Because it seems to me there may be many letters out there, anthrax-contaminated letters right now that we do not know about yet.

Mr. CARUSO. I will ask some other people to give you a fuller answer to that and your answer is across the country. We can provide you with fuller details but I will tell you that with reference to the mail that was bound for Capitol Hill, that mail, well over 100,000, 150,000 pieces, as I understand it, has been placed in 280 55-gallon drums apiece. That is 280 times 55. They have been moved to a location away from here. We are going through those. We have identified a location. We have built a special facility to handle that or reconfigured an existing facility to handle that.

What we have done now is we have moved those 280 55-gallon drums filled with mail. We are opening up each one of the 288, they have been sealed, and we have been swabbing those to see which ones, if any, have anthrax, and that is how we are going to prioritize going through that.

Senator EDWARDS. What about that—excuse me for interrupting you but what about the non-Capitol Hill mail?

Mr. CARUSO. I need to have some other individuals get back to you to tell you precisely what we are doing in those other areas. The Capitol Hill mail, there is a precise approach that I am aware of right now. All across the country there are other approaches and I can get you the information that talks about those various approaches and how many.

Senator EDWARDS. Are there different approaches being used around the country with respect to the mail?

Mr. CARUSO. No, I do not want to tell you that there are not and then I may find that there is a variation that is particular to a particular locality that is needed there.

Senator EDWARDS. I do not know what that means. Are you using different processes at different places in the country or not?

Mr. CARUSO. I said I was not sure if we were using the exact same process across the country because various localities may have a particular requirement that has a variation that works for them and not some other place.

Senator EDWARDS. Is it true though that there are still millions of letters yet to be decontaminated? Is that true or not?

Mr. CARUSO. I would suggest that you go to the U.S. Postal Service and get their best estimate. That is their business, mail handling. We work in partnership with them but that would be your—

Senator EDWARDS. Is the decontamination process affecting your ability to get to the information you need?

Mr. CARUSO. We have a good partnership with the U.S. Postal Service.

Senator EDWARDS. But that was not what I asked you. Is the decontamination process and how long that is taking affecting your ability to get to the information you need?

Mr. CARUSO. It slows down our ability to conduct forensic tests on certain items because we have to ensure that it is safe for the people in our laboratories and the people handling it, so there is some delay.

Senator EDWARDS. Madam Chairwoman, I have just one other question if I could ask it very quickly.

Chairperson FEINSTEIN. Go ahead.

Senator EDWARDS. This comment is for Mr. Reynolds, you or Mr. Caruso, either one. This goes to the issue of hoaxes and what other action we need to take.

It seems to me that there are prosecutions on-going under existing law for these hoaxes and I am just interested in finding out, and Senator Kyl made mention of this, specifically what it is that existing law does not already cover, number one, and number two, if we need additional legislation, are you suggesting that there would be a specific kind of criminal intent that would be required? And secondly, would you require that there be some sort of effect, in other words, some emergency response that was generated by the hoax in order for it to be a crime under the new statute?

Mr. REYNOLDS. The details of the statute remain to be worked out and we are very much willing and solicit an opportunity to work with staffs up here.

The issue of what we are doing right now, in the bio area there is no, as I said earlier, no hoax statute so what we are using is other statutes, such as threat statutes, mailing threatening communications, or threatening to use a weapon of mass destruction. Threat law is somewhat different from the hoax statutes. The threat law looks toward a projection by a person that they are going to do an act in the future, whereas hoax will often involve simply the conveyance of knowingly false information, does not suggest that the perpetrator is going to do anything but conveys false information.

We very much need a hoax statute to assist with these cases so that we are not put in the position of using statutes that really are not well designed, not well tailored for the use that we put them to. Does not mean that we are not having some success; we are. But there are cases that we simply cannot bring based on the lack of a hoax statute.

As relates to your second issue about a mens rea, the two basic points that we see to one of these statutes is that they would only relate to a person who conveys information about a weapon of mass destruction knowing that information to be false, knowing that information to be false, and secondly, that the conveyance of that be under circumstances where it is reasonable to believe that people are going to take that statement seriously.

Those are, as we would perceive it, the two core elements of the statute. Others have suggested placing other terms into the statute. We would hope not to encumber the statute with a number of what I think we may be able to perceive to be unnecessary additions that burden the prosecution, but the knowing dissemination of false information and doing it under circumstances where it is reasonable that it will be taken seriously, core elements of the statute.

Senator EDWARDS. Thank you. I would like to discuss that further with you at some later time.

Madam Chairwoman, thank you for your patience.

Chairperson FEINSTEIN. Thanks very much.

I just have a couple of quick questions for you, Mr. Reynolds. Is it possible to take a clinical specimen of anthrax intended for diagnosis or reference purposes and culture it in such a way that it can later be produced in a quantity and quality viable for use as a biological weapon?

Mr. REYNOLDS. I wish I could answer that. We spent a couple of days ago two hours in a conference call with the CDC scientists asking questions just like the question that you asked but I need to defer that type of question to HHS and to the scientists.

Chairperson FEINSTEIN. I will ask the next panel.

One other quick question. Current regulations exempt labs from registering with the CDC any transfer of a clinical specimen that is used for diagnostic verification or reference purposes. Does this mean that the anthrax found in Florida, in the Hart Senate Building and in New York and New Jersey, all of which were sent to various labs for diagnostic testing, was not registered with the CDC?

Mr. REYNOLDS. If I understood your question correctly, I think the answer, and again I would suggest that the authoritative answer comes from HHS, but I do not believe that any of the samples of anthrax—the swabbings, the testings that were done—could be sent to a clinical lab, one of those accepted labs. I am sure I will be corrected by the next panel if I am wrong, based on my understanding.

Chairperson FEINSTEIN. I am not quite sure that is the answer to my question. My question is whether the anthrax samples were registered with the CDC or whether these particular ones were exempt, which I suspect they were.

Mr. REYNOLDS. Whether the samples were registered? You are talking in terms of the transfer regulations that HHS has—

Chairperson FEINSTEIN. Yes, it exempts labs from registering with the CDC any transfer of a clinical specimen if that specimen is being used for diagnostic, for verification or for reference purposes. So all of these specimens found in Florida, the Hart Building, New York and New Jersey were sent to various labs for diagnostic testing. The fact that they have not come up with something would indicate to me that they were not registered with the CDC; therefore presenting us with another huge loophole.

Mr. REYNOLDS. These are specimens that are sent through law enforcement channels tightly controlled by the FBI. They are, my understanding is, exempt from the transfer regulations but they are also highly, highly controlled. They are evidence and they are tracked as evidence.

Chairperson FEINSTEIN. I understand that but they came from somewhere. Before they were used illegally they came from somewhere.

Mr. CARUSO. So they were either misplaced or stolen or modified in some fashion from a registered laboratory.

Chairperson FEINSTEIN. Correct.

Mr. CARUSO. I will use Mr. Reynolds's statement and say I may be corrected later but the best information we have is that the anthrax that was found in those letters, we have not been able to take and trace them to—we do not believe that they were stolen or misplaced from a registered laboratory.

Chairperson FEINSTEIN. Which is the loophole I am talking about because there is a huge quantity out there that does not have to be registered, I gather, right?

Mr. CARUSO. The laboratories and other areas is an industry or an effort that also needs to look at itself, as we all are doing right now across the country and saying where can we improve the systems that we have.

Chairperson FEINSTEIN. Mr. Caruso, am I correct, is there an amount out there that does not have to be registered, that is just floating around in individual hands?

Mr. CARUSO. I do not have an official position on that. I just cannot answer the question.

Chairperson FEINSTEIN. I was not asking for an official position. I was just asking for your professional opinion based on what you have found so far.

Mr. CARUSO. We have insufficient information for me to make a declarative statement about this or that. We have questions that need to be answered at this time. It is still a work in progress.

Chairperson FEINSTEIN. Thank you very much, gentlemen. We appreciate your testimony.

Oh, Mitch? Excuse me, Senator McConnell.

Senator MCCONNELL. I am here principally for the second panel so I am happy to move on to the second panel.

Chairperson FEINSTEIN. Thank you very much. Appreciate it. I would like to defer to you. We will now be introducing our second panel. It is my understanding that you have a very distinguished constituent that you would like to introduce.

**STATEMENT OF HON. MITCH MCCONNELL, A U.S. SENATOR
FROM THE STATE OF KENTUCKY**

Senator MCCONNELL. Thank you, Madam Chairman. I congratulate you on holding these hearings on probably the most timely subject in America today and take particular pleasure in being here as a member of the Subcommittee to introduce a constituent of mine, Dr. Ron Atlas.

Dr. Atlas is here representing the American Society for Microbiology where he serves as the organization's incoming president and co-chair of its Task Force on Biological Weapons.

The American Society for Microbiology is the single largest life science society, representing more than 40,000 scientists. As we know, microbiologists are on the front lines in our efforts to detect biological agents in the environment and treat those who have been exposed to them.

I have had the pleasure of working with Dr. Atlas in his capacity as the dean of the University of Louisville Graduate School and the director of U. of L.'s Center for the Deterrence of Biowarfare and Bioterrorism. With Dr. Atlas and U. of L.'s assistance, my home town of Louisville is at the forefront of communities developing plans to respond to biological attacks.

Through the course of this year I have worked with Dr. Atlas and U. of L. to secure funds for the center's initiatives in the fiscal 2002 Labor, Health and Human Services appropriations bill. In recent weeks Dr. Atlas has shared his expertise with the White House, the Centers for Disease Control and Prevention and various news outlets and I am grateful he is able to join us today and offer his insight to our panel and thank him for all of the leadership he has demonstrated during this trying time. We are very, very proud of him at home and grateful that he is here today.

Chairperson FEINSTEIN. Thank you very much for that introduction, Senator McConnell.

Why don't you proceed, since you had that wonderful introduction? Go ahead and then we will introduce the remaining panelists.

**STATEMENT OF RONALD ATLAS, PRESIDENT-ELECT,
AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, D.C.**

Mr. ATLAS. Thank you, Senator McConnell, for that very kind introduction and thank you, Senator Feinstein, for inviting me to testify today on behalf of the American Society for Microbiology and thank you, Senator Kyl, for your role in helping us combat terrorism.

I would like to just summarize some of my comments and ask that the full testimony be added to the record. What I would like to say is that this misuse of microorganisms has shocked the more than 42,000 members of the ASM. The criminal and deliberate spread of anthrax is completely contrary to the ends of science and the principles for which ASM stands.

To minimize the risks of bioterrorism, the ASM has consistently advocated appropriate government oversight and monitoring. ASM's view is that legislation and regulations can, should and must ensure protection of public safety but that they should do so without encumbering legitimate scientific and medical research or the clinical and diagnostic medicine needed for the detection and treatment of diseases.

In 1999 I testified before the House that the ASM strongly supported the registration for possession of all facilities that had select agents so that we very much support the position that you have advocated, that registration is necessary. In our view though, registration through appropriate federal regulatory mechanisms is tantamount to certification and those regulations can and should control who has access to the agents and the biosafety and biosecurity measures that, in fact, need to be in place.

Concerning who should be responsible for that oversight, the ASM feels that this should be in the hands of the Centers for Disease Control and Prevention. That is the organization that understands public health, that has a relationship with the scientific community and can best provide the necessary oversight. We think that the CDC should have the resources that they need and that they should periodically revise the list of select agents so that we have those true biothreat agents at the top of our list, that they should promulgate additional regulatory measures that ensure biosafety and biosecurity, and that they should notify the Department of Justice of any concerns that they may have about who is, in fact, possessing these agents.

We think the CDC has a long history of regulatory oversight concerning biosafety and that their biosafety manual outlines both biosafety and biosecurity measures that, in fact, should be in place.

We need to recognize though that bioterrorists are not going to follow the biosafety manual. They are not likely to register and it really is only the biosecurity and shipping aspects of those regulations that may help us identify where agents have come from.

Regarding who should be entitled to work with select agents, we support the concept of setting reasonable limits upon persons who may possess those select agents. We fully support the restrictions that preclude individuals who are disqualified from purchasing firearms from possessing select agents. We, though, recognize that some care needs to be exercised when we extend this, for example, to cover aliens. We support the provisions of the USA Patriot Act which restricted possession for aliens from those countries that are designated as supporting terrorism but we are concerned about an extension of this to all aliens—to Canadians, to other allies who, in fact, join us in our fight against infectious disease.

This is a global fight. Infectious disease occurs all over the world. It is a national security threat when it occurs naturally and we have to enlist the aid of people from around the world and in that regard we have to ensure that we do not take actions that will form roadblocks between us and the international community in our effort to, in fact, combat infectious disease.

In that regard we have some concern with the USA Patriot Act concerning the fact that it did not provide any ability for an exemption. If the secretary of HHS and the attorney general feel that someone should work with pathogens that are on the select agent list, even if they are from one of the countries that supports terrorism, we think that the appropriate government officials should have been able to propose such an exemption, so that is a concern of ours.

With regard to criminal penalties, we think these really have to be specific and that they can and should be enacted in a way that does not turn all of us legitimate scientists into potential criminals where we run away from doing the necessary work of developing diagnostic and vaccines and pharmaceuticals that combat infectious disease, including those that threaten us, like anthrax, in cases of bioterrorism. So we urge extraordinary specificity in those very clear rules of the road so that we know what we are doing and we follow those rules.

In conclusion, we feel that legislative acts to enhance national security should add protection, that there are criminal acts of bioterrorism that should be dealt with, and that we need to act in ways that improve the health of Americans and those beyond our shores with the development of new pharmaceuticals and vaccines and diagnostic capabilities that will protect the health of all Americans from both natural diseases and those that may come from criminal bioterrorist attacks.

In closing, I want to thank you, Senator Feinstein, for holding this hearing and allowing me to address the Subcommittee. This is a very important topic.

And finally, I would just like to express the view that working together, the government and scientific and medical communities

can defeat the future threats of bioterrorism. Thank you very much.

[The prepared statement of Mr. Atlas follows:]

STATEMENT OF RONALD M. ATLAS, PH.D., PRESIDENT-ELECT, AMERICAN SOCIETY OF MICROBIOLOGY, CO-CHAIR, ASM TASK FORCE ON BIOLOGICAL WEAPONS

Introduction

Thank you, Senator Feinstein and members of the Subcommittee, for inviting me here today to discuss issues related to the regulation of dangerous biological agents and toxins and to present the perspective of the American Society for Microbiology (ASM). My name is Ronald M. Atlas. I am Professor of Biology, Dean of the Graduate School at the University of Louisville in Kentucky and co-director of the Center for Deterrence of Biowarfare and Bioterrorism at the University of Louisville, a major research institution with over 4,000 graduate students.

I am appearing today as President-Elect of the American Society for Microbiology, and co-chair of the ASM's Task Force on Biological Weapons Control. The ASM is the largest single life science society in the world. The ASM publishes 10 scientific journals, each of which focuses on a distinct specialty within the microbiological sciences. The ASM also annually publishes numerous scientific books and sponsors many scientific meetings, conferences, and workshops on a broad range of microbiological subjects. The ASM's membership consists of over 42,000 microbiologists, ranging in profession from laboratory clinicians to research scientists and Nobel Prize laureates. A common appreciation of science and a commitment to scientific integrity unites this large and diverse scientific community.

The recent misuse of microorganisms has shocked the academic and scientific communities. The deliberate and criminal spread of anthrax is beyond comprehension for civilized people. It is completely contrary to the ends of science. I hope our testimony today will be helpful to the fashioning of legislation that will substantially diminish the threat of bioterrorism, advance our nation's ability to respond to bioterrorism, and encourage aggressive research against the global problem of infectious diseases.

Interest of ASM in Bioterrorism Legislation

The ASM's mission is to advance the microbiological sciences 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. Our members recognize a duty to propagate a true understanding of science. Scientists have an obligation to work for proper and beneficent application of scientific discoveries. The ASM and its members are committed to preventing misuse of microbiology contrary to the welfare of humankind.

The ASM has a long and distinguished history of bringing scientific, educational, and technical expertise to bear on issues surrounding biological weapons. Over the past 15 years, the ASM has worked with the Department of Health and Human Services (DHHS), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health, the Department of Defense U.S. Army Medical Research in Infectious Disease Command (USAMRIID), the Department of Agriculture (USDA), and Congress. The ASM supports legislation and regulations that are based upon the essential 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 premises its review of legislative and regulatory approaches on the need to pursue two goals with equal vigor and commitment. We must do everything possible to prevent bioterrorism or endangerment of the public welfare and, at the same time, we must continue to work with endless energy to eradicate the scourge of infectious diseases throughout the United States and the world.

As unfathomable as it is to the civilized mind, criminal attacks are occurring in the form of bioterrorism. Most certainly, therefore, the government, academic, and scientific communities are duty bound to take every reasonable precaution to minimize any risk of misuse of microorganisms for terrorism. The ASM unequivocally supports the urgent development of responsible safeguards against the dissemination of biological agents for misuse rather than for peaceful scientific purposes.

Even as we strive to prevent bioterrorism, however, we must recognize that legislation and regulation cannot provide absolute assurance that additional acts of bioterrorism will not occur. As important as our duty to attempt to prevent bioterrorism is, it is equally important to pursue aggressive research and public health improvements aimed at developing the most effective possible responses to acts of biological terror.

Those of us in the legislative, regulatory, academic, and scientific communities who must confront the prevention of bioterrorism face a dilemma. Implementation of restrictive controls to impede access to biological agents is inherently difficult and potentially could also deter the critical research and diagnostic activities to combat terrorism. Much of the material and equipment is in widespread use and commercially and internationally available; dangerous pathogens are naturally occurring; and, the research and technology knowledge base relevant to biological weapons is publicly available. This means that policy measures intended to limit access and use of dangerous biological agents may adversely affect legitimate research and clinical diagnostic testing. At the same time, we know that research and public health responses to terrorism are critical components of the public policy response to the threat that exists. All of us, therefore, must strive for the proper balance between safeguards that prevent bioterrorists from gaining access to select agents while not burdening important research or clinical diagnostic testing.

While we must deal with bioterrorism, we cannot lose sight of the fact that infectious diseases daily end the lives of thousands of Americans and tens of thousands around the world. Infectious diseases continue to be the third leading cause of death in the United States. 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. We must remember 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.

Because the prevention and treatment of infectious diseases is critical to our population, we must minimize any adverse impact upon vital clinical and diagnostic research related to infectious diseases. The ASM believes that an essential part of obtaining the proper balance is cooperation and communication between and among government, academia, and scientific communities. The ASM is committed to a frank, open, and ongoing dialogue, and we welcome the opportunity presented by this Subcommittee and other members of Congress to work together to achieve the right balance between research, public health and law enforcement responses to the threat of bioterrorism. The ASM is committed to recommending approaches for additional policies that appropriately balance the crucial war on terrorism with vital research that is needed to counter terrorism and eradicate disease.

RESOURCES AND FUNDING FOR BIOSECURITY

We continue to emphasize, that the Congress and the Administration must recognize that such an expansion of existing regulations requires additional financial and other resources for the CDC. The CDC must be funded properly if it is to carry out its important functions. Further, Congress must fund adequate prevention, control, and countermeasure programs on a national, regional, state, and local basis. We know, Senator Feinstein, that you and members of this Subcommittee and other members of Congress are committed to research and to development of countermeasure programs, and we welcome your understanding that such measures are very, very important.

EXISTING BIOSAFETY LEGISLATION

While we recognize that much remains to be done, particularly in light of the recent shocking bioweapon attack on U.S. citizens, we should not overlook that progress has been made in developing safeguards against bioterrorism without unduly inhibiting research or clinical diagnostic testing. The 1989 Biological Weapons Act authorized the government to obtain a warrant to seize any biological agent, toxin, or delivery system the possession of which, under the circumstances, has no apparent justification for prophylactic, protective, or other peaceful purposes. The ASM worked with Congress to ensure that this legislation did not restrict legitimate research and the Senate report accompanying the bill stated that the bill would not interfere with such activities. The 1989 statute also authorized federal officials to intervene rapidly through an injunction or through a seizure made without a warrant based on probable cause. The right to intervene rapidly when there is probable cause to believe that possession of biological agents or toxins is not justified for peaceful purposes adds to the legal weapons against terrorism while protecting legitimate scientific endeavors.

The Antiterrorism and Effective Death Penalty Act of 1996 broadened penalties for development of biological weapons and illegitimate uses of microorganisms to spread disease. The ASM testified before the 104th Congress regarding the trans-

portation of select agents and supported passage of Section 511(d) of the Act. Like the 1989 Biological Weapons Act, the Antiterrorism Act of 1996 protects dual public interests of safety and free and open scientific research through promulgation of rules implementing a program of registration of facilities engaging in the transfer of select agents.

The 1996 Antiterrorism Act expanded CDC's responsibilities and the regulatory structure for transporting dangerous biological agents. The Act added the responsibility to "prevent access to dangerous biological agents for use in domestic and international terrorism or for any other criminal purpose." It directs the Secretary of HHS to maintain a list of biological agents that have "the potential to pose a severe threat to public health and safety." The Secretary also must establish and enforce procedures for shipping such agents safely to ensure that laboratory facilities can appropriately handle, contain and dispose of them and must provide safeguards against access to them for illegitimate uses. Registration may be denied if there is "evidence that the facility has or intends to use covered agents in a manner harmful to the health of humans." The regulations authorize inspections of facilities, for cause or at random, to ensure compliance. Shipping institutions or individuals that wish to ship a select agent must check that the receiving facility is registered and must file a notification of the shipment with the registering facility.

The recipient must acknowledge receipt of the shipment. Importantly, the Antiterrorism Act of 1996 provides for "appropriate availability of biological agents for research, education and other legitimate uses." The ASM worked with the CDC to develop regulations that balance the needs for legitimate research and diagnostic testing with protection against the inappropriate acquisition of biothreat agents. The ASM also assisted in the development of a list of select agents that focused on the most dangerous with the highest potential for use as a biological weapon.

The final regulation exempts CLIA certified clinical laboratories if the agent is part of diagnostic, reference, verification, or proficiency testing. Isolates of covered agents from clinical specimens are to be disposed of after diagnostic, reference or verification procedures have been completed. This exemption ensures that clinical diagnostic procedures are not impeded and also averts the problem of having the system deal with several hundred thousand clinical laboratories and shipments of routine diagnostic specimens.

Regulations promulgated under the Antiterrorism Act of 1996 require that laboratories shipping and receiving select agents follow the biosafety guidelines in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," Fourth Edition. These regulations effectively codify biosafety guidelines for laboratories receiving select agents. ASM members must abide by these regulations and the ASM provides information on the regulations and the necessity of compliance through its site on the Internet.

EXTENDING CURRENT REGULATIONS TO POSSESSION

Indeed, the ASM favors extending the current CDC regulations to cover possession of select agents that may be used for bioterrorism. In 1999 ASM testified that additional measures should be taken to "prohibit possession of listed biological agents or listed toxins unless they are held for legitimate purposes and maintained under appropriate biosafety conditions." ASM supported "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. The ASM specifically recommended that:

"The CDC's responsibilities should include the duties to: (1) Continue to establish and periodically revise the list of select agents. (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."

The ASM believed then, and continues to believe today, that the law should prohibit institutions and individuals from possessing cultures of select agents unless such institutions or individuals maintain the agents under appropriate biosafety and biosecurity conditions.

We believe H.R. 3162, Section 817, benefited greatly from discussions with the scientific community to avoid unintended consequences. The language originally proposed in early drafts of this provision illustrated the difficulties of criminalizing use

of biological agents and did not take into account the fact that biological agents exist naturally in the environment. The final language in HR 3162, which we support, takes into account this qualification and excludes bona fide research from the reach of the revised Section 175 of Title 18.

The ASM agrees that the possession of biological agents, toxins, and delivery systems should be for prophylactic, protective, bona fide research, or other peaceful purposes. The ASM also completely agrees that some individuals should not have access to select agents. Therefore, we agree with the basic tenet of the provision that prevents restricted persons from knowing possession of a select agent. Candidly, the ASM believes the Act should have permitted the Attorney General, upon recommendation of the Secretary of HHS, to waive the prohibition against possession of select agents by aliens from countries designated as supporting terrorism if, and we emphasize this point, if there was a specific finding that a waiver for the particular individual served our national interest. However, our disagreement with the failure to provide the opportunity for a waiver for specific aliens does not diminish our support for the concept of setting reasonable limits upon persons who may possess select agents.

The ASM further supports the development of standards for possession of select agents to prevent access to such agents for use in terrorism. By placing this requirement within the structure of the Antiterrorism and Effective Death Penalty Act of 1996, Congress recognizes the benefits of using the existing regulatory system. The ASM concurs. The CDC is the only federal agency with the expertise and experience to act quickly and competently in this area. Further, and very importantly, the CDC currently possesses the confidence of the scientific community that it will act responsibly to balance the interests of preventing bioterrorism and advancing research in the area of infectious diseases and clinical diagnostic measures.

In summary, Congress has taken several significant steps in dealing with the threat of bioterrorism. Today, possession or use of a biological agent or toxin as a weapon is a serious criminal offense; knowing possession of a biological agent, toxin, or delivery system, of a type or quantity, not reasonably justified by peaceful purposes is a serious criminal offense; it is a serious criminal offense for persons who have engaged in specific types of misconduct to possess, ship, or receive select agents; a facility must register with the Secretary of HHS before transferring or receiving a select agent. These are significant steps in the right direction, but the ASM agrees that Congress must do more. We submit that, in taking additional action, Congress and federal agencies should continue to consult carefully with the scientific community to achieve the critical balance that is the underlying theme of our testimony.

COMMENTS ON PENDING LEGISLATIVE PROPOSALS

Given that a number of legislative proposals are being considered, it is to that legislation that we now direct our attention. In the remainder of our testimony, we will address legislative proposals for: listing of select agents; registration of facilities possessing select agents; the definition of restricted individuals; imposition of civil penalties; unsafe handling provision; proposals for licensure of equipment; and the need for federal support of aggressive countermeasures programs.

A. LISTING OF SELECT AGENTS POSING A THREAT OF BIOTERRORISM

ASM supports the need for periodic reviews of the list of select agents. These reviews must include consideration of agents that may be used in domestic or international bioterrorism. We believe that the CDC is the proper agency to lead such reviews. Such reviews must, and undoubtedly will, include close coordination and communication with other government agencies. Further, the CDC should view the scientific community as a partner in these endeavors. Only through active consultation with scientists may the CDC and other federal agencies hope to achieve a comprehensive, integrated regulatory system that serves the public interest by preventing terrorism without undue disruption of vital research and clinical diagnostic testing.

B. REGISTRATION OF FACILITIES FOR POSSESSION OF SELECT AGENTS

The ASM supports registration of laboratories that possess select agents and recommends that CDC conduct registration as an extension of the current select agent rule.

1. *The Need for Registration.* The CDC, acting in cooperation with the scientific and biomedical communities, and with public notice and input, should establish rules and provide regulations for governmental monitoring of possession of select

agents posing a risk of bioterrorism. 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. It is the institution that ultimately is responsible for ensuring compliance with its legal and regulatory obligations.

These institutional responsibilities include assuring safety through proper procedures and equipment and through training of personnel. Thus, the institution must bear the final responsibility for training employees regarding the biosafety requirements, including the necessity for following those requirements, including 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 fulfills governmental requirements related to select agents. The institutions also should be required to maintain records of authorized users and to ensure that users are properly trained, as is currently the case for work with radioisotopes. Intentional removal of select agents from a registered facility should subject the individual to criminal sanctions.

However, in light of the expedited deadlines that are likely to be imposed for initial reporting, facilities should be allowed to report select agents found after the initial reporting deadline without incurring severe penalties. If strong sanctions are imposed at an early point, some institutions may be forced to destroy collections if they have not been able to determine whether they are free of select agents by the reporting deadline. Time is of the essence, and compliance with appropriate procedures is important. However, we need not act with such haste in the reporting area that entire collections are lost solely due to the inability to complete an inventory process by an arbitrary deadline.

2. Procedures: Registration, Inspections, and Regulations. CDC has an existing inspection mechanism. Additionally, the existing select agent rule incorporates biosafety and biosecurity procedures from the CDC Biosafety Manual. That manual is an appropriate starting point for standards and procedures in laboratories possessing select agents. The ASM understands that this Subcommittee is considering a "certification" program. We are not certain whether "certification" would mean something more than mandatory registration, safety and security procedures, standards, training, proper laboratory facilities to contain and dispose of select agents, and inspections, all of which the ASM supports.

We believe reasonable allowance should be made for the reporting of select agents later if they are discovered in inventories of archived samples. Otherwise, laboratories may need to destroy potentially valuable research tools. Institutions should report possession when they become aware of an agent they did not know they possessed without penalty.

3. Congress Must Recognize that Pathogens Occur in Nature and Craft Legislation Accordingly. Current legislative proposals appear to deal exclusively with research laboratories and to ignore the clinical side of the microbiological sciences. Consequently, the proposals ignore many of the exclusions that need to be made and which have been recognized in other legislation.

For example, regulations should provide exemptions for laboratories on the same basis as they are granted under the current regulations for shipment and receipt of select agents at 42 CFR §72.6(h). Further, the proposals should exempt state public health and veterinary laboratories as they deal with naturally occurring pathogens without any effort to cultivate, collect, or extract such pathogens in a manner that lends itself to bioterrorism or public health risk.

In this vein, we know that Congress understands that pathogens exist in nature and people develop diseases from some of these pathogens each year. We recognize that the proposed definitions of a biological agent and toxin exclude a biological agent or toxin that is in its naturally-occurring environment, if it has not been cultivated, collected, or otherwise extracted from its natural source. ASM is uncertain that such language will prevent the unwarranted application of penalties to areas of scientific inquiry of naturally occurring phenomena. Legislation should focus on cultures rather than organisms.

4. Laboratory Practices. Registration with the CDC is tantamount to certification under current law. Language in some proposals we have seen raises difficult issues related to laboratory practices and the scope of application of procedures to individuals. Are individual couriers (or their employing enterprises) that transport select agents going to be certified? The scientific community must be able to get samples through the Laboratory Response Network to the public health labs and the CDC. In addition, cultures of some of these agents are transported to reference laboratories for identification. Certainly, proper procedures must be established and fol-

lowed for the shipment of select agents but the CDC will need to consider carefully each of these special circumstances in developing regulations. Congress should not mandate procedures that prevent such consideration and the crafting of regulations that protect the public but permit maximum, appropriate freedom for the scientific research community and as expeditious as possible action by clinical diagnostic laboratories. Again, the ASM believes the CDC's Biosafety Manual, which covers both biosafety and biosecurity, should be the starting point for such regulations.

5. *Disposal of Select Agents.* Although the specific mandate may be left for regulation, ASM suggests that an appropriate authority should require destruction of pathogens within laboratories rather than through disposal as medical waste. Although the ASM does not discount entirely the possibility for exceptions, as a rule, pathogenic organisms should be destroyed (even by clinical laboratories) inside the laboratory. These materials should be autoclaved or killed by other means before disposal as waste in landfills. We recognize that this could require significant costly changes in protection currently employed by some diagnostic laboratories.

6. *Protection of Intellectual Property.* The ASM recognizes that existing legislative proposals contain provisions protecting information on registration statements from disclosure under the Freedom of Information Act. Certainly, such a provision must be included in any legislation. Congress, CDC, and other federal agencies must respect and protect the intellectual property rights of individuals and enterprises. Any authorized disclosure of such information must result in the imposition of a penalty upon the person, including government employees, responsible for a violation. We must be certain that confidential information is secure and protected.

7. *Physical Security of Facilities.* CDC and research laboratories recognized previously that the regulatory regime governing access to, and use of potentially dangerous biological agents, needed to anticipate theft or intentional misuse. Existing biosafety guidelines categorize biological agents into four groups according to the highest level of physical containment that is necessary to protect those who work with these agents or those in the surrounding environment. They specify access controls and physical barriers to agent release. In our new environment, CDC and laboratories will need to review carefully requirements for the physical security of facilities that house select agents. We must prevent unauthorized individuals from obtaining these agents. Government must recognize that increased security and limiting access to select agents will impose costs and other burdens on facilities and researchers who use these agents for legitimate research.

The ASM urges, as with all aspects of eventual regulations, that the government impose security measures that are proportionate to the expected improvement in public safety. ASM will support such rational measures and is confident that the research community will accept costs that are proportionate to their benefits. As institutions develop and institute new standards for physical protection resulting in increased financial and operational implications, government assistance in offsetting costs of such security improvements is appropriate.

At the same time the ASM recognizes and supports the need for heightened awareness of the need for physical security, it recognizes that there are various sources of supply of dangerous agents. There should be no illusion that tightening security and access controls at research institutions in the United States will solve the bioterrorism problem. To the maximum extent possible, the United States should strive to extend reasonable physical security standards to laboratories on an international basis.

C. DEFINITION OF RESTRICTED INDIVIDUALS

Congress must recognize that research regarding the causes and remedies for infectious disease proceeds on a global scale. For example, hundreds of foreign scientists attend scientific conferences, not just to learn but to contribute importantly to the exchange of scientific information. There are many hundreds or thousands of foreign nationals at work in laboratories in the United States where they are contributing to biomedical research.

A broad, mandatory prohibition that could significantly exclude qualified aliens from work in research and diagnostic laboratories is not in the best interest of the United States. The broad exclusion of aliens could have a serious impact on academic medicine. Almost certainly, it would restrict collaborative studies and critical training of individuals who will deal with the many diseases that occur throughout the world requiring advanced diagnostic methods and treatments.

1. *Treatment of Aliens.* Under the USA PATRIOT Act (H.R. 3162), the term "restricted person" includes aliens from countries designated by the U.S. as supporting terrorism. H.R. 3160 goes further and would expand that exclusion to all aliens admitted to the United States under a non-immigrant visa. We recognize that H.R.

3160 permits the Secretary to designate categories of individuals who have expertise valuable to the United States. However, without knowing the intended scope of this provision, we are very concerned that the initial classification of all aliens as restricted persons may adversely affect legitimate and essential biomedical research, including diagnostic laboratories. These laboratories are critical for diagnosing anthrax and diseases that may be caused by other biothreat agents.

ASM favors the narrower restriction on individuals from countries that are designated as supporting terrorism as enacted in the USA PATRIOT Act (H.R. 3162). Even then, as we testified before, we believe that Congress should authorize the Attorney General to grant a waiver for specific foreign nationals from those nations when it is in the interest of our nation.

If Congress finds that it must impose broadened restrictions on alien scientists, the Committee could include a special provision regarding registration by aliens and/or by the facility at which they work. Such a specific statement would alert authorities to the identity and presence of an alien at a facility and permit a greater degree of scrutiny. Finally, if Congress decides to retain a general prohibition, it should modify the current waiver language ("expertise valuable to the United States regarding select agents") to permit the Secretary to include other categories that the Secretary finds to be "in the interest of the United States."

2. *Testing of Drug Abusers.* The definition of "restricted persons" in H.R. 3160 refers to 18 U.S.C. § 922(g) that, in turn, includes any person "who is an unlawful user of or addicted to any controlled substance." The ASM assumes that inclusion of this category of individuals within the meaning of restricted persons will not require mandatory pre-employment or on-going drug testing of employees. If Congress intends to require mandatory drug testing, it should do so explicitly rather than through reference to 18 U.S.C. § 922(g).

D. IMPOSITION OF CIVIL PENALTIES

Current legislative proposals establish very substantial civil penalties for individuals or entities that violate regulations on the shipment, receipt, or possession of select agents. These penalties may reach \$250,000 on individuals and \$500,000 on any other person. The present regulations governing shipment and receipt of select agents provide for a criminal fine or penalty for violations of the regulations. To the best of the ASM's information, no prosecution has occurred under this provision. Of course, there is a substantial difference between a criminal prosecution under a "reasonable doubt" standard of proof and the imposition of a civil penalty.

As we testified earlier, the ASM envisions an integrated, comprehensive set of guidelines for the possession of select agents. The ASM has suggested that the CDC's guidelines in its manual "Biosafety in Microbiological and Biomedical Laboratories" should be the starting point for any regulations.

Imposition of civil penalties on individuals or facilities is an area in which it is especially important to strike the proper balance between deterrence of bioterrorism and protection of the public welfare versus discouragement of scientific research and clinical laboratory diagnostic testing. The ASM understands and supports the need for a substantial inducement for compliance with regulations regarding possession of select agents. At the same time, the Committee should recognize the significance of imposing civil penalties and the impact of potential penalties up to \$250,000 on individual employees. A civil penalty provision must be a thoughtful and well-designed provision.

The provision should take into account and specify: (a) in the first instance the facility, rather than an individual, is liable; (b) standards for determination of the amount of a penalty based upon a host of factors including the size of the facility, the significance of the violation, the degree of culpability, and other factors; (c) mitigating circumstances; (d) the means for adjudicating liability for, and the amount of, the penalty, (e) other factors related to a system for adjudicating civil liability. The Committee should not adopt a measure that simply provides for a penalty without any of the details necessary to assure the fair and appropriate administration of the penalty. To do so would engender unnecessary and unwarranted fears and burdens upon the very persons who are at the forefront of dealing with the threat of bioterrorism as well as the ongoing hardship of infectious diseases.

E. UNSAFE HANDLING PROVISIONS

The ASM supports the principle that scientists must follow safe practices. Perhaps more than anyone else, ASM members recognize that unsafe handling of such agents places workers and the public at severe danger.

Of course, requirements related to handling procedures are largely not relevant to the prevention of bioterrorism. The prospect of a criminal penalty for unsafe han-

dling of select agents will not deter a bioterrorist. Only in the area of assuring the security of select agents are handling procedures related to bioterrorism.

Handling procedures are relevant to the more general issue of protecting the public welfare related to laboratories that possess select agents. However, the specter of severe criminal penalties on the basis of laboratory procedures raises perhaps one of the most difficult areas for balancing between protection of the public and chilling the willingness of laboratories and scientists to engage in important research. Criminal penalties based on imprecise legal standards may unduly impede research. The ASM believes that the urgency with which the Congress is now dealing with the threat of terrorism does not make this a good time to strike the appropriate balance in this area. In this regard, the ASM does support the registration of laboratories and individuals. It further supports a duty to comply with "Biosafety in Microbiological and Biomedical Laboratories," Fourth Edition.

For the present, the ASM believes regulations based on these standards and practices by laboratories in the context of the registration process is the best approach in this area as they provide standards that are clear and coherent, streamlined and integrated, based on real risks, and effectively communicated to research facilities and individual researchers. It allows the scientific community a better understanding of what they are prohibited from doing, rather than attempting to follow an amorphous negligence or recklessness standard that is understood by attorneys but with which most scientists are unfamiliar. The goal of legislation must be sound scientific practices rather than a chilling of scientific inquiry through the threat of criminal penalties under imprecise standards.

F. LICENSURE OF EQUIPMENT

The ASM understands and appreciates the concept that it may be easier to control the possession of pieces of equipment used for manufacture of weapons of bioterrorism than the actions of individuals or the quantities of select agents. The ASM further appreciates that, rather than specifying equipment or controls, the proposed legislative language we have seen would require promulgation of regulations after consideration of a broad range of factors. Indeed, in many respects, it is accurate to say that the weaponization of a biological agent raises engineering issues rather than microbiological issues.

At the same time, to be realistic, we must recognize that efforts to control equipment almost invariably encounter the problems that would limit the effectiveness of such measures. For example, equipment that could produce biological weapons is in wide use and as equipment is regulated, terrorists will turn to other types of equipment.

It is our understanding, for example, that UNSCOM revealed that Iraq was able to produce large quantities of biological weapons without using sophisticated fermentors. As worrisome as it may be, small flasks, canisters, home brewing bottles, and other similarly mundane equipment provide all that is needed to grow the bacteria that cause anthrax, plague, and other select agents. Thus, we must at least question the benefits of establishing any significant regulatory burden on a list of equipment and particularly the types of equipment found in many research and clinical laboratories as well as the biotechnology industry. For example, virtually every industrial biotechnology operation uses controlled fermentors. Every pharmaceutical company uses them and many universities have this equipment as well.

To cover the size relevant for bioterrorism one would have to capture everything of 5 liters and above and that would still not eliminate the possibility of growing the organisms in simpler vessels. Similarly, large temperature controlled centrifuges are present in virtually all microbiology and biochemistry laboratories, often many per lab. Certainly, biosafety hoods are present in most if not all clinical labs as well as many research labs. These hoods prevent environmental exposure to the pathogens being worked on. Freeze drying equipment is very widely distributed in research labs as well as in various industrial settings such as coffee making.

In essence, this is a cost-benefit issue for the Congress. There may be relatively little to gain by imposing an extensive regulatory regimen on widely used legitimate equipment, such as centrifuges, laminar flow hoods and fermentors. Indeed, we again point out that at this point, we do not know if the anthrax used in the bioterrorist attacks was produced overseas or in domestic facilities.

G. FEDERAL SUPPORT OF AGGRESSIVE COUNTERMEASURES PROGRAMS

The ASM endorses significant government funding for development of countermeasures. Although we can never provide absolute protection, we can take aggressive steps to be prepared to control and counteract an attack. We need to be better prepared for a bioterrorist attack by spending the time, effort, and funds necessary

to develop new vaccines and pharmaceuticals. Of course, we hope that we never need to use such new products to deal with a substantial bioterrorist attack. If one occurs, however, we need to have such protection. If we are fortunate and avoid such attacks, then the research inevitably will serve the important purpose of combating infectious diseases and, therefore, will serve the interest of every person on the globe.

CONCLUDING REMARKS

In conclusion, legislative actions to enhance national security by adding protection against the criminal acts of bioterrorism can and must be done in a way that does not have a detrimental impact on the legitimate biomedical research. We need to improve the health of Americans and those beyond our shores. We need to ensure that we will have the vaccines, pharmaceuticals, and diagnostic capabilities to protect the public health of all Americans in the future from both natural infectious diseases and those from criminal bioterrorist attacks.

In doing so we must recognize that biomedical research is a global effort. If we fail to eradicate infectious diseases that occur primarily in other countries we run the risk that those diseases will threaten our country. We must work across international borders to improve public health and to combat the natural occurrences of infectious diseases that threaten global security. We cannot isolate our biomedical research community by excluding those legitimate scientists from other countries who like American scientists are fighting against the dreaded impacts of infectious diseases. The war against infectious diseases and the scientific and university communities around the world must join in the battle against bioterrorism.

We support a strengthened biological weapons convention that would criminalize the misuse of biological agents and the establishment of acceptable normative practices for the shipment, possession and safe use of select agents. We support the ongoing initiative of the Administration to strengthen the Biological and Toxins Weapons Convention and to achieve this aim through mechanisms that would harmonize the legal and regulatory frameworks for the possession, use and exchange of select agents, adopted in the United States with those of other nations. We support the efforts of Congress and the Administration to deter bioterrorism and provide strict criminal penalties for those who carry out egregious acts using biological weapons.

Even as we strive to prevent bioterrorism, we must recognize that no set of regulations can provide absolute protection against bioterrorism. Even as we strive to prevent acts of bioterrorism, 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.

Chairperson FEINSTEIN. Thank you very much and I certainly hope you are correct. Thank you.

Next I would like to introduce Michael V. Drake, M.D., vice president of health affairs for the University of California Office of the President. Dr. Drake was appointed University of California's systemwide vice president for health affairs in March of 2000. He oversees education and research activities at the University of California's 15 health sciences schools. That is medicine, dentistry, nursing, pharmacy, public health, optometry, veterinary medicine, including five academic medical centers—UC-Davis, UC-Irvine, UCLA, UC-San Diego and UC-San Francisco. The university is the largest single producer of trained physicians in the United States.

He is a member of several scientific and scholarly societies and he is also the principal investigator on active grants and contracts, totalling more than \$11 million, and is a practicing ophthalmologist. We are delighted to have you with us, Dr. Drake.

STATEMENT OF MICHAEL V. DRAKE, M.D., VICE PRESIDENT FOR HEALTH AFFAIRS, UNIVERSITY OF CALIFORNIA, AND STEVEN P. SHEARING PROFESSOR, DEPARTMENT OF OPHTHALMOLOGY, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO SCHOOL OF MEDICINE, SAN FRANCISCO, CALIFORNIA

Dr. DRAKE. Thank you very much, Senator Feinstein.

Madam Chair, distinguished members of the Committee, I would like to request that my written testimony be submitted for the record.

Chairperson FEINSTEIN. So ordered.

Dr. DRAKE. I have been asked to speak on our responses to the events of the last several weeks. In response to the unfortunate case of inhalation anthrax in Florida in early October, California Governor Gray Davis contacted the University of California and other institutions with questions regarding our state's ability to respond to such an attack. He followed this contact with an executive order establishing, under the auspices of the State Strategic Committee on Terrorism, a series of Subcommittees, including the Subcommittee on the Protection of the Public Health. I co-chaired this Committee, along with Dr. Diana Bonta, director of the California Department of Health Services. The Committee met on October 19 and submitted its confidential report to the governor on October 25. The Committee includes representatives from the University of California, medical and health care associations, public health organizations and state agencies and departments.

While the specific recommendations to the governor remain confidential due to the sensitive nature of the information, I am pleased to share with you today a general sense to the Committee on several important issues related to bioterrorism.

First and foremost, our Committee found that there is a great need to improve the communication between and training of personnel in the continuum of public health services, from the initial response teams to the treating physicians and nurses. This involves improving information services directed at both public health professionals and the general public, improving coordination among local, state and federal agencies, and doing all of this in ways that will strengthen the public health system, even in the hopeful event that no further terrorist attacks occur.

Several efforts in this regard have been initiated by the CDC and obviously the events of the past several weeks teach us that we should accelerate our efforts to make these programs fully operational and to expand their reach.

In all cases it is crucial to make certain that our crisis management infrastructure and protocols enhance our ability to manage the ubiquitous chronic problems that affect the public's health on a daily basis. There is a common aphorism used on the wards of our teaching hospitals that states, "When you hear hoofbeats it is more likely to be a herd of horses than a stampede of zebras." Stated differently, common diseases occur in uncommon ways more often than uncommon diseases occur.

In preparing for attacks of bioterrorism we are guarding against the uncommon but we must not lose sight of the myriad problems that we were dealing with on September 10. We were very engaged in issues of great importance to the health of the public on a daily

basis and those problems did not disappear on September 11. Our public health system is understaffed and underfunded. Many Americans are vulnerable to disease and injury in ways that we could avoid. We should seek solutions that not only enhance our national security but that also improve the public safety.

In demographically diverse states like California, it is very important to provide public information in a culturally competent manner and in multiple languages.

In addition to the public health response, university faculty are actively pursuing solutions to problems that may affect us in the future. For example, researchers working in the field of biofiltration are investigating ways of removing highly toxic materials from the air, as well as novel detection techniques and methods for degrading toxic pollutants. Researchers in the Environmental Energy Technology Division at the Lawrence Berkeley National Laboratory are developing building management strategies to reduce occupant exposures to an unexpected release of toxic aerosol or gas.

Although much of our country's attention over the past month has been appropriately focussed on bioterrorism, we remain cognizant of the possibilities of other threats, as well. And two of our newly funded state initiatives, the California Institutes for Science and Innovation, are also conducting research in ways to defend critical infrastructures, such as telecommunications, the power grid, air traffic control system and financial markets.

Our research scientists are critical to this endeavor in another way. At a recent meeting hosted by the Association of Academic Medical Centers, Tara O'Toole from the Center for Civilian Bio-defense Studies at Johns Hopkins, observed that biology is on the precipice of losing its innocence in the 21st century the way that physics lost its innocence in the 20th century.

But unlike weapons of mass destruction arising from the realm of physics, biological weapons did not necessarily require a state-supported program. They can be developed by a few individuals with fairly modest resources. We will be increasingly dependent on the scientific community to work with law enforcement and other branches of government to develop effective measures for ensuring the public safety. My colleagues at the University of California, and I am certain I speak for the faculty at other academic institutions, as well, would welcome the opportunity to work with you on developing policies that increase laboratory security without compromising laboratory research.

Our fundamental mission, of course, is education and we have added new courses for our students and our broader constituency to learn more about the potential causes, effects and repercussions of terrorism on our shores. For example, 50 new courses were added at UCLA and at UCSF the noon lecture series open to the public has begun a series featuring discussions of topics ranging from bioterrorism to religious intolerance.

The Association of American Medical Colleges last week announced an initiative to help educate and prepare the nation's physician workforce to respond appropriately to terrorist attacks and one component of this project will focus on integrating bioterrorism education into the medical school curriculum. I note that when I was in medical school in the early 1970s we learned about smallpox

and then that was removed from the curriculum because this was a disease that had been eliminated. This year it was re-added to the curriculum.

Research universities take seriously their public service responsibility to respond to threats to our health and security. This is particularly clear to us at the University of California because of our half century of management of the national labs in Berkeley, Livermore and Los Alamos. The marriage between academic scientific inquiry and national security has been sound and mutually beneficial and we, along with our sister institutions, stand ready to address prevention and response to attacks and natural disasters. We are actively pursuing these issues at the present time and look forward to working with you as we refine and improve our programs that address the reality of terrorism in the future.

Senator on behalf of the University of California, we applaud your leadership on this issue and we look forward to working with you and your colleagues as you continue to work on the many difficult issues facing the nation. Thank you for your time and attention.

[The prepared statement and an attachment of Dr. Drake follow:]

STATEMENT OF MICHAEL V. DRAKE, M.D., VICE PRESIDENT FOR HEALTH AFFAIRS, UNIVERSITY OF CALIFORNIA, OFFICE OF THE PRESIDENT AND STEVEN P. SHEARING PROFESSOR, DEPARTMENT OF OPHTHALMOLOGY, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO SCHOOL OF MEDICINE

Madame Chair, Distinguished Members of the Subcommittee: I am Michael V. Drake, Vice President for Health Affairs at the University of California and a member of the faculty at the University of California, San Francisco School of Medicine.

The University of California's mission includes a strong emphasis on basic research in the public interest. The University manages 10 campuses and three national laboratories, including 15 health sciences schools such as medicine, public health, and veterinary medicine.

Speaking of the national laboratories, UC is proud of the contributions for over 50 years by our faculty and staff to our nation's national security through the Los Alamos, Lawrence Livermore and Lawrence Berkeley national laboratories. Scientists at Lawrence Livermore, for example, have developed an advanced hand held analyzer that can identify pathogens based on DNA. Some cities have already deployed this device. At Los Alamos, researchers have developed technologies that can identify the unique origins of biological organisms based on DNA. This technique can help authorities establish a library of genetic profiles of different strands of organisms, including anthrax.

A COORDINATED, STATEWIDE RESPONSE

In response to the discovery of anthrax in Florida in early October, California Governor Gray Davis contacted the University of California and other institutions around the state to learn more about this biological agent and our state's ability to respond to such an attack. He followed this contact with an Executive Order establishing—under the auspices of the State Strategic Committee on Terrorism—a series of subcommittees, including the Subcommittee on the Protection of the Public Health. Along with Dr. Diana Bonta, Director of the California Department of Health Services, I co-chaired this committee. The committee met on October 19 and submitted its confidential report to the Governor on October 25. Per the executive order, the committee includes “representatives from the University of California, medical and health care associations, public health organizations and state agencies and departments.”

While the findings and recommendations to the Governor remain confidential due to the sensitive nature of the information, I am pleased to share with this committee today a general summary of our findings and recommendations on several important issues related to bioterrorism.

Our subcommittee found that there is an acknowledged need to improve the communication between and training of personnel in the continuum of public health

services, from the initial response teams to the treating physicians and nurses. This involves improving information services directed at both public health professionals and the general public; improving coordination among local, state and federal agencies; and doing all of this in ways that will strengthen the public health system, even in the hopeful event that no further terrorist attacks occur.

As part of the 1999 Bioterrorism Initiative of the Department of Health and Human Services, the Centers for Disease Control and Prevention took the lead in an effort to improve the nation's ability to respond to an attack. A multi-faceted program is currently underway. The Rapid Response and Advanced Technology laboratory and the newly established National Pharmaceutical Stockpile Program are products of this effort. The Health Alert Network, National Electronic Data Surveillance System and the Epidemic Information Exchange will facilitate communication among health professionals, particularly between clinical providers and public health officials and epidemiologists. Obviously the events of the past several weeks teach us that we must accelerate our efforts to make these programs fully operational and expand their reach.

In all cases it is crucial to make certain that our crisis management infrastructure and protocols enhance our ability to manage the ubiquitous chronic problems that affect the public's health on a daily basis. There's a common aphorism used on the wards of our teaching hospitals that states : "When you hear hoof beats it's more likely a herd of horses than a stampede of zebras." Stated differently, common diseases occur in uncommon ways more often than uncommon diseases occur. In preparing for attacks of bio-terrorism we are guarding against the uncommon. But we must not lose sight of the myriad problems we were dealing with on September 10th. We were very engaged, rightfully so, in issues of great importance to the health of the public on a daily basis. Those problems did not disappear on September 11th, although they have been obscured to some degree by the enormity of the events of that day, and the unfortunate biologic events of the past month. Ideal solutions must address both of these concerns. Our public health system is understaffed and under funded; many Americans are vulnerable to disease and injury in ways that we could avoid. We should seek solutions that not only enhance our national security, but that also improve the public safety.

In demographically diverse states like California it is important to provide public information in a culturally competent manner and in multiple languages. Recent health care financing decisions, which have led to the increased marginalization of vulnerable communities, have had the additional effect of compromising the State's ability to deal with serious public health challenges regardless of the origin (i.e. terrorism or a naturally occurring epidemic).

UNIVERSITIES AND ACADEMIC MEDICAL CENTERS

In addition to the public health response, the University of California, like other universities in the state and across the nation, has volunteered assistance and expertise in many ways. While some of the work has taken place in specific response to recent events, much of it highlights or accelerates activities that were already underway. For example, University faculty working in the field of bio-filtration are investigating ways of removing highly toxic materials from the air, as well as novel detection techniques and methods for degrading toxic pollutants. Researchers in the Environmental Energy Technology Division at Lawrence Berkeley National Laboratory are developing building management strategies to reduce occupant exposures to an unexpected release of a toxic aerosol or gas.

Although much of our country's attention and concern over the past month has appropriately focused on bio-terrorism, we remain vigilant to the possibilities of other types of threats as well. Within the field of cybersecurity, researchers are exploring new developments in computer security, encryption, online secrecy and monitoring of Internet communications. The Center for Digital Security at UC Davis, with funding from the United States Air Force, uses physical and mathematical modeling to investigate threats to communications networks that might develop in the next five to ten years and countermeasures that will allow people to defend these networks. Two of our newly funded California Institutes for Science and Innovation are also conducting research into ways to defend critical infrastructures such as the telecommunications system, power grid, air traffic control system and financial markets against physical cyber attacks.

UC also continues to work internally with university officials to assess the levels of campus and laboratory security, both in terms of employee safety, which has properly been the overriding focus of regulations over past years, and in terms of protecting valuable laboratory equipment, and materials. Laboratory safety and laboratory security are related, but not identical. Developing procedures for protecting

the public from exposure risk to hazardous substances is an ongoing enterprise, and applicable campus and government regulations have been re-examined by campus officials. These steps take place on top of already stringent laboratory security response procedures. For instance, in regard to anthrax, which is often collected from the field and freeze-dried for use by diagnosticians, isolates are kept in a separate, locked area in a locked keycard access room. Any sharing of these samples must be cleared first with the CDC.

Our research scientists are critical to this endeavor in another way. At a recent meeting hosted by the Association of Academic Health Centers, Tara O'Toole from the center for Civilian Biodefense Studies at Johns Hopkins observed that biology is on the precipice of losing its innocence in the 21st century, the way that physics lost its innocence in the 20th. Unlike weapons of mass destruction arising from the realm of physics, biological weapons do not necessarily require a state supported program. They can be developed by a few individuals, with fairly modest resources. We will be increasingly dependant on the scientific community to work with law enforcement and other branches of government to develop effective measures for insuring the public safety. It is important that the federal government continue to work with the scientific community on this issue, and that we avoid regulations or policies that curtail the ability of our scientists to advance their craft in beneficial ways. My colleagues at the University of California, and I am certain I speak for faculty at other academic institutions as well, would welcome the opportunity to work with you on developing policies that increase laboratory security without crippling laboratory research.

Another area in which the University's faculty and academic medical centers can have an immediate impact is by providing timely information to our students, residents and other trainees, as well as the practicing community and general public. Academic medical centers—enterprises that include a hospital, medical school, and at least one other health sciences school, such as a school of nursing or pharmacy—serve as a unique locus for education, training and multi-disciplinary research. With their academic and volunteer faculty, they also provide an important link to medical practitioners in the community. Although the vast majority of physicians will not see a case resulting from a chemical or biological attack, our hospitals and community providers will see an influx of frightened patients with flu symptoms this winter. We must arm practitioners with the ability to tell the difference, and to address the mental health issues that arise in a population living in a heightened state of anxiety.

Collectively, the country's academic medical centers are also organizing several new activities that will pool their resources and strengths. The Association of Academic Health Centers is addressing this issue. As part of this effort it held a day long planning meeting here in Washington yesterday in advance of a national meeting devoted to the topic of the appropriate bio-terrorism response for academic medical centers across the country. And joined by some of your esteemed colleagues, the Association of American Medical Colleges last week announced an initiative to help educate and prepare the nation's physician workforce to respond appropriately to terrorist attacks. One component of this project will focus on integrating bio-terrorism education into the medical school curriculum.

Research universities, medical schools, and academic medical centers take seriously their public service responsibility to respond in any appropriate manner to major threats to our health and security. This is particularly clear to us at the University of California because of our successful half-century of management of the national laboratories in Berkeley, Livermore, and Los Alamos. The marriage between academic scientific inquiry and national security has been sound and mutually beneficial. We, along with our sister institutions here and around the world, stand ready to address prevention and respond to terrorist attacks and natural disasters. We are actively pursuing these issues at the present time, and look forward to working with you as we refine and improve programs that address the reality of terrorism in the future.

Senator, on behalf of the University of California, we applaud your leadership in the wake of the recent threats to our homeland security and we look forward to working with you and your colleagues as you continue to work on the many difficult issues facing our nation.

Thank you for your time and attention. I would be pleased to answer any questions you may have.

EXECUTIVE ORDERS

EXECUTIVE DEPARTMENT, STATE OF CALIFORNIA

EXECUTIVE ORDER D-47-01 BY THE GOVERNOR OF THE STATE OF CALIFORNIA

WHEREAS, on September 11, 2001, civilians, buildings and government facilities in the State of New York, Washington, D.C. and the Commonwealth of Pennsylvania were the target of multiple, coordinated terrorists attacks causing tremendous damage, injury and loss of life; and

WHEREAS, on September 14, 2001, the President declared a national emergency as a result of these attacks; and

WHEREAS, on September 24, 2001, the President issued an executive order finding that there is a continuing and immediate threat of further terrorist attacks on the United States constituting an unusual and extraordinary threat to the national security; and

WHEREAS, the federal government has primary responsibility for the security and safety of the nation, state and local officials must assure California's readiness to prevent and respond to terrorists attacks and recommend such additional measures as may be necessary; and

WHEREAS, the California Anti-Terrorism Information Center was established on September 25, 2001 to coordinate the exchange and assessment of information regarding terrorism between state and local law enforcement agencies within California; and

WHEREAS, in 1999, the Governor's Office of Emergency Services joined with federal, state and local agencies to establish an inter-disciplinary committee known as the State Strategic Committee on Terrorism to plan for and develop programs to address terrorist threats;

NOW THEREFORE, I, GRAY DAVIS, Governor of the State of California, by virtue of the power and authority vested in me by the Constitution and statutes of the State of California, including the Emergency Services Act of Government Code section 8550 et. seq., do hereby issue this order to become effective immediately:

IT IS ORDERED that the State Strategic Committee on Terrorism shall:

1. evaluate the potential threat of terrorist attack;
2. review California's current state of readiness to prevent and respond to a potential attack; and
3. establish and prioritize recommendations for prevention and response.

IT IS FURTHER ORDERED that the State Strategic Committee on Terrorism will consider the following areas:

- The public and private infrastructure that support the people and the economy of California;
- The facilities and systems for manufacturing, processing, transporting, disposing of and storing potentially dangerous substances;
- The farms, ranches, feeding, processing, storage, delivery, and other systems that are part of the agricultural industry;
- The railways, bridges, roadways, terminals, ports, and other transportation arteries;
- The hospitals, emergency medical systems, and other health facilities and systems that are critical to our ability to rescue and administer to those who may be affected by terrorist acts;
- The computers, computer networks, and other computing systems that provide essential data processing, systems control, and information channels;
- The procedures of agencies and departments responsible for issuing licenses and/or regulating materials or processes that pose a potential terrorist threat;
- The public employees, facilities, and systems that provide services necessary for the protection of our state.

IT IS FURTHER ORDERED that in developing its recommendations the State Strategic Committee on Terrorism shall consult and coordinate with the Commissioner of the California Highway Patrol, who serves as the Governor's Intelligence Officer and liaison with the California Anti-Terrorism Information Center.

IT IS FURTHER ORDERED that a Subcommittee on the Protection Public Health to the State Strategic Committee on Terrorism be established to develop recommendations on the public health response to biological and chemical threats. The

Subcommittee shall include representatives from the University of California, medical and health care associations, public health organizations, law enforcement, and state agencies and departments.

IT IS FURTHER ORDERED that the State Strategic Committee on Terrorism through the Office of Emergency Services shall include consultation with leaders of private industry who have knowledge and experience in security practices to solicit their expertise and recommendations.

IT IS FURTHER ORDERED that the State Strategic Committee on Terrorism shall facilitate the development and review of educational and public information materials on prevention of and responses to conventional, nuclear, biological, chemical, cyber and agricultural-related terrorist threats.

IT IS FURTHER ORDERED that all State agencies reporting to the Governor shall cooperate with the State Strategic Committee on Terrorism and assist in the implementation of this Executive Order. All other State agencies as well as federal and local agencies, particularly those participating on the Committee, are requested to assist the Committee in carrying out its responsibilities under the Executive order.

IT IS FURTHER ORDERED that Dallas Jones, Director of the Governor's Office Emergency Services and Chair of the State Strategic Committee on Terrorism, shall report by October 30, 2001, the Committee's initial recommendations in each of the above areas.

I FURTHER DIRECT that as soon as hereafter possible, this order be filed in the Office of the Secretary of State and that widespread publicity and notice be given to this order.

IN WITNESS WHEREOF I have hereunto set my hand and caused the Great Seal of the State of California to be affixed this the tenth day of October 2001.

GRAY DAVIS

Governor Of California

Chairperson FEINSTEIN. Thank you very much, Dr. Drake.

I would like to say that the record will remain open till the end of the day to receive statements and I would like to add to that record the statement of the chairman of the Committee, Senator Patrick Leahy.

[The prepared statement of Senator Leahy follows:]

STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

I commend Senator Feinstein for holding this hearing on the threat of bioterrorism. Today's discussion is important for both symbolic and practical reasons.

It is symbolically important because, as everyone here knows, just a few weeks ago, terrorists unleashed anthrax here in the Senate office buildings. Today we are here to discuss how to overcome this threat. But our very presence here is a testament to the resilience of the Senate, and of the American people whom we are privileged to represent. I would like to thank everyone who is here today, and the security and public health personnel who have made it possible for us to be here today, for all your hard work. By making this hearing possible, you have sent a message loud and clear to the terrorists: no menace, however scientifically sophisticated, will silence our democracy.

Today's hearing is practically important because we need to stay one step ahead of the terrorists. The President has called on all Americans to be on the alert. That means anticipating new dangers that we have yet to encounter as well as improving our response to what we have already seen. We here in the Senate can play our part in that effort by doing what we do best: listening to the experts and then crafting the rules that will enable our government to protect our people and their liberties in the most effective way possible. That process should be swift, but it should also be based on a careful analysis of the facts, and on testimony that, insofar as national security allows, is fully available to the American public. Today's hearing is a key part of that process.

Some people, particularly our witnesses today, have been alert in this area for a long time. I want to commend in particular Senator Biden. Well before September 11 and the subsequent outbreak of anthrax-related incidents, Senator Biden had been working to strengthen our Federal laws regarding biological agents and toxins. It was a bill that he introduced in the last Congress—the Dangerous Biological Agent and Toxin Control Act of 2000—that provided the basis for the bioterrorism provisions in the initial draft of the USA Act of 2001. These provisions filled a gap

in the Federal criminal code by creating new criminal offenses relating to select biological agents and toxins, and called for more exacting regulation of these substances by the Federal Government.

Like the USA Act, the Administration's original proposal to Congress included new crimes as well as certain regulatory provisions that would have further strengthened our Nation's ability to protect against bioterrorist attacks. Unfortunately, the Administration chose to withdraw its regulatory proposals—and to oppose the stronger regulatory language that Senator Biden and I had proposed—apparently because of its inability to resolve inter-agency conflicts. Given the grave importance of this issue, I urge the Administration to resolve these disputes and work with the Congress to provide these additional protections.

The other bioterrorism provisions in the Administration's original proposal, with a few modifications that I will describe shortly, passed the Senate on October 11 as part of the USA Act, S.1510. To my surprise, the House dropped these provisions before passing a version of the Senate-passed bill on September 12, but it eventually accepted the Senate's position on the need for such provisions and added them back to the final bill, renamed the USA PATRIOT Act.

As enacted, the USA PATRIOT Act creates two new criminal offenses that address the threat of bioterrorism. The first prohibits certain restricted persons from possessing select biological agents and toxins. The definition of "restricted persons" was taken from the original version of the USA Act, and includes non-resident aliens from countries that support international terrorism. The Senate rejected an early Administration definition of "restricted persons" that would have included any alien admitted to the United States under a non-immigrant visa—an unduly broad definition that was not in the best interest of science and clinical medicine.

The second new offense created by the USA PATRIOT Act, punishable by up to 10 years in prison, prohibits the possession of any biological agent, toxin, or delivery system "of a type or in a quantity that, under the circumstances," is not reasonably justified by a peaceful purpose. As originally proposed by the Administration, this provision specifically stated that knowledge of whether the type or quantity of the agent or toxin was reasonably justified was not an element of the offense. Thus, although the burden of proof in a criminal prosecution is always on the government, every person who possessed a biological agent, toxin, or delivery system was at some level of risk. At my urging, the Administration agreed to drop this portion of the provision.

Nevertheless, I remain troubled by the subjectivity of the substantive standard for violation of this new criminal prohibition, and question whether it provides sufficient notice under the Constitution. As I noted upon passage of the USA PATRIOT Act last month, I also share the concerns of the American Society for Microbiology and the Association of American Universities that this provision will have a chilling effect upon legitimate scientific inquiry that offsets any benefit in protecting against terrorism. While we have tried to prevent against this by creating an explicit exclusion for "bona fide research," this provision may yet prove unworkable, unconstitutional, or both. I urge the Justice Department and the research community to work together on substitute language that would provide prosecutors with a more workable tool.

In addition, I am heartened to see that the Department has been aggressively addressing the serious issue of so-called "hoax" cases. I note that law enforcement authorities have been able to prosecute these cases using existing threat and false statement statutes, and that they have been able to prosecute even "non-credible threats and hoaxes" in this area, as the testimony today will show. I know that we are discussing the need for additional legislation specifically dealing with the area of hoaxes, but we must also be careful that if we act in this area, that we craft any legislation to deal with the specific problem of serious hoaxes that we are attempting to address. Overall, as I said when we passed the USA PATRIOT Act, I believe it does a good, though imperfect, job of strengthening the American people's protection from bioterrorism. But there is more that we can do. I have identified two areas for improvement—the loss of the original bill's regulatory provisions and the subjectivity of one of the Act's new criminal provisions. I hope we will be able to identify some more today. We must always be on the alert for new threats and new and innovative ways of dealing with them; and we must be prepared to fight the next battle against bioterrorism, not just the last.

The threat of bioterrorism in America is no longer theoretical; it is all too real. I thank the witnesses for coming today to share their expertise on this important issue.

Chairperson FEINSTEIN. I would now like to introduce John Parachini. Mr. Parachini is a policy analyst at RAND. Previously

he served as executive director of the Washington office of the Monterey Institute of International Studies and the Center for Nonproliferation Studies. He is editing a volume of case studies analyzing terrorist motivations and behavioral patterns involving the use of radiological, biological and chemical weapons. Prior to assuming duties at the Monterey Institute Mr. Parachini was a senior associate at the Henry L. Stimson Center. He has taught at the University of Southern California and Baruch College of the City University of New York. He has had short assignments—U.S. State Department's Operation Center, Bureau of Political-Military Affairs, Intelligence and Research, and Ocean Sand International Environmental and Scientific Affairs. He holds an MBA from Georgetown, an MA from Johns Hopkins and a BA from Haverford College.

Welcome, Mr. Parachini.

**STATEMENT OF JOHN PARACHINI, POLICY ANALYST, RAND
WASHINGTON OFFICE, WASHINGTON, D.C.**

Mr. PARACHINI. Thank you, Madam Chair, for the privilege and the opportunity to testify on this topic. I, too, would like to request that my written statement be entered into the record.

Chairperson FEINSTEIN. So ordered.

Mr. PARACHINI. I would like to focus on the recent anthrax attacks as a case study of a paradigm shift, that has occurred in the whole field of biological weapons terrorism. The sophisticated quality of the material sent to Senator Daschle here at the Senate really has called into question assumptions about three possible perpetrators. Heretofore we have not thought that states would attack us in peacetime and indeed the quality of the material that arrived here was of that level—state-level quality.

Heretofore we have not thought that a state would give this type of material to a terrorist group or to an individual and yet that is a possible perpetrator here.

Heretofore we have really not thought that a terrorist group or an individual could by themselves culture and develop material of the sophisticated quality that we saw here in the Senate. So something is happening that is fundamentally different than it was before these incidents occurred.

They are serious but we should maintain some perspective on the nature of the threat. They are serious and there has been some traffic loss of life and indeed some exposures but it does not compare in any way to what happened on September 11 in which approximately 5,000 people died in short order. So while we are troubled by these anthrax attacks, we need to keep in perspective what did occur on September 11 and how in a very short period of time terrorists turned an ordinary means of modern transportation into a fuel-laden cruise missile that destroyed major buildings, both in New York and over at the Pentagon.

We have not been able to identify any link between what happened on September 11 and the anthrax attacks or between the September 11 terrorists and the Iraqi government but there are suspicious moments of connection between all three, but I think at this time with this fundamental shift we ought to keep our mind open to what the possibilities might be.

The historical record on the use of weapons of mass destruction for terrorism is remarkably small, given how vulnerable we are as an open society. So we have to ask ourselves fortunately, why is that record so small? It is both small in terms of terrorist use but also in terms of nation state use. Nation states certainly have the ability to assemble the people and the industrial capabilities to make these types of weapons and yet on the battlefield fortunately they are comparatively small dataset when they have actually been used.

But in the last 15 years there have been some disquieting developments. There has been a change in how terrorists have operated. In contrast to the terrorists who used to strike at symbolic targets and then issue long turgid manifestos articulating their point of view, we now are in a period in which terrorists strike indiscriminately and kill lots of people and never claim credit, or at least never claim credit until they've been captured, tried and imprisoned.

So are we at a fundamental historical dysjuncture? I think that is a question we need to ask ourselves. The historical data suggest that this is comparatively rare that this happens but indeed there are some disquieting new trends.

I think we want to also bear in mind that while we are unusually vulnerable and there are capabilities out there and I thought the questioning with some of the government witnesses was very revealing about some of the possibilities that are out there that we should be concerned about, that we need to balance those concerns about possibilities with what are some of the obstacles and indeed disincentives for terrorists and individuals to use these types of weapons. Otherwise it would be occurring much more often than it is. And perhaps if we examine in some detail some of the obstacles and disincentives we can, in a broad effort, try to augment those disincentives and those obstacles the make it less likely.

We are never going to eliminate the problem of terrorism, we may never eliminate the problem of proliferation, but we can certainly narrow the possibilities.

Technical and operational barriers are important and they have heretofore made a significant difference in the nature of this threat that we face. We should examine those technical and operational difficulties in greater detail and try to augment them.

There also are readily available alternatives, unfortunately. That is, more terrorists have used explosives, high explosives, and killed more people than have died in all of the terrorist attacks using unconventional weapons.

So there are these alternatives that a determined terrorist will turn to, as opposed to sort of going through the elaborate process of trying to develop very sophisticated heretofore thought to be just military-grade weapons.

With biological agents there is not the psychic gratification of immediate response that the bomber gets. Biological agents require delayed gratification and there is not the immediate response; they occur over there. So there may be a psychic difference here that we ought to understand, as well.

Finally, the fear or retaliation is something that gives people pause, even determined killers.

Let me conclude by pointing out that in this new phase there are some contradictory indications. One is we have seen a paradigm shift but I think the response of the Congress, the executive branch, local responders is helpful in showing that we can manage a limited biological weapons attack. This may prove in the end that these are not as effective weapons, if indeed your design is really to kill lots of people. But the enormous attention on these attacks is likely to stimulate interest in others so we should proceed with great caution and great concern.

I think we should reenergize our efforts to find preventive tools to add to our tool kit to stop the proliferation of these materials to individuals and subnational groups and indeed states way out in front, long before they ever come to our shores.

Finally, it is hard to maintain perspective on relative dangers in the moment of a crisis but I think that is the challenge of leadership and that is what we need to do. And on September 11 lots of people died and the task that we have now is to address what is a serious biological attack but on a different scale and magnitude.

Let me conclude there and thank you once again, Madam Chair, for the opportunity to testify and I look forward to your questions and the questions of the other senators.

[The prepared statement of Mr. Parachini follows:]

STATEMENT OF JOHN PARACHINI, POLICY ANALYST, RAND CORPORATION,
WASHINGTON, D.C.

Thank you, Madam Chair, for the privilege and opportunity to testify before the Subcommittee on Technology, Terrorism and Government Information. Information about the quality of the anthrax used in the letter sent to Senator Daschle indicates a potentially significant paradigm shift in the scope and magnitude of the bioterrorism threat. My remarks will focus on the potential perpetrator of the recent anthrax attacks. Examining who is behind these attacks provides a current case study to review the threat of bioterrorism. In my opinion, bioterrorism includes any organization, even a state, or individual who seeks to terrorize, incapacitate or kill with disease and biological material. In conclusion, I will review some preventive measures that aim to diminish the proliferation of biological agents to states and terrorists.

The sophisticated quality of the Anthrax used in the letter sent to Senator Daschle suggests that the bioterrorism threat has reached a new level previously viewed by many analysts, myself included, as possible, but unlikely. At the moment, this new level of threat is manageable, but we must take into account the profound implications of this shift if we are to devise effective preventive and protective policies.

There are at least three possible explanations for the origins of the sophisticated Anthrax contained in the letter sent to Senator Daschle; all of them have heretofore been considered possible, but unlikely. First, these attacks could be the clandestine act of a state either rolling towards wider conflict or secretly inflicting harm because it believes it can do so without detection and attribution. Second, a state could have engaged a terrorist group to conduct the attack or provided the material to a subnational entity for its own purposes. Third, a terrorist group or individual could have produced this sophisticated quality of anthrax itself or received assistance from scientists willing to sell their expertise. All of these three explanations represent a break with the historical precedents.

The historical data set of biological weapons use by states or terrorists, covertly or overtly, is very limited.¹ Given our potential vulnerabilities, it is a small wonder that states and terrorists have not used disease more often. Understanding why the use of biological weapons has been so infrequent may constructively focus our exam-

¹For an insightful discussion of the history of weapons of mass destruction and their use by states and terrorists see, David Rapoport, "Terrorism and Weapons of the Apocalypse," *National Security Studies Quarterly*, Vol. V, No. 3, (Summer).

ination of the current anthrax attacks on measures to reduce the possibility of other attacks in the future.

STATE PERPETRATED BIOTERRORISM

When it comes to the feasibility of using biological weapons, states are most likely to have the resources, technical capabilities, and organizational capacity to assemble the people, know-how, material, and equipment to produce such weapons and to be able to clandestinely deliver them to valued targets. Mustering the resources and capabilities to inflict a devastating blow with biological agents has proven to be a formidable task even for states.

The quality of the anthrax sent to the U.S. Senate reportedly has characteristics generally associated with state biological weapons programs. Clandestine use of a biological agent by a state against the United States has traditionally been viewed as highly unlikely. Fear of devastating retaliation is generally believed to deter states from conducting such attacks. Retaliation would potentially be devastating because some uses of some biological agents can serve as strategic weapons. For example, wide dispersal of anthrax that could be aerosolized or strategic distribution of an infectious agent such as smallpox or plague could produce significant casualties and greatly disrupt life in America. Conventional wisdom is that states might use a biological weapon like anthrax as a weapon, but only as a last resort.

The United States and the former Soviet Union dedicated considerable national defense resources to their biological weapons programs, and both countries encountered significant difficulties along the way. Iraq also dedicated considerable resources to its biological weapons program; although Iraq's effort was more successful than most experts imagined possible, it still encountered a number of significant challenges. A state's ability to command resources and organize them for certain priority scientific and industrial objectives presents the potential for the greatest threat of bioterrorism. Given advances in biological sciences and the plethora of information made public about biological weapons in the last five years, other countries may have learned how to produce Anthrax with sophisticated properties.

However, there are three circumstances when a state might clandestinely wage biological terrorism. First, a state struggling for its existence might be willing to use biological weapons clandestinely as a means to forestall or to prevent imminent defeat. There is no historical example of a state responding with a biological weapon in a moment of desperate struggle for its existence, but it is conceivable.

While the Taliban government of Afghanistan might be an example of a government in danger of being eliminated, the anthrax attacks started before the United States commenced military operations. Even the logic that a desperate government such as the Taliban or Iraq's Saddam Hussein might lash out against the United States as a desperate move seems improbable. The best the clandestine state attacker could hope for would be to inflict a large number of casualties and to avoid discovery. A successful state biological weapons strike, clandestinely delivered against the United States, might cause many casualties, but it would not lead to the end of the American form of government or ensure the conquest of American territory. Short of a barrage attack of ballistic missiles, the U.S.'s ability to reconstitute itself remains robust. Even a significant clandestine biological strike on a major city would not topple the system of government in the United States. Thus, the inherent limits of hiding a significant attack constrain the realm of the possible.

Second, if a state felt it could attack with biological weapons and be undetected, it might do so. In the twentieth century, there are only two significant examples of states using biological agents clandestinely except during times of war. For example, in the First World War, Germany sought to disrupt allied logistical capabilities by infecting horses with glanders.² The other case involves Japanese use of biological agents during its occupation of China. Only during wartime have states conducted indiscriminate attacks with biological weapons. In the few instances, the attacked state did not have the ability to respond with devastating force. Given the long and powerful reach of modern states, it is hard to imagine a state risking the political and military consequences of discovery.

A third situation when a state might engage in biological terrorism would be if it attacked its own citizens. In the 1980s, both the Bulgarian and the South African governments used biological materials to kill domestic political opponents. South Africa had a significant clandestine chemical and biological program that supported

²Mark Wheelis, "Biological sabotage in World War I." in *Biological and Toxin Weapons: Research, Development and Use from the Middle Ages to 1945*, Edited by Erhard Geissler and John Ellis van Courtland Moon, SIPRI Chemical & Biological Warfare Studies NO. 18, (Oxford, UK: Oxford University Press), pp. 35-61.

a major effort against regime opponents. Little is known about the Bulgarian program, but government operatives are believed to have assassinated a Bulgarian dissident in London with the toxin ricin, which they received from the Soviet KGB. Both of these cases entailed discriminate uses of biological weapons. Aside from state assassinations of regime opponents, states have been extremely reluctant to use biological weapons.

If the current anthrax attacks are the work of a state, this suggests that states might use biological weapons for non-strategic purposes. That is, the current anthrax attacks could be the work of a state that wished to inflict revenge on the United States. The state would not seek to conquer the territory of the United States or end the American system of government. The Iraqi government is one that comes readily to mind as a state that might have this motive. The United States defeated Iraq in military battle and killed many of its military personnel and civilians. But this is a theoretical explanation. Yet, at the moment, there is no evidence positively linking Iraq to the spate of attacks.

Other than the quality of the anthrax sent to the U.S. Senate and inferences one might draw about grievances other states hold against the United States, there is no evidence at the moment that a state is the perpetrator. It is imaginable that we are at the start of a war and another state is clandestinely attacking with anthrax as a diversion. Similarly, it is imaginable that the state perpetrating these attacks is willing to take great risks. And finally, it is imaginable, that a state is attacking the United States with anthrax as a trial to see how we respond. All of these scenarios are possible, but there is no evidence supporting them at the moment. Until additional evidence becomes available, state conduct of these attacks is highly unlikely.

While states can amass the resources and capabilities to wage biological terrorism, considerable disincentives keep them from doing so. A state that undertakes a clandestine attack using biological weapons risks the prospect of the attack being traced back to them. The response to an attack with biological weapons could be devastating, which gives states reason for caution.

STATE ASSISTANCE TO SUB-NATIONAL ENTITY

An alternative possibility is that a state has provided this sophisticated anthrax to a terrorist group. The terrorist group is either serving as a surrogate for a state or a state is transferring biological weapons to a terrorist group for its own purposes. Both possibilities have heretofore been viewed as unlikely.

There are no widely agreed upon historical examples in the open source literature of states providing sub-national groups with biological weapons for overt or covert use. Money, arms, logistical support, training, and even training on how to operate in a chemically contaminated environment are all forms of assistance states have provided to terrorists. But historically they have not crossed the threshold and provided biological weapons materials to insurgency groups or terrorist organizations. State sponsors have a great incentive to control the activities of the groups they support, because they fear that retaliation may be directed against them if they are connected to a group that used biological weapons. Even if states sought to perpetrate biological attacks for their own purposes, they would probably not trust such an operation to groups or individuals that they do not completely control.

Some argue that Saddam Hussein's Iraq is the type of state that might cross this threshold.³ In the case of Iraq, the leadership would probably make the decision to undertake such a risky operation. In most countries in an adversary relationship with the U.S. what is more likely than a conscious decision by a country's command authority is that an unauthorized faction within a state might take it upon itself to use a sub-national group to do its dirty work. The alleged involvement of the Iranian government security services in the attack on American military personnel in Khobar Towers seems to be an example of this type of involvement. Thus, while the probability of states using sub-national groups or individuals to perpetrate a biological warfare attack on its behalf seems low, it is not zero.

Meetings between some of the September 11th terrorists and Iraqi intelligence operatives raise the questions whether Iraq or a faction within the Iraqi intelligence service is involved. Thus far, there is no publicly available evidence linking Iraq to

³Laurie Myroie, *Study of Revenge: Saddam Hussein's Unfinished War against America*, (Washington, DC: The AEI Press), 2000. See also Laurie Myroie, "The Iraqi Connection", *The Wall Street Journal*, September 13, 2001, p. A20. For an alternative view of Iraqi involvement in the 1993 bombing see John Parachini, "The World Trade Center Bombers (1993)," in Jonathan B. Tucker, ed., *Terror: Assessing Terrorist Use of Chemical and Biological Weapons*, (Cambridge, Massachusetts: MIT Press, 2000).

the September 11th terrorists or linking the September 11th terrorists to the anthrax attacks. However, the contact between the Iraqis and the terrorists is suspicious. Ongoing U.S. enforcement of no-fly zone in northern and southern Iraq may cause Saddam Hussein to view his state in perpetual war with America. Given the dictatorial fashion in which Hussein rules the country, it is hard to imagine a rogue element within the Iraqi government acting without his knowledge and approval. Furthermore, the enforcement of the no-fly zones does not present an imminent challenge to the survival of the Iraqi regime. Thus, until new evidence becomes available, the contacts and the timing of the anthrax attacks remain suspicious, but provide no smoking gun.

SUB-NATIONAL ENTITY PERPETRATES BIOTERRORISM

Sub-national groups or individuals can develop or acquire their own biological weapons capabilities for clandestine use, but it is not easy. Terrorist groups and individuals historically have not employed biological weapons because of a combination of formidable barriers to acquisition and use and comparatively readily available alternatives and disincentives. Procurement of materials and recruitment of people with skills and know-how are formidable barriers. Even if some of the materials and production equipment are procurable for legitimate scientific or industrial purposes, handling virulent biological materials and fashioning them into weapons capable of producing mass casualties is beyond the reach of most sub-national groups or individuals.

In the last twenty years, there are only two significant cases of sub-national groups using or attempting to use biological weapons and a few cases where groups or individuals made efforts to acquire biological materials. In 1984, the Rajneeshees, a religious cult group located in Oregon, sought to win a local election by running its own candidates and intentionally poisoning local townspeople who they expected would vote against them.⁴ Using their medical clinics, cult members ordered a variety of bacterial cultures from the American Type Culture Collection located in Maryland. They contaminated ten salad bars with a strain of salmonella, sickening at least 751 people. They used commercially available biological agents to incapacitate people clandestinely, because it was important for them to avoid attracting attention. The intentional character of the outbreak was not recognized for over a year, when members of the cult revealed details about the attacks to authorities in exchange for lighter sentences stemming from other charges.

The other case occurred more than ten years later, when another religious cult, a Japanese group called the Aum Shinrikyo, sought to develop and deliver biological agents against a number of targets. The Aum's unsuccessful attempts at biological terrorism came to light after it released liquid sarin on the Tokyo subway.

The cult's leader Shoko Asahara wrote songs about sarin. In addition to this pernicious obsession, Aum leaders had delusions of grandeur that far exceeded reality. They imagined a world they sought to create that was not constrained by the world in which they lived. To bring this imaginary world into being, they sought weapons they believed might trigger an apocalypse from which they would emerge as a dominant power. Aum leaders may have deluded themselves into thinking that their organization was a government and military-in-waiting, and hence, seeking to acquire weapons it believed states possessed seemed legitimate. Instead of seeking lower-grade pathogens, Aum sought pathogens that are generally associated with military biological weapons programs. Aum exhibited this unique combination of obsession, delusions of grandeur, and belief in an apocalypse they could launch that would enable them to reign like leaders of a state.

In the years since the attack, fears that the Aum attempt to acquire and use biological weapons heralded a new age in such terrorism have been a constant refrain. Yet so much about the Aum is so unique that it is hard to imagine it ever being repeated. Japanese law enforcement authorities tend to make arrests only when they have an ironclad case against the perpetrator of a crime. There were several incidents prior to the March 1995 sarin attack on the Tokyo subway that in retrospect should have raised suspicion. Additionally, Japanese legal provisions protecting religious organizations from intense government scrutiny inhibited authorities from intervening until long after the group committed a number of heinous acts. The Aum leadership presents another anomaly. Shoko Asahara, Aum's leader, was a controlling leader with an obsession with poisons. He wrote songs in praise of

⁴W. Seth Carus, "The ajneeshees (1984)," pp. 115–137, in Jonathan B. Tucker, ed., *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons*, (Cambridge, Massachusetts: MIT Press, 2000). See also, Judith Miller, Stephen Engelberg, William Broad, *Germs: Biological Weapons and America's Secret War*, (New York, NY: Simon & Shuster), pp. 15–33.

sarin. He also greatly admired another mass poisoner, Adolph Hitler. The leadership mindset of Aum explains a great deal about the group's use of unconventional weapons. They were fascinated by the means to catalyzing an apocalypse more than they were fascinated by killing large numbers of people. In contrast, Timothy McVeigh, Ramzi Yousef, and Mohammed Atta were determined to kill large numbers of people and the means to do so was merely instrumental.

Two aspects of the Aum biological weapons experience deserve special note when considering the threat of biological terrorism. Aum's global effort to procure biological materials for its nefarious purposes deserves much greater examination. While there is no open source information indicating that the Aum obtained any radiological, biological, or chemical materials in Russia, it certainly tried. That the group tried and succeeded in getting meetings with Russian scientists, some of whom had weapons expertise, is troubling.

Aum members also traveled to Zaire believing they could obtain samples of the Ebola virus. There is no evidence to indicate that they were successful in their venture. What may have inspired their trip was a newspaper account of a Japanese tourist who developed a hemorrhagic fever after returning from a game safari in Africa. In fact, during period when Aum members traveled to Zaire there were no reported outbreaks of Ebola. Aum was trying to obtain biological material from infected people or corpses for weapons purposes. This highlights a very different source of material than the weapons laboratories of the former Soviet Union. It is probably easier to monitor scientific institutes that were once or are currently affiliated with weapons programs than it is to monitor the sites of deadly disease outbreaks that occur around the globe. Some thought and attention needs to be given to how natural disease outbreaks might be exploited for pernicious purposes.

BIOTERRORISM IN CONTEXT

While recent reports do suggest that we need to adjust our perspective of the bioterrorism threat, we should not lose sight of the scope and magnitude of the tragic events on September 11th and a number of other mass casualty terrorist attacks in the 1990s that involved conventional explosives, not nuclear, biological or chemical weapons. Amidst the evolving bioterrorism threat it is difficult to keep perspective on the relative dangers different terrorist attacks pose. Critical to our thwarting the designs of the perpetrator of the anthrax attacks and succeeding in the campaign of civilized society against barbarism is putting dangers into perspective and calibrating our actions accordingly.

In these uncertain times, it is important to maintain some perspective of the relative dangers. Despite the recent anthrax attacks, the history of biological warfare, terrorism, and crime is still much less deadly than that of the history with conventional explosives. While history is not a perfect guide to the future, it does provide a context for our thinking.

Since the future is impossible to see clearly, we must anticipate a number of possible scenarios. We need to take account of history and hedge against imponderables of the future. Although the prospects of a major biological terrorist attack are remote, small-scale biological attacks are much more likely. In this light, the challenge before the government is how to put relative dangers in proper perspective and yet still hedge against future eventualities that are unlikely, but possible.

WHY HAS BW USE BEEN SO INFREQUENT?

The use of disease and biological material as a weapon is not a new method of warfare. What is surprising is how infrequently it has been used. Biological agents may appeal to the new terrorist groups because they affect people indiscriminately and unnoticed, thereby sowing panic. A pattern is emerging that terrorists who perpetrate mass and indiscriminate attacks do not claim responsibility.⁵ In contrast to the turgid manifestos issued by terrorists in the 1960s, 1970s and 1980s, recent mass casualty terrorists have not claimed responsibility until they were imprisoned. Biological agents enable terrorists to preserve their anonymity because of their delayed impact and can be confused with natural disease outbreaks. Instead of the immediate gratification of seeing an explosion or the glory of claiming credit for disrupting society, the biological weapons terrorist may derive satisfaction from seeing society's panicked response to their actions. If this is the case, this is a new motive for the mass casualty terrorist.

⁵ Bruce Hoffman "Why Terrorists Don't Claim Credit," *Terrorism and Political Violence*, Vol. 9, 1 (Spring 1997), pp. 1-6.

There are a number of countervailing disincentives for states and terrorists to use biological weapons, which help explain why their use is so infrequent. The technical and operational challenges biological weapons pose are considerable. Acquiring the material, skills of production, knowledge of weaponization, and successfully delivering the weapon, to the target is difficult. In cases where the populations of the terrorist supporters and adversaries are mixed, biological weapons risk inadvertently hitting the same people for whom terrorists claim to fight. Terrorists may also hesitate in using biological weapons specifically because breaking the taboo on their use may evoke considerable retaliation. The use of disease as a weapon is widely recognized in most cultures as a means of killing that is beyond the bounds of a civilized society.

From a psychological perspective, terrorists may be drawn to explosives as arsonists are drawn to fire. The immediate gratification of explosives and the thrill of the blast may meet a psychological need of terrorists that the delayed effects of biological weapons do not. Causing slow death of others may not offer the same psychic thrill achieved by killing with firearms or explosives.

Perhaps the greatest alternative to using biological weapons is that terrorists can inflict (and have inflicted) many more fatalities and casualties with conventional explosives than with unconventional weapons. Biological weapons present technical and operational challenges that determined killers may not have the patience to overcome or they may simply concentrate their efforts on more readily available alternatives.

Putting aside the spectacular quality of the Aum subway attack with liquid sarin, far fewer people died or were injured than in similarly spectacular attacks with explosives. In comparison to the bombings of the Murrah federal building in Oklahoma City, the Khobar Towers military barracks in Saudi Arabia, and the U.S. embassies in Kenya and Tanzania, fewer people died as a result of the sarin release. In comparison with the recent attacks on the World Trade Center and the Pentagon, the Tokyo subway incident, though clearly tragic, was simply an event of much smaller scale.

But even if the possibility of a catastrophic biological weapons attack is remote, government has a responsibility to do all that it can to prevent, protect against, and respond to events that seem unlikely. The challenge is to determine how much to prepare for a low-probability, albeit potentially catastrophic attack, while at the same time, guarding against not focusing enough on more probable events with significant, but not necessarily catastrophic, consequences.

NONPROLIFERATION MEASURES TO ADDRESS BIOLOGICAL TERRORISM

The recent anthrax attacks highlight a number of improvements the United States needs to undertake in order to better protect its citizenry against bioterrorism. The positive side of these frightening attacks is that they are forcing an upgrade of our capabilities to handle bioterrorism. I will focus most of my remarks on some long-term preventive tools. In the fight against bioterrorism, a full set of tools will be needed because there are no silver bullet solutions to the threat. The tools I discuss below complement others in the fields of intelligence, law enforcement, counterproliferation, medical diagnostics and forensics, and disease surveillance, to name just a few.

Preventive nonproliferation measures can form the basis for a frontline of defense against attacks with biological weapons. After attack response is important because it can help limit the loss of life, destruction of property and political implications of an attack. However, after attack measures are not a substitute for preventive and preemptive measures. Completely eliminating the possibility of an attack with unconventional weapons is probably not possible, but reducing the opportunity for states and sub-national groups to acquire unconventional weapons is possible.

The United States rejected the text resulting from several years of negotiations toward a draft protocol to the Biological Weapons Convention (BWC) as unsatisfactory for the task: preventing the proliferation of biological weapons.⁶ The challenge for the Bush administration is to reinforce the normative prohibition against biological inscribed in the BWC and at the same time propose measures that genuinely strike at the long-term problem of biological weapons proliferation to states and sub-national entities.

States trying to strengthen the BWC will meet this month, and the Bush administration will need to describe measures that the international community should consider to counter the biological weapons proliferation problem. Given the events in

⁶ Statement by Ambassador Donald Mahley to the Ad Hoc Group of Biological Weapons Convention State Parties, July 25, 2001.

the United States, the timing of a constructive international discussion could not be better.

There are three tools the international community should consider that address the problem of biological weapons that could form the basis for a new international approach to biological weapons proliferation. One portion of the rejected draft protocol that warrants consideration outside the context of the negotiations is the guidance on investigations of unusual outbreaks of disease.⁷ Early detection of unusual outbreaks of disease, rapid communication of a diagnosis, communication of the diagnosis to public health authorities and delivery of appropriate antibiotics, can save many lives and turn a potentially large outbreak into a manageable incident.⁸

These investigations do not necessarily require a new international agency like a Biological Weapons Convention Organization (BWCO). The Conventional Forces in Europe (CFE) treaty provides one example of how a grouping of states could investigate agreed upon problems such as suspicious outbreaks. The findings of experts from regional groupings of states could be reported to the UN Security Council, the World Health Organization, an existing multilateral security organization in the region of the outbreak, and the individual states in the region of the outbreak.

Another option is described in a UN General Assembly mandate providing the UN Secretary General with powers to investigate alleged use of chemical and biological weapons. This provision permits the UN Secretary General to dispatch a group of qualified experts to conduct an investigation and report back to the General Secretariat or the UN Security Council. This model was outlined in the UN General Assembly under its resolution 42/37C in November 1988.⁹ In October 1989 a group of experts provided a report on how investigations of alleged use might be conducted. Even if these investigations do not discover clandestine weapons programs, they will make a contribution to international public health. Enhanced monitoring of global disease outbreaks provides both a public health benefit and a security benefit. Thus, for every dollar or yen invested, there is a clear public health benefit and a potential security benefit.

A new global effort must be made to stop the proliferation of dangerous pathogens to irresponsible states, organization and individuals. There are almost 100 culture collections in the United States and more than 450 collections around the world. The U.S. improved its system in 1995 after an individual with ties to anti-government groups fraudulently sought disease cultures from a culture collection, but it still may require further improvements.¹⁰ A national baseline of where dangerous pathogens are currently located needs to be established. Additionally, a national registry should be established that lists all the scientists who are working with such pathogens. It is frightening to note what little regulation other countries have governing the transfer, storage, and use of dangerous pathogens.

The international community must strive to strike a balance between pathogen commerce for legitimate commercial and scientific purposes and preventing the transfer of deadly materials to people who will use them as weapons. The combination of national export controls and the Australia Group coordination is simply not sufficient for regulating commerce in pathogen samples. Many countries with culture collection do not participate in the Australia Group. Similarly, national laws governing exports of biological materials vary tremendous from country to country, and not all of them meet model international standards. New standards that are more universal in character and more appropriate to the commodity in question are needed.

Finally, the current international legal regime system is inadequate for the current crisis in part because it focuses on the activities of states and not sub-national groups. While the Chemical Weapons Convention (CWC) does require each state party to pass and to implement national legislation penalizing individuals and companies that violate the provision that apply to the state, many countries remain in technical violation of this requirement. Less than half of the CWC state parties have drafted implementing legislation, which is a troubling example of technical non-com-

⁷Michael Moodie, "The BWC Protocol: A Critique," *CBACI Special Report 1*, June 2001, pp. 28-29.

⁸Jonathan B. Tucker, Testimony before the Subcommittee on Labor, Health and Human Services, Education, and Relation Agencies of the U.S. Senate Committee on Appropriations, Improving Infections Disease Surveillance to Combat Bioterrorism and Natural Emerging Infections, October 3, 2001, (<http://www.cns.miss.edu/research/cbw/testtuck.htm>) (Viewed on October 9, 2001).

⁹Draft Report of the World Health Organization on Chemical and Biological Weapons.

¹⁰Jessica Eve Stern, "Larry Wayne Harris," in Jonathan B. Tucker (ed.), *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons*, (Cambridge, Massachusetts: MIT Press, 2000)

pliance.¹¹ Additionally, among the countries that have enacted legislation, the issue of penal legislation has been inadequately addressed. The international community must urge CWC state parties to pass the required domestic legislation. This is one of those small, but important aspects of treaty implementation that the international community has not adequately addressed in an era when there is more attention paid to negotiations.

The Harvard Sussex Program on CBW Armament and Arms Limitation has proposed an international accord criminalizing possession, transfer and use of chemical and biological weapons by individuals. In essence, this draft convention provides the international legal framework to prosecute anyone, from the terrorist to the head of state, who uses chemical or biological weapons. The initiative seeks to fill a gap in existing international legal framework.

As the international community considers this valuable stopgap measure it also needs to consider how to ensure effective implementation. National governments need to provide adequate financial and law enforcement resources to make this convention meaningful. More treaties need to be complemented by the law enforcement capabilities sufficient to apprehend chemical and biological weapons terrorists and the political will to prosecute them to the fullest extent. Far too often the international community and national government bless unfunded mandates and expect results.

CONCLUSION

The recent anthrax attacks represent a fundamental shift in the nature of the biological terrorism threat. Fortunately, the scope and magnitude of this shift is far less devastating than the events of September 11th. As we face this new phase of biological weapons terrorism, it is important to maintain perspective even though the ability of the perpetrator of the anthrax attacks to terrorize the country is distressing. Fortunately, there have been comparatively few casualties. These attacks should serve to spur government action on a number of fronts to strengthen our national ability to prevent the proliferation of biological weapons, deny and dissuade states and sub-national groups from using them, and develop rapid means to detect an attack and track down the perpetrator should preemptive and preventive measures fail.

Chairperson FEINSTEIN. Thank you very much. I appreciate this. Thank you.

I have in front of me a current CDC list of biological pathogens, viruses, bacteria, fungi and toxins and there are about 40 of them and I am just reading what they do and they are absolutely devastating.

Mr. Atlas, let me begin with you. In your estimation how many labs in the United States currently possess or work with these select biological agents?

Mr. ATLAS. I guess the answer to that is probably a few hundred, 250 plus laboratories. That is based on a survey that we did at the University of Louisville under subcontract from the Department of Energy where we surveyed all universities in the United States, all 2,500 institutions, and came up with that sort of estimate in terms of universities anyway having select agents.

Chairperson FEINSTEIN. And they would work with one or some of this list of 40?

Mr. ATLAS. That is correct, one or some. We have gone back, Madam Chairman, and looked at anthrax in particular and the estimate there is probably 20 to 30 laboratories having anthrax at universities, not necessarily all having virulent forms. Some could be vaccine strains. We did not differentiate between whether it was

¹¹ Barry Kellman, "National Legislation to Implement Legal Assistance and Cooperation, International Symposium: Cooperation and Legal Assistance for the Effective Implementation of International Agreements, The Hague, Netherlands, February, 2001. See also, Barry Kellman, "WMD Proliferation: AN International Crime? *The Nonproliferation Review*, vol. 8, no. 2, Summer 2001.

a pathogen or not. In fact, the CDC list, unless it is a licensed vaccine, does not differentiate between the real disease-causing forms and those that are not capable of causing disease. The only exemptions in that shipment list are for the strains of particular organisms like the bacterium that causes anthrax if it is licensed as a vaccine.

Chairperson FEINSTEIN. What is the significance of that?

Mr. ATLAS. It means that of the numbers I am giving you, in fact, fewer labs probably have virulent strains, those strains of these agents that could cause disease or be used by bioterrorists.

Chairperson FEINSTEIN. Okay. Do you believe that anyone not affiliated with a legitimate health or research institution should be able to possess his or her own personal supply of anthrax?

Mr. ATLAS. Absolutely not. These agents should be restricted to legitimate facilities and the workers there must be pursuing research or diagnostic activities that are for the public good.

Chairperson FEINSTEIN. Well, I strongly agree with you. Then why do universities oppose this? Why is there this—it is all sub rosa but as soon as you begin to surface with really a strict certification system and make possession of these death-producing toxins illegal, there is a reaction to it. I do not understand it because I do not understand why anybody should have to have these things unless you are part of a legitimate certified research lab.

Mr. ATLAS. I agree with you that the ASM has agreed with that basic tenet. I think there is a sense, in part among universities, of regulations, of how we are able to deal with regulations that will cause some heartburn for some administrators. But there also has been some concern that we could cause people to destroy legitimate cultures, that legitimate researchers would walk away. I think as long as—

Chairperson FEINSTEIN. Well, what is wrong with that? If all these things produce death and can be misused, why would we worry if they destroyed them?

Mr. ATLAS. Because we need the researchers to find the vaccines and the pharmaceuticals. If we destroy the cultures and we do not have legitimate researchers doing research on anthrax, we will not have the drugs and the vaccines in future to combat any bioterrorist attack. Much of that research goes on at our universities, as well as in the federal labs and other industrial laboratories. That is absolutely critical to the welfare of the nation.

Chairperson FEINSTEIN. Is the toxin or the virus or the pathogen in the possession of the individual or the lab when you work for a lab?

Mr. ATLAS. I think it ought to be in the possession of the laboratory and then we need to look at who has access to that within the laboratory, but it never should be removed from that laboratory setting. It is in that setting where the appropriate biosafety and biosecurity measures are in place and where the CDC can and should oversee them.

Chairperson FEINSTEIN. And today they are removed from the lab.

Mr. ATLAS. Not that I know of. I mean obviously someone has taken an agent now from somewhere and spread it but to my knowledge, legitimate researchers do not take these agents home,

they do not remove them from the laboratory setting. They should not endanger the public that way.

Chairperson FEINSTEIN. The USA Patriot Act signed into law by President Bush prohibits certain restricted individuals, such as dishonorably discharged veterans, felons, fugitives, illegal aliens and drug users, from possessing or transferring any select agents. Do you believe these restrictions are appropriate? Are there any classes of individuals who should be on the restricted list who are not?

Mr. ATLAS. I think we think that that list is appropriate. I think, as I indicated in the testimony, the only thing that we might have liked to have seen was the authority resting with the attorney general to grant an exemption if it was in the national interest.

Chairperson FEINSTEIN. Let me just be clear. The attorney would essentially have a waiver of these things and be able to give a prior felon—

Mr. ATLAS. The recommendation of the ASM as this was being developed was that the secretary of HHS be able to make a recommendation to the attorney general on an individual basis to grant an exemption if indeed it was in the interest of the United States to have such an individual have possession.

Now that may never have occurred but we do think that at that level it is appropriate for government officials to be able to say we need an expert. Let us say that we had someone come from Iraq who could provide expertise who currently would be, under the USA Patriot Act, excluded. If the secretary of HHS and attorney general said we really need this person, we think we should provide that ability.

Chairperson FEINSTEIN. All right. My red light is on but in the next round I do want to ask you about the current registration requirements. So I will defer to Senator Kyl.

Senator KYL. Thank you.

Dr. Atlas, you testified there are about 250 university labs that would have access to these materials but you were not identifying the number of nonuniversity labs. Is that correct?

Mr. ATLAS. That is correct. We did not do our own survey of that. There have been publications from the—

Senator KYL. Do you have any estimate based on other publications about how many other labs might also—

Mr. ATLAS. The total number that we have seen in the literature is about 550 within the United States.

Senator KYL. Thank you.

Chairperson FEINSTEIN. In addition to 250?

Mr. ATLAS. No, a total of 550.

Senator KYL. Half university.

Mr. ATLAS. Mm-hmm.

Senator KYL. Now with respect to the equipment, let me just understand how sophisticated this equipment has to be. Let us take the kind of anthrax spores that were mailed in the Daschle letter because there is at least some information about the quality of those spores. Can you give us some sense of the kind of equipment that would be necessary to produce that and how ubiquitous that equipment might be and how sophisticated it might be and whether there is any point in trying to regulate somehow the possession of that particular equipment?

Mr. ATLAS. Let me divide that into two, part of which I can answer. It is easy to grow the organism. It is easy to isolate the organism even from nature if we do not get it from a laboratory, and that equipment is very widely dispersed. I could not begin to count how many laboratories have that capability and how many of us who have been trained as microbiologists have the expertise to isolate and grow up to a point where you could create a biocrime but not the bioterrorist sort of event that we are seeing.

Beyond that, frankly I cannot answer the question because I do not have the knowledge of how to go from that state to creating a true bioweapon, as has been described as the spores in the Daschle letter. That is more an engineering phenomenon of milling or other technology to bring it into a form where the electrostatic charges have been diminished where it can become aerosolized.

So not knowing that step, I cannot answer the question as to how many individuals would have that. Given the ubiquity of the microbiological side of the equipment, if I was going to look at equipment to regulate I would look at that engineering side of the milling equipment and that has sort of been also discussions that I have had in negotiations on the Biological Weapons Convention, where equipment has been at the fore of what we might, in fact, look at.

Senator KYL. We will need to define more precisely if we are going to identify any equipment what that might be and I look forward to working with you.

I have a question for you, Mr. Parachini, but do you have any addition to that last question?

Mr. PARACHINI. I guess the only thing that I would add, and I know the scope of the jurisdiction of this Committee is largely domestic, but we should also keep in mind that there are lots of foreign universities and laboratories. We should get a handle on our own problem first but we should be aware that other places there is not near the accountability as we have in this country and this problem may be global in scope. Indeed the Ames strain of anthrax has been sent around the world for years.

So even if we get our own house in order, which is not an easy task, we have another sort of circle of challenge before us.

Senator KYL. Excellent point.

Now in the introduction of your background there was mention of your work in radiological as well as biological threats. Could you comment on, discussing this new paradigm, how you would fold in the radiological threat with the kind of legislation that you hear us talking about here today or anything else that you would recommend? And by this I am distinguishing between the nuclear weapon and the infusion of radiation-producing materials into some other kind of weapon which could then disperse them in a widespread way.

Mr. PARACHINI. I think your line of questioning, Senator, is very good. I think we have focussed too much in the last six years on weapons-grade or military-like weapons falling into the hands of terrorists. That is important and a concern but the probability of that is low, albeit the consequences could be quite high but the probability is low. What is much more likely is industrial chemicals and hazardous waste being used inventively as weapons because they are much more present and the regulations on them are not

near that which there are on nuclear power plants or indeed on nuclear weapons.

So much more attention needs to be paid to this more readily available material that could be used as a weapon. After all, we saw a group of people turn a passenger aircraft into an incredible weapon. It is not that difficult to go the next step and turn a truck of hazardous waste that are being shipped around for legitimate industrial purposes all the time in our country, turning that into a weapon, as well.

Senator KYL. Well, do any of you have a comment specifically with respect to radioactive materials that could be used in this fashion? I mean we can talk to other people about that. I just wanted to see if any of you did.

[No response.]

Senator KYL. Okay, that is fine. We appreciate very much the expertise that you have brought to bear here and as we develop legislation we will want to make sure that we cover all of the bases in terms of registration, certification that is required but also realize there are some new trends taking place and the bad guys will not follow the law and therefore to balance the legitimate needs of science, the realization that there are certain kinds of people who, however finely we draft this, are not going to comply and therefore try to balance the way that we legislate in a way that will do the most good to protect our people and do the least damage to the scientific inquiry that we all support.

Thank you, Madam Chairman.

Chairperson FEINSTEIN. Thanks, Senator Kyl.

Senator McConnell?

Senator MCCONNELL. Thank you, Madam Chairman.

Dr. Atlas, did I hear you correctly in response to one of Senator Kyl's questions that it is beyond your area of expertise to know whether there is equipment that is specific to the production and so-called weaponization of biological agents?

Mr. ATLAS. Yes, that is correct. I think that goes outside of the realm of microbiology. Microbiologists would take something to a point but then at least my understanding of how one would weaponize anthrax spores, it is more an engineering feat of getting the right particle size in the 2-micron range, the uniformity, the charges. It is not something that we train microbiologists to do or that I would know how to do.

Senator MCCONNELL. Well, assuming there is somebody out there who could answer that question, which we may need answered in order to decide what, if anything, to regulate in order to reduce the threat of bioterrorism, that is a question we do need answered by someone, right?

Mr. ATLAS. I would think that one would turn to USAMRID, who had experience with the U.S. military operation prior to 1969, who has a great understanding of what is, in fact, required to go from having spores to having a weaponized type of spore.

Senator MCCONNELL. We spent a lot of time discussing the measures that Congress ought to take to safeguard U.S. labs from potential terrorists. Obviously all of our best efforts might be moot if would-be terrorists are able to acquire biological agents overseas.

As we move forward with these legislative initiatives, what in your judgment should we be doing internationally?

Mr. ATLAS. I think we have to work for an international agreement that would criminalize bioterrorism. A number of members of the scientific community have posed such an act. We also need to harmonize the rules by which agents are exchanged and maintained. It does us, I think, little good to know who possesses agents within the United States if we do not similarly know who possesses those agents around the world. It does not do us a lot of good to tighten our national regulations over the exchange or possession of agents if one can go to another country and simply obtain them.

Senator MCCONNELL. You estimated there were 500 or so labs in this country. I gather we have no idea how many there might be worldwide?

Mr. ATLAS. Somewhere probably 1,250, 1,500 labs around the world would possess the select agents. It is a crude estimate.

Senator MCCONNELL. Beyond the 500 or including the 500?

Mr. ATLAS. Including the 500. So 1,000 outside of the United States would be a quick estimate of that but that is a lot of places then who are not following the rules that we currently do under CDC shipment regulations.

Senator MCCONNELL. How might the various legislative initiatives we are considering here to control access to dangerous pathogens impact different types of laboratories? I think you touched on that earlier but specifically how might they impact clinical laboratories, for example, differently from research laboratories?

Mr. ATLAS. I think that there is a real difference between the research laboratory and the clinical laboratory. The research laboratory that is trying to develop a vaccine or a pharmaceutical is in true possession. They know what they have; they know it is there; they know if they know if they anthrax working with it. It is easy to register those facilities.

The clinical laboratories, though, do not know when a patient comes in what they are going to isolate. They are not necessarily preregistered to tell you we are going to be in possession of anthrax. And in fact, under the national laboratory network that we have established for laboratories, the local clinical lab does not really accomplish the identification; that goes on to a public health lab or to the CDC to do. So the clinical lab may, in fact, be in possession and never know they have the agent.

Now Senator Feinstein asked earlier about the CLIA exemptions under the current select agent rule and in fact, that is a necessary part because we do not want to delay the shipment of the diagnostic specimen on up. If in the case of Boca Raton, for example, we had to get rid of that sample and not send it on because they had not preregistered for potential possession of anthrax we would have had a serious problem in knowing, in fact, that we were under a terrorist attack.

Now those clinical labs need to follow a different set of rules. They need to destroy the agents once it has moved on and that is, in fact, what the current select agent rule does. But tens of thousands of CLIA-certified laboratories, probably something like 150,000 diagnostic laboratories in the United States. If we begin registering all of those who do not really possess the agents then

I think we have a mammoth bureaucratic nightmare ahead of us that does not allow us to focus the attention where it needs to be focussed.

Senator MCCONNELL. Thank you, Dr. Atlas.

Thank you, Madam Chairman.

Chairperson FEINSTEIN. Thanks very much, Senator.

Dr. Atlas and gentlemen, my staff has just handed me a copy of a list of categories of equipment that would be covered by the bill we are putting together involving this equipment. It includes things like sophisticated fermentation equipment, large temperature-controlled high-speed differential centrifuges, cross-flow filtration equipment, freeze-drying equipment, aerosol inhalation chambers, and certain modifications with respect to airplanes, trucks, et cetera.

Would you take a look at this before you leave? Also there is some bill language attached. Perhaps you would take a copy with you and give us your input on that because I am sure there are things that we have missed.

The Anti-Terrorism and Effective Death Penalty Act of 1996 set up a registration system for laboratories that transfer and receive dangerous biological agents. The registration system that the CDC has has a number of exemptions.

In light of this new threat, I would like to ask you about the appropriateness of these exemptions. A, samples used for diagnostic verification and reference purposes. What is the American Society of Microbiology's view of exemptions for diagnostic verification and reference purposes? Why shouldn't a lab have to register if it keeps a reference sample of anthrax or smallpox permanently at the lab?

Mr. ATLAS. I think the answer is if they keep a specimen beyond 48 hours they have to register and should have to register. The only question on the exemption is the initial 48 hours during which a sample is being processed and sent on to be identified, after which they have to destroy it. So it is not that they should be able to maintain it. If they do, they have to register like any other laboratory under the select agent rule.

The question, as I indicated a few minutes ago, is in case of Boca Raton don't we want that laboratory to be able to possess it long enough to move it onward for the proper diagnosis? But no—

Chairperson FEINSTEIN. But it is also a loophole for mischief.

Mr. ATLAS. I do not know that there is any way of closing that loophole when we are dealing with agents that occur naturally. In the senator's home state of California where I lived before coming to Kentucky, we see several cases of plague occurring each year. The agent is present in various animal populations in the state. We need to be able to allow both the veterinary and the clinical diagnostic laboratories to make appropriate diagnoses and then we must demand that they either register, transfer them to registered laboratories and destroy the agents within the set time limit, but again I would not want to prevent someone from making the right diagnosis that is going to save lives.

Chairperson FEINSTEIN. Now let me ask all of you this question. Why do you think the FBI and the Justice Department is having such a difficult time determining the source of this? I mean we

know certain things about it that limits it to very few sources of production so why is it so difficult?

Mr. PARACHINI. They are not here and I do not want to comment but they have a culture that focusses on the crime and works backwards. So you might ask, why haven't they worked backwards this far? I think they follow the particular crime and go back how that leads them, as opposed to sort of asking the question, what is the full realm of possibility here and let us identify all of the laboratories and all of the workers, which would be one of the things one would want to do to have a complete baseline of what is the potential out there.

I think it is their cultural approach about how they pursue an investigation, which might be different or they might be aided by more regulation in this area that started with a clear baseline of what is out there and who has access to the facilities.

Chairperson FEINSTEIN. So you are saying go immediately to these 500 sources?

Mr. PARACHINI. Or whatever the number might be. It could be a good deal more than that. I am sure that Dr. Atlas's laboratory is different but people work with things in their laboratory and then they move on to other places and they forget what the vials are in the place where they have worked or people get sick and then die and their laboratories still have the material in there. Mistakes happen. A clear accounting of all of what is out there is probably a good place at some point for us to get to.

Chairperson FEINSTEIN. Dr. Atlas?

Mr. ATLAS. Senator, there also is an inherent difference between biological weapons and other sorts of weapons of mass destruction. If I fill this glass with water—it's a chemical—and someone takes half of it, you know it is gone but if it is a biological agent and I fill it with water, I need to take only a pinpoint out of there that you would never notice and then I can grow tons of it elsewhere.

The other aspect that is different is with the exception of smallpox, all of the other agents occur naturally.

One assumes right now that someone has gone into some laboratory or culture collection and obtained the strain of anthrax that is being spread maliciously through the mails. Reality is that that same strain undoubtedly also exists in nature and is killing animals and one could have found it out there.

Unless we eradicate these infectious diseases, terrorists will have sources of anthrax and plague and any number of other agents in nature. So while we definitely should tighten the regulations from a biosafety and a biosecurity standpoint on our research and even our clinical labs, that does not eliminate the threat of a bioterrorist acquiring agents that can cause mass casualties.

Mr. PARACHINI. In fact, Senator, I might add that it is worth remembering that Aum, the Japanese cult group, actually did go to Zaire thinking that they could acquire some Ebola virus. Now they went in a period where there were not actually outbreaks but they thought about it so they did exactly that. And it may be more difficult to actually monitor who is going in and out of hot zones where there are emerging infectious diseases, as opposed to laboratories where we know where they are, for example, in the former Soviet Union and can focus our attention on improving the secu-

rity. We should do that but we should also be aware of this more elusive source that pops up around the world according to its own design and that it is hard to anticipate where it is.

Chairperson FEINSTEIN. But as everyone has said, this was highly purified and there was a substantial amount of it, two grams, in the envelope, and there was some kind of coating on it, as yet undefined, as I understand it, which indicates to I think everybody that has looked at it that a process took place which was a sophisticated process.

So to me, that has to come from somewhere. It did not likely come from someone in their bathroom cooking this stuff up. It had to have come from somewhere. Then you get to the point of well, if it is two grams, why was it only two grams? Is there more? Is it three grams or four grams or five grams? I guess if it takes certain equipment in certain labs to get that, it seems to me that no-way, no-how in this country should individuals be able to possess that outside of the lab setting, which I gather right now our laws do not guarantee.

Mr. ATLAS. If we could identify that equipment that went from A to B, that is what took the agent and refined it and treated it that way and there is specific equipment, then I think I would agree with you that we should not possess that.

The other sort of equipment though, sort of going from just a cell of bacillus anthracis to two grams of material—not weaponized, not purified—that Iraq showed us could be done in very small containers, in very nonsophisticated ways and that we would not be able to capture or prevent individuals even from having the sort of jars and jugs at home that one could do that in.

Chairperson FEINSTEIN. Well, now I am confused. You cannot grow to the level of this anthrax at home, right?

Mr. ATLAS. In my opinion you are correct but it is after you have grown it. In other words, I think that the early part of being able to culture the bacteria, to grow two grams of bacteria, that is not a very sophisticated technology. Going from there to reducing the charge or the engineering aspects, once you go out of my area of expertise of microbiology to someone else's area, in my view that becomes far more sophisticated and it really is where the issue of equipment and a different sort of expertise that tells you how to make a biological weapon exists.

Chairperson FEINSTEIN. Well, what do your microbiologists say? Speculate just for a moment and this is pure speculation. Where they do they think this kind of thing came from?

Mr. ATLAS. I do not think we know. I think we really are looking and waiting and we really do not know. I would say every day I get a phone call telling me it came from somewhere else, I know where it came from and that night it changes.

So I really wish I had a clue as to where it came from, who is responsible. I do not know.

Chairperson FEINSTEIN. One last question. In the CLIA labs, the ones that are not required to register with CDC, I trust you believe they should be?

Mr. ATLAS. No. Again those are the laboratories that are the diagnostic laboratories. They are required to destroy their cultures. Those are the laboratories like the hospital in Boca Raton that had

the unfortunate experience of isolating bacteria from a patient who was dying of anthrax and where they then transferred that and destroyed the culture and did not actually register as a laboratory that had been in possession technically, I guess, of anthrax during the time of the 48 hours when they had isolated and until it was transferred and destroyed.

Now had they maintained it, had they gone beyond that, then they are required, they are not exempt and they are required to register and that should, in fact, be done.

Chairperson FEINSTEIN. You do not think it is worthwhile having CDC know? Well, they do know.

Mr. ATLAS. I think the CDC does know. I think that because there is a requirement that it move from that laboratory to a public health laboratory, that that is a requirement, that the public health laboratory needs to notify the CDC, that there is no question that there is a record of where it came from.

Chairperson FEINSTEIN. Okay. And what is the verification process when it is destroyed, that it has been destroyed?

Mr. ATLAS. I do not know that there is a verification process and that is something that could be looked at in my view in terms of the regulatory oversight. As the secretary of HHS presumably in the near future, depending on which regulations we see come forward, will be charged with a new set of regulations, I think that is a very appropriate question of how that laboratory disposes of it and how we verify that it has been appropriately disposed. There is a requirement that it be either incinerated or autoclaved on site but that verification, I think, is a good point, Senator.

Chairperson FEINSTEIN. Right, thank you very much.

Does anybody have a last comment they would like to make?

Dr. DRAKE. I just have a comment. You mentioned universities and the interest the reaction that people have when they hear that new regulations are coming down and I just would like to echo what Dr. Atlas was saying.

Participating in the process of defining what those rules and regulations are going to be and having people who are working in the field who can say gosh, this is something that is likely to confer protection or this is something that is likely to be an unusual burden are what people are concerned about. So I just think that having an opportunity to participate in the development of what the regulations are so that they enhance our security but do not curtail the legitimate and beneficial purposes that are going on in the laboratory, I think that is one thing that is important.

Another comment I have on the concept of excluding categories of individuals without exception, I would find that to be limiting in many ways. I will use an example, not necessarily a good example but let us say someone who might have been dishonorably discharged from the military for sexual preference decades ago or some other things like that. There might be people who have had wonderful careers in research and other things that are really contributing to the national good and by exempting or excluding entire categories of individuals without an opportunity for exception, I think we again could be limiting our ability to do legitimate quality work.

Chairperson FEINSTEIN. Well, as was pointed out, there would be a waiver so that it could be waived, but at least the case would have to be looked at.

Dr. DRAKE. Sure.

Chairperson FEINSTEIN. One of the problems now is anybody can possess it and I have a real problem with that.

Mr. PARACHINI. Senator, I would just add that it is important that the Committee and you and your colleagues look at not only the technology and baselining what we have at our laboratories but it is not just a matter of the material and the equipment but there is also the know-how an we have to be creative about how we secure the know-how of doing this. As Dr. Atlas mentioned, moving from developing a culture to actually making the sophisticated material that showed up in the Senate is an understanding about how you work with that material that really weapon scientists have had, so there is the knowledge of weapon scientists and then there is the skill of doing that.

So we need to be creative in thinking about how we control that or how we know where that is; that is, the know-how and the skill, which are different. I realize that goes into other Committees' jurisdictions but I think this is a problem that has many facets and to look at only one part of it in isolation of the other, we may miss useful connections.

Chairperson FEINSTEIN. Well, if you have some suggestions we would be happy to hear them.

Let me say thank you very much. This has been a very interesting hearing. I appreciate your expertise and the information that you have added for our consideration.

So thank you and the hearing is adjourned.

[Whereupon, at 12:27 p.m., the Subcommittee was adjourned.]

[A submission for the record follows.]

SUBMISSION FOR THE RECORD

Statement of Claude Allen, Deputy Secretary, Department of Health and Human Services

Good morning. I am Claude A. Allen, Deputy Secretary, Department of Health and Human Services (HHS). I am pleased to be here to describe HHS's role in regulating the possession, use, and transfer of select agents that are capable of causing substantial harm to human health.

OVERVIEW OF EXISTING 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. Recent use of anthrax as a bioterrorist agent has heightened this concern. In general, the safety and security record in the sale and transfer of these agents and substances for research has been good. 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. Each year in the United States, thousands of samples of infectious agents are shipped without incident.

Historically, HHS's Centers for Disease Control and Prevention (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 partners in the scientific community to develop and implement the regulation on behalf of HHS.

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 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 biological 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, 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 4th edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL). 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 registered 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 approximately 60 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 October 24, 250 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 2500 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 with FBI personnel and other authorized law enforcement agencies to provide access to the information when necessary.

PROPOSED CHANGES TO REGULATION

This month, Secretary Thompson developed a draft bill for the consideration of Congress to improve the Department's ability to prevent or respond to public health emergencies created by terrorist attacks. The bill, the "HHS Bioterrorism Prevention and Emergency Response Act of 2001," makes amendments to the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and related statutes to address several issues related to bioterrorism, including select agents. Among other issues addressed, new authority would be provided to regulate the possession, use, and transfer of those select agents that the Secretary found to be a national security threat. The Secretary would develop and implement an appropriate regulatory framework to accomplish these safeguards.

Title II of the bill includes these provisions. Section 203(b) would add to title III-F of the Public Health Service Act a new section 351B, directing the Secretary, by regulation, (1) to establish and maintain a list of those biological agents and toxins listed under section 351A of that Act that the Secretary determines to be a national security threat; and (2) to provide for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of such agents and toxins designed to protect public safety and national security, including safeguards to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose. Violations would be subject to civil penalties of up to \$250,000.

In determining whether to include an agent or toxin on the lists for regulation of transfer or of possession or use, the Secretary will consider the effect on human health of exposure to the agent or toxin, the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans, the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin, and other appro-

appropriate criteria. In making these determinations, the Secretary will consult with public health, scientific, intelligence, and military partners.

Through the regulatory regime established, the Secretary will provide for the establishment and enforcement of safety procedures for the transfer of these biological agents and toxins. The regulations will also provide safeguards to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose. Due to the extremely sensitive nature of the information collected, the bill also provides an exemption from the Freedom of Information Act for any information provided to the Secretary under these regulations, or under CDC's current Select Agent regulations.

REGULATION WITHIN HHS ROLE FOR PUBLIC HEALTH RESPONSE

The Secretary will develop and implement these expanded regulations within its overall framework for public health preparedness for and response to acts of bioterrorism. HHS is responsible for the public health response to any biological or chemical attack, as well as for disease surveillance and medical preparedness. Our anti-bioterrorism efforts are focused on improving the nation's public health surveillance network to quickly detect and identify the biological agent that has been released; strengthening the capacities for medical response, especially at the local level; expanding the stockpile of pharmaceuticals for use if needed; and expanding research on disease agents that might be released, rapid methods for identifying biological agents, and improved treatments and vaccines.

HHS 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

The Department of Health and Human Services is committed to working with other federal agencies as well as state and local public health partners to ensure the health and medical care of our citizens. We have made substantial progress to date in enhancing the nation's capability to respond to a bioterrorist event. But there is more we can do to strengthen the response. 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, HHS 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.

Mr. Chairman, that concludes my prepared remarks. I would be pleased to answer any questions you or members of the Subcommittee may have.

