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FIGHTING BIOTERRORISM: USING AMERICA'S SCIENTISTS AND ENTREPRENEURS TO FIND SOLUTIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND SPACE

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

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COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

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C O N T E N T S

FIGHTING BIOTERRORISM: USING AMERICA'S SCIENTISTS AND ENTREPRENEURS TO FIND SOLUTIONS

TUESDAY, FEBRUARY 5, 2002

U.S. SENATE,
SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND SPACE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:30 a.m., in Room SR-253, Russell Senate Office Building, Hon. Ron Wyden, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. RON WYDEN, U.S. SENATOR FROM OREGON

Senator WYDEN. The hearing will come to order. Today, the Subcommittee on Science, Technology, and Space convenes the second in a series of hearings on how America can rally its best scientists and technology experts to combat terrorism. I am going to have an opening statement, and I want to recognize all of my colleagues as well in a moment. But the Senator from Georgia is under time constraints this morning, and I would like to recognize him first.

STATEMENT OF HON. MAX CLELAND, U.S. SENATOR FROM GEORGIA

Senator CLELAND. Thank you, Mr. Chairman. I do have two other committees that are wanting my attention. I did want to be here today to make a very special introduction. Mr. Chairman, I would like to thank each of the witnesses for their contribution to our understanding of the crucial role of scientists and entrepreneurs in fighting the war against bioterrorism, with the focus of today's hearing on how the Federal Government can better utilize private industry and its technical expertise in the continuing war against bioterrorist attacks.

I am convinced we could more effectively pool our resources in order to form a fast, effective response to this threat. Such resources are available to us today in this country because of the knowledge, skills, and technical expertise of the American entrepreneur. However, the small business entrepreneur, and I am on the Small Business Committee here in the Senate, Mr. Chairman, cannot just go it alone. Small, high tech companies often need Federal assistance to fully develop new, cutting edge technology ideas and see those ideas come to fruition. The result of this collaborative effort between the Federal Government and private enterprise can

often be a new product which improves the quality of lives for the citizens of this country.

Today, I am pleased to introduce to the Subcommittee one such example of entrepreneurial success. Mr. John Edwards is President and CEO of Photonic Sensor, an Atlanta-based firm which produces a unique new product in the war against bioterrorism. In his testimony, Mr. Edwards will emphasize the story behind his company's product, how it was developed, how it was brought to mainstream use, and the role the Federal Government played in this process.

The threat of terrorist attack is as real today as it was on September 11. We know all too well of the real danger of biological attack, having lost several American lives to anthrax. We as a Nation must be prepared for any such future attacks, and we simply cannot afford to overlook the promise of protection offered by America's scientists and entrepreneurs. Once again, we thank you, Mr. Chairman, for your leadership on this critical issue. I look forward to working with you in the ongoing war against bioterrorism, and I would like to thank our panelists, all of them, for coming today.

Senator WYDEN. I thank my colleague. I know my colleague has been very involved in the bioterrorism debate, and we look forward to his expertise as we move forward.

Just as John F. Kennedy gave America's youth a forum for public service, I believe now is the moment that government should throw open its doors to the ideas, the creativity, and the energy of a generation raised on information technologies that is willing to fight the terrorist threat. This hearing is going to explore opportunities to respond to the threat of bioterrorism in particular.

Our country has begun to mobilize its public sector, government, military, and law enforcement to fight terrorism. Analyzing the events of September 11, this Subcommittee found the private sector was ready and willing to contribute, but found too many obstacles. Some could not get proper credentials to get into the disaster site. Some simply could not find the right place to offer their people, their expertise, and their equipment.

In the event of a bioterror attack, it appears many communities are going to face the same confusion. Right now, if a town is hit with a biological agent and looking for the closest medical authority, in most cases, there is no comprehensive list of certified experts available locally to assist. Where do those local leaders turn to find help nearby? Where can doctors, scientists, and technology experts go to offer their aid? Most do not know, and right now the Federal Government has few clear answers. At least 20 Federal agencies are charged with some part of fighting the bioterror threat.

In the State of the Union address, the President said he would not wait on a fence while dangers gather around the public. I agree. America must marshall the efforts of technology experts and entrepreneurs, top scientists and medical minds before the next bioterror event. Among the objectives this Subcommittee should explore are: establishing a clear point of contact for those in the private sector offering help; putting the names of bioterror experts into the hands of local governments in every corner of this country; and creating a national testbed for private sector technologies that can help save American lives.

After September 11, I proposed that the government launch the technology equivalent of the National Guard. I describe it as the National Emergency Technology Guard, or NET Guard, a cadre of volunteers from the private sector with the ability to help prevent these tragedies and to fix broken systems and create new networks wherever possible. In response, key Federal agencies must help establish a single point of contact of consistent policy for organizing the technology sector's help.

Today I say that scientists, doctors, and entrepreneurs need an entry point with the government as well. This organization can help safeguard not just our technology infrastructure, but the very health of our citizens. A National Association of Counties study released just last week specifically calls for the development of up-to-date contact lists for local public health departments. It states that less than 10 percent of the counties surveyed feel ready to handle a bioterror attack.

America's communities need a registry of the best scientists and doctors to deal with biological incidents as soon as they become apparent. Bioterror attacks are not always announced by a plume of spores from an opened letter, like the anthrax attack on the Senate. Too often, the agent spreads, as it did in postal facilities, undetected until victims become sick or die.

A comprehensive database detailing experts' qualifications and locations could empower communities to get help as close to home as possible when the precious hours count. Once identified, specialists can be kept in the loop with ongoing training and information about new threats. Their advice will also be essential in developing a strategic reserve of supplies, a strategic technology reserve, as I would describe it, that would not just be medicines, but equipment and technologies to aid in the event.

Since September 11, thousands of experts and entrepreneurs have contacted the Federal Government offering new technologies. I firmly believe the private sector can make a significant contribution to early detection of an effective bioterrorism response, but today two witnesses will testify that their efforts to offer a bioterrorism detection device and new vaccines were hampered by a confusing, lengthy maze of red tape.

I am going to let them tell their own stories, but what concerns me about their testimony is that instead of being able to spring to the aid of their fellow citizens, they found themselves forced to run a bureaucratic marathon. Multiple agencies require separate, complicated, and slightly different applications. Companies can spend months waiting just to get their technologies to the top of someone's in-box. Who knows how many of these private entrepreneurs have simply run out of the time, financial and human resources demanded to navigate the current process. Companies should not have to hire lobbyists, as one California firm has, in order to figure out how to help their fellow Americans.

I understand some agencies are making a special effort to accept private sector suggestions, and we will hear about that today, but more needs to be done. A central clearinghouse in particular should be created to accept and test private sector technologies that could detect and diminish the bioterrorist threat. Major General John S.

Parker and others have made very thoughtful proposals in this area.

With unanimous consent, I will put the rest of my prepared statement in the record.

[The prepared statement of Senator Wyden follows:]

PREPARED STATEMENT OF HON. RON WYDEN,
U.S. SENATOR FROM OREGON

Today the Subcommittee on Science, Technology and Space convenes the second in a series of hearings on how America can rally its best scientists and technology experts to combat terrorism. Just as John F. Kennedy gave America's youth a forum for public service, I believe now is the moment the government should throw open its doors to the ideas, the creativity and the energy of a generation raised on information technologies, willing to fight the terrorist threat. This hearing will explore opportunities to respond to the threat of bioterrorism in particular.

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In the event of a bioterror attack, it appears communities will face the same confusion. Right now, if a town is hit with a biological agent and looking for the closest medical authority, there is no comprehensive list of certified experts to help them. Where do local leaders turn to find help nearby? Where can doctors, scientists and technology experts go to offer their aid? Most don't know—and right now the Federal Government has few clear answers. At least 20 Federal agencies are charged with some part of fighting the bioterror threat.

In his State of the Union address, President Bush said he would not wait on events while dangers gather around the American people. I agree. America must marshal the efforts of tech experts and entrepreneurs, top scientists and medical minds *before* the next bioterror event.

Among the objectives this Subcommittee should explore are: establishing a clear point of contact for those offering help; putting the names of bioterror experts into the hands of local governments; and creating a national test bed for private sector technologies that could save American lives.

After September 11, I proposed that the government launch a technology equivalent of the National Guard. I describe it as a National Emergency Technology Guard, or NET Guard: a cadre of volunteers with the expertise to fix broken systems, create new networks, and help prevent disasters wherever possible.

In response, key Federal agencies agreed to establish a single point of contact and a consistent policy for organizing the tech sector's help. Today I say that scientists, doctors and entrepreneurs need an entry point with the government as well. This organization can help safeguard not just our technology infrastructure, but the very health of our citizens.

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Once identified, specialists can also be kept "in the loop" with ongoing training and information about new threats. Their advice will also be essential in developing a strategic reserve of supplies—not just medicines, but equipment and technology to aid in the event of a bioterrorist attack.

Since September 11, thousands of experts and entrepreneurs have contacted the Federal Government offering new technologies. I firmly believe America's private sector holds the keys to early detection and an effective bioterrorism response. I also firmly believe government must do a better job of accepting and implementing their creative solutions.

Today two witnesses will testify that their efforts to offer bioterrorism detection devices were hampered by a confusing, lengthy maze of red tape. I will let them

tell their own stories, but I will tell you now what concerns me about their testimony. Instead of being able to sprint to the aid of their fellow citizens, they found themselves forced to run a bureaucratic marathon. Multiple agencies require separate, complicated, and slightly different applications. Companies can spend months waiting just to get their technologies to the top of someone's in-box.

Who knows how many have simply run out of the time, financial and human resources demanded to navigate the current process? Companies should not have to hire lobbyists, as one California firm has, to figure out how to help their fellow Americans.

A central clearinghouse should be created to accept and test private sector technologies that could detect and diminish the bioterrorist threat. Recently, Major General John S. Parker of the Army Medical Research and Materiel Command suggested a "national test bed" for new anti-terror inventions. Last fall, firefighters asked this Subcommittee for a test bed to evaluate bio-hazard technologies. A national test bed is part of my NET Guard legislation. Once verified, these innovations can be a crucial component of our Nation's response to terror.

As I have said, I envision a modest role for the government in this endeavor. NET Guard is not intended to be a huge bureaucracy. Rather, it will be a gateway for the private sector to bring its resources to bear on the war against terrorism. There is no time to waste.

The Subcommittee will hear testimony from two panels today: Dr. Georges Benjamin, President of the Association of State and Territorial Health Officers; Mr. John Edwards, President of Photonic Sensor; Dr. Richard Hatchett of the Civilian Medical Reserve Working Group; Dr. Richard Klausner of the National Academy of Sciences; Dr. Bruno Sobral of Virginia Tech University; and from the Federal Government, Ms. Anna Johnson-Winegar from the Department of Defense and Dr. Lisa Simpson of the Department of Health and Human Services.

Senator WYDEN. Even though there is a vote on the floor, I want to allow Senator Allen and Senator Rockefeller to make their full prepared statements. Why don't we see if we can get Senator Allen's in, and then we will come back and recognize Senator Rockefeller.

STATEMENT OF HON. GEORGE ALLEN, U.S. SENATOR FROM VIRGINIA

Senator ALLEN. Thank you, Mr. Chairman. I will try to be brief. First, I want to commend you, Mr. Chairman, for having this hearing on a very important aspect of our homeland security. Biology and biosecurity, bioterrorism are all involved in part of what is great about what is going forward, and that is a lot of advancements in biotechnology, but in all of those wonderful advancements we also see, obviously, some of the worry of using some of these advancements in the wrong way. I want to welcome and thank all of our experts who will be testifying here this morning, and I particularly want to thank Dr. Sobral for being here. He is with the Virginia Bioinformatics Institute at Virginia Tech, and very much a part of what will need to be the coordination and efforts here.

We saw what effect this anthrax attack had here. We still do not get mail on time from our constituents, and let me apologize for all Senators when people say we are not getting our letters answered. Just understand, we are not getting your letters in a timely manner, so e-mail us or fax us, or send it to our home offices. But nevertheless, we saw the attack on major media outlets as well. We need to recognize, obviously, if there are future bioterrorist attacks, the impact, as bad as it was here, and we certainly mourn the loss of five lives, it is most likely to affect more people than what we have seen in this recent attack.

These attacks emphasize why this Subcommittee hearing is so important. We need to have more innovative research to develop an

early warning system for bioterrorist attacks; we need new vaccines and treatment for biological agents; and we need prompt, accurate, coordinated response methods to any future attacks.

I think we will find here, with the help of the witnesses here today, we are going to find that we have many good, on-going programs in the private sector, in our universities as well as with Federal Government agencies, trying to address these areas and advancing technologies to hopefully address—prevent, if possible—but if there is an attack, make sure there is a rapid response to prevent as much harm as possible.

I have been reading through the testimony. There is, for example, a hand-held device that uses biosensors to detect bioterrorist attacks. The study by Dr. Sobral, Virginia Bioinformatics Institute, is working to understand the spread of deadly diseases. The University of Virginia project is working to modify red blood cells to destroy deadly pathogens that are among the different private sector research initiatives.

The Federal Government obviously should review this research, whether it is what I mentioned or others, to determine whether they can be applied in our preparations for future biological attacks. Many of the Members of this Subcommittee, including myself, are cosponsors of the Frist-Kennedy Bioterrorism Response Act, which I believe shows the Senate taking a leadership role in this area of concern, and I commend the Bush Administration in at least their prioritization in the budget.

Much of the research and prevention responses is going to require what I like to call a team effort, and it is going to be a large team that is going to involve the private sector; universities and research being done there; hospitals; the medical profession; civilian and military research at the Federal level; and obviously, working with State, local, regional, and Federal officials to assess the situation of the challenges and the assets that we have. We will then need to determine where improvement needs to be made in addressing this threat, and next will, of course, be the coordination of all of these resources and assets—and all of these are equally important. Finally is the communication, the easy and rapid communication among all these different team members so that we can respond promptly, efficiently, in the best way possible to protect the people of America.

So I thank you, Mr. Chairman, and look forward to the testimony.

Senator WYDEN. I thank my colleague.

We have a vote on the floor, then we are going to come back and recognize Senator Rockefeller.

[Recess.]

Senator WYDEN. The hearing will come to order. We thank our witnesses. I do want to recognize Senator Rockefeller, because he has decades of experience in the public health field, and chairs the Finance Subcommittee on Health, and I am so pleased to recognize Senator Rockefeller.

**STATEMENT OF HON. JOHN D. ROCKEFELLER IV,
U.S. SENATOR FROM WEST VIRGINIA**

Senator ROCKEFELLER. Senator Wyden, as part of that glorious introduction, it occurs to me our panelists have been waiting a long time, and what I have to say may be of somewhat less interest than what they have to say, at least from my perspective. I would encourage you to go to them, and I will just work my thoughts in as I go along.

Senator WYDEN. We are going to do that, and I am going to recognize you first for questions when they are done, and I thank you for your graciousness.

Our first panel is Hon. Georges Benjamin, M.D.; Mr. John Edwards; Dr. Richard Hatchett; Dr. Richard Klausner; Dr. Una Ryan; and Dr. Bruno Sobral.

Let us begin with you, Dr. Benjamin. We are going to make your prepared remarks a part of the record in their entirety, and please proceed.

STATEMENT OF HON. GEORGES C. BENJAMIN, M.D., PRESIDENT, ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICERS; SECRETARY, DEPARTMENT OF HEALTH AND MENTAL HYGIENE, STATE OF MARYLAND

Dr. BENJAMIN. Thank you very much for allowing me to be here today. I am here wearing two hats. One is the Secretary of Health for the State of Maryland, but more importantly as the President of ASTHO, which is the Association of State and Territorial Health Officials. This is the organization which supports all of the State health officials in the country.

You know, for the past 5 months we have been struggling with this whole issue of biological terrorism, but more importantly we have been struggling with how best to get information, how best to get access to the right people at the right time to give us the ideas that we need to make very, very sound public health decisions, and Mr. Chairman, let me tell you, that has been real tough.

You know, I can take you back even prior to bioterrorism. Back in 1997, we had a little organism that showed up on the Eastern Shore of Maryland called pfiesteria pisscida. It is a fish disease, and some of us in North Carolina had been struggling with this for some time, and frankly, in Maryland we did not have a clue about that going on. But when it hit the waters in Maryland there was some concern that some of the people in Maryland were getting sick from that organism. We had to search and find some people that knew something about it, some people that knew about that class of organisms. What normally happens is you pick up the phone and call the CDC. The CDC gets you to an expert, that expert gives you good advice, and you do what you need to do. It turns out they did not have one in that particular area. It turns out we not only had one, but we had two of those folks, one at the University of Maryland and one at Johns Hopkins. The University of Maryland is down the street from my office. It is a little embarrassing that we would find these folks right in our own backyard. They were able to give us some expert advice, and we were able to solve that public health crisis.

We move forward to September 11. This one was a communications issue. We had a great deal of difficulty talking back and forth. We needed secure communications. We needed to be able to share medical information not just within my department, not just within Maryland State government, but intrajurisdictional between Maryland, DC, and Virginia, and frankly, we did not have the technology to pull that off right away.

We had put some things in place, standing conference calls, a few cell phones, but it was very, very difficult because of the needs of the public health system, but more interestingly, trying to find people to deal with anthrax who had actually seen it. Now as we begin to make our plans to look at smallpox, trying to find people who have actually seen smallpox has really been a challenge.

One of the things we have done is, we have gone out to the medical society, we have gone out to the various teaching hospitals, and we have begun to put together a list of people who have actually seen it and done it. So we know they are out there, but we certainly think that is something that needs to be done nationally. All States need to do this. They need to find ways to identify experts to give them advice real-time. When a disaster happens that is not the time to be scrambling to try to find experts. We had the same issue around technology in terms of our cleanup.

Some folks would say, "well, most of this anthrax stuff occurred across the street in DC and at the Brentwood Station." But I got a call one day a few days after Brentwood from the president of a bank who said, "I have a mailroom that looks just like Brentwood, big machines, sorting machines. It is downstream from Brentwood. And we need to have you come and test our facility." I mean, they got their mail directly downstream from Brentwood.

The Governor was prepared to do that. Maryland State government was able to step up and do that. But we needed to figure out how to do it, what were the testing protocols, are there some new technologies out there that we can utilize to do this quicker, more expediently? How do we bring our staff—and at that point it was another State agency, the Department of Environment—up to speed very quickly to be able to do that testing?

Now, we did struggle through that. The good news is, we did not find any place, at least on our side, that was positive, but these were the kinds of things that happened to us in a very, very quick manner.

I think that the most important thing that we saw during these anthrax outbreaks, at least nationally, was the speed in which information moved, the fact that we were practicing what I called "a science of the day" mentality. Today it was real, tomorrow it was not. We kept changing what we knew, what we did not know, and that was because information was moving so quickly, and we had a very, very difficult time validating what was real, what was not real, and where we needed to go.

So that is your clarion call. For us to pull together the world's experts for us to have access to, I believe, is a crucial next logical step for the public health community.

With that, Mr. Chairman, I will stop and take questions whenever you choose to take those questions.

[The prepared statement of Dr. Benjamin follows:]

PREPARED STATEMENT OF DR. GEORGES C. BENJAMIN, M.D., F.A.C.P. SECRETARY, MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Good morning Mr. Chairman and Members of the Committee. I want to thank you for inviting me to speak to you today about the needs of the public health system and how we can improve our response to a bioterrorism attack. I am here today in my role as President of the Association of State and Territorial Health Officials (ASTHO). ASTHO is the national organization that represents public health agencies and the chief health officials in the country, the District of Columbia and the U.S. Territories. We are dedicated to formulating sound national public health policies and to assuring excellence in State-based public health practices.

For the past 5 months, the clarion call of health officials has been the need to improve the public health infrastructure. Today, I want to talk with you about the role that America's entrepreneurs, scientists and expert clinicians can play in enhancing the public health infrastructure to protect our Nation.

On October 2, a 63-year-old male presented to a Florida emergency department with fever and confusion. During the evaluation he was found to have a widened mediastinum and gram positive bacilli in his cerebral spinal fluid. Further testing revealed he had "inhalation anthrax." He died 3 days later.

This was the index case of an outbreak of anthrax caused by bioterrorism. At its conclusion, 18 people became ill and thousands were potentially exposed. Eventually, 11 cases of inhalation anthrax and seven cases of cutaneous anthrax were diagnosed. There were five deaths from inhalation anthrax. Over 33,000 people in several areas of the country required prophylactic antibiotics and a small subset elected to receive the anthrax vaccine as part of an investigational protocol for additional protection. Epidemiological and criminal legal investigations identified several letters filled with "weaponized" anthrax spores as the vectors of this attack.

Prior to this attack the Nation had experienced several anthrax hoaxes delivered through the mail. Many of these threats contained powdery substances, which were not infectious or toxic. Based upon this experience and the limited clinical understanding of the pathophysiology of anthrax, bioterrorism planners reached several conclusions that subsequently proved to be incorrect. Some of these beliefs included:

- Anthrax was easy to grow but hard to weaponize. This placed the emphasis on State-sponsored terrorism that then became the focus of our training and preparations. State sponsored was frequently interpreted as large-scale aerosolization.
- A letter had to be opened in order to expose people.
- Weaponized anthrax would stay put and exposure would be a local event. Therefore re-aerosolization probably would not occur.
- Cross contamination would not be a significant problem.
- Inhalation anthrax is 90 percent fatal.

These beliefs were challenged in our real world scenario and found to be untrue. In addition, the speed at which new knowledge was produced during this event was unparalleled and was utilized so quickly that keeping current was a major endeavor. This created a "science of the day" environment which was often confusing and suspect.

I believe there is an important lesson that we must utilize in order to develop and enhance our capacity to rapidly access, exchange and disseminate new knowledge and information. These capacities fall into the following three areas: learning new information; building linkages to scientific experts; and the ability to identify and validate new or existing technologies.

During the Anthrax investigations in October, State public health laboratories throughout the Nation tested thousands of samples of suspicious powder every day. In Maryland, for example, we tested over 2,000 powders, nasal swabs and clinical specimens. Our scientists were performing these tests for the first time. We also learned how to properly perform environmental testing. For example, we learned that cotton swabs are not as reliable as nylon swabs in detecting Anthrax spores.

Over the course of 3 weeks, the Maryland Department of Health and Mental Hygiene investigated eighty-five (85) suspected cases of Anthrax, including two deaths; tested thirty (30) private mailrooms for spores and opened clinics across the State to distribute antibiotics to individuals who were potentially exposed. At the conclusion of the event we had supplied Ciprofloxacin or Doxycycline to over three thousand (3,000) individuals as initial prophylaxis for potential anthrax exposure. Furthermore, we re-deployed staff from the tuberculosis program, the AIDS administration and the immunization clinics to handle more than one hundred (100) telephone calls a day to help with the surveillance investigation. The knowledge curve was steep and our resources were stretched to the limit. We shared this knowledge, as did others, with our public health partners across the country through a series of daily conference calls, e-mails and faxes.

While some medical personnel in the Midwest and the Southwest are familiar with cutaneous anthrax., very few physicians and medical practitioners in the Eastern United States have ever seen it. The clinical symptoms of the other potential bioterrorist threat agents such as smallpox, plague and tularemia are also unknown to many of today's practicing physicians. If we are to be successful we need access to the clinicians and scientists who have actually seen these diseases. It is not just a matter of early recognition but we need their clinical "pearls-of-wisdom" about the treatment and management of these diseases. Hands-on experience is an essential key to making truly informed public health decisions. The modern technology at our disposal today makes it easier to access the knowledge, skills and information experts possess.

The medical community responded during the Anthrax attacks with a thirst for new information. The public health system tried to quench that thirst by increasing our understanding of the diagnostic and therapeutic options and letting practitioners know where to call for administrative or clinical help. The goal was to raise the clinical index of suspicion across the Nation.

New systems are needed for the rapid dissemination of this knowledge to the practicing healthcare community. Systems under development include rapid fax, e-mail and beeper systems. Teleconferencing and videoconferencing were frequently utilized to share important information on both anthrax and smallpox, but we need to develop more of these of educational services for the full range of biological threat agents (36 in all). Computer education through the Internet can be used in the future as an additional tool.

On September 11, the Federal Centers for Disease Control and Prevention freely shared alerts and protocols with the public health community. For a variety of reasons, however, over time the information slowed to a trickle. The Health Alert Network—our nationwide communications information/training system—served as an essential tool in information sharing and even helped us clarify the appropriate role of the rapid screens used for environmental testing. This is an important example because at the height of the anthrax investigations, health department officials were being inundated with calls, e-mails, faxes and packages from vendors trying to sell "quick-detection-devices."

During the investigation, new linkages and relationships between a broad range of non-medical professionals such as environmentalist, disaster preparedness experts, fire and law enforcement officials and the medical professionals including emergency medical services personnel, occupational safety officials and "bioweaponeers" occurred. It is essential that these linkages are developed before a bioterrorist event occurs. Access to a core group of specialists in every State can be achieved by surveying the practicing community. There are a number of practitioners, scientists and researchers who have seen these threat agents in clinical settings. They should be identified now and asked to provide their expertise when an event occurs. In States like New York, New Jersey, Virginia and Maryland the medical and public health organizations are compiling databases of names, telephone numbers and e-mail addresses of experts for future reference.

Access to cutting edge research is also important. This past summer, researchers in Canada performed an experiment to demonstrate the impact of opening an envelope filled with a biological agent in a sealed room. The results of this study served as an important tool in our understanding of how anthrax spores contaminate an enclosed space. The knowledge gleamed from this study was also important in the debate surrounding post-exposure vaccination.

The need for new knowledge is not limited to the realm of bioterrorism. In the summer of 1997 in Maryland the public health community was challenged when fish with lesions began showing up in waters on Maryland's Eastern Shore. The need for information concerning a new and deadly fish disease became apparent immediately. In August of that year we not only faced the dilemma of fifty-thousand (50,000) dead and dying fish but we had to address the concerns of the watermen and fishermen who worked on those rivers. They were complaining about strange and unusual medical symptoms that defied explanation and were coupled with the belief that these symptoms were somehow related to the sick fish. We found ourselves in the midst of something completely new—pfiesteria piscida.

One of the most significant lessons learned during that time was how little information was known or available about the disease that up to that time had only been seen by a handful of people in North Carolina. The information was so scarce that the disease did not even have an official name. While we utilized our standard disease surveillance protocols to investigate and track reports of illness, our pool of information resources was limited to a small cadre of fish researchers in Florida and North Carolina who were not experts in human health. We discovered just how little information was available about pfiesteria.

As we started our quest to identify if these watermen could have a medical condition, it became clear we would have to find an expert in dinoflagelates, the family of organisms that includes pfiesteria. These organisms were poorly understood or unknown by most public health or medical professionals. Like most public health agencies, we utilize the U.S. Centers for Disease Control and Prevention for expert advice. In most cases you simply pick up the telephone to talk to a disease expert. In this case we called and no expert was on staff who could answer our questions. They did refer us an expert who had previously worked for the CDC. He is currently the Chairman of the Department of Epidemiology and Preventive Medicine at the University of Maryland School of Medicine. He put a team together and was able to find another expert on the other side of town at the Johns Hopkins School of Public Health. In essence, the expertise we needed was in our own backyard and we did not know it.

Related to the issue of accessibility of resources is assuring that the information, expert advice or technology is accurate and reliable. Every day I receive packets of brochures from companies, experts, inventors and vendors who want to demonstrate their products. They range from environmental testing equipment, gas masks and biohazard suits to gadgets that allegedly detect bioagents in the air. We must know if these products are legitimate and we must be able to verify that equipment is appropriate for use in the healthcare setting.

In closing, I want to emphasize how well the public health system responded to the events of September 11th and the anthrax bioterrorism attacks. Our current system was stretched to the limit but we were able to mobilize quickly to address these public health threats. But these events were an eye-opener. We have discovered how much more we need to do to be effective and successful. We must increase the pools of resources so that credible information, reliable equipment and knowledgeable experts are available at a moment's notice.

Thank you again for giving me this opportunity to speak to you today.

Senator WYDEN. Thank you.

Mr. Edwards, welcome.

STATEMENT OF MR. JOHN G. EDWARDS, PRESIDENT AND CEO, PHOTONIC SENSOR

Mr. EDWARDS. Good morning, Mr. Chairman and Members of this Subcommittee. Thank you for inviting me to testify. I appreciate the opportunity to provide a perspective on how entrepreneurs and the government can work together in fighting against bioterrorism. I am President and Chief Executive Officer of Photonic Sensor. Photonic Sensor is a small, high tech company based in Atlanta, Georgia. We develop and manufacture biological and chemical sensing systems based on this tiny chip that I am holding in my hand.

What I would like to share with you briefly this morning is the promise of this extraordinary chip as a part of the bioterrorism defense arsenal and how a combination of university scientists, entrepreneurial spirit, and government support led to its development. The creative spark came from Nile Hartman and his coworkers at the Georgia Institute of Technology almost a decade ago.

The potential of their optical sensor that revolutionized biological and chemical sensing was immediately evident. Sadly, there is often a disconnect between what is exciting for science and what is exciting for business. Revolutionary technologies mean major changes in the way things are done. Major changes mean big risk, and big risks scare big companies. They have too much to lose. That is where entrepreneurs enter the picture.

Photonic Sensor was formed in collaboration with, and eventually spun out of, Georgia Tech solely for the purpose of commercializing this optical sensor chip. Startup companies are very different from big companies. We like big risks. The bigger the risk, the better our

chances of eventually growing into a risk-averse big company, which is, after all, what we want to do.

Without early big company interest, small high tech companies must turn in other directions for support. The Department of Energy, the Department of Defense, and especially the National Institutes of Health have been major sources of support and guidance in bringing our optical sensorship from laboratory promise to commercial reality. The development path was long and winding, but the outcome was the successful emergence of a developed technology with a risk reduced to a level where big companies are now willing to get involved.

It turns out that our optical chip has considerable advantages for detecting biowarfare agents such as anthrax, botulism, and smallpox. Current biodetection instruments, even the advanced instruments under development for the military, are very complex and costly. They are simply not practical for widespread domestic deployment. A place we see a particular chance to help is with so-called first responders—fire departments, police and medical alert teams in towns from Eugene, Oregon, to Albany, Georgia. Photonic Sensor can provide a simple, low-cost tool to meet the needs of these first responders.

Photonic Sensor's work on bio agent detection began about a year-and-a-half ago, but the urgency has obviously accelerated since September 11. We are now responding to calls from the Department of Defense Technical Support Working Group and the National Institutes of Health for innovative antiterrorism tools. Our partners in these efforts are the Environmental Technologies Group of Baltimore, Maryland, a leading supplier of biological and chemical agent detection systems—and I should add, a very big company—and the Centers for Disease Control and Prevention, our neighbor and frequent collaborator. In addition, Photonic Sensor Environmental Technologies and D.A. Technologies of New York are exploring the development of a bio agent monitoring system for the New York City subway.

Thanks to previous government supports, Photonic Sensor is in a position where it can contribute to the fight against bioterrorism. However, I know this Subcommittee is interested in how it can make the process easier for us and others like us.

I would like to offer two observations about our experience. First, it is difficult for small companies like Photonic Sensor to get visibility within large agencies like the Department of Defense. Good contacts are just as important as good technology. However, a small marketing budget and no staff in Washington severely limits our ability to develop good government contacts. These Small Business Innovator Research, or SBIR program, addresses this problem to some extent, but even the SBIR process is something of a shot in the dark, and its multiphase solicitation proposal review and award cycle can easily outstretch the financial staying power of a small company.

A second challenge is the many compliance and reporting requirements that come with government grants, especially with multiple agencies. Each imposing their own rules and regulations. Particularly frustrating for Photonic Sensor has been the seemingly redundant financial audits by each agency, and even being told in

the course of these audits that a required financial practice of one agency is absolutely unallowed for another.

Photonic Sensor's story is, of course, just one of many. Nevertheless, I hope it has been helpful. Thank you for your interest.

[The prepared statement of Mr. Edwards follows:]

PREPARED STATEMENT OF JOHN G. EDWARDS, PRESIDENT & CHIEF EXECUTIVE OFFICER, PHOTONIC SENSOR

Good morning Mr. Chairman and Members of the Subcommittee. Thank you for inviting me to testify today. I appreciate the opportunity to provide a perspective on how entrepreneurs and the government can work together in the fight against bioterrorism.

My name is John Edwards, and I am President and Chief Executive Officer of Photonic Sensor. Photonic Sensor is a small, high tech company based in Atlanta, Georgia. We develop and manufacture biological and chemical sensing systems based on the tiny optical sensor chip I am holding in my hand. What I would like to share with you briefly this morning is the promise of this extraordinary optical chip as a tool in our bioterrorism defense arsenal, and how a combination of university scientists, entrepreneurial spirit and government support led to its development.

The creative spark came from Nile Hartman and his coworkers at the Georgia Institute of Technology almost a decade ago. The potential of their optical sensor chip to revolutionize biological and chemical sensing was immediately evident. Sadly, there is often a disconnect between what is exciting for science and what is exciting for business. Revolutionary technologies mean major changes in the way things are done. But major changes mean big risks, and big risks scare big companies: they have too much to lose. That is where entrepreneurs enter the picture. Photonic Sensor was formed in collaboration with and eventually spun out of Georgia Tech solely for the purpose of commercializing this optical sensor chip. Startup companies are very different from big companies. We like big risks. The bigger the risk, the better our chances of eventually growing into a risk-averse big company, which is what we really want to be.

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Small Business Innovative Research (or SBIR) program addresses this problem to some extent. But even the SBIR process is something of a shot in the dark, and its multi-phase solicitation, proposal, review and award cycle can easily out-stretch the financial staying power of a small company.

A second challenge is the many compliance and reporting requirements that come with government grants, especially with multiple agencies each imposing their own rules and regulations. Particularly frustrating for Photonic Sensor has been the seemingly redundant financial audits by each agency—and even being told in the course of these audits that a required financial practice of one agency is absolutely unallowable for another!

Photonic Sensor's story is, of course, just one of many. Nevertheless, I hope it has been helpful. Thank you for your interest.

Senator WYDEN. Dr. Hatchett.

STATEMENT OF DR. RICHARD J. HATCHETT, M.D., COORDINATOR, CIVILIAN MEDICAL RESERVE WORKING GROUP, CLINICAL ASSISTANT ATTENDING, MEMORIAL HOSPITAL, MEMORIAL SLOAN-KETTERING CANCER CENTER

Dr. HATCHETT. Good morning, Mr. Chairman. First, I would like to commend and fully support your efforts to establish a strategic technology reserve. It feeds very clearly into the sorts of things we have been working on. I would like to thank you for inviting me to appear before you to discuss the ways that the coordination of medical professionals can enhance the ability of our Nation's communities to respond to acts of bioterrorism.

I served as one of the coordinators of the medical volunteers after the attacks on the World Trade Center, and I am currently coordinating the Civilian Medical Reserve Working Group, which is a citizens' initiative of medical professionals and public health professionals advocating the creation of a Medical Reserve Corps. Last week, President Bush endorsed the creation of Medical Reserve Corps as part of his USA Freedom Corps initiative. The Medical Reserve Corps is currently a division that will consist of retired or inactive doctors, nurses, and allied health professionals organized at the local level and integrated into local emergency response plans.

Reservists will be trained as first responders, and capable of setting up field and triage sites to assist uniformed personnel and thereby decompress existing facilities in the event of mass casualties, but their key function will actually be as reserve personnel capable of being integrated into hospitals and clinics and public health systems during events that place stress on such systems. These events may be natural, such as severe epidemics or natural disasters, or they might develop after attacks with weapons of mass destruction.

Local units of the reserve will be flexible and adaptable and the service will be as capable of manning field triage sites as staffing, vaccination, and antibiotic distribution points, and as ready to work in community hospitals as deliver care to patients in their homes if the need arises.

I would like to say a few words on the subject of emergency preparedness. I think everyone in this room is aware we are not sufficiently prepared to respond to acts of bioterrorism or for attacks of weapons of mass destruction. Our hospitals are inelastic, our public health systems are not robust, our first responders need more training and more equipment. Article 3 of Frist-Kennedy, mobi-

lizing over $1 billion to improve bioterrorism, is a positive step, as is the President's request, announced yesterday, to dedicate $5.9 billion in the next fiscal year to finance improvements in the Nation's public health system.

The expansion of the national pharmaceutical stockpile, and the dedication of nearly $2 billion to the National Institutes of Health basically speak of the Administration's commitment to this endeavor, and we commend these efforts as well. We are definitely moving in the right direction.

At the same time, one of the things we want to remind the Subcommittee is that we cannot neglect the resources we already have, the assets that are already available. Merely having assets do not make them useful. The value of assets are not fixed. Assets become useful and they become valuable when they are organized, with structures to fix them in relation to each other.

Hernando de Soto, the Peruvian political economist, has pointed out the poor of the world's developing nations actually possess assets, but these assets, because they have not been included in formal property systems, have not been capitalized and thus cannot interact with each other. I think much the same can be said for our medical and public health assets.

The mitigation of acts of bioterrorism can be viewed broadly as a problem of resource allocation under budget constraints. No community in America will ever develop the capacity to take care of 20,000 extra patients. I think that it is unrealistic to expect them to do so. Preparedness will not mean having beds waiting in reserve on empty wards, but it will mean being able to quickly reorganize the assets at hand and maximize their utility.

This will mean, in the first place, knowing what assets exist. We have advocated actually the creation in every community of a medical registry, a census of the total available medical assets, including doctors and nurses and pharmacists, but also retired and otherwise inactive professionals, including hospital beds, but also decommissioned wards, potential auxiliary facilities, and including such things as quarantine facilities, staging areas, evacuation routes, and supply depots.

Knowing what we have will improve our capacity to use it, and it will also let us make the hard choices that may need to be made with as much confidence as we can muster. President Bush's Freedom Corps initiative creates a Medical Reserve Corps, and it also mobilizes AmeriCorp's Senior Corps and Serve Study volunteers in the cause of homeland security. Many of these volunteers will be devoted to projects related to public health and bioterrorism preparedness. The number of such volunteers called to service will be substantial, perhaps as many as 100,000. In bringing such a large force to bear on the problems that now confront us, we should not let the opportunity to create a cohesive and organized force slip from our hands.

I see little reason the Medical Reserve Corps and Community Emergency Response Teams and other volunteers should not be brought together under one overarching structure as a true Civilian Medical Reserve. Over time and training and drilling together and participating in team-building activities such a Civilian Medical Reserve would become a truly formidable force ready to serve

our country in a crisis and be the backbone of a sustained response in more prolonged events.

[The prepared statement of Dr. Hatchett follows:]

PREPARED STATEMENT OF RICHARD J. HATCHETT, M.D., COORDINATOR, CIVILIAN MEDICAL RESERVE WORKING GROUP, CLINICAL ASSISTANT ATTENDING, MEMORIAL HOSPITAL, MEMORIAL SLOAN-KETTERING CANCER CENTER

Mr. Chairman, Distinguished Members of the Committee: Thank you for inviting me to appear before you to discuss the ways that medical professionals and voluntary organizations in the private sector can contribute to the war against bioterrorism. My name is Richard Hatchett. I am an Emergency Room physician at Memorial Hospital in New York City and coordinated the efforts of medical volunteers at the Stuyvesant Triage Center in the days after the attacks on the World Trade Center. In 1997 I served as Clinical Coordinator of the Yale University Ebola Project in Makokou, Gabon and I recently coauthored a privately circulated white paper on smallpox with Professor Jacob T. Schwartz of New York University. Over the last 4 months, I have served as the coordinator of the Civilian Medical Reserve Working Group, a citizens' initiative advocating the creation of a Medical Reserve Corps to enhance the capacity of local communities to respond effectively to epidemics, acts of terrorism, and natural catastrophes. Last Wednesday, in an Executive Order, President Bush endorsed our effort by calling for the creation of a Medical Reserve Corps as one component of his USA Freedom Corps initiative.

I called the first meeting of what became the Civilian Medical Reserve Working Group within a couple of weeks of the attacks. The efforts of volunteers after the events of September 11 were characterized by intense camaraderie, and the dedication, endurance, and integrity of the volunteers was awe-inspiring. In terms of human capital, one could ask for nothing more: the doctors and nurses, medical students and residents who converged on Ground Zero were hard-working, intelligent, independent, and used to taking responsibility for their actions. Where their efforts were well coordinated they performed almost miraculously. The problem was that because the response was spontaneous, in most cases the efforts of the volunteers were *not* well coordinated.

From an operational point of view, the spontaneous flocking of medical volunteers to Ground Zero highlighted the problems associated with an uncoordinated response. Dr. Antonio Dajer, the Associate Medical Director of the Emergency Department at NYU Downtown Hospital, an institution located four blocks from Ground Zero, has written eloquently of his frustration at finding "trauma triage areas" run by volunteers set up on the street within a few blocks of his fully equipped emergency room. The triage areas that were set up operated independently, outside the New York City Office of Emergency Management's Incident Command Structure and with no overall system of coordination. The chains of command governing such sites were thus ambiguous or non-existent. Several operated in areas that had not been cleared by structural engineers. The lack of coordination also meant that there was no functional system of communication or supply, even for the "approved" triage facility at Stuyvesant High School, and no way to assure continuity of staffing. The credentials of volunteers could not be verified, and security was compromised by the continual flow of self-declared "volunteers" across the established police perimeter. Finally, hospitals throughout the city reported significant concerns that their own staffing would be compromised because their employees were "helping out" at Ground Zero.

It was to explore ways to address these problems while harnessing the extraordinary talents of civilian medical professionals that we convened what became the Civilian Medical Reserve Working Group. As mentioned above, we gathered for the first time before the end of September—which is to say, before anthrax was distributed through the United States Mail. We had considered abstractly whether an organization such as we envisioned might prove useful in the event of biological or chemical attack; the anthrax episodes convinced us that it would. One of my colleagues, Eric David, participated as a volunteer in the distribution of antibiotics at the Morgan postal facility and witnessed firsthand the difficulty of educating and dispensing antibiotics to large numbers of anxious employees of varying educational backgrounds and degrees of sophistication. Ed Carubis of the New York City Department of Health notes that the evaluation of a single case of anthrax at Manhattan Eye, Ear, and Throat Hospital required setting up 12 registration stations to process worried patients and employees (personal communication). In more widespread outbreaks, the need to ramp up and create field stations for epidemiologic

interviews, sample collection, and distribution of antibiotics or vaccines would rapidly overwhelm even the most robust Departments of Health.

While causing only 23 infections and 5 deaths, the anthrax attacks did in fact place a severe strain on the American government and public health system. Activities of all branches of the Federal Government were disrupted, approximately 300 postal and other facilities were tested for the presence of anthrax spores, and approximately 32,000 persons initiated antimicrobial prophylaxis following potential exposure to *B. anthracis* at workplaces in Florida, New Jersey, New York, and Washington, D.C. The November 9 *Morbidity and Mortality Weekly Report,* reported that "For the week of October 21-27, Colorado, Connecticut, Louisiana, Maryland, Montana, North Dakota, Tennessee, Wisconsin, and Wyoming reported 2,817 bioterrorism-related calls (mean per State: 313; range: 23-800) and approximately 25 investigations of bioterrorism threats in each State. From eight to 30 full-time personnel are engaged in these responses in each State . . . For the same period, public health laboratories in 46 States participating in the Laboratory Response Network reported receiving approximately 7,500 specimens and isolates for *B. anthracis* testing." The obvious lesson is that even limited attacks can cause major disruption.

Biological weapons are agents of terror. In this regard, they succeed so well precisely because they are so insidious. They exert a profound multiplier effect, creating a vast number of "worried well" patients, many of whom will crowd medical facilities seeking treatment or reassurance. Because infections with anthrax share many clinical features with those of influenza, and the threat of anthrax emerged just as the flu season was getting under way, this effect was exacerbated, so that many patients who ordinarily would have been diagnosed with flu or an unspecified viral syndrome received Cipro or other antibiotics "just in case." The anthrax episodes precipitated a public health crisis; what they did not do was precipitate a crisis in the Nation's hospitals. With a different mechanism of distribution and larger quantities of spores, the situation could have been quite different. The release of a few grams of highly refined spores in a crowded stadium or into a subway station at rush hour could conceivably produce hundreds or thousands of victims, many of whom would be critically ill, within a few days. These victims would present to local emergency rooms and be admitted to local hospitals; and it might be days before anthrax was identified as the causative agent.[1] Very large cities, such as New York, might be able to handle the surge of patients; smaller cities would surely be swamped.

For a variety of reasons, it is difficult to estimate the true capacity of hospital systems. For one reason, the systems are seldom if ever tested. September 11 might be regarded as a full test of the New York City hospital system, which contains more than 100 hospitals. Most hospitals within the city cleared their emergency rooms, created extra emergency room capacity by adding beds, electively discharged or transferred patients to more distant facilities, and canceled elective operative procedures. Because of the violence of the collapses, however, most people who survived and were injured qualified as "walking wounded" and did not require admission. The emergency departments of the four hospitals closest to the World Trade Center and another hospital serving as a burn referral center reported treating 1103 survivors in the first 48 hours after the attack, but of this number only 181 (16 percent) required admission (data from *Morbidity and Mortality Weekly Report,* January 11, 2002). NYU Downtown Hospital treated in excess of 400 patients between 9 a.m. and 1 p.m. and cleared its emergency room by early afternoon (Antonio Dajer, personal communication). No formal assessment of the actual admitting capacity of New York City hospitals on September 11 has been performed, but based on information collected by the Greater New York Hospital Association from a number of hospitals it is possible to extrapolate that the system possibly could have absorbed about 3000 patients. How many critically injured patients requiring mechanical ventilation the system could have absorbed is unknown. By comparison, in testimony before the U.S. Senate Governmental Affairs Subcommittee on International Security, Proliferation and Federal Services on July 23 of last year, Dr. Tara O'Toole reported that the State of Maryland, home to more than 60 hospitals and two academic medical centers, would be unable to handle an emergency that produced 100 patients needing ventilators.

The United States health care system is fiercely competitive and notoriously inelastic. Hospitals are under tremendous financial pressure, with thin and falling margins forcing many to decommission beds and switch to "just-in-time" models of staffing and supply. An aging population and reduced lengths of stay mean that the beds that are available are filled by older and sicker patients, who require compara-

[1] Although this seems unlikely, given the currently heightened awareness among physicians about the disease and its manifestations.

tively more attention. My hospital, for example, has reduced its bedspace by approximately 20 percent over the last few years and reconfigured several of the floors thus emptied. This means that only a portion of the decommissioned beds can be brought back into service in any reasonable timeframe. A slight surge in hospital admissions 2 weeks ago left 17 sick cancer patients requiring admission sleeping in the Urgent Care Center, which itself contains only 12 beds, overnight. It took until about 3 p.m. the following day for beds to be found for all of these patients. One can imagine, then, the crises that would develop should a real and sustained surge in patients occur.

The dynamics of an attack with a contagious agent such as plague or smallpox would be quite different from even large-scale attacks with noncontagious agents such as anthrax or botulinum toxin. The effect of such an attack would not be an outbreak, as with the latter agents, but an epidemic. And epidemics, once they pass a certain critical threshold, are difficult to control, contain, or predict. The scope of the epidemic might accelerate for weeks and not peak for several months. Depending on the agent used, patients might require respiratory isolation and need to be admitted to specially vented rooms, which (it goes almost without saying) are in extremely short supply. Depending on the size of the epidemic, and to some extent on the virulence of the causative organism, it might be necessary to convert schools, gymnasiums, hotels, or armories into auxiliary facilities or quarantine stations. It might even be necessary, as was the case during the Spanish Influenza epidemic in the fall and winter of 1918, to switch over to a system of home care.

And the issue of bedspace may, in fact, pale beside the issue of staffing. Tara O'Toole has argued that "The big problem is not beds as everyone seems to suppose—it is staff. And there is no way to fix that in the short term." Staffing shortfalls may be exacerbated by the fear and flight of persons inadequately trained in the management of infectious diseases and other illnesses related to biological or chemical terrorism. Such staffing shortages would undoubtedly be particularly acute in the event of an outbreak sufficiently large to require the opening of auxiliary facilities or switching to a system of home care.

This was the complex bundle of problems we set out to address. The model we have evolved for a Civilian Medical Reserve incorporates the Medical Reserve Corps as an essential element but also relies on the dedicated work of AmeriCorps and other volunteers. It requires the creation of a medical registry, the purpose of which is to enumerate and incorporate in community-wide planning what we have called "hidden" human and institutional assets. It also requires tight integration and coordination of the Medical Reserve Corps into local emergency response planning and anticipates the development of certain information technology assets and capabilities. In the sections that follow I will attempt to lay out a blueprint of what we believe an adequately structured and sufficiently funded Civilian Medical Reserve can accomplish.

THE ROLE OF THE MEDICAL RESERVE CORPS[2]

The Medical Reserve Corps will consist of physicians, nurses, and supporting personnel who coordinate and work with the other elements of the Metropolitan Medical Response System. The Medical Reserve Corps will be led by doctors, nurses, and other medical professionals who receive special training in disaster medical response, the theory and practice of triage, biocontainment, and other relevant disciplines. As part of our proposed Civilian Medical Reserve, they would be assisted by a substantial group of civilian volunteers drawn from outside the medical profession and trained within the Medical Reserve itself. Local units of the Medical Reserve Corps will be pre-equipped and coordinated with existing municipal disaster plans, so that in the event of a major structural disaster they can be activated and establish field triage sites within three to 6 hours. They will also provide back-up in the event of major public health crises (particularly bioterrorist attacks) placing unusual demands on the medical system and be trained to detect and manage the agents of concern in such situations (e.g. anthrax, smallpox, plague, tularemia, viral hemorrhagic fevers, etc.).[3] They will augment the efforts of public health authorities

[2] In the sections that follow, "Medical Reserve Corps" refers specifically to the voluntary organization created within the USA Freedom Corps to recruit and train retired or otherwise inactive healthcare professionals as an emergency preparedness initiative. "Civilian Medical Reserve" refers to a larger initiative in which the Medical Reserve Corps would work in conjunction with AmeriCorps, Senior Corps, and Federal Work Study Program volunteers and be charged with a wide range of tasks relating to biopreparedness.

[3] Advance training and drilling considerably reduces the anxiety associated with caring for patients with frightening infectious agents, and specially trained teams could deploy to hospitals caring for patients with diseases such as Marburg or Ebola fevers.

in administering vaccines and performing epidemiologic investigative work during outbreak situations or bioterrorism events, and they can assist with non-emergent, large-scale community medical projects during "peacetime".

Designing the Medical Reserve Corps so that it remains flexible and adaptable is essential. The Medical Reserve Corps must be capable of responding to both mass casualty incidents and evolving crises. With mass casualty incidents, local coordination is crucial. Studies of mortality patterns in earthquakes consistently demonstrate that response time is pivotal, that 25 to 50 percent of those who are injured and die slowly could have been saved if first aid had been rendered immediately, and that the greatest demand for patient care occurs during the first 24 to 48 hours after the disaster. Thus, the most critical needs of an affected population must be met by local providers. So must the needs of a community grappling with a severe epidemic or the consequences of a bioterrorist attack. We believe the development of locally coordinated and potentially mobile medical reserve units can play a role in enhancing the State's preparedness to deal with such situations.

In the immediate aftermath of a disaster, the responsibilities of reservists might include triaging patients, providing essential medical care, and preparing patients for evacuation to local hospitals. In the twenty-four to seventy-two hours after a disaster, their role will likely shift to providing frontline support to search-and-rescue workers. In evolving crises triggered by bioterrorist attacks or severe epidemics their role in supporting overtaxed medical systems would be equally important. The establishment of mutual aid arrangements with Reserves in nearby cities will create a mechanism whereby care can be expanded into auxiliary facilities or provided in patients' homes as the need arises.

Given recent events, we strongly believe that the general medical community will find the concept of the Medical Reserve Corps extremely attractive and that such an organization will have no difficulty attracting volunteers. The Medical Reserve Corps will provide for the special training and continuing education of its members and enable the State to identify and coordinate those physicians and other medical professionals with special experience and expertise. A properly trained and coordinated Medical Reserve Corps will be ready to meet the needs of our communities in acute crises and to provide the backbone of a sustained response in prolonged ones.

IDENTIFYING HIDDEN ASSETS

One of the major activities of local units of the Civilian Medical Reserve will be the creation and maintenance of comprehensive medical registries in the communities they serve. These registries will include but not be limited to practicing professionals and existing institutions. Perhaps the best reason to create such a registry, in fact, is to identify "hidden" human and institutional assets. By enumerating these assets, the registry will permit emergency planners to put together a census of the "total available medical assets" within a given community. The ways in which such information can then be used to facilitate planning and enhance preparedness are discussed at greater length below.

The idea of accounting for hidden assets evolved from an event on September 11. Dr. Mark Robson, a breast oncologist at Memorial Hospital and a man who gives chemotherapy for a living, called me to see if he could assist in preparing the Urgent Care Center to receive patients. He explained that prior to joining the staff at Memorial he had served in the military and received training in triage and mass casualty response. Subsequently we realized that in any community there must be many physicians with special skills or relevant prior experience not reflected in their practice designations. Such experiences include but are not limited to military service, work in refugee camps or other austere environments, involvement with medical relief efforts in complex humanitarian emergencies, and prior employment in emergency rooms. This realization made us ponder other ways in which available but untapped medical expertise might be hidden or buried. Other hidden human assets we have identified include:

- Retired medical professionals.
- Persons with prior medical training and licensure who no longer practice (because they are administrators, entrepreneurs, scientists or consultants).
- Medical professionals who work outside of traditional hospital settings (in community health centers, visiting nurse practices, etc.)
- Medical and nursing students.

Registration with the Civilian Medical Reserve will create a mechanism for calling such persons into the hospital system in the event of a severe crisis, and persons with special skills or prior experiences can be deployed where and as needed. We

believe finding and registering such personnel represents a quick and exceedingly cheap way to enhance local response capacity.

As there are hidden human assets, so also are there hidden institutional assets. The first step would be to assess a community's existing resources in terms of beds, isolation facilities, and critical care capacity. The Reserve would then assess the extra capacity provided by community health centers, post-anesthesia care units (which can provide intensive care), decommissioned but restorable clinics and wards, and potential auxiliary facilities such as schools, gymnasiums, and armories. This information would be useful in elaborating community-wide plans, assessing gaps in current levels of preparedness, and identifying thresholds at which mutual aid arrangements would need to be activated, auxiliary facilities opened, home care provided, and responsibilities devolved (from physicians to nurses, medical students, etc.).

The administrative work of establishing and maintaining the medical registries would be performed by AmeriCorps or Federal Work Study Program volunteers under the supervision of the Medical Reserve Corps' full-time medical staff.

THE ROLE OF OTHER USA FREEDOM CORPS PROGRAMS AND VOLUNTEERS

The President, in his Call to Service, has recognized and called upon the industry, goodwill, and commitment of the American public in this time of national need. By creating the USA Freedom Corps Council and naming John Bridgeland to head the affiliated office within the White House, President Bush has signalled his faith in the capacity of normal citizens to contribute in areas related to national security and domestic defense and demonstrated his strong personal commitment to this endeavor. By calling for the expansion of AmeriCorps, Senior Corps, and Serve Study programs, he has dedicated his Administration to mobilizing a vast number of citizens in this effort. By establishing Citizen Corps and the Citizen Corps Councils, he has created a mechanism of coordinating these efforts in the interest of homeland security. And by asking Congress for more than $500 million in Fiscal Year 2003 to support these initiatives, he has called for the funds needed to transform this vision into reality.

The Citizen Corps Councils have been tasked with developing community action plans that include assessments of infrastructure vulnerabilities and possible threats, available local resources, and the best ways to organize and expand local efforts. These plans will coordinate the community-based prevention and preparedness efforts of the programs falling under the mantle of the Citizen Corps (Medical Reserve Corps, Volunteers in Police Service, Neighborhood Watch, Community Emergency Response Teams, etc.). FEMA will provide $144 million in matching funds in Fiscal Year 2003 to help create and maintain the efforts of the Councils. I would urge the local Councils to allocate a portion of this funding to censusing available medical assets in the manner described above, and to make performing such censuses a very high priority. The resulting registries could then be maintained by AmeriCorps or Federal Work Study Program volunteers working in conjunction with local emergency offices and Departments of Health and under the supervision of the Medical Reserve Corps' full-time medical staff.

Coordinating the response to and remediation of acts of bioterrorism poses considerable technical and logistical challenges. One of the biggest obstacles is that the groups whose activities must be coordinated (EMS and other first responder services, Departments of Health, hospitals) function autonomously in their day-to-day activities and historically have not forged strong links with each other. A Civilian Medical Reserve has the potential to become a nexus connecting these groups and promoting the formation of enduring institutional alliances. Municipalities implementing the Civilian Medical Reserve model would coordinate the Medical Reserve Corps and Community Emergency Response Teams with AmeriCorps, Senior Corps, and Serve Study volunteers engaged in public health and disaster preparedness and relief programs. Volunteers would interact on a regular basis, to foster team building and esprit de corps, and participate in drills and exercises together. These activities would lay the groundwork for a broad-based but coordinated civilian response in times of crisis.

President Bush and Senators McCain and Bayh have called for an expansion of the AmeriCorps National Civilian Community Corps program to support homeland security, public health, and disaster preparedness and relief activities. I would urge that some of these new recruits be specifically assigned to Civilian Medical Reserve units to provide administrative and other support to members of the full-time medical staff. A large fraction of the AmeriCorps volunteers thus assigned would, when not otherwise engaged, be detailed to local hospitals to help implement hospital pre-

paredness plans and foster the development of interhospital communication and coordination.

A Civilian Medical Reserve unit would consist of a small full-time medical staff, the Medical Reserve Corps, and non-medical staff. The non-medical staff would engage in training and self-organization activities and have the following responsibilities when mobilized during disasters or other public health crises:

- Providing general assistance to physicians and nurses.
- Transporting patients and handling supplies.
- Tracking patients and maintaining medical records.
- Maintaining communication and supply networks.
- Providing security.
- Performing situational tasks appropriate to their level of training.

Under normal circumstances, the non-medical staff would have the following functions:

- Developing communication and database systems.
- Developing and distributing training materials.
- Contingency planning.
- Nurturing alliances with private voluntary organizations.
- Exchanging solutions with other Civilian Medical Reserve units.
- Creating and maintaining the medical registry.
- Assisting local authorities in their efforts to foster communication and coordination between hospitals and implement hospital preparedness plans.

The problems of designing and implementing Civilian Medical Reserve structures will vary from community to community, depending on what human and institutional assets are available and how these are organized and configured. A solution that works in Boston may not be relevant in Buffalo and almost certainly will not be applicable to Binghamton. Creating a central clearinghouse to which local Citizen Corps Councils can refer for guidance and inspiration would permit communities the freedom to develop solutions appropriate to their needs and resources while allowing them to profit from each other's experience.

THE ROLE OF OTHER VOLUNTARY ORGANIZATIONS

Volunteers provided many critical services in the days after the attacks on the World Trade Center, from transporting workers and supplies from staging areas to Ground Zero to providing food and comfort to uniformed personnel and assisting in search and rescue efforts. Existing and spontaneously evolving voluntary organizations usefully channeled the outpouring of public support and provided their members with the ancillary, but by no means negligible, benefit of being able to do something. The emotional devastation of the attacks was compounded for many by the frustration of having no meaningful way to respond. The desire to respond and demonstrate solidarity with the survivors and rescue workers explains the long queues at blood donation centers across the country, the tremendous and immediate charitable giving, and the formation of numerous new voluntary organizations.

One of the most interesting phenomena of the last few months has been the persistence of these spontanteously evolved organizations. Such organizations have emerged to meet specific local needs, from the provision of clothes and supplies to construction workers to the "staffing" of cheering points along the West Side Highway and advocacy of victims' rights. Not surprisingly, many of these organizations are highly adapted to the functions that define their purpose. They were able to respond (and respond rapidly) to events because of their lack of rigid structure. Collectively, they demonstrate the ingenuity and initiative of affected populations and represent a wonderful, bottom-up mechanism for addressing new and previously unrecognized societal needs.

Several of these new organizations address problems related to homeland security, and many of these are organized along disciplinary lines. Our Civilian Medical Reserve Working Group is but one of many examples. Andrew Rasiej, who has been involved with the effort to establish NET Guard, was instrumental in organizing Silicon Alley Cares, a consortium of about 1500 volunteers from New York City's information technology community. Sue Pinco, a social worker at Columbia, has put together a group called NYC-CAN that last week sponsored a weeklong "Training Institute for First Responders" with the goal of developing multidisciplinary crisis-response teams to address acute mental health care needs after future disasters. The needs that will arise after acts of bioterrorism will be complex and have consequences that extend beyond the domain of public health. Voluntary groups organized along disciplinary lines will give emergency management officials a way to mobilize otherwise widely distributed social assets.

Such initiatives, to be useful, however, must be coordinated and publicized. Ed Carubis, the Chief Information Officer of the New York City Department of Health, speaks of the acute need of his office for additional manpower during the anthrax crisis but was unaware that Silicon Alley Cares existed, and Silicon Alley Cares is not affiliated with the New York City chapter of VOAD (Voluntary Organizations Active in Disaster) or New York Cares, both of which coordinate requests for volunteers. Coordinating private philanthropic efforts related to homeland security and disaster mitigation is a function that the new Citizen Corps Councils may want to consider assuming.

INFORMATION TECHNOLOGY IN COMMUNITY-WIDE PLANNING

Finally, I would like to say a few words about the information technology needs that are likely to arise during severe epidemics or after acts of bioterrorism. This is a vast topic, obviously, so I will limit my remarks to how information technology can address certain logistical concerns. Our experience demonstrates that epidemics and acts of bioterrorism can profoundly stress local hospital and public health systems and that such events are dynamic processes. To respond to and mitigate the consequences of such events, then, we will need to capitalize on every asset at our disposal. And to do this, to allocate our resources effectively, what we will need first and foremost is reliable data. We must be able to detect unusual spikes in emergency room visits. Then, as the event unfolds, we will need to know where patients are presenting, which hospitals and emergency rooms are already overloaded, which hospitals need which supplies, and how to distribute supplies arriving from Federal reserves such as the National Pharmaceutical Stockpile.

We are making progress on the detection front. In part as a result of the West Nile Virus outbreak a few years ago, the New York City Department of Health has implemented a much lauded "syndromic surveillance" system. This system, which depends on cluster analysis and cluster modeling, produces spatial representations down to the census tract and ZIP code level of where events are happening. The data fed into the system has so far been based on EMS coding, with certain types of call (e.g., respiratory distress) being specially flagged. This system may soon expand to the hospitals, though. Thirty hospitals now participate in emergency room surveillance, submitting patients' chief complaints to the Department of Health within 12 hours of the patients' arrival (and often prior to their discharge). An additional benefit of this program is that it has opened up contact between the Department of Health and emergency rooms and hospitals and enhanced the information stream flowing between them. Syndromic surveillance has predicted the onset of the flu season well in advance of other techniques each of the last 3 years. In hospitals that depend on just-in-time staffing and supply, this kind of advance notice allows for smoother ramping up of resources.

There are also promising developments on the response and mitigation front. Dr. Eliot Lazar and colleagues working in the New York Presbyterian Hospital system (which contains about 30 hospitals), in conjunction with the New York State Department of Health, have tested a data acquisition system that allows for essentially real-time collection of information about the availability of hospital beds and inventory throughout the system. This system creates a common platform that theoretically could be used in all hospitals and that could interface with the vendor-managed inventory system employed by the National Pharmaceutical Stockpile. Such a system will greatly enhance the efficiency with which supplies collected at central staging points are distributed, and in an epidemic situation it could be used to route patients away from overtaxed facilities.

Geographic Information Systems (GIS), which encode data spatially and generate updatable maps, show great promise as a tool for responding to and mitigating bioterrorism attacks. GIS has often been employed in epidemiologic investigations and thus used represents a technological enhancement of traditional medical detective work. Because GIS has fast response capabilities and permits fast access to integrated layers of information, the potential uses of GIS in bioterrorism events are numerous. The great strength of GIS is that it has strong analytic capabilities and permits the powerful visualization of spatial data. For example, by geocoding environmental samples (e.g., powders suspected of containing anthrax) and looking at the pattern of positives, GIS may permit the development of more rational prophylaxis and remediation strategies. Geocoding patients as they arrive at points of distribution (POD) of antibiotics and vaccinations will allow for more reliable and efficient follow-up (patients living next door to each other, but presenting to different PODS will appear next to each other on a computerized map and can be visited by a single public health worker). GIS can also be used to develop emergency response plans by identifying the location of schools, medical centers, staging areas, and evac-

uations routes. Just before September 11, New York City's Office of Emergency Management implemented an Emergency Management Online Locator System (EMOLS), a Web-based application that allows New York City residents to enter an address and see the location of the nearest emergency shelter.[4] This application could theoretically be linked with the New York Presbyterian Hospital data acquisition system described above and allow EMS units (or even patients themselves) to avoid overcrowded hospitals and determine alternative routing. ESRI, the GIS industry leader, has developed wireless technology that allows uploading and downloading of data in the field and has great potential to enhance all of these capacities.

Such technologies must continue to be developed and tested. Once implemented, they must be widely distributed and tightly integrated with existing emergency management operations. In terms of bioterrorism preparedness, this is one of the main challenges that we as a Nation will face in the coming decade.

CONCLUSION

We can anticipate that if a significant bioterrorist attack occurs on United States soil, it will cause massive disruption and panic and that it will severely affect the operational tempo of government. Given budgetary constraints it is highly unlikely that hospitals will build in new reserve capacity, that public health departments will massively expand their laboratories and personnel rosters, and that vaccines to the agents of concern will be developed any time in the near future. To meet the threat of bioterrorism, we will have to maximally leverage existing resources, identify untapped assets, and rely on the goodwill, industry, and intelligence of civilian volunteers. We have a unique opportunity to do so, and the USA Freedom Corps demonstrates great promise. Let us capitalize on both.

Senator WYDEN. Thank you.

Dr. Klausner.

STATEMENT OF DR. RICHARD KLAUSNER, M.D., SENIOR FELLOW AND SPECIAL ADVISOR FOR COUNTER-TERRORISM, NATIONAL ACADEMY OF SCIENCES

Dr. KLAUSNER. Senator Wyden, Senator Rockefeller, it is good to be here for the first time in 7 years testifying in front of the Senate not as a Federal employee. I announced that I was stepping down from directing the National Cancer Institute on September 11, at about 9 a.m. Little did I know that within about 2 months I would agree to a request from the Executive Office of the President, particularly Jack Marburger and the National Academy of Sciences, to return to a type of public service, and that is to address some of the issues that are being raised at this table, and that is to report to the government, which I will tell you about as soon as possible, about ways to engage the multiple communities we call the science and technology communities in this country in order to best address, in this case, not just bioterrorism but, in fact, all aspects of terrorism. So my position now is Senior Fellow at the National Academy of Sciences and Liaison to the White House.

It is interesting, the National Academy of Sciences was set up by President Lincoln in the middle of the Civil War in order to provide advice that would be independent advice, and hopefully, objective advice to the government and to the Nation about science and technology and, in fact, I was very moved and pleased that the leadership in the White House again recognized that we are not going to be able to address in the way we want to the current threats and future threats that we might be able to predict and things that we

[4] Currently this application is dedicated to helping residents determine whether locations of interest fall within one of the city's Pedestrian and Vehicular Traffic Restriction Sectors. The EMOLS webpage is located at *http://www.nyc.gov/htmVoeni/html/emols/emols wtc.html.*

can predict without engaging the science and technology communities, who, I can tell you, are extremely committed to and enthusiastic for helping in what the Nation needs.

The National Academy is engaged in many activities which I will submit to you, but let me tell you about two. The major activity is to provide to the Executive Office of the President by June a road map and overall strategic plan for the government and for the Nation about how to mobilize the science and technology communities in the government, in academia, and the private sector about all aspects of terrorism, from the fixed infrastructure to nuclear radiologic, to chemical, to bio, to the transportation system, et cetera, for indeed, these systems overlap and interact with each other.

A bio attack in the context of disrupting communication or transportation, the fact that a bio attack can use a transportation system, the mail, in essence, demonstrates that one of the challenges is going to be to respond with science, with technology, with decisionmaking, with an intellectual base that does not and that cannot be constrained through the traditional silos of either our government agencies or either our traditional scientific disciplines, and I think that is abundantly clear in listening to the Photonics.

And so we will be presenting this report by the beginning of June, and at that point I will be delighted to come back to the Hill and brief this Subcommittee and others about these recommendations, but they will be recommendations aimed at specifically how the government needs to either structure or restructure itself for better communication, for better access to the scientific community, how to evaluate the thousands of technologies, how to set standards, how to engage individuals, how to identify expertise.

Along those lines, beginning in October we recognized that there was an immediate need, and so for the first time the academy set up basically an immediate response consultation service, where we have been linking Federal agencies to real-time consultation about critical issues such as decontamination, bioforensic, how to deal with new analytic problems.

We had a 1-day meeting with the U.S. Postal Service, out of which came the advice about different technologies that they may use. What we all saw in that was that in issues of homeland security the government is going to have to be able to avail itself of, evaluate and deal with science and technology advice, including the nonscience agencies that have never had experience with this. We are just beginning these experiments. We need to do more.

I know the hour is running late. Let me just raise a few issues. As I said, the challenges for the public health system, which I will not comment on, other than that it needs an enormous amount of support and rebuilding. It is not just the public health system, but it is also the medical and clinical response system, but what they are going to respond with will depend upon new tools, reliable information, a process that allows beforehand modeling, decisionmaking, red-teaming, as we have done for other aspects of national security, but which has not been done in this context.

I think those will be some of the issues we will be addressing in our report, but it is not just access to what is there now. We must recognize that we do not have all the knowledge now that we will

need in the future. We do not have all the technological capacities and capabilities we would like to have, and that is why we need a sustained commitment to science and technology.

Some of the challenges are, we have not been all that good, I can say this from running one of these science agencies, at connecting technology development, technology deployment with science. We need to address how we break down some of those silos, very important issues about how we connect the private sector, the academic sector, and the government sector, for a variety of reasons, not the least of which is that there may be many technologies, many approaches for the prevention and amelioration of bioterrorism that will not be driven by normal market forces.

We will need to create products for which there may be not markets in the normal sense, but markets that must be driven, I suspect, by the government recognizing national needs or potential national needs, and those are going to take new ways to think about how we engage the biologic research community, public-private academic, with the government in ways that we have not done before.

I will stop there, and I am pleased to answer any questions about what we are doing.

[The prepared statement of Dr. Klausner follows:]

PREPARED STATEMENT OF DR. RICHARD KLAUSNER, M.D., SENIOR FELLOW AND SPECIAL ADVISOR FOR COUNTER-TERRORISM, NATIONAL ACADEMY OF SCIENCES

Good morning Mr. Chairman and Members of the Committee. I am Dr. Richard Klausner, Senior Fellow at the National Academy of Sciences and Special Advisor to the Presidents for Counterterrorism. I am also Chair of the National Academies' Committee for Science and Technology (S&T) Agenda for Countering Terrorism. The Academies include the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The National Academy of Sciences was chartered by Congress in 1863 to advise the government on matters of science and technology. The National Research Council (NRC), the operating arm of the Academies, was established in 1916. The National Academy of Engineering was established in 1964. The Institute of Medicine was established in 1970. These institutions provide independent advice on science and technology and related policies for the Federal Government, including executive and legislative branches.

The National Academies began mobilizing the S&T community to address the threats presented by terrorism immediately after the horrific events of September 11. It assembled a distinguished group of scientists, engineers, health care professionals, industrialists and former high level government officials on September 26 to develop a series of initiatives which the Presidents, themselves, could immediately initiate from their own resources while government was mobilizing its own activity. Among the suggestions emerging from that meeting which have all now been initiated, were the following:

1. The development of an S&T agenda for addressing the comprehensive range of vulnerabilities our country faces extending over the next decade and how S&T can best respond to them; this work is being undertaken by a distinguished, eclectic committee which I co-chair with Professor Lewis Branscomb of the Kennedy School at Harvard. This work is being closely coordinated with the Office of Science and Technology Policy (OSTP) and, through that office, with the Office of Home Land Security. I shall provide some details of the committee's work subsequently;

2. Near-term technical assistance to the government through real time advice by scientific experts on topics panels chosen by the inter-agency Technical Support Working Group (TSWG) and, separately, by the U.S. Postal Service.

3. An intensification of international activities on both a bilateral and multi-lateral basis through a variety of institutional mechanisms. These include discussions with scientists in key countries on how to lessen the risk of proliferation of weapons of mass destruction under the auspices of the NAS Committee on International Safeguards and Arms Control. They also include multi-lateral academy-academy discussions under the Inter Academy Panel and Council and bilateral activities of

a wide variety of sorts, including discussions with national academies in Moslem countries.

5. Technical and policy work on bioterrorism under the broader, on-going activity on infectious diseases and vaccine policy, largely within the Institute of Medicine.

5. Workshop and studies on issues affecting universities arising out of Terrorism Events. Issues include student visa and tracking policies and systems and the management of biological research security in university laboratories.

In addition to the kinds of specific initiatives enumerated above, there have been a number of counter-terrorism activities related underway under the auspices of the more than 80 standing boards throughout the National Research Council. Some of these are activities and and studies were begun considerably before September 11, but they are even more timely because of the events of that day.[1] Others have been initiated since September 11th in response to agency requests.

I have attached a document, entitled "*Summary of Selected Counter-Terrorism Initiatives by the National Academies*," dated December 18, 2001, which summarizes the comprehensive scope of activities which have been initiated either by the Academy Presidents or by standing committees throughout the National Academies complex.

I wish to offer several perspectives on the role of science and technology as related to bioterrorism, as an example of broader application, in the time remaining.

It is clear to me that we cannot solve the comprehensive and daunting threat presented by bioterrorism without the active and sustained effort of the science and technology community. Indeed, the S&T community is ready and willing to respond. But how do we connect all the relevant S&T communities with the many requirements bio-terrorism presents at both the national and local level?

One part of the approach is embodied in the comprehensive S&T visioning project for combating terrorism I am co-chairing. This project is aimed at helping the Federal Government, and more specifically, the Executive Office of the President, to use effectively the Nation's and the world's scientific and technical community in a timely response to the threat of catastrophic terrorism. Under the sponsorship of the National Academies, a distinguished assembly of scientists and engineers will help the government develop a vision for how S&T can address the complex challenges presented by terrorism.

The project will undertake the following tasks to be presented in a report in 6 months: prepare a carefully delineated framework for the application of science and technology for countering terrorism, (2) develop a comprehensive threat-based agenda by which S&T can address challenges presented by terrorism to our security; (3) characterize cross-cutting issues, and (4) address implementation hurdles with recommendations for overcoming them.

The S&T vision and agenda will be developed in the following areas:

- Biological.
- Chemical.
- Nuclear and Radiological.
- Information technology.
- Transportation.
- Energy facilities, cities and fixed infrastructure.
- Behavioral, social and institutional issues.
- Systems cross-cutting issues.

We believe the work of this committee will provide the an integrated science and technology vision and program plan, extending over a decade, for combating terrorism. We know of no similar activity underway anywhere else. We believe it will be quite useful in helping the executive and legislative branches in allocating resources against the comprehensive threats presented by terrorism. After completion of our report in May, I would be happy to return to present the report's key findings and recommendations.

Parallel activities are underway to help connect the relevant S&T community with *immediate* technical requirements of Federal and local agencies. One is a project in which the Academies are inviting scientific experts to meet with government representatives in 1-day meetings to address how better to address near term requirements of Federal and local agencies. Although no written reports are produced and no formal Academy advice is provided, the dialog is beneficial to Federal agencies, including the 80 member, inter-agency Technical Support Working Group

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[1] Examples include the work by the IOM on anthrax vaccine policy for the military and the development of tools for evaluating the metropolitan medicine response system program. (See, Phase 1 Report, Frederick Manning, Lewis Goldfranks, Eds, Strategic Mechanisms for Improving OEP Analysis of Preparations for biological, Chemical, Radiological Terrorism, Washington, D.C.: National Academy Press, October 10, 2001.)

(TSWG) on counter-terrorism. In December, we invited scientific experts to engage in dialog with TSWG panels on bio/chemical forensics and bio/chemical decontamination. Another meeting is planned next month on through-structure imaging. Earlier, we met with U.S. Postal Service personnel to assist the service in evaluating radiation technologies to sanitize contaminated mail.

Within the Institute of Medicine (IOM), a number of public health strategies to address terrorist threats have been undertaken. The goal of this activity is to provide guidance on specific issues of national, local and individual concern, within the framework of a comprehensive strategy to assure the health of the public in the 21st Century. Projects include a comprehensive bioterrorism threat assessment. This assessment was initiated within the Forum on Emerging Infections. A November workshop, addressed "Biological Threats and Terrorism: How Prepared Are We?"

Other components of the IOM Strategy include communications, legal authorities, and vaccine policy components. The adequacy of surveillance systems and laboratory capacity are being addressed as well as the psychological consequences of terrorism and the long-term mental health consequences of asymmetric warfare. The IOM has already commenced the evaluation of the adequacy of local public health agencies and organizations to address the new bioterrorism threats with which they are confronted on top of the general spectrum of naturally occurring infectious diseases.

Many agencies throughout the government work with scientists within their respective domains. But the task for the Office of Home Land Security is to cut across all these domains and mobilize scientists for the new challenges presented by terrorism and to connect scientists working in relevant disciplines with the requirements presented by counter-terrorism over the long term.

We currently do not have adequate processes and structures in place to carry out the necessary connectivity not only among agencies but among the participants in the S&T enterprise: sponsoring agencies, users (both Federal and local), and the diffuse research community that must be mobilized to address terrorism.

There are three over-arching issues relating to bioterrorism that I believe require focused attention.

The first issue is to determine the ingredients necessary to mobilize all the relevant S&T communities to address the range of threats presented by bioterrorism. These threats include both the potential bio-terrorist weapons which exist today, e.g. smallpox, anthrax, botulism, as well as genetically modified organisms that can be made toxic and used as weapons. To engage the S&T communities fully will require effective communication of government needs and priorities as well as a sustained financial commitment by government to address these priorities.

The second issue is how do we solve specific bio-challenges, solutions to which may span the "silos" of existing disciplines, agencies and sectors. We must develop the necessary linkages between S&T, the private sector (a necessary partner for technology development), and the government, which is the most significant sources of resources for scientific research and development. We need to find ways to make the necessary linkages across the "silos" that exist presently in agencies, disciplines and sectors. Are the agencies funded in such a way today that they have sufficient incentives to ensure that they do come together for the purposes we now must urgently address across many agencies? Do government agencies have the tools to encourage participation of and partnering with the private sector? Can agencies mobilize communication and management strategies that will engage creative solutions from needed disciplines or across existing disciplines?

The third issue we must address is how the public and private sectors may more effectively partner to address bio threats at all stages of development: from research, through development, final product introduction and market penetration and wide use. The "products" are varied. They include drugs, vaccines, detectors and other items across the complete spectrum of prevention, detection, response, recovery and attribution. We realize that we need very large dose numbers of vaccines, anti-bacterials, anti-virals and mocrobial agents to protect the public and limit the spread of disease. Yet the "market," alone will not produce these in sufficient numbers and at the quality needed. The government will have to ensure that promising projects in priority areas can be shepherded through to a productive end point and made available for use of the appropriate Federal, State, county, local and public levels. This will require a reassessment of management tools and traditions as well as new infrastructure.

As the Council of the Institute of Medicine stated in its Statement on Vaccine Development, dated November 5, 2001:

The events following the tragedies of September 11, 2001, have reemphasized a serious defect in America's capacity to deal with biological agents used in terrorist attacks. The capacity to develop, produce, and store vaccines to deal with these agents are inadequate to meet the Nation's needs. In 1993 the Institute of Medicine

published *The Children's Vaccine Initiative: Achieving the Vision.* In assessing the national and international situation, the committee said, "because the private sector alone cannot sustain the costs and risks associated with the development of most CVI vaccines, and because the successful development of vaccines requires an integrated process, the committee recommends that an entity, tentatively called the National Vaccine Authority (NVA), be organized to advance the development, production, and procurement of new and improved vaccines of limited commercial potential but of global public health need." [2]

In a 1992 report, *Emerging Infections: Microbial threats to Health in the United States*, another IOM committee recommended the development of an integrated management structure within the Federal Government for acquiring vaccines, as well as a facility for developing and producing vaccines with government support.[3]

Evidence for the inability of the private sector to meet the country's needs for vaccines has accumulated substantially since the 1993 report. Fewer private companies are manufacturing vaccines. Continually needed vaccines such as the tetanus and influenza vaccines are in increasingly short supply. The availability of influenza vaccines has been delayed over the past several years and in 2000, one company stopped production. Pneumonococcal conjugate vaccine is unavailable in several States because of the sole source manufacturer's inability to meet demands. Only one source is currently available for meningococcal varicella and measles-mumps-rubella vaccines.

There are just four major vaccine manufacturers in the world today, and only two in the United States.[4] There were four times that number only 20 years ago. There are many small new research and development companies backed by venture capital and devoted to vaccine development. Many are working on anticancer vaccines for which market forces may be enough to keep them in production. However, good products developed by these startups to combat infectious diseases often do not come to market because of the very large costs of testing in pilot studies and in manufacturing.

Prior to the events of September 11, the delays and problems faced by both the Department of Health and Human Services and Department of Defense in developing and procuring a cell-culture smallpox vaccine provide convincing evidence that major changes are needed at the national level. With the government guaranteeing payment in this time of national need, several potential manufacturers have come forward. This is an ad hoc example of a larger national need for mechanisms to obtain other public-good vaccines on an ongoing basis, and not just under extenuating circumstances when there is a great deal of public awareness of the need for vaccines.

. . . The Children's Vaccine Initiative committee listed the functions of a National Vaccine Authority . . . They now have a broader importance to America, as the potential need for vaccines required to meet biological threats increases. The IOM Council believes the Authority should focus its attention upon vaccines that will not be adequately produced by existing public or private entities.

Recently, proposals have been made for the creation of a government-owned, contractor-operated national vaccine facility. The IOM Council believes this is one in a spectrum of public-private ventures by which a NVA could facilitate development and production of needed vaccines . . . While a major priority for this facility would be to develop vaccines necessary to protect American troops and for use against bioterrorism, the facility also should be charged with production of other vaccines that are in scarce supply and would not otherwise be provided in the public or private sectors. In some cases in which there are few private sector uses, the facility would become the principal source of such vaccines. In other cases, as variety of public and private partnerships could be undertaken to produce needed vaccines.[5]

The Council of the IOM believes that the development of a National Vaccine Authority is long overdue. It could be created within the Department of Health and Human Services, in collaboration with the Department of Defense or as a joint effort of the two departments. Moreover, the Council believes that establishment of a gov-

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[2] Mitchell, V.S., Philipose, N.M., and Sanford, J.P., eds. The Children's Vaccine Initiative: Achieving the Vision. Washington, D.C.: National Academy Press, 1993.

[3] Lederberg, J., Shope, R.E., and Oaks, S.C., Jr., eds. Emerging Infections: Microbial Threats to Health in the United States. Washington, D.C.: National Academy Press, 1992.

[4] Merck Vaccine Division (parent company is Merck Pharmaceuticals) and Wyeth-Lederle Vaccines (parent company is American Home Products Corporation) are U.S.-based companies. Aventis Pasteur and GlaxoSmithKline operate within the United States and have products licensed by the FDA for use in the United States, but they are companies based in other countries.

[5] Pearson, G.W. The Children's Vaccine Initiative: Continuing Activities. Washington, D.C.: National Academy Press, 1995.

ernment-owned, contractor-operated facility for research, development, and production of vaccines is essential to meeting the country's public health needs, particularly those related to bioterrorism and protection of our armed forces.[6]

I believe there are three actions that should be initiated with the encouragement of Congress:

First, the National Institutes of Health (NIH) needs to consider whether it needs to establish an Advanced Research Projects Agency—perhaps modeled on the DARPA model—to more effectively engage and harness critical creativity and better link it to both local and Federal requirements and accelerate the rate of introduction of new technology into broad use.

Secondly, the government should implement The Institute of Medicine recommendation to establish a National Vaccine Authority (NVA), charged with carrying out the functions spelled out in the November 5 IOM Statement.

Thirdly, serious consideration should be given to the establishment of new funding and management tools that encourage and sustain public-private partnership. Lessons should be captured from successful existing examples such as the efforts undertaken by MAID and expanded upon to meet current needs.

We clearly need a better national approach for anti-toxin, anti-microbial drugs development, production and storage. We are on the cusp of an explosion in genome development. In addition to the benefits of such an evolution are great risks: there will be the potential for many more drug "weapons." Markets, alone, will not drive this development and production activity, yet partnership with the private sector is essential for realizing the goal.

Underlying the effectiveness of all of the recommendations is the need for complete and effective communication and information exchange. This applies across Federal, State and local agencies; among the government, academia and industry; and across the silos of scientific, engineering, and health care disciplines. Critical to this effort is the need to develop ways to better access information and affect more rapid response capability for use at both the national and local levels. Part of this challenge is related to improved information management systems; another is to assuring the existence of accurate and authoritative information sources; yet another to addressing the need for better training, and better real-time linkages among those public and private-sector institutions which share responsibilities and capabilities to protect (and improve) the health of the public in the 21st century.

I have appreciated the opportunity to testify before the Senate Committee on Commerce, Science, and Transportation today on the important issues you have raised relating to Home Land Security against bioterrorism.

I would be pleased now to answer any questions you may have and request my complete statement and attachment be included in the record.

SUMMARY OF SELECTED COUNTER-TERRORISM INITIATIVES BY THE NATIONAL ACADEMIES

S&T AGENDA FOR COUNTERING TERRORISM

This project is aimed at helping the Federal Government, and more specifically the Director of the Office of Science and Technology Policy, Dr. Jack Marburger, to use effectively the Nation's and the world's scientific and technical community in a timely response to the threat of catastrophic terrorism. A committee of distinguished scientists and engineers with supporting panels will help to develop an integrated science and technology program plan and research strategy. Phase 1 of the project will in 6 months prepare a carefully delineated typology or taxonomy for the application of science and technology for combating terrorism and using additional experts serving on panels will prepare research agendas in seven key domains (biological; chemical; nuclear and radiological; information technology, computers, and telecommunications; transportation; energy facilities, buildings, and fixed infrastructure; and behavioral, social and institutional issues). The committee will also examine a series of cross-cutting and multidisciplinary issues, including interdependent vulnerabilities. Phase 2 will review key government research programs and provide recommendations for building improved interagency capabilities and coordination. A final report will be produced by September 11, 2002. ($2 million—$1 million from the Academies and $1 million expected from Federal agencies and foundations)

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[6] The complete *Statement* is attached to this testimony. It includes the listing of specific functions appropriate for the NVA.

NEAR-TERM ASSISTANCE FOR THE U.S. GOVERNMENT

On urgent topics where the government needs immediate assistance, the Academies are inviting scientific experts to meet with government representatives in 1-day meetings. Although no written reports are produced and no formal Academy advice is provided, the dialog is very beneficial to Federal agencies, including the inter-agency Technical Support Working Group (TSWG) on counter-terrorism. Recent examples include a meeting for the U.S. Postal Service on sanitizing the mail (11/14/01); a meeting for the Dept. of Justice on how to analyze the anthrax-infected letter to Senator Leahy (12/7/01); a meeting on human factors for the FAA's sky marshall program (12/5-6); a meeting on biological and chemical forensics for TSWG (12/11); and a meeting on biological and chemical decontamination for TSWG (12/14), (approximately $30 thousand per meeting; treated as project initiation activities)

COMBATING TERRORISM: PRIORITIZING VULNERABILITIES AND DEVELOPING MITIGATION STRATEGIES

The National Academy of Engineering will undertake a 12-month project to identify, assess, and prioritize vulnerabilities to the Nation's vital infrastructures posed by global terrorism, and outline strategies (technologies, policies) to mitigate priority vulnerabilities in a manner consistent with a free, open, and prosperous society. Using various fact-finding, forecasting, consensus-building, and risk analysis techniques, the project committee will seek to integrate expert knowledge of the nature of modern terrorism (motives, capabilities, sociology, psychology), terrorist weapons and delivery systems, and the vulnerabilities of vital infrastructures to measure and rank order the myriad terrorist threats to the Nation (supported by the NAE).

INTERNATIONAL COLLABORATIVE ACTIVITIES WITH FOREIGN COUNTERPARTS TO REDUCE NEAR-TERM THREATS AND LONG-TERM ROOT CAUSES OF TERRORISM

Priority activities include:

- Cooperation on Preventing Terrorists from Obtaining Nuclear Materials in Russia, which will include two projects. The first will be a joint effort with the Russian Academy of Sciences to produce a "white paper" assessing the steps that can be taken immediately by the two governments to reduce the risks that nuclear weapons or materials could fall into the hands of terrorists. Working together, the two academies will also identify an agenda for longer-term U.S.-Russian cooperation, including continuing inter-academy attention to problems that may arise and how they might be overcome. The second project will examine the problems that will be faced by economically stressed Russian institutions in maintaining and operating recently installed physical security and accounting systems for protection of plutonium and highly enriched uranium within the framework of cooperative projects when financial support is no longer available from the United States and will assess approaches to ensuring the long-term sustainability of the systems. ($150,000 from the MacArthur Foundation and further support expected from the Nuclear Threat Initiative foundation);
- Continuing of the U.S.-Russian InterAcademy Project on conflicts in multiethnic societies (support sought from foundations and partial support up to $200,000 from NRC funds if needed);
- InterAcademy meetings on both a bilateral basis with scientists Pakistan, Iran, and other Moslem nations and on a multi-lateral basis through the InterAcademy Panel (support sought from foundations and partial support of approximately $100,000 from NRC funds if needed);
- Planning meeting for a study on building the capability of foreign affairs and development agencies to help in reducing the risk of terrorism, a study that would complement NRC report on "The Pervasive Role of Science, Technology, and Health in Foreign Policy: Imperatives for the State Department" ($35,000 in program initiation funds);
- Continuation of the joint U.S.-Russian InterAcademy Project on high-impact terrorism (supported by the Carnegie foundation).
- Cooperative Research in Russia on Dangerous Pathogens. This project provides for two 2-week familiarization visits each year by three or four American investigators (including young investigators) to elected Russian research institutes that had formerly participated in the Soviet biological warfare program. Each year these visits are followed by individually tailored visits of one to 3 months to the institutes by three or four of the investigators who are interested in pursuing joint civilian research activities in collaboration with Russian colleagues. These projects provide a mechanism for gaining regular access to the facilities and specialists

and thereby promote transparency. They also provide research opportunities for Russian scientists who might otherwise look to countries with hostile intentions for support. At the same time, cooperative research helps develop technologies that will be useful in public health, agriculture, and counterterrorism activities in Russia and the United States.

PRELIMINARY EVALUATION OF U.S. INDUSTRIAL VULNERABILITIES AND NEAR-TERM PROTECTIVE MEASURES

Evaluations by the appropriate NRC boards in cooperation with volunteers to identify vulnerabilities in key industries, e.g. chemical and energy industries, and measures that might lessen this vulnerability or reduce the consequences of strikes to key infrastructure. The Board on Chemical Sciences and Technology met with chemical industry representatives on this topic on 12/9/01 and with Federal agencies on 12/10/01. The Board on Life Sciences and the Board on Agriculture and Natural Resources have held similar meetings. Other boards will meet with relevant industries in the weeks ahead. ($30,000 in project initiation funds)

AN ASSESSMENT OF NAVAL FORCES' DEFENSE CAPABILITIES AGAINST CHEMICAL AND BIOLOGICAL WARFARE THREATS

At the request of the Chief of Naval Operations, the Naval Studies Board is conducting a study to: (1) examine existing and potential chemical and biological warfare threats to naval force operations in littoral regions and deep ocean regions of the world; (2) examine and project chemical and biological defense technologies, tactics, and procedures; (3) evaluate R&D and identify priorities for providing naval forces with needed capabilities; and (4) examine testing and evaluation procedures (in conjunction with training procedures) for ensuring adequate defensive capabilities. It is anticipated that a published report will be available by July 2002.

IMPROVING CYBERSECURITY RESEARCH IN THE UNITED STATES

A study by the Computer Science and Telecommunications Board will be conducted to determine the extent and nature of current Federal research in cybersecurity and to identify areas of research that are not adequately supported. ($129,000 from NRC funds and a matching amount expected from the National Science Foundation).

INFORMATION AND SECURITY: ENHANCING INFORMATION MANAGEMENT AND DATA MINING CAPABILITIES FOR COMBATING TERRORISM WHILE PROTECTING CIVIL LIBERTIES

A planning meeting for a study is being organized by the Computer Science and Technology Board (CSTB). The study will consider research opportunities in data mining as well as ways to minimize the privacy and civil liberties implications of anticipated increased collection and integration of personally identifiable information. ($40,000 in project initiation funds).

ISSUES AFFECTING UNIVERSITIES ARISING OUT OF TERRORISM EVENTS: WORKSHOP ON IMPLICATIONS FOR RESEARCH, SCIENTIFIC COMMUNICATION, AND FOREIGN STUDENTS

A workshop was held on December 13 and 14. Issues such as visa and foreign student tracking policies will be discussed by representatives of major research universities. Also discussed will be whether sufficient protections can be achieved to avoid the diversion of biological agents from research facilities. The implications of possible restrictions on biomedical research, scientific communication, and on graduate student participation will be examined. ($60,000 in project initiation funds).

IMPROVING RESEARCH STANDARDS AND PRACTICES TO PREVENT MISUSE OF BIOTECHNOLOGY RESEARCH

A study will review and assess the current rules, regulations, and institutional arrangements and processes in the United States that provide oversight of research on dangerous biological pathogens, including within government laboratories, universities and other research institutions, and industry. The review would focus on how choices are made about which research is and is not appropriate, and how information about relevant ongoing research is collected and shared. It will consider, but not be limited to, the "biosafety" practices that govern the conduct of research and the handling and transport of materials. The study will recommend changes to improve U.S. capacity to prevent the destructive application of dangerous biological pathogens while still enabling the conduct of legitimate research. (Supported by the Sloan Foundation and the Nuclear Threat Initiative Foundation).

COMMUNICATING TO LOCAL GOVERNMENTS AND PRIVATE CITIZENS ABOUT PREPAREDNESS FOR TERRORISM EVENTS

A meeting requested by Dr. Marburger will be held in January to plan how better to link Federal and State governments on S&T policy, including for combating terrorism. Science representatives of each of the States will attend. ($30,000 in program initiation funds).

PUBLIC HEALTH INITIATIVES

The Institute of Medicine will conduct new activities as well as capitalizing on work currently in progress to develop and communicate anti-terrorism strategies based on public health principles. The goal is to provide guidance on specific issues of national, local and individual concern within the framework of a comprehensive strategy to assure the health of the public in the 21st century. Priority (near term) activities include:

- A series of workshops under the Forum on Emerging Infections. The first was held on November 27/28 and addressed Biological Threats and Terrorism: Assessing Science and Response Capabilities. The second will focus on antibiotic resistance and its implications for counter-terrorism responses.
- A comprehensive study of the safety and efficacy of anthrax vaccines will be released in February. Completion of this Department of Defense funded study was accelerated in response to the current need to make decisions regarding manufacture and use of anthrax vaccine.
- On November 5th, the IOM Council issued a Statement on Vaccine Development, assessing the country's capacity to develop, produce and store vaccines. The recommendations include creation of a National Vaccine Authority.
- The 1992 IOM report on Emerging Infectious Diseases is being updated and expanded. The committee will include an extensive discussion of issues related to bioterrorism. The report will be issued in early 2003.
- A committee report providing a vision for assuring public health in the 21st century will be issued in the Spring of 2002. It will provide a framework for integrating investments and activities related to counter-terrorism into the overall public and private sector infrastructure to assure public health.

AGRICULTURAL BIOTERRORISM

The Board on Agriculture and Natural Resources is conducting a study to evaluate the ability of the U.S., to deter, prevent, detect, thwart, respond to and recover from an intentional biological attack against the Nation's food and fiber supply. The report is expected in summer 2002 (supported by the USDA).

WHAT TERRORISTS VALUE

The Division of Behavioral, Social Sciences, and Education will conduct a study on what high profile terrorists groups value (especially the groups that caused the attack on September 11) with the goal of understanding how better to deter and defeat them. ($500,000 funded by DOD).

ASSESSMENT OF TECHNOLOGIES DEPLOYED TO IMPROVE AVIATION SECURITY

This study by the National Materials Advisory Board (NMAB) sponsored by the Federal Aviation Administration, is assessing the operational performance of passenger screening, explosives detection systems and hardened cargo containers in airports and compare that performance to their performance in laboratory testing, with a focus on ways to deploy these systems more effectively to improve aviation security. The Committee plans a second status report in early 2001 and a third and final report in the fall of 2002 that will examine a technology development strategy for aviation security.

ASSESSMENT OF PRACTICALITY OF PULSED FAST NEUTRON ANALYSIS FOR AVIATION SECURITY

This National Materials Advisory Board study, sponsored by the Federal Aviation Administration, is assessing the practicality of pulsed fast neutron analysis (PFNA) for detecting explosives and other contraband in cargo and passenger baggage in an airport. The capabilities of PFNA are compared with the capabilities of explosives-detection equipment currently available for deployment and with the expected future development of current equipment. The Committee plans publication of their findings early in 2002.

ADVANCED ENERGETIC MATERIALS AND MANUFACTURING TECHNOLOGIES

This study by the Board on Manufacturing and Engineering Design is investigating and assessing the manufacturing technologies required to scale up and produce bulk quantities of advanced energetics and suggest opportunities and strategies for government investment. Although these new materials are more difficult to manufacture when compared to standard explosives, they are equally difficult to detect using current systems. The study is sponsored by the Department of Defense.

MATERIALS AND MANUFACTURING PROCESSES FOR ADVANCED SENSORS

This study by the Board on Manufacturing and Engineering Design is examining potential technologies for detect-to-warn systems for biological agents. Their charge is to review the DTRA-specified requirements for these systems and identify those requirements that will especially drive the detection concepts and architectures—e.g., less than 1 minute detection times, continuous operations with attendant implications for consumables and their costs—and understand to what extent, if any, these, or related, parameters (e.g. detection sensitivities), may be relaxed. The committee is also considering examples of representative operational scenarios or architectures (to be provided by the sponsor), which will be invaluable in putting these system requirements and tradeoffs in context.

CURRENT ADDITIONAL SPECIFIC BOARD-BASED ACTIVITIES

Support for Transportation Security Research (TRB)

The Transportation Research Board administers two cooperative research programs, one for State departments of transportation and one for the public transportation industry. $2 million allocated from the Transit Cooperative Research Program to provide flexible, ongoing rapid response research on transportation issues related to emergency incident prevention, preparedness, response, and recovery, paying particular attention to potential terrorist threats. Consultants have been selected and work is expected to get underway in early 2002. The National Cooperative Highway Research Program is currently supporting the development of manuals for vulnerability assessments and emergency response planning and is expected to program significant funding next year for security related research.

Standing Technical Committee on Critical Infrastructure Protection (TRB)

TRB maintains approximately 200 standing technical committee that support information dissemination activities in transportation. The Committee on Critical Infrastructure Protection, which was established 2 years ago, facilitates the dissemination of state-of-the practice and state-of-the-art information on infrastructure security and protection and encourages research in this field. It sponsors TRB's website on security and has organized security sessions at TRB's Annual Meeting.

Survey on Vulnerability Assessment (TRB)

TRB is conducting, in cooperation with the American Association of State Highway and Transportation Officials, a survey of States to determine whether and to what extent they have addressed infrastructure planning and security in their planning efforts.

TRB Annual Meeting (TRB)

TRB's Annual Meeting is one of the largest gatherings of transportation professionals in the world. The January 2002 meeting will include over 30 security and recovery related sessions. An overview session will involve the DOT modal adminstrators and the Deputy Secretary and cover a dozen topics, from port and waterway security issues to aviation safety.

Transportation Associations—Information Sharing (TRB)

TRB organized a meeting of a number of transportation associations to share information about the security issues they are confronting and the activities under way. The group will meet again in 3 months.

Redundancies in Transportation Systems (TRB)

A planning meeting will be held to examine multi-modal transportation infrastructure redundancy to enhance defense against terrorist disruption. ($30,000 in program initiation funds).

Emergency Evacuation in Metropolitan Areas: Barriers and Opportunities (TRB)

A planning meeting will be held to discuss technical and institutional barriers to improved metropolitan-wide evacuation and emergency response. ($28,000 in program initiation funds).

Vulnerability of the Electric Power Transmission and Distribution System to Terrorism (BEES)

A planning meeting will be held to discuss reducing the impact of terrorist attacks on the electric transmission and distribution system. ($40,000 in program initiation funds).

Safety of Our Nation's Water Supplies (WSTB)

A series of activities will be held to discuss safety of the short term security and longer term research initiatives relevant to water supply safety from terrorist attacks. ($14,000 in NRC funds).

Forum on How Natural Disaster Research Can Inform the Response to Terrorism (NDR)

The Natural Disasters Roundtable (NDR) will conduct a 2-day workshop to develop thoughts on how responses to natural disasters might be applied to threats provided by terrorism. Topics to be considered include engineering design, promoting public awareness and understanding, evacuation planning, recovery planning, utilization of technology to detect and monitor public health risks, public health system needs, and mental health consequences. ($30,000 in NRC funds).

Interdependent Vulnerabilities for Critical Infrastructure Protection (BICE)

A 1-day workshop was held on October 31 to help develop methodologies to analyze interdependent vulnerabilities. The Board on Infrastructure and the Constructed Environment is developing a workshop series to address these problems.

Chemical Stockpile Activities (BAST)

The Board on Army Science and Technology has conducted a fast-track review of proposed process changes for the *expedited* disposal of the chemical weapons stockpile inventory. Letter reports are being provided to the Army within the month (funded by the Army).

A second BAST activity is an examination of the state of the stockpile as delivered to disposal facilities and the effects of stockpile condition on processing, handling, monitoring and stakeholder reaction. A third activity is an evaluation of process changes for alternative technology at the Aberdeen Bulk-Only Chemical Agent Disposal Facility (funded by the Army).

Forum on Terrorism (Committee on Law and Justice) (DBASSE)

As part of the Academies' investment in "root-cause" analysis of terrorism, the Forum will discuss relevant social science tools to summarize the knowledge base on terrorism. The objective would be to improve understanding of the current situation, giving rise to terrorism both in the United States and in the Muslim world. A series of workshops and commissioned papers will examine such topics as:

- Understanding International Terrorism with emphasis upon research from political science and sociology.
- A more specific contextual examination of terrorism in the Middle East.
- Organizational analysis and terrorism.
- A profile of terrorists.
- Recent uses of profiling and their application to combating terrorism.
- Money laundering.
- Collective behavior of populations under the threat of danger ($30,000 in planning initiation funds).

General Education of the Media and Public on Terrorism Vulnerabilities and Responses

On 12/6/01, the Academies and the Foundation for American Communications (FACS) co-sponsored a Conference for News Executives ["Terror and Homeland Defense: Bringing the Stories Home"] at the Reserve Officers Association. Approximately 50 media representatives attended. (Supported by the NAE and FACS).

Cybersecurity and Authentication Technologies (CSTB)

The Computer Science and Telecommunications Board has issued a letter report synthesizing a decade of work on cybersecurity, focusing on issue identification and practical guidance. CSTB's Committee to Study Authentication Technologies and Their Implications for Privacy has undertaken to develop a brief, interim report addressing issues associated with the concept of national identification systems. The resulting pamphlet will be ready in the winter.

Chemistry and National Security (BCST)

The Board on Chemical Sciences and Technology is holding a workshop in January on "chemistry and national security."

Mathematics and Homeland Security (BMS)

The Board on Mathematical Sciences is holding a workshop in April on mathematical topics relevant for homeland security, including pattern recognition and data mining, epidemiological modeling, voice and image recognition.

Senator WYDEN. Thank you. The country is lucky to still have you out there, and we will have some questions in a few moments.

Dr. Ryan, welcome.

STATEMENT OF DR. UNA S. RYAN, Ph.D., PRESIDENT AND CEO OF AVANT IMMUNOTHERAPEUTICS, INC.

Dr. RYAN. Thank you very much, Mr. Chairman, Senator Rockefeller. Thank you very much for inviting me to testify this morning. I would like to enter my written testimony into the record and just speak in summary extemporaneously for a moment.

I am the President and CEO of AVANT Immunotherapeutics, a biotechnology company in Needham, Massachusetts, and I am also a member of the board of BIO, the Biotechnology Industry Organization, and it is in this capacity that I am here this morning to address some of the Subcommittee's concerns about how the Federal Government and the biotechnology industry can work together.

We as an industry are unanimously against the use of biotechnology in any offensive sense, and we are united in wanting to help in the defense against bioterrorist attacks, so the question is, how can the government, and your Subcommittee in particular, help us in contributing?

Let me tell you how I see it from my vantagepoint. As the CEO of a small, publicly traded biotech company, AVANT makes vaccines against both bacterial and viral diseases. That is our core peacetime business. We even have a vaccine that raises your good cholesterol, but that is not a bioterrorist threat at the moment.

We have worked with the government, both the military and the civilian sector, for as long as I can remember, in particular in trying to develop vaccines against anthrax and plague. We have worked for 8 years with eight different branches of the government, culminating last October 10 in an announcement that we had licensed our technology for a protective antigen to Dynport as a part of the Department of Defense's efforts for a second generation anthrax vaccine, and we are very proud of having done that, and I think it shows that with an 8-year lead we can work with the government, but it is not all that we or my fellow biotech companies want to do.

We as a collection of companies have devices, diagnostics, vaccines, drugs, for prevention, treatment, containment, and we want to help. Let me give you an example from my own company. We make travelers' vaccines, and travelers are picky people, and so we have made single dose oral vaccines that protect very rapidly. The idea is, you sip and go. You jump on the plane and you will be protected by the time you get there.

Again, they are oral and they are single dose. These are against such diseases as cholera and typhoid fever, and the dysenteries, but we believe we can use this technology, use a cholera organism, for example, as a Trojan Horse, a bus into which you could vector or introduce what we call epitopes, but you can think of as soldiers to fight different bioterrorism threats, so you would get cheap, ef-

fective, safe, rapidly-protecting oral and single dose, together with versatility.

These are the kinds of things we would like to offer and find the right home in the government to protect, not only the military, but also the civilian American population, and it is very difficult to do, so I would like to come up with three questions, very close to some of your own suggestions, that I believe would help us as an industry interact with the government.

The first is, I believe we must have a plan, a unified plan. So what are the government's unified requisitioning and development plans? As I said, we have worked with many different groups in the Department of Defense and in the NIH, and they were all productive sorties of their type, very interesting interactions. But I just have a sense that we were never in a part of any unified plan, and therefore we never really progressed. It was as if we were all busy and in Grand Central Station instead of in the Superbowl where everybody is working on one end. You have to forgive me. I am from New England.

The next question I have is, again, to echo yours. We need a clearinghouse. We need a central source where we biotechnology companies can find out how these great appropriations that we hear about are going to be funneled out into the various agencies. My company is not naive about working with the government. We have done it before. We understand SBIRs, we understand CRADAs, but we cannot keep screening every agency to find out who is offering an RFP. We would like a clearinghouse for one-stop shopping.

I think the third thing we would like to ask is if the biotechnology industry could have some input into the legislative process, and I say this because I think it would be helpful on both sides not only for the industry, but also for the government. I will give one example. I believe that we are sort of stuck in a time warp. I answered two sets of questionnaires recently by companies that were helping prioritize programs for the DOD, and HHS, and the first two questions were: "How many injections for your vaccine?" And the next, "What is the adjuvant?" That is something that improves the immunogenicity. That denies the government all of the advances we have made. No injections. It is oral. No adjuvant. It is very effective in a single dose.

So in summary, we would like to hear the plan. We would like to hear it well-communicated and have a place where we can access information, and finally, we are united in wanting to contribute.

Thank you very much.

[The prepared statement of Dr. Ryan follows:]

PREPARED STATEMENT OF DR. UNA S. RYAN, PRESIDENT AND CEO, AVANT IMMUNOTHERAPEUTICS, INC.

Mr. Chairman and Members of the Subcommittee, thank you very much for inviting me to testify this morning. I appear before you this morning wearing two hats. I am the President and CEO of AVANT Immunotherapeutics, Inc., a biotechnology firm headquartered in Needham, Massachusetts. I am also a member of the Board of Directors of the Biotechnology Industry Organization (BIO). I appear representing BIO to address the Subcommittee's concerns about how the Federal Government and the biotechnology industry should work together to meet the newly evident threat of bioterrorism. My comments are based, of course, on my experience as the CEO of a company that develops and produces vaccines that support that effort.

We sit this morning at ground zero of the new war against bioterrorism. Just yards from where we sit is where the anthrax-laden letter addressed to Senator Daschle was opened; just a mile away is the Brentwood facility where postal workers were lethally infected by the contents of that same letter. As awful as these events were, we all know that in some senses we were lucky in that a larger, coordinated, camouflaged anthrax attack could have been far deadlier.

As the Federal Government embarks on a campaign to fight bioterrorism and biological warfare, let me assure you that the biotechnology industry stands ready to contribute and work toward its success. The Biotechnology Industry Association (BIO) is made up of companies that develop and supply a wide variety of products essential to biodefense. Many are already working on defense-specific technologies under contract with the Federal Government, while others are at work on products that can be used for both conventional health care and biological defense. These technologies and products include vaccines to inoculate citizens against infectious agents, devices to detect biological or chemical attacks, enzymes to decontaminate buildings and people, tools to diagnose victims of these attacks, and therapies to treat them.

I think it is important to note that the entire biotechnology industry is absolutely opposed to the development of offensive biological weapons. This is BIO's longstanding policy, which is spelled out in the organization's Statement of Ethical Principles. The development and supply of biodefense products, however, is right in line with the central purpose of the industry, to save and improve the peoples' lives.

The President and Congress have made it clear that biodefense is a top national priority. Be assured that my firm and its fellow biotechnology companies stand poised to offer solutions to bioterrorism threats, both known and envisioned. Those that did not focus on the bioterror threat before last fall have certainly begun to direct their attention toward this crucial challenge. The question we all now face is how will the government enable our industry to contribute?

Let me speak briefly of how the biodefense effort looks from my vantage point. My company, AVANT, develops a variety of therapies that harness the body's immune system, including drugs to lower cholesterol levels, reduce the permanent damage inflicted by heart attacks and strokes, and prevent the rejection of transplanted organs and tissues. The area of AVANT's work most relevant to the national biodefense effort is our development of vaccines that fight both bacterial and viral diseases.

Our vaccine business to date has focused on the market for travelers' vaccines-protecting against cholera, typhoid, and dysentery—and on anti-viral vaccines to combat herpes, diarrhea in babies. However, we have worked with the Department of Defense, in particular the Army, in the biodefense effort even before September. One result of that work is that last October AVANT licensed its recombinant protective antigen for anthrax to Dynport Vaccine Company, a Defense Department contractor developing a second generation anthrax vaccine. This protective antigen is the crucial ingredient of an anthrax vaccine, the protein that prompts the body to develop immunity to the disease so that if the person is infected, it already has protective antibodies in its arsenal.

Although we are proud of this contribution to the biodefense effort, we stand ready to play a much more significant role. Our most advanced technology offers the prospect of biodefense vaccines that are far more effective, safer, less expensive, and faster acting than current generations of vaccines. For example, the current inventory anthrax vaccine provided to U.S. troops is administered through multiple injections, which are often painful because of the reactive side effects of the vaccine. Once the series of injections is begun, immunity develops gradually over several months.

Compare this to the vaccine that we at AVANT, using our live attenuated vaccine vector technology, have successfully developed to fight cholera. This vaccine, called CholeraGarde, is administered in a single oral dose. It is safe and easily tolerated by the recipient. Immunity develops very quickly, in as little as 7 days. Manufacture of this vaccine is easy and inexpensive compared to current generation vaccines. While this particular vaccine fights cholera, our vector technology enables us to develop quickly an anthrax vaccine that is similarly effective, safe, and convenient. And we wouldn't have to stop there. Our technology enables us to adapt our vaccines to fight a wide range of bioterror agents.

As a biotech CEO, let me tell you the questions I would like answered as I consider whether and how my firm can contribute to this national effort.

1. What are the government's development and purchasing plans for biodefense products and systems? For vaccines, drugs, detection devices, and the entire array of biodefense materiel, what are the overarching goals and acquisition plans?

Before I, or any biotech executive, can make a decision about whether and how to provide biodefense products, we have to know what the government needs—what is the national plan. Formulating a single unified plan is no simple task, as there is no obvious authority to create such a plan. Before September 11, the biodefense program consisted principally of the Department of Defense effort to develop vaccines and treatments for forces in the field. That's why my company has worked with the Army on development of an improved anthrax vaccine since before September, for the purpose of inoculating U.S. troops. The Department of Health and Human Services played a key role in supporting research and development of related vaccines and drugs, but it had little active role in the procurement, stockpiling, and distribution of vaccines and other therapies for biodefense. My company's work with HHS has focused principally on basic research and clinical trials.

The new bioterrorism threat requires a capability to protect all Americans, military and civilian. Biodefense policymaking, previously split between two major agencies with divergent missions, must coalesce around a single national strategy. Acquisition authority and capability has been distributed widely among research labs and offices with varied program objectives. The Federal Government must coordinate these authorities and assets to ensure a rational use of resources in support a unified biodefense plan. Once that single plan is formulated and made available, I can determine how my company can contribute to the national effort.

2. How will I access information about the national biodefense effort?

Once the Federal Government puts a national biodefense plan in place, it is vital that my fellow biotech executives and I have ready access to its contents in a usable form. There needs to be a clearinghouse for information that lets me know exactly which government agencies, offices, and labs are responsible for research, development, procurement, and policy relevant to my products.

Until such a resource is available, I will have to navigate a complex network of government entities, searching for the key contacts on vaccine development and biodefense procurement. Until there is a biodefense liaison office to industry and a well-maintained website providing the latest details on national biodefense policy, my colleagues and I will spend significant time and money searching for where the real authority lies, wondering if we are talking to the right people. Such a clearinghouse, will make the biodefense effort more efficient for both the government and its aspiring biotech contractors.

3. Will the biotech community have input into the policymaking process?

There will be two key players in making the national biodefense plan succeed: the Federal Government, which will determine goals, policy, and requirements and which will oversee the acquisition process; and industry, which will provide the goods and services the biodefense program requires. The national interest will best be served if the parties work together to formulate and implement the national program.

This may seem like an obvious and generally accepted recommendation, but I believe the particular case before us demands extra attention to the matter of government-industry collaboration. Although the Federal Government has done some business with the biotechnology industry, it is a mere fraction of the biodefense acquisition effort about to be launched. This leap in activity will make government and industry much closer partners, requiring far closer cooperation and deeper understanding of each other's goals and motivations.

From my perspective, I am most concerned that the government take into consideration the harsh economic realities of the modern biotech marketplace. Vaccine development, like development of any drug, is an extremely expensive and risky venture. Unlike the development of most drugs, vaccines have very limited sales potential, as the best vaccines eliminate their markets by eradicating the disease they target. Moreover, we have enormous liability issues as vaccines are generally administered to healthy individuals. All of these factors must be taken into account by the government as it considers the price and terms of contracts for the purchase of biodefense vaccines.

In summary Mr. Chairman, the biotechnology industry stands ready to join the Federal Government in meeting the nation's biodefense needs. We ask that for its part the government formulate a coordinated, coherent biodefense plan, that all aspects of the plan and its implementation are readily accessible to industry participants, and that both partners open a continuous dialog about how to work together to meet the plan's vital goals.

This plan should be accompanied by a clearinghouse of information on biodefense acquisition covering everything from policy to points of contact. If these steps are taken, we can look forward to a future where the best of our technical and management skills can protect all of us from some of the most terrifying threats of a new and dangerous era. Thank you very much.

Senator WYDEN. Dr. Ryan, excellent presentation. We will follow up on your suggestions.

Senator Rockefeller was the author of the CRADA statute, so this comes at an ideal kind of time for your input.

Let us hear from Dr. Sobral, then we will have questions.

STATEMENT OF DR. BRUNO W.S., SOBRAL, Ph.D., DIRECTOR, VIRGINIA BIOINFORMATICS INSTITUTE; PROFESSOR, PLANT PATHOLOGY, PHYSIOLOGY AND WEED SCIENCE AT VIRGINIA TECH

Dr. SOBRAL. Good morning, Mr. Chairman and Members of the Subcommittee. I would like to thank you for this opportunity to appear before you and discuss the work of university research and the Virginia Bioinformatics Institute. Among other things, September 11 has made us acutely cognizant of our Nation's dependency on science and technology. We also know that science and technology will provide the best mechanisms to prevent, detect, and mediate bioterrorist attacks. Bioinformatics is at the forefront of disciplines that hold the greatest promise to achieve these goals. Early identification and intervention in any disease outbreak are pivotal to both control and abatement. This requires rapid diagnostic tools, a system to track diseases as they evolve, and epidemiological data to determine pathogen origin and inhibit dissemination.

We must also consider indirect threats to our food and water supplies. Agriculture accounts for roughly one-sixth of the total U.S. GDP. A lone terrorist could introduce disease into livestock or crops, which would set off a chain reaction touching virtually every segment of this Nation's economy. An attack might also be used as a feint to divert critical response personnel from other primary terrorist targets.

Currently, the fundamental science to support detection, identification, forensics, risk assessment, and mitigation is fragmented across many Federal and State agencies, academe, several nonprofit organizations, and industry. In addition, that science is presently found in both varied contexts and diverse syntax. A critical need still to be addressed, according to the President's Science Advisor, John Marburger and others, is our seriously incomplete knowledge about pathogens, especially those that can be used as weapons. This cannot be emphasized enough. To handle bioterrorist attacks we need a global pathogen science portal where data and computational analysis tools come together and are made available to all stakeholders.

VBI can create a single bioinformatics interface to access available information required for a comprehensive surveillance program. With access to such a system, researchers, public health workers, and security officials, could quickly access the threat and options for mitigation. Although VBI has comprehensive bioinformatics capabilities in-house, the completion of the information pipeline requires a strengthened partnership among government, academe, and industry.

This partnership depends upon ractive inclusion. Partnerships with both IBM and Sun Microsystems ensure the necessary technology for information translating, routing, and accessibility are

present. Partnerships with biomedical researchers, like Johns Hopkins Bloomberg School of Public Health, will provide field data on malaria, AIDS, measles, and tuberculosis for our information system.

VBI is in a unique position to help defend against agro-terrorism. We are located on the campus of Virginia Tech, which has strengths in agriculture, engineering, and information technologies. We have already worked with USDA and DOD to identify a list of high-priority pathogens. We can become an information nexus for pathogen identification, origin, and signature determination.

With bioterrorist threats especially, the preferred solution is always prevention. Scenario-building is a technique to anticipate "what-if" situations and develop mechanisms for an event "to not occur," or at a minimum, to have a carefully crafted response plan. Since we cannot prevent what we do not fully understand, all research must be available for access, and ongoing research must continue.

Once a bioterrorist agent is released into the environment, the damage is extremely hard to combat and isolate. With advances in sensors, many researchers and entrepreneurs could collaborate in scenario-building sessions and in developing sensor-based alarm or warning systems. The VBI integrating hub can plan an important part in both the identification and remediation of bioterrorism as well as the anticipation and prevention of a bioterror fallout.

Consensus will be essential to make decisions regarding access that will ensure both scientific progress and national security. At VBI, we are developing a flexible infrastructure applicable in times of peace and in times of national emergency, a new resource in this new century.

Thank you. We look forward to working with you.

[The prepared statement of Dr. Sobral follows:]

PREPARED STATEMENT OF BRUNO W.S. SOBRAL, PH.D., DIRECTOR, VIRGINIA BIOINFORMATICS INSTITUTE; PROFESSOR, PLANT PATHOLOGY, PHYSIOLOGY AND WEED SCIENCE AT VIRGINIA TECH

Senator Wyden and distinguished Members of the Subcommittee:

Good morning and thank you for this opportunity to appear before you and discuss the work of the Virginia Bioinformatics Institute (VBI). The resources of the Institute and university research in general, provide powerful tools and assets to combat bioterrorist threats.

THE ROLE OF ACADEME AND RESEARCH

The Federal Government has a long, rich tradition of funding research in our Nation's colleges and universities. For the past 50 years, Federal funding has provided continuous support to develop the fundamental science and technology that pushed disciplines, such as genomics and bioinformatics, to new frontiers. Federal support began, in large part, as a result of the significant role that scientists played in winning World War II. Our accrued knowledge from decades of research support already serves new objectives brought about by events that began on September 11.

Since 9/11, the need for increased scientific and engineering knowledge has become abundantly clear. Every discussion—whether about airline safety, failure of communication links, contamination of food and water supplies, bioengineered weapons, and countless other concerns—depends on our Nation's scientific and engineering knowledge and expertise. In times such as these, we are acutely cognizant of living in a society defined by, and dependent on, science and technology.

Once again, the experience, research, and measured debate conducted by academe can bring both historical context and analytical order to elucidate public discussion and public policy, and marshal technologies and tools needed to mitigate the threat of bioterrorism. As OSTP Director John Marburger III said in his keynote remarks

before AAAS last December, "Harnessing the Nation's collective S&T expertise is critical for long-term success in the war on terrorism." VBI's interdisciplinary approach—marrying bioinformatics, biology, information technologies, and mathematical modeling—is positioned to play a pivotal role.

THREATS OF INFECTIOUS DISEASE AND BIOLOGICAL WEAPONS

It is generally agreed that 21st century biotechnology and bioinformatics herald a new era for science and engineering, promising healthier and longer lives and further advances against infectious diseases. But like a double-edged sword, technologies with the potential to control disease might also be used to develop an arsenal of bioterrorist weapons.

We are also aware that new antibiotic-resistant pathogen strains sometimes evolve faster than we develop new therapies. For instance, the resurgence of tuberculosis in the United States in the early 1990s was associated with the emergence of a multi-drug resistant tuberculosis strain. Many other diseases currently overwhelm our preventative and therapeutic measures—HIV, Ebola, West Nile virus, and malaria—just to name a few. Infectious disease concerns are global in scope. In today's world of rapid travel and large migrant populations—diseases of humans, livestock, and crops, regardless of introduction mode (intentional or accidental)—pose a growing threat to our health, agriculture, and economy.

IMPACTS ON HUMAN HEALTH

Even before the anthrax attacks that followed September 11, many public health and national security officials voiced their concern over the potential threat of biological weapons. In the March 25, 1999 Senate Public Health and Safety Subcommittee meeting, the American Society for Microbiology warned that: "National security measures against biological warfare must include building up the Nation's public health infrastructure to respond to bioterrorism." The Dark Winter scenario reinforced this position by illustrating the catastrophic potential of smallpox if used as a weapon. It underscored the need to inform the comprehensive medical and healthcare community about the symptoms, behavior, and virulence of known pathogens if millions are to have any chance of survival. Early identification and intervention are pivotal to both control and abatement.

For each of the biological weapons considered by experts to be the most serious threats to America—anthrax, botulism, plague, smallpox, and tularemia—modern medicine has some effective means of responding, whether by vaccination, antibiotic, or antitoxin. To inhibit the spread of a biological attack or a "normal" disease outbreak in humans, livestock, or crops, we must have rapid diagnostic tools, a public health system to track disease as it evolves, and epidemiological data to determine the origin. Fundamental research and expertise provided by universities will be essential to complete these tasks. It will provide the foundation to deliver the tools with which we will prevent, detect, protect, and treat victims of biological terrorist attacks.

IMPACTS ON AGRICULTURAL PRODUCTIVITY

We have already experienced direct threats to human life through bioterrorism using infectious disease, but what about indirect threats? Though we must certainly take precautions against human diseases, we must also consider indirect threats on our food and water supplies. We now know, for instance, that Al Qaeda plotted out landmarks and public water supplies of most major American cities. We also know that many countries considered to be epicenters of terrorist activity have experimented extensively with agro-terrorism. For example, Iraq was developing wheat cover smut as a weapon in the late 1980s, most likely to use against Iran.

A single agricultural terrorist could launch a pathogen that, spread by wind, water, or soil, could cause an irremediable chain reaction. The food supply and industries involved directly in food production and distribution are especially vulnerable. The agriculture sector accounts for roughly one-sixth of the total U.S. Gross Domestic Product. A terrorist wishing to cause severe and reverberating financial consequences could simply introduce a foreign disease into American livestock or crops that would set off a chain reaction touching virtually every segment of this Nation's economy.

Larry Madden of Ohio State University perhaps captured it best when he said, "It would be a continuing, recurring problem, like a permanent bomb going off." The recent UK foot-and-mouth disease debacle is a case in point. Nearly four million (3,915,000) animals were slaughtered. The UK cattle industry was still reeling from the approximately $6 billion of lost agricultural revenue from the mad cow disease outbreak starting in 1996. This estimate does not include the billions in revenue lost

by the tourism industry. Many farmers, their livelihoods destroyed by the disease, committed suicide. As in other parts of the world, we are ill-prepared to cope with an epidemic, whether a biological weapon, an accidentally introduced exotic pathogen, or a naturally mutated pathogen. In this country, we have little experience dealing with epidemics of any proportion.

If an indirect agricultural bioterrorist strike does occur, we must also be cautious when deploying emergency personnel. An attack might be used as a feint to divert resources from critical command posts, leaving them vulnerable. For instance, a major livestock disease outbreak in Texas would shift our primary command and control emphasis there, as well as large numbers of military personnel. This would leave cities like New York, Washington D.C., and Fort Knox open to assault. We must be prepared to ensure that no potential targets are at risk.

ROLE OF VIRGINIA BIOINFORMATICS INSTITUTE AND PARTNERS

To handle such a scenario, a common place where molecular data about pathogens, their host's responses, and computational analysis tools come together and are made available to all stakeholders is paramount. At VBI, our recent efforts to create a comprehensive pathogen information system parallel national necessity. We recognized—prior to 9/11—the need for a common language to assess biological threats; avoid information, research, and analysis duplication; and facilitate interagency cooperation and coordination.

At the numerous and diversified agencies playing a role in national biological security, the underlying scientific research to support detection, identification, forensic attribution, risk assessment, and mitigation is very similar. However, this fundamental science is conducted in a slightly different context or syntax in over 40 Federal and State agencies, at multiple colleges and universities, in several non-profit organizations, and throughout industry. Thus, an interface and infrastructure to connect and organize the molecular biological databases in these various sectors is critical. This "science portal," or comprehensive pathogen information system, will be able to draw on already available resources to completely characterize known pathogens and their near relatives. This comprehensive and easily accessible system will serve as a fundamental knowledge and decisionmaking tool.

VBI will provide genetic sequencing of pathogens as needed, but our primary mission is to create a single bioinformatics interface to access the already available information required for a comprehensive surveillance program. We integrate, and provide when necessary, molecular information regarding pathogens, their hosts, and their interactions within the environment. Our goal is to create a common language that can be understood by all accessors. To reiterate, we are not a comprehensive storehouse of information, but we are like a tour guide and translator who can also exchange currency.

With access to such a system, researchers, public health workers, and security officials could quickly assess threats and options for mitigation. Platforms for detection and identification of pathogens are ultimately dependent upon distinctions between pathogenic and non-pathogenic organisms and the distinctions of one pathogen from another. Therefore, bioinformatic interpretations of disease-host-environment interactions are crucial in finding solutions.

Although we have comprehensive bioinformatics capabilities in-house, the completion of the information pipeline—from basic research, to data interpretation, to useable information, to knowledge, to applications and technologies—requires a strengthened partnership between government, academe, and industry. We realize that connectivity is a critical first-link in our endeavor. Therefore, we are drawing upon diverse research expertise that is only available through partnerships. VBI will actively promote inclusion; there can be no prima donna in a system that will act as a common asset serving such a crucial national need.

As a case in point, our biological resources are IT integrated and we rely on partnerships with both IBM and Sun Microsystems. We have already established partnerships with industry that will ensure the necessary technology for translating and routing information and making it accessible. In addition, since we are riot a medical research facility, we have recently established a partnership with Johns Hopkins Bloomberg School of Public Health to study many major infectious diseases, including AIDS, malaria, measles, and tuberculosis. In the malaria study, for example, Johns Hopkins researchers—working in collaboration with local health officials where malaria outbreaks occur—will provide the needed field data to integrate in our pathogen database.

Along with our partnerships to fight human infectious diseases, VBI is in a unique position to help defend against agro-terrorism. As part of Virginia Tech, a land-grant university, we are among the top five agricultural research universities

in the country. We have already identified a list of high-priority livestock and crop pathogens, which would form another contingent of our pathogen science portal.

Using bioinformatics as a tool, we can integrate genomic and other databases with information on pathogens that will allow for rapid detection, attribution, and mitigation. VBI's primary role will be to integrate the molecular (genomic, metabolomic, proteomic) and toxicological signatures for pathogens and host responses. Overlaid field data records will be geospatially accurate to identify the origin of each strain, primarily through additional partnerships with users of Geographic Information Systems (GIS). At present, some molecular data exists but it is often incomplete, insufficient, or in formats that need to be translated. As these data are brought together, they will be translated, completed where necessary in-house, and integrated. This will enable work on threat assessment, pathogen detection, attribution, medications, vaccines, and disease prevention. We will create a common source of fundamental scientific information that has been fragmented to date. Integration on this new level will promote proaction rather than reaction.

SCIENCE AS PREDICTION AND PROTECTION

VBI can serve as the "integrating hub" of knowledge among government, law enforcement, healthcare professionals, and local communities nationwide. We can become an information nexus for identification of pathogens, their origin, and their signatures. In addition, our outreach mission could be expanded to serve as an educational arm for first responders, i.e., law enforcement, doctors, community officials, to biological crises. Intensive 2-day sessions could be developed to familiarize first responders with identifying data. Knowing symptoms and the most effective antidotes in times of outbreak—including isolation, vaccination, and treatment—can help prevent panic and save lives. Preparation is paramount in these cases, as is reaction time. In the post-September 11 era, university researchers should not only teach and expand the frontiers of knowledge, but also serve the public by providing an understanding of the science and engineering that affects their lives. Director of the National Science Foundation, Dr. Rita Colwell, recently called this, "science as patriotism." It is time to further extend this capacity.

Today, science is our common path to generate new knowledge or to solve an existing problem. With bioterrorist threats especially, the preferred solution is always prevention. However, it is impossible to prevent what we do not fully understand.

In all research scenarios we are trained to ask questions and hypothesize. This "scientific method" is also an important tool for what many specialists call the prediction/prevention approach. Although scientific knowledge is the most powerful force for knowledge-based prediction, the research community needs to become increasingly proactive in that direction. With the advent of serious bioterrorist threats, prediction/prevention is critical.

For many years, defense specialists have used a technique called scenario-building to anticipate and plan for even the most unlikely circumstances. The most successful results are achieved by bringing together thinkers and doers from diverse perspectives—everything from philosophers to practitioners. Anticipating "what if" situations leads to mechanisms for an event to "not occur" or, at a minimum, to have a carefully crafted response plan if it occurs.

Once a pathogen is released into the environment—whether the postal service, a ventilation system, our water supply, or any number of other scenarios—it is extremely hard to combat and isolate. With advances in sensors, many researchers and entrepreneurs could collaborate in scenario-building sessions and in developing sensor-based alarm or warning systems. No one need remind the Senators whose offices are in the Hart Senate Office Building of this need.

The VBI integrating hub can play an important part in both the identification/remediation of bioterrorism as well as the anticipation/prevention of a bioterror fallout. We can pinpoint a pathogen and describe its known qualities so that remediation can be swift and pathogenspecific. We can be partners in scenario building to anticipate or forewarn about biological incidents and help in suggesting and developing mechanisms for prevention and protection.

PARADOX OF PUBLICLY AVAILABLE INFORMATION

I realize that as we discuss science and technology fixes, solutions, or preventions today, we are also talking about an issue of societal ideals and the public's will.

Let me add at this time what I believe is an important overarching understanding on these issues. Alexander Hamilton expressed the opinion that "to be more safe, [people] at length become willing to be less free." This is not an idle concern for the most democratic Nation in existence today.

We must recognize that if information is publicly available, it is by definition available to wouldbe terrorists. If requests for proposals are publicly solicited, then the description of the project and the solution sought will give both well- and ill-intentioned applicants vital information. For terrorists, open information is like a window on someone else's thinking.

For example, after the 1993 World Trade Center attacks took place, some hearings and investigations were open to the public. The informative descriptions of the Towers' structure provided key information for the September 11 terrorists.

History provides other lessons. In the 1950s, physicists were pivotal. They possessed the primary knowledge to create new weapons of mass destruction. However, these experts needed sophisticated facilities to carry out their work. In contrast, biological weapons can be manufactured in relatively simple facilities by a single individual. To detect and destroy bioterrorist facilities, new tactics will be needed.

We understand that public access to useful knowledge may arm a potential enemy. Limiting accessibility to scientific information may be the only blockade we possess. At the same time, science thrives on open discourse. Measures that inhibit dialog will impede progress. We cannot limit scientific interaction without limiting scientific progress. This presents a conundrum.

It would be naive, however, to not anticipate problems with access and build in safeguards. Once again, collaboration among government, industry, and academe will be essential as we make access decisions regarding science and technology that will ensure both scientific progress and national security. We all agree the whole world has benefited from science, engineering, and technology conducted in our public institutions.

SUMMARY

We have been gathered today to contemplate collaborations among the various sectors of our society and, in particular, the vital role university research can play. This pattern of integration will also be translated into a peacetime counterpart which will not merely familiarize our armed services with the progress made in science and industry, but also draw into our planning for national security all the civilian resources that can contribute to the defense of our country.

At VBI, we are developing a flexible, collaborative infrastructure applicable in times of peace. Broad connectivity will allow access to a comprehensive knowledge source that will be key to tackling a host of complex problems: human, animal, and plant disease; environmental degradation; and economic recession.

In summary, the Federal Government has provided continuous support to our Nation's universities. Academe has much to offer this partnership in terms of knowledge, research, and resources. University experts should be engaged in shaping public policy on the critical issues pertaining to biological weapons. Virginia Bioinformatics Institute, one such example, will provide a unique and centralized source for data compilation to help understand, mitigate, and control infectious disease pathogens, whether intentionally or accidentally introduced. This "scientific portal" will integrate underlying scientific research, genomic and other molecular data, and epidemiological information to support agencies addressing biological threats to humans, livestock, and crops. To accomplish this task, VBI has forged, and will continue to promote, crucial partnerships among universities, industry, and government agencies. Partnership among the three will be vital as we balance the access of scientific information to protect our country but not hinder the scientific engine. Access to information by the scientific community will be critical as we develop strategies to prevent biological attacks—the ideal solution.

Senator WYDEN. Doctor, thank you. All of you have been excellent.

We will begin the questioning with Senator Rockefeller.

Senator ROCKEFELLER. Thank you, Mr. Chairman. I have a multilayered question which will come out in whatever free form it will come out in. A couple of thoughts. Cooperation is easy to talk about and very hard to do. Research tends to follow money. If you work for a Federal agency, you may not have to worry about that as much as you would if what you have been doing has only been funded by the Federal Government, and if it has not, you have an additional problem. There is also the constant problem of the slowness of large agencies, which includes the NIH.

The Department of Veterans Affairs ought to be included, incidentally, in all of this talk of preparedness, because it does good work. We passed legislation 3 years ago requiring the VA to do long-term care, which is the veterans' basic need these days. That was under the Clinton Administration. We still have not seen the beginnings of any effort on their part.

So why do I say that? Simply to say that because you are in health care, whether it is research or as a practitioner or as a government agency, it does not mean you are moving rapidly.

You spoke of getting technology to the counties. I have been all over West Virginia in the past 4 or 5 months talking with law enforcement, with public health, with hospitals, with FBI, everybody in sight. The National Guard actually has been the most effective. They all have humongous needs which are not going to be met by the money which is now going to be available to us if the Congress votes that through, so they are doing it on their own.

Now, that is good, except that 80 percent of them have been losing money for the last 4 or 5 years. If you need a hazmat facility which costs $300,000 because you are on an interstate with a lot of hazardous chemicals passing by, you are probably going to build one, but that is about it. That is about all you will be able to do.

Universities do research, and they do basic research—and actually I have heard quite a lot of this recently. They do basic research to the extent sometimes that they come not to understand that there are people waiting for the results of that research who could be helped by that research, and this is something of a quandary. Companies do research for the purpose of being able to sell products, and that is not wrong. That is our system.

If, let us say, smallpox is a very, very large potential problem but does not have a large commercial market—we will just say that hypothetically, because it has not happened—will industry do the research? You can count on industry, I think, to do the research to get it to market.

So you have, on the one hand, the research for research's sake, and then sometimes that gets done under rather careful strictures. On the other hand, you have research done for the purpose of getting it to market, but it may not be that which is needed at the right time, because what happened was not what you expected.

So my question is—I am going to end up with an odd thing. I serve on the Intelligence Committee. It is a very good Committee, and there are some very good groups who work in intelligence, but always our best hearings are when we have about six people who are from totally outside the purview of intelligence—in other words, they do not get paid by it. They work for companies that do unbelievable things, and they all think way out of the box, and they think about the future. They have been doing it for 10 years, and they do it because they love it, and because they want the Nation to be secure. They have all of these really interesting thoughts which our intelligence agencies decline to use.

So we sit there as a committee, enthralled by what they are saying, probably knowing not much attention is going to get paid to it. You can do what you will with my mix in answering, but it is the whole question of the disconnect between the world of the university and the world of industry—and I will include counties,

where there is a lot of talk about doing public health, but not a lot of talk about, for example, connecting public health up with law enforcement, or having the means to do that, via the Internet, for example.

The West Virginia State Police is a wonderful organization, but only 7 of its 60 detachments have Internet capacity. Fifty percent of the police departments do not have any at all.

It is a world of terrific statements, of strong will and determination, overlaid with an enormous amount of disconnection, it seems to me. Having probably already extended my time, I would be interested in what you think.

Dr. BENJAMIN. I think, Senator, in summary you said that great ideas do not survive real-world analysis. I think, at least in my State, we started thinking about bioterrorism about 4 years ago, and I went around the State talking about it for lots of reasons. But there was this huge blank stare and lots of vacant rooms, and people thought, "nice guy, that Benjamin guy, but he is on another planet," because they could not visualize how this would help them in their daily lives.

So I think one of the ways that you might try to make that technology transfer is figure out how to make that stuff relevant to what happens on a daily basis. Now, one of the arguments we have made on the public health infrastructure side of things is, this is great technology to have, but does it really help us? We think it should make the food safer to eat, and the water safer to drink on a daily basis. I think if that technology can be developed in that context, then it will certainly be there when we need it.

And quite frankly, my experience in the emergency medicine world has been that people tend to do what they do every day, so that if you build that technology to function in the real world on a daily basis, it has utility, it has staying power in the marketplace. Those folks that look at me like I am crazy will think they will want to use it.

Dr. RYAN. I think you are absolutely right that there is a disconnect, but I am not sure that there really needs to be a disconnect, and I think that there is a way to harness the cart to the horse. I gave you an example of some technology that was developed without any thought of providing it as part of the country's defense, so in a way the government can get all those years of research and improvement as a freebie. That is done.

We also recognize that we have to go for large markets where there are large margins, and the government is not willing necessarily to pay those margins, but when you have technology that is so applicable to the defense effort, and one has seen this in previous wars where great inventions have come out of something for wartime, I think that it is relatively easy to take the advantages, take the need, the current need of the government, and couple them together without trying to get the returns that we would expect in a normal marketplace.

I will give you one example. If the U.S. Government would help small biotechnology companies build plants that could be used to manufacture and stockpile vaccines that the country needs in down time, slow time, or when the stockpile is complete, that is an incredible advantage to us. The government would get the advantage

of the technological know-how, a reasonable return for the product, and the company would have an ongoing benefit.

I can think of lots of other examples. It does not have to be building plants, but I do think progress has taken place. I think the need is clear, and if the government will define a market, companies are nimble enough to find ways that they can fit into the profit margins that government will require and get something that is beneficial.

Dr. HATCHETT. I just want to amplify on Dr. Benjamin's remarks about doing what we normally do. A little anecdote to address Senator Rockefeller's concerns. I was at the Sloan Foundation about a month ago meeting with Jack Harrald and Joe Barbera from George Washington University here, who are working on a regional response plan, and with Tom Inglesby and Tara O'Toole from the Center for Civilian Defense at Hopkins. We were sitting around discussing issues relating to hospital preparedness and sort of speaking up in the ether about what we would do, and Ralph Gomory, the President of the Sloan Foundation, stopped us and asked: "I am giving you 6 months to prepare. What would you do?"

He said, "I am not going to tell you what you are preparing for, but what would you actually do?" And then we began to think, "Well, what would we do in the first 6 weeks, in the first 12 weeks, what would we hope to have accomplished after 3 months?"

I think in talking about the disconnect that you mentioned, I think one of the things we need to bear in mind is what might happen at the end of 6 months in Dr. Gomory's scenario is that the window of opportunity closes. There is a tremendous receptivity in all these communities to forge links, to establish connections. There is new interest in the public health community, in the hospital community, which traditionally, because they are competing with each other, have not been interested in sharing information. There is a new willingness to share information and to establish these links and to create the types of coordination that are going to be necessary to maximally utilize the assets we have.

And then also, just to amplify on Dr. Benjamin's remarks, I think in terms of doing what we normally do as we move forward, if we can think about creating dual use, you mentioned the vaccine technologies that already exist. If our bioterrorism initiatives are created in a way that they will be useful no matter what happens, there will be a place for moving forward and establishing something that will be there. It has to be useful, even if there is never another bioterrorisn event. The initiatives we create have to have value in the marketplace, even without the actual event of bioterrorism.

Obviously, there will be a risk of severe epidemics, another Spanish influenza that would approximate a bioterrorism event. I think as long as we keep in mind that we are trying to accomplish public health goals and hospital preparedness goals that do not depend on a successful bioterrorism event, I think we will have success.

Senator ROCKEFELLER. Mr. Chairman, can I ask one further question? I want all of this to be positive. I recognize the way I asked my question was not, but that was deliberate. The business of hospitals and public health and, let us say, CDC improving its website so that it is useful—not just to a scholar, but to a hospital

administrator, or the head of nursing who really needs to get an answer right now because they are not quite sure what just walked in the emergency room, and nobody is trained really to figure out what that particular disease might be—I think the need is real. I agree with you, I think people are trying to connect.

But I also think, and I suspect Dr. Benjamin ran into this, too, that the hospitals, the public health infrastructure is, as I indicated, going broke. They are trying to make it from week to week, and they cannot pay their bills, and they cannot pay their doctors, and they are losing all kinds of services. My question is, was September 11 enough of a stimulus to make what you are all saying, what those three of you that have replied have said, to make that come true? That is, the sense of connection, the willingness to adjust, to change behavioral patterns?

Yes, we will find our way of making this little niche work even if we do not make a ton of money from it. Incidentally, I approve of your approach. I am for research that can be applied to making people better, to improve the welfare of mankind. I think that is what ultimately counts in life, and I think sometimes government agencies are slow to do that, and universities are slow to do that sometimes because of the demand for research and the Nobel that you get 20 years after you have done it, and that is not cynical.

Now, the West Nile virus first broke out two years ago in New York. I think there was an interesting result from that that I would like your comments on. Beyond New York, throughout the Mid-Atlantic region, there has been kind of a wake-up call toward this business of "pulling together." It did not get a lot of attention, but it has pulled together public health, it pulled together the medical community, it pulled together the veterinary community, and a lot more. It inspired public health to develop active surveillance software that collects data from pharmacies, emergency rooms, even school absence data.

Now, it had a very interesting effect, and you could postulate that if this could go on, why could not this kind of software communication and syndrome surveillance be developed between regions, certainly within States, but really more regionally, even nationally?

So was September 11, in fact, a wake-up call that is sufficient to the way your colleagues, let us say, have or are changing their behavior in your mind? I am trying to get an honest answer.

Dr. KLAUSNER. It is probably too early to tell. I think the current feeling is that an enormous amount changed on September 11. What changed was our perception. The threats did not change, the weapons did not change. It was our perception. I think we all know it remains to be seen how sustained the interest, the concern, and that is going to require leadership.

I think the government is going to be very important in maintaining a sustained interest in what has to be invested in, but there are several things, and of course we do not know what is going to happen when and whether and what sort of next event there will be. I think very few people do not think that at some point there will be other events. We are in an age of technology that gives people the capacity to produce terrorism.

What has been said is that of the dual use, that so much of what we are talking about fixing needs to be fixed independent of bioter-

rorism or other forms of terrorism, hopefully is another part of sustaining our interest, but I think the level of interest is very real. I think it is very deep. I think September 11 was a profound and profoundly traumatizing event for the country and the world, and I suspect it will be sustained, but I think there is some uncertainty, and I must say that is one of the roles of government, is to provide that sustained leadership.

There is a lot of worry about that in the scientific community, recognizing the things that have to be solved are not going to be solved today or over the next year or in the next fiscal cycle. But some of these things are going to require, as I said earlier, as a lot of people have said—sustained investment in infrastructure, in communication and technology, and in fact, that curiosity-dependent science, that driven science that actually provides us with answers that we are going to need when they come up, that we actually can predict now. It is one of the problems with overdefining the direction of research.

I think your question is a really important one, and what is really important probably is to continue to raise it. Will this be sustained? The more we remind ourselves it needs to be.

Senator ROCKEFELLER. You said quite apart from September 11, these things should be going on, and I think that was kind of the heart of what you had to say, was it not?

Dr. KLAUSNER. Yes.

Senator ROCKEFELLER. That the changes are taking place anyway?

Dr. KLAUSNER. Right.

Senator ROCKEFELLER. Then you said we have to keep reminding you and pushing you. We will be doing that because of September 11, and because of what you mentioned. It is just interesting to me you would say that September 11 was important in the change of mind-set, the change of perception, it was interesting that you said that that had been going on anyway. I guess I had not noticed that, and I guess part of that will be defined in what NIH is going to spend this money on. How do they decide where they are going to spend their money? It will be different from what it was 2 or 3 years ago.

Dr. KLAUSNER. I suspect it will be, from what I see, but if I could just say one other thing, you did mention something, and that is the sort of fantasy of overall coordination. I think we have to be careful. Coordinating everything often sounds good and is often called for and it is probably impossible. What you need to instead is to have standards that are set about transparency, about quality of communication, about whether each entity, even if it is many different agencies, have a plan, it is clear, it is looked at, it is reported on, it is evaluated. I think that is a much more important goal than some sort of fantasy of complete coordination between such a complex organism as our society.

Senator ROCKEFELLER. Well, still admitting that the West Nile outbreak created some coordination that was useful, I am not talking about Soviet-style coordination.

Dr. BENJAMIN. Senator, let me say two things. One that certainly in Maryland, West Nile virus got several of our State agencies working and playing well together. It was therefore very helpful

when we had bioterrorism that the Department of Natural Resources and the State police and our Department of the Environment and Department of Agriculture all knew each other and had worked very closely together during West Nile virus. I do have two things, though.

Obviously, the public health community in general is always skeptical around funding, because our history has been you get funding for tuberculosis, you get rid of tuberculosis, and the funding goes away. So we have a history, a long history, of skepticism. Then, of course, is when tuberculosis comes back, it comes back in a more virulent form, antibiotic-resistant.

We obviously cannot afford to do that with the Nation's defense. We have to have an infrastructure in place. We have to recognize that infrastructure is here for the long haul. We have to understand what that infrastructure means. It means an adequate staff of epidemiologists and disease-control specialists. Without those disease detectives, we are nothing. We cannot track disease.

Do not be fooled by anthrax. Anthrax was kind of an occupational health exposure. It was a terrible event, but it was contained. As epidemics go, smallpox is not going to go like that, as you know. West Nile virus, again, was a vector-transmitted disease process. Many of us stood back in Maryland watching New York struggle with this when it first occurred, and it slowly crept down. Each season it came down the coast, and now it is going toward the Midwest and the Nation has been able to watch that and learn by that experience. We clearly would probably not have that opportunity in a purposely-designed epidemiological outbreak with something like smallpox or plague. So that infrastructure is absolutely essential to have in place and to have it there for the long haul.

Senator WYDEN. Senator Allen.

Senator ALLEN. Thank you, Mr. Chairman. I am sorry that I have only been able to read your statements because I was with the Secretary of Commerce and we were talking about broadband by the way—in the midst of all of this—and I know the Chairman and my colleague from West Virginia would be happy with that as well.

Let me ask a few questions to Dr. Sobral. I have read your statement, your written testimony. I assume you stated it for everyone, and it fits in with Dr. Klausner, who was answering one of the questions.

Senator Rockefeller, you were talking about the role, and recognizing various things that you recognized even prior to September 11 for the need of a common language to assess biological threats, avoid information research and analysis duplication, and facilitate interagency cooperation and coordination.

Dr. Klausner said "Well, maybe it is not so much that, but standards." I think you are all saying the same thing. It is a matter of phraseology, I suppose. People just need to communicate.

I think he also referenced that VBI could serve as an integrating hub of knowledge among law enforcement, health care professionals, the government, and local communities nationwide.

Now, how can you design this to ensure that there is fast and effective communication to all of these various stakeholders at different levels of government, some in the private sector, some in law

enforcement as well, especially in the early stages of a biological attack? How can you assure all of that, that the hub is going to get the information?

Dr. SOBRAL. Thank you very much, Senator Allen. Those comments are right on the money. The critical part of ensuring broad access, even though you are talking about a system, actually is its implementation. Information technology capabilities, by their very nature, are very decentralized. We have been, for example, recently in North Carolina talking to the supercomputer center about the building of a Biogrid to support these kinds of capabilities.

Senator ALLEN. Building what?

Dr. SOBRAL. A biological grid, basically an intelligent Internet that would handle pathogen data. I cannot emphasize how important collaboration and integration are, recognizing the structural problems in academia. We are a young institute. We are only 18 months old, but we were built outside of the traditional college structure. The reason was to integrate mathematicians, chemists, biologists, engineers, all under one place, working in teams and building together the capabilities and standards that need to be deployed. But, we are still yet only one component.

I mentioned in my oral statement that Sun Microsystems, IBM, and others like them need to play a critical role. We are also reaching out to Johns Hopkins Bloomberg School of Public Health. Dr. Klausner made a very important point about the implementation of data standards. It is not so much "where does all of the data reside?" It is about creating a single, one-stop-shop where people can easily access data, distribute it. Then, the data communications standards are agreed upon across all agencies, groups, participants, whether they be in industry, academia, or elsewhere. We are a member of a consortium that is working on data communications standards for biological data. I think that is the enabling part of this system.

Senator ALLEN. With this network—you obviously have not put this network into place. You are formulating this network. I assume in the midst of it there will be very secure ways so that you do not get viruses within your network, so to speak?

Dr. SOBRAL. Certainly the network has to have appropriate access information and appropriate levels of access. Those things can be implemented.The technologies exist already. It is not so much about reinventing the wheel. It is taking what has been applied in other communities and applying it to the biological problem.

Senator ALLEN. How far away are you, do you think, in working with all of this multitude of stakeholders—government, private, military and all the rest—to developing this standard for communications?

Dr. SOBRAL. Those standards will be an ongoing effort. However, we have intermediate deliverables that are scheduled before October of this year, and we are working on 18-month deliverables right now as a team. This is going to be an ongoing sustained effort, as we have heard others say here. This needs to not go away when the worry about the next bioterrorism attack fades. It needs to continue and have its own sustained infrastructure. Most importantly, if I could also add, we are missing a lot of critical data about the pathogens.

We must move from reactive, like when anthrax recently showed up. Our knowledge at that time about anthrax, despite 40 years of research, was quite fragmented. In addition, we had very little capability to identify which strain or its origin. I suggest that before smallpox, plague, or any of these other organisms are here, let us make sure we fund the creation of those data and make it available through this kind of distributed, collaboratory, virtual portal available to all stakeholders.

Senator ALLEN. Well, in light of the comments you just made in answer to a question, I think that gets to the point. As far as identifying the strains, would not the CDC or, in contract with, say, the ATCC, would they not be able to—you are familiar with the American Type Culture Collection. Would they not be able to assist in identifying that? Isn't that information already there in a variety of organizations? Most of them, of course, are not private organizations, but quasi-governmental.

Dr. SOBRAL. Yes. There are a number of different lists of high priority pathogens generated by a number of different agencies, and that is probably appropriate, because they have different needs and objectives.

What we have been able to share with the Departments of Agriculture and Defense are critical lists, some of which came from defense work with ATCC and elsewhere, of high priority pathogens. But again, it is a matter of agreeing as a group which are the highest priority, which ones we should deal with today, which ones we should deal with tomorrow. I would also add that it is very important that these lists are not always just pathogens of humans because of the threat to our agricultural systems, and food and water supply. The list we have at this point in time, which has been shared through others, includes pathogens of humans, plants, and animals.

Senator ALLEN. Thank you so much.

Senator WYDEN. If you need any extra time, go ahead.

Senator ALLEN. One final question, and maybe you all can answer it, but I would just ask Dr. Sobral. One of the concerns is that there are all these different research efforts going on. There is research going on at UVA and at Virginia Tech, and West Virginia University, and Oregon State, and elsewhere. I want to know, are there existing mechanisms for all of these outstanding research institutions to discuss their research with Federal agencies, and how effective are any of these methods of communication?

Dr. SOBRAL. I would like to just address this, because, of course, we need to be careful we do not duplicate. I think in the case of biological terrorism, which is the infectious disease problem, we are actually spread way too thin. There is not a big concern of duplication.

What I do believe is that the communication across the groups needs to improve, and the implementation of these kinds of distributed systems, if nothing else, will help us know what it is that we do not know or what crucial data is missing. Just bringing the information together is critical. We have heard this in a number of different contexts today. But in terms of the actual data about pathogens, their genomes, identification, and epidemiological data, which we require to build response capabilities, just bringing that

data together to know what is missing will be very helpful. I think we will find there is not a lot of duplication. We are actually missing a lot of parts.

Senator ALLEN. Does anybody else want to comment?

Dr. RYAN. I think your question relates very much to Senator Rockefeller's, too, which was, was September 11 enough to bring all of this cooperation and coordination together?

I think the public, and I would include all of us as the public, can with goodwill and a lot of effort, probably come together, but I am not sure that is true for the government. Certainly, we cannot do it. Since September 11, the biotech industry has stepped up security at companies, stepped forward with ideas and products, has cross-agency products, and we do not know how to get in front of people. For example, we believe we would like to protect all Americans, military and civilian. I do not know how to put research ideas in front of the HHS and the DOD simultaneously, because the rules for applying and the rules for requisitioning are completely different. It may be that I just do not know how to do it, but I actually think that there are legislative barriers in the ways the agencies are set up that make it very, very difficult to cross the boundaries, and I think on that kind of cooperation we will need the government's help, not just our goodwill and patriotism.

Senator ALLEN. That is a very good point. I think every Senator has run into this situation, where people at universities or private companies say, "I want to help, I have a great idea, but I have no idea if it is a good idea." It may be very good, and they may be good salespeople.

They may have a product that is worthwhile. Being a fairly new Senator, I have not yet figured the process out. But, when you hear that sort of a concern that somebody has an idea that they would like to get evaluated to determine whether it will it work, it is important that we allow those who have developed maybe some good ideas—some good products for that matter—to be able to get a quick analysis, or relatively quick. Some of these are too complicated to get a quick analysis—or at least a fair analysis of the value and usefulness to, say, a governmental function or to a military function.

I do not see why you cannot have—and the procurement is enough of a nightmare as it is—dealing with the government. You might as well at least try to have it uniform within the Federal Government. As you go through each State they are naturally going to be slightly different from State to State, but that is the nature of the Federal system, so thank you for that point.

Senator ROCKEFELLER. Can I just add a point, not a question, but a point? I think it is a really important point. I cannot imagine anything more discouraging. If I am a researcher, my mind is in the lab, and yes, I have got to get funded and I have got to apply and all that kind of thing, but I have heard so many examples of what you call 16-page application forms that have been reduced upon pressure to 1- or 2-page application forms coming out of the government. I think it ought to be the job of us as an oversight committee to figure out within the world of bioterrorism and applications how do something about it, with your help. That is, you can

help us, giving us cases in point to haul some of these agencies before us.

George, I still have not gotten over our experience with the Persian Gulf War Syndrome, where the Department of Defense threw up a shield of impenetrability that I have never seen. I mean, my wife does not pull that on me.

[Laughter.]

Senator ROCKEFELLER. It was extraordinary. I think we can solve that, with a combination of you giving us examples, real-time examples, so to speak, real-world examples, because this is basic to making progress on bioterrorism. We do not have to take on the whole world on this. Let us just start with bioterrorism research and the problems scientists have had. HHS does this, DOD does that, so you give up. Well, that is not in the national interest.

I am finished.

Dr. HATCHETT. If I can make a comment on Senator Allen's point, which also touches on your point, Senator Rockefeller. The value of a lot of these initiatives and applications obviously will emerge as they are implemented, and this touches on the question of sustainability and whether September 11 was enough of a stimulus to really change the way things are done in America.

The West Nile virus is actually an excellent example. New York City Department of Health, as I am sure you know, partially in response to the West Nile virus, introduced a system of syndromic surveillance into its surveillance system. The way syndromic surveillance works, or the way it initially worked was you responded to EMS calls—and EMS in New York City has something like 51 different calls that they lodge with the central unit. So for example, they flag several different types of calls as things that should initiate increased surveillance: respiratory distress. If there was a sudden flare in the number of patients with respiratory distress, that would have turned the Department of Health on to looking at what was going on, why is it happening. The system has been refined down to the zip code and census tract level now in New York City. The value of that system, especially related to the hospitals, is a lot of hospitals have gone to what is called "just-in-time" staffing, and "just-in-time" supply. It is almost like the Dell computer model of running a hospital. They determine the number of nurses they need for Friday based upon the number of patients in the hospital on Thursday, and the same goes for inventory and pharmaceutical supplies.

The value of having syndromic surveillance is, it gives hospitals prior notice. It lets them ramp up their resources as events begin to happen, and the syndromic surveillance system in New York City has actually predicted the onset of the flu season well in advance of any other methods for the last 3 years running.

What is interesting in terms of the sustainability is that the hospitals now realize that syndromic surveillance is a valuable tool, and so they have got a pilot program in New York where the emergency rooms—it previously was the EMS units, ambulances bringing people in—now the emergency rooms are getting interested. So hospitals have developed a pilot program involving 30 hospitals in New York City where the emergency rooms are reporting to the Department of Health the complaints of the patients coming in

within 12 hours of their arrival. That includes people coming in on ambulance, but also people walking in off the street.

The value of that system is that it increases the information stream between the Department of Public Health and the hospitals, and it begins to create alliances which become useful, and will have that kind of dual use purpose. One, the emergency rooms will pick up bioterrorism events quickly, but it is also useful to the hospitals in their day-to-day operation. So it is a wonderful example of showing how that type of approach can create alliances which then become self-sustaining because they are useful, and because they have a dual use. This type of thing is something that a lot of Departments of Health and Departments of Public Health are watching in New York City closely, because they are really ahead of the curve on this issue.

Senator ALLEN. Well, thank you, Dr. Hatchett. That is something that I think CDC, for example, as a repository, would like to be able to see for the whole country, not just New York City. They would like to see the hospitals in the Shenandoah Valley, what symptoms are coming in versus the Piedmont, versus over the mountain, again, over to West Virginia, for example. So they can see a pattern, and while seeing that pattern, it may not mean anything to Harrisonburg or Rockingham Memorial Hospital, or it might not mean anything to Martha Jefferson Hospital in Charlottesville, but you would see a pattern. You see lots of the same, Martinsburg, West Virginia; Carlisle, Pennsylvania; and you say, "Wait a second, there is something going on here." You are treating it as a flu-like symptom, but it may be something more. So that is why that is great. I would like to see that same sort of information quickly available for the whole country. Granted, it helps run the hospital and it has an economic value. All the better. All the more reason to do it.

Thank you, Mr. Chairman.

Senator WYDEN. I thank my colleague. All of you have been a terrific panel. You can see my colleagues, Democrat and Republican are like-minded in terms of this challenge. Since late September, I have been trying to draft a piece of legislation to essentially incorporate the sensible ideas you have heard from Senator Rockefeller and Senator Allen, and the Administration has been exceptionally helpful. Joe Albaugh, Richard Clarke—across the board have been very helpful. I think there is an understanding now about what the job is.

This is an organizational challenge as much as anything else. We have got to mobilize the scientists, the information technology specialists, and entrepreneurs, and properly done, this can make a huge difference in terms of both preventing problems and responding to problems. Suffice it to say there is a lot of history here that we have got to try to reverse.

I am holding up here a book put out by the National Academy of Sciences a couple of years ago, "Chemical and Biological Terrorism." It goes through, at some length, a variety of recommendations put out by NAS—the country's leaders like Dr. Benjamin on the panel. As far as I can tell, not a whole lot of those recommendations ever got implemented, and I gather that there are scores of

other reports out there that are essentially gathering dust in exactly the same way.

So what I would like to start with, I am going to draft this bill. I am going to have it out for comment very shortly in terms of mobilizing the scientists, information specialists, entrepreneurs, and I think probably central to turning this around is the fact that there are 20 Federal agencies and scores of people who would like to offer their ideas and suggestions to define how the President of the United States and the Congress can work together on this. Joe Albaugh has made the suggestion, and I think it is a very thoughtful one, that the Congress basically tell the Administration they want it done in a couple of years, give them a little freedom, and see how they have done in 2 years.

My sense is there needs to be more direction than that, but I think you get the sense that there is an awareness both on this side of the dais and in the Bush Administration that this is an organizational kind of challenge, mobilizing the scientists and the experts. I was struck by reading something Condoleeza Rice said that really paralleled what I have been saying. She said, "we are mobilizing everybody else. How is it we cannot mobilize this sector?"

So I think what I would like to do before I get into some of the nuts and bolts of this bill is have Dr. Klausner and Dr. Benjamin talk to me, because you have been through similar debates about how you would see, as we draft this bill, the Executive Branch and the Congress working together to mobilize the scientists and the experts in this field.

Why don't we start with you, Dr. Klausner?

Dr. KLAUSNER. I would be happy to look at any proposal. We have asked actually our committee to consider structural ways and organizational ways to do exactly the types of things you are asking for. I do not want to avoid—I am a little hesitant, since we have asked a committee that is now working hard on this——

Senator WYDEN. I understand. I am asking your opinion, because what we are likely to do is have this draft proposal out well before your committee is done, and to the extent we can get people's input and ideas, it is helpful.

Understand also that this is going to be a thoroughly bipartisan kind of effort. This is not something that is going to get done unless you get the Executive Branch and the Congress to work together. That is why I think—and you saw it here today with Senator Allen and Senator Rockefeller—we are singing from the same hymnal here. What the job is, is to find that set of ideas that is going to advance as quickly as possible, so all I am doing is asking for your opinion today.

Dr. KLAUSNER. My feeling is we need to do the types of things to identify where expertise is and where capacity is. That is really very important. But once we do that, we really need an ongoing system that deals with how you move that information back and forth. How do you have a quality control system to know the information is correct, recognizing things you do not know? How do we make sure that, coupled with that sort of system, whether it is a corps, or whether instead of it being a corps, whether we are making sure that we actually have the systems that we have in place now. That is a part I am not sure about, to be honest. Whether it

is that we are underfunding, underserving, undersupporting the structures that exist now versus need, a separate entity. That we have to figure out whether there was an unintended consequence of pulling people away from—people that are away from where they are because most of their time for all of this is going to be spent not in responding to bioterrorism, but in making sure that we have a constantly working public health system.

So my major concern is that we have a bill, that there would be a bill that would address the functionality and dysfunctionality of our current linkages between those who generate information and resources and how they get distributed. How we create a communications system to know what is going on, to know how people rapidly get information, and where to turn for that information, and I am not sure exactly what the structure of that is, but I want to make sure that we do not actually create a new entity, which now the current entities have an added complexity of figuring out how they interface with.

I do not know if that gets at what you are asking.

Senator WYDEN. Dr. Benjamin.

Dr. BENJAMIN. Senator, there may be a model you want to build on. A few years ago, we took some of our tobacco settlement dollars, Governor Glendening made a strong commitment to both antitobacco and anticancer efforts, and we gave dollars to our two academic medical centers, both Johns Hopkins and the University of Maryland. Part of that deal, though, was when they came up with hopefully new and exciting discoveries, we wanted to make sure that we had a capacity to translate that research into action, so we actually have an office in the State of Maryland which does that. It works with private industry to take new discovery, so if someone wants to take it to the marketplace to translate that actually into the market it also has a way of working with other places, so that we can reinvest and research. I am not sure that is exactly the model, but it is along that line, and you may want to take that and look at that and maybe build on that. That may be one way to achieve the goal you are trying to accomplish.

Senator WYDEN. Well, thank you. That is what we are looking for.

Dr. Ryan, if you want to comment further on it, central to this will be to have one set of rules as it relates to procurement and developing these products. I have spent a lot of time looking at this, and the irony of this situation with respect to procurement is that virtually everybody in these agencies means well.

In other words, once in a while you will find somebody who does not, but that is not the rule. There is nobody at the Department of Defense or at the Department of Health and Human Services, as far as I can tell, who gets up in the morning and says, "I want to be rotten to BIO and hold up innovative ideas." But what happens is, absent this kind of coordinated effort, everybody goes off on their own.

In other words, we are going to hear from HHS in a little bit. Secretary Thompson is talking about this. This is a very good man who is committed to this. They started their own private initiatives effort, and it is going to be good. But they are going to have a set of rules, and then we are going to have the other 19 agencies in-

volved in bioterrorism again with similar kinds of efforts, and so we are going to stay at it this time. I am committed to doing that so that we hit the kind of principles you are talking about, a unified plan, one set of procurement rules, the clearinghouse I talked about in the opening statement.

The one thing you all did not mention, and then I have some more specific questions, is, I am absolutely committed to making this user-friendly for the first responders in local governments. We have got to do that, because there is a real danger out there, and I have been meeting with a lot of these first responders in recent months. There is a real danger out there that what will happen in Washington, DC is all of us in our suits give big speeches about fighting bioterrorism, and we pass bills, and off it goes to people at the local level, and they do not have the dollars to carry it out.

It will not be called that, because I think people understand the way laws are written, but it would be sort of a terrorist version of an unfunded mandate, where somebody passes a law in Washington, DC and by the time it gets to Jackson County in my home State, where we have been working with the fire and rescue people, there are not the dollars. So we are going to get the uniform set of procurement rules, and we are going to make this user-friendly for the first responders and the local governments, because those are the people that are on the front lines.

So let me now, because you all have been so patient, sort of get into some of the nuts and bolts of these kinds of issues, and let us start with first, and perhaps this is one that Mr. Edwards, Dr. Sobral, and Dr. Ryan might all want to take a crack at. Tell us all a little bit about getting products into the Federal system. I gather you, Dr. Ryan, you spent 8 years with respect to one of your particular products. That seems to set a land speed slowness record even for the Federal Government. Why don't you tell us a bit about what it took to get the attention of these Federal agencies, and then perhaps you, Mr. Edwards, and you, Dr. Sobral, could do that as well.

Dr. RYAN. Well, I again want to emphasize all of these interactions were very, very pleasant. There was never any adversarial spirit here at all. In 1994, we began with a CRADA with Walter Reed. We worked with various agencies, including USAMRID on anthrax and plague vaccines using one of our adjuvants at the time. This progressed through various studies, using SBIRs and CRADAs, support from, as you can see, the NIH and the DOD. But I would say that it was not until January of 2001, when we began to work with Dynport, a contractor of the DOD, that we began to get to language we could understand, like what was it we were going to license, what were the terms of the license.

Senator WYDEN. Between 1994 and 2001, you basically sort of shuttled back and forth between one agency or another, and it was impossible to really get the project zeroed in on?

Dr. RYAN. Well, it was not that we were stopped at the front door. We did get into these agencies, but we would do one set of experiments with one group, another set of experiments to test another idea with another group, and I would say that most of it was the kind of thinking where, could we make an improvement on

something that existed. There was no real attempt to get into new vaccine concepts of the 21st century.

When we began to work with Dynport, I would say it went relatively fast from January until October, when we did a license. Then we realized that in working with the Department of Defense, we had made it virtually impossible to work with NIAID. We went in all starry-eyed and said, "now we want to do this for the civilian population," and it is very difficult to do it. The material would have to be obtained from the DOD contractor, and it is a cumbersome process. Though we consider our second generation anthrax vaccine, the single dose oral, very versatile approach that I am talking about, we have not yet been able to find fertile ears. Everybody loves the idea and says, "oh, this is much cheaper, it is much quicker, very innovative." But in the case of the NIH they said, "well, we are working on a Continuing Resolution. We do not know how the money will come in."

Everything is believable, everything is real, but we want to compete. We do not mind at all having to go through even a 6-page application. We would be very willing to do that. We just do not know how to go about it, and we do not want to forfeit working with the civilian population in order to work with the military.

Senator WYDEN. Let me make a pledge to you. As we work to come up to this plan for a uniform set of rules, we are going to ask BIO and a variety of public interest groups, not just industry groups but a variety of public interest groups, to sort of walk us through, step by step, how it would work for them to ensure that it is possible to actually get answers. So we are going to be asking for your input on that.

Dr. RYAN. We appreciate that very much.

Senator WYDEN. Mr. Edwards, your experience, and let us get you that microphone.

Mr. EDWARDS. The one word I would use to characterize our experience is perseverance. That is just the name of the game and a fact of life for small companies. There is kind of a catch-22. Big companies have connections, and you made a deal with a big company and boom, it was easy to get in. I am not saying easy, but it was easier, because of the connections they have, but in order to make a deal with a big company you have got to be somewhat established, so there is this catch-22 of, we are too innovative and risky for them to deal with us. On the other hand, they have got to make a buck, so the government does supply a very valuable, valid role in bridging the gap of still too risky to get us far enough along, but that makes for a very long cycle.

So you start with the government to get the seed, then you go back to the big company once you have done the seed, and the big company you can really go in and do something productive either at the civilian or military level, it does not matter which, so perseverance is unfortunately the name of the game.

Now, how you get around that, how you short-cut that, I leave that to our elected Senators to come up with the wisdom. I observe it is a problem. One cautionary note I would throw in, however, is, in coordinating things we do not want to overcoordinate to the point where we stifle innovation.

The ability to go the Department of Justice which has a specific need for first responders versus the military, which has a true protection need, versus NIH, which has a more medical need, that gives you multiple opportunities to have multiple eyes perhaps recognize the value of your technology, and if it is all too well-coordinated then you have a uniform decision made and you cut off the option for innovations percolating up, but something to shorten the whole process is really valuable for a small company.

Senator WYDEN. In my mind, rather than see it as a coordination exercise, I see it more as a streamlining exercise. We have got all of these agencies; it is almost as if the Federal Government is muscle-bound here. It is so big, and so bulky, it is having trouble moving in order to get these decisions made, and that is a good point. Dr. Sobral.

Dr. SOBRAL. Yes. I think one of the things that comes out in thinking about this is that agencies, as our colleague said, have a history. They were built in some cases for a specific motive that now is sort of transcended by a need, so we need to think across these, to use Dr. Klausner's word, silos. This is very critical, because the basic science and technology we need to deal with infectious diseases, bioterrorism, and pathogens is pretty much the same because of the underlying science of life on earth is actually very similar.

In some instances, tools, applications, and software systems that could be used by Defense could be developed specifically to serve the needs of NIH or USDA, et cetera. We need to be very, very clear about trying to remove the obstacles of having technology move from one domain or agency to another.

The other critical component is the real partnering that has to happen to take basic research ideas and concepts all the way to products. We have seen some examples here today of discoveries that have spun out of universities. It is extremely important that universities are optimized to do the big "R," little "d" preparations, paired with industry, which is typically little "r," big "D." Together they form a very important network. Partnerships for innovation, rather than traditionally putting things in bins of agriculture, human health, or defense, should overcome that in a very important way. Some vaccine production, for example, may require technologies to be developed to express genes in plants, for example. We need to link to those technologies.

Recently I heard Steve Briggs give a talk on this. Together, we were invited to Mitre Corporation to speak about the production of these things in a rapid experimental mode using, for example, corn plants. I think it is really about breaking down "silos," as Dr. Klausner has used it. Any help that occurs from the government in doing that will help all of us.

Senator WYDEN. Dr. Benjamin, let me talk to you, if I might, about how you and your colleagues who are on the front lines are going about this task of evaluating new devices and products in this fight against bioterrorism.

You mentioned in your testimony that during the anthrax crisis that the health department officials were inundated with offers of new, quick detection products from vendors. That is consistent with what Joe Albaugh was telling us in terms of FEMA. It is what I

hear from fire officers at home in Oregon. How are your people dealing with the scores of products that come across their desks in terms of evaluating them? What ought to be done to try to assist them?

Dr. BENJAMIN. It is very difficult. One of the things, I get two or three e-mails a week from somebody trying to share a new technology or a new idea with me. It has trickled off some, but it is still continuing.

The biggest problem we have is one of validating whether that technology does what it says it is going to do, so we kind of use our old medical model. We look for things that are certified by the various Federal agencies. For example, if it is a clinical device, obviously the FDA plays a prominent role in that, but the biggest problem we have is that a lot of people walk in the door every day, particularly when you are in a State like Maryland, which has a phenomenal number of new biotechnology companies and research centers that are doing lots of good work.

Frankly, we do not have the expertise to make that assessment, so frankly the way we do it is the way we do procurement. If it's an authorized device, you get it. If it's a new cutting edge device that has not quite gone through all the hoops, you do not, and you basically utilize what you get, and the problem with that is that you often do not get cutting edge stuff. Particularly when you are in very, very constrained fiscal times you do to get to buy twice, so once you get it, you have got it, and we are certainly doing a lot of that.

The current debate on the table, of course, is all of the new surveillance systems. Maryland also has a much more rudimentary system than New York has, but we also have a surveillance system that as a part of our new bioterrorism efforts we are looking at putting together not only a surveillance system for Maryland, but one for the region, and we have lots of people coming to us with ideas on how best to do this, and again it is very, very difficult to evaluate those systems, because you tend not to have the experts around, and this, as I talk to my colleagues around the country, is going to be a very, very trying debate as to how to put those systems in place, how to make sure that they have the connectiveness so that no matter what we ultimately get, we have not wasted the dollars, and those dollars will be able to talk to one another. It is kind of like putting up the Internet in one fell swoop versus having that system grow up in an evolutionary nature.

Senator WYDEN. Dr. Benjamin, I am going to include in my legislation, the bill that we will have out for comment shortly, a national testbed, in effect, that would allow us to evaluate new homeland security devices, and we want to do everything we can to make sure that this is useful to States and localities that are trying to prepare themselves. Is it your sense that something like this would be well-received by people, by your colleagues at the State and local level?

Dr. BENJAMIN. I think so. We all have the capacity to do some kind of early evaluation and research. The issue is access, procurement, and funding.

Senator WYDEN. Dr. Hatchett, a question for you. We have some real issues based upon our review around the country of trying to

verify the credentials of people who would like to help, and it is especially important with respect to public health to get it right.

For example, in our first hearings we looked at the communications side. I was told by Intel, which is a very large employer, of course, in my home State and others, that they were anxious to send their people and their equipment and basically nobody was there to essentially verify that they were from Intel, and they had this expertise in the health area.

It is also very sensitive. If you call the Centers for Disease Control, you do not have to question the credentials of the person on the other end of the line, but we have got to make sure that in that registry that I would like to have in communities across this country, that if somebody, say, claims to treat smallpox, that they actually have that expertise.

How would you go about trying, as a part of this legislative effort, to try to make sure that there is a registry of doctors and specialists available across the country in the case of a bioterrorist threat? How would you go about setting it up, and also how would you go about keeping it up-to-date, because you do not want to write something that suddenly is useless to everybody and not very far down the road.

Dr. HATCHETT. Just in referring back to the experience after September 11, briefly credentialing was a major issue and was actually one of the things that stimulated our group to get together to begin to think about coordinating health professionals.

On September 12 and September 13, inside the perimeter around the World Trade Center credentialing amounted to flashing a hospital ID badge, and there was no way to credential volunteers beyond that, and you essentially had to take their word for it, and you had to somewhat keep an eye on them. There were unfortunately people who abused their hospital affiliations merely to get inside the perimeter to look at the site, and there were people who were actually working in some of the triage centers that we regarded as questionable, and we made sure they did not have access to narcotics or other controlled substances, and it was a major problem.

Credentialing is a terrifically difficult issue. It is one thing to have volunteers sign up for the registry. The process of actually checking up on their references and checking their institutional affiliations is a large problem. I do not have the specific solution. In some of these issues the question may not be technology as much as manpower. Just literally generating people to follow up on issues of credentialing is one example. That might be a function for the AmeriCorps, or the Senior Corps, or the study volunteers, or mobilizing a large number of people and establishing the database. I do not think you will have any shortage of people signing up for it. Following up on their credentials, making sure the database is maintained, is something that will take a significant effort, a significant commitment of manpower, and probably a significant degree of funding.

Andrew Rasiej, who I think you may know, in New York has put together a group called Silicon Alley Cares, which we have been working with, and they volunteered their services for the creation

of databases that function efficiently and that can be queried in a way that maximizes their utility.

I think there will have to be a combination of bringing people with information technology expertise into the system in terms of creating these databases at a local level. You will subsequently need to mobilize volunteers. I would think you would want to mobilize and organize volunteers such as AmeriCorps volunteers, rather than civilian volunteers, to maintain that database. I do not think there is a panacea or magic bullet to that issue. A lot of that is just going to involve sweat and effort, basically.

Senator WYDEN. Well, Mr. Rasiej has been very helpful to this Subcommittee, and a lot of the innovative thinking that has been done in this area has really come from him, so we will be calling on him. I am also told that we can get the professional societies at the local level to be involved in what you are talking about. Again, these are well-meaning people, and my sense is because they license and to some extent accredit their members already, it may be possible to get them with a modest amount of cost, for example, to be involved in it. So we are going to follow up with you, and we would welcome your ideas on that.

One last question, if I might. It was triggered by something Dr. Sobral included in his written testimony, but something that when I saw it I would be interested in any of you making comments on it. As you know, as a big part of this exercise we want to make sure that we share information, that people have state-of-the-art information about these technologies, how to fight bioterrorism, and the issues that we are talking about. At the same time, we know there may be some who try to exploit that information-sharing, and who would do this country harm as a result of being able to access that information. In fact, it would turn these good deeds against us.

I wonder if any of you have thought about the kinds of safeguards that the science and technology sector is going to need in order to make sure that as we share the information, and it gets out to all of these small communities that would not have it if it was not shared, that at the same time it is not turned on the goodness of the American people.

Why don't we start with Dr. Klausner, and any of the others that would like to comment.

Dr. KLAUSNER. This is a really complicated and worrisome issue. There is a tradition from the nuclear experience with science and research of in some ways—and this evolved over time, that know-how was restricted much more than knowledge, that I think we have learned over time that restricting knowledge probably does not work, and it may just backfire. This becomes a much more difficult problem with bioterrorism, because one of the distinctions between bioterrorism and, say, nuclear weapons is the fact that the distance between knowledge and know-how is shrinking, knowledge about an organism and how you might misuse it.

I think there are ways that we need to think about in our laboratories around the country where we have primarily thought about safety and environment to also think about security. I think that is part of it. I do not know the answer about the secrecy of biologic information, information about organisms, about genomes. How-

ever, what I do believe is that this has capacity to both limit research in ways we might not want.

This may not be a great answer, but I really think we must convene, which we have begun to do, the scientific community to have a discussion about secrecy about information, about the control of these things. It is real, it is very complicated. We cannot have a reflex. There should be no discussion of it. I do not know how it will come out. I think there has already been efforts and legal efforts to determine who has access to clearly pathogenic organisms and how they can be traced and tracked.

So I think there is a whole series of things, from control over materials to safety issues, to the most difficult thing being whether there should or should not be controls over information, as opposed to the application of information.

Dr. SOBRAL. Information follows this hierarchy, beginning with data that later becomes usable knowledge. We have learned this is the whole Pandora's Box problem. Science thrives on openness, and there are a lot of great people in this country who need to have access to different levels of information so that we can come up with countermeasures, for example.

At the same time, I do believe that in the interest of national security there are certain data products that become knowledge that should be done in specific areas with appropriate security. There are currently ways to implement levels of access in these kinds of systems that would guarantee that.

Dr. HATCHETT. I would like to just touch on that as well. I think we need to acknowledge the fact that it is inevitable that these technological developments will create opportunities for people with malevolent intentions. They will find ways to leverage what we create in ways against us in the same way they have discovered that airplanes could serve as flying missiles.

Dick Garwin, who is at the Council for Foreign Relations now, I think it was a December 12 *New York Review of Books* did an article about red-teaming and vulnerabilities and actually received criticism for detailing ways we were still vulnerable.

One example of the technology that is incredibly useful and that has been incredibly helpful in public health terms, Steve Morse, who is now at the Center for Public Health Preparedness at Columbia, and was really one of the people that created the concept of emerging diseases, was also the founder of an e-mail network called PROMED, which is the Program for the Monitoring of Emerging Diseases, and what PROMED is is an e-mail network.

People can sign up for it, and then when they are on the list they receive e-mail updates, and that has been very useful in identifying outbreak situations in remote areas. Somebody who is in the Sudan and sees an outbreak of what looks like a Hemorrhagic Fever can e-mail PROMED and then the information is widely distributed. It moves information quickly. It is very helpful to WHO. It is helpful to CDC. It is helpful for improving and increasing the speed of response, but it also becomes something that a terrorist could mobilize, or could make use of.

Aum Shinrikyo, the Japanese terrorist organization, is known to have sent people to Zaire during the mid-1990s to search for Ebola, and if somebody beams out an outbreak that there is Hemorrhagic

Fever in northeast Gabon, the first person on the scene might be a terrorist. It might not be a public health worker.

The question of restricting access to information is a very thorny one, and I think we may be shooting ourselves in the foot by doing that. No matter what we do terrorists will find ways to leverage that against us, and I think maintaining open access and maintaining the information flow and the information stream ultimately will serve us better than trying to restrict it in the interest of national security, within reasonable limitations, obviously.

Senator WYDEN. Well, I will tell you I go into this discussion having a very strong orientation in favor of getting out as much information as possible just for the reason you are talking about. Just with the Internet there are millions of content-creators worldwide. You are not going to be able to restrict that under any scenario, and at the same time, as you said, there have to be efforts to make sure that in every way possible, that the openness and the goodness of our free society is not turned against us. Trying to figure out how to do that is the challenge.

I would probably ask a number of other questions of this group. We have not even gotten into matters like the compatibility of communications systems at the local level and the like, which was certainly a concern on September 11, but you have been terrific and very patient. The people who are behind me on the dais are going to be working over the next few weeks to try to put in place a draft for this proposal to mobilize the scientists and technology specialists. We are going to work very closely with the Administration, as I say. They have been very cooperative with all of our efforts.

Dr. Klausner, that what you are doing will be available in June is extremely important, and as much as anything I think if Congress and the Executive Branch can work with people like yourselves, this time it can be different. You will not have committees coming back in 5 years holding up books that were written in the aftermath of September 11 and everybody saying, oh, my goodness, why weren't they acted on, and it is really going to sort of be our lodestar in all of this.

If any of you would like to add anything further, we would welcome you. Otherwise, we will excuse you at this time. Any last comments any of you would like to make? We will excuse you at this time. Thank you for your cooperation.

Our next panel will be Ms. Anna Johnson-Winegar, Ph.D., Deputy Assistant Secretary of Defense for Chemical and Biological Defense Programs; and Dr. Lisa A. Simpson, Deputy Director, Agency for Health Care Research and Quality. We welcome both of you, and let me at the outset say that both of your departments have been extremely cooperative with our efforts, and we are very appreciative, and your departments, as I mentioned, the entire Administration has been very constructive and helpful. We will make your prepared remarks a part of the record in their entirety.

Dr. Johnson-Winegar, why don't you begin, and then we will hear from Dr. Simpson.

STATEMENT OF DR. ANNA JOHNSON-WINEGAR, Ph.D., DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE FOR CHEMICAL AND BIOLOGICAL DEFENSE

Dr. JOHNSON-WINEGAR. Thank you very much for the opportunity to be here this morning. I certainly would like to take a few moments to summarize my remarks, which you have for the record, highlighting the fact that I think the tragic events of September 11 and the anthrax cases resulting from the letters sent to Members of Congress and to the media have heightened the public's awareness of the biological terrorism threat, but it has been one that has been high on the priority for the Department of Defense for quite some time.

Today, I would just like to highlight for you some of the efforts ongoing in the Department of Defense to counter the threat of biological weapons, including some instances of how we are leveraging the capabilities of the private sector scientific community and, in addition, I will describe some ways in which I think the scientific community will continue to be integral to developing our response to address the biological threat.

First of all, I would just like to summarize the process by which the Department of Defense defines our requirements and programs, second to outline some programs we have ongoing, including how we are using the scientific community and, third, some planned efforts and processes by which the Department coordinates with the scientific community to assure ourselves that cutting edge technology can be evaluated and incorporated.

The Department of Defense has long had an established set of requirements for enabling us to complete military operations in a chemical and biological environment and, as such, our research and development and procurement efforts are, indeed, structured to support the framework of that mission, which is primarily one of contamination avoidance that includes such things as detection, identification, and warning; second, protection, which includes individual, collective, and medical protection, and third, decontamination.

In order to address these concerns, we have been at war against biological agents for quite sometime, and since September 11 we have been more at war against terrorism, and I think it is clear to all that the Department of Defense community has been fully engaged in supporting both our combat operations overseas as well as our role in homeland defense.

I think you are well aware, because of the Department's specialized expertise in both chemical and biological agents, and because of our many unique research facilities and capabilities, the DOD does, indeed, play a very strong role in addressing bioterrorism.

As we all know, technology advances are being pursued across the board in research, development, and manufacturing of vaccines and pharmaceuticals, as we heard from our first panel, that will help prevent the lethal and incapacitating effects of biological warfare agents. Clearly, the Department of Defense has a major role to play in that and has indeed funded research and development to address a number of these products for many years now.

I think that through the execution of our chemical and biological defense program the private sector, academia, and other Federal

agencies are invited to apply their knowledge, skills, and ideas to help us solve our needs. We use, as you are well aware, a number of different mechanisms, including broad agency announcements, requests for proposals, request for quotations, the small business innovative research program and others. In addition, we publish all of our requests in the Federal Business Opportunities, known to the world, I am sure, as FedBizOpps, and in addition to that, shortly after the September 11 attacks the Department of Defense established a specific announcement to accept proposals from all sources on how to respond to terrorist threats. At latest count, over 12,000 ideas had been submitted, and indeed, hundreds of these apply specifically to the biological terrorist threat.

Finally, I would like to point out that there are numerous conferences in which the Department's programs in chemical and biological defense are presented to academia and industry organizations, providing other opportunities for the scientists in the private sector to become aware of how they can contribute to the program and addressing the biological and terrorist threats.

I have personally participated as a speaker and panelists in a number of those conferences and symposia, as well as other people from my office. I think that, indeed, we are all well aware that the anthrax attacks of late last year pointed out to many in the public and to the Congress and the Administration the real dangers of biological weapons, and while these attacks have increased the priority of our efforts, the Department of Defense has long been drawing upon the Nation's scientific expertise to develop and field effective defensive capabilities to protect our military forces and now our Nation's citizens and others from the use of biological weapons by adversaries.

We are fully aware of the fact that advances in genetic engineering, biotechnology, and other related scientific disciplines, require continued vigilance to be sure we are prepared for the threat, and that we are not caught by technological surprise.

I would like to conclude by just saying I resonated very much with a number of the comments made by the first panel today, and I look forward to continuing opportunities for the Department of Defense to work with our sister Federal agencies, as well as the private sector and academia.

[The prepared statement of Dr. Johnson-Winegar follows:]

PREPARED STATEMENT OF DR. ANNA JOHNSON-WINEGAR, DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE FOR CHEMICAL AND BIOLOGICAL DEFENSE

Mr. Chairman and distinguished Subcommittee Members, I am Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense. My office is the single focal point within the Office of the Secretary of Defense responsible for oversight, coordination, and integration of the Department's Chemical and Biological Defense Program. The tragic events of September 11th and the anthrax cases resulting from the letters sent to Members of Congress and the media have heightened the public's awareness of the biological terrorism threat. I was invited to speak to the committee today about means by which to harness the potential of America's scientists and private sector to address bioterrorism. In order to address the committee's concerns, I will discuss the extensive efforts underway by the Department of Defense (DoD) to counter the biological weapons threat, including highlights of how we are leveraging the capabilities of the private sector scientific community. In addition, I will discuss some means by which the scientific community will continue to be integral to developing material responses to address the biological threat. My testimony today is in three parts:

First, I will discuss the processes by which the Department defines requirements and programs to support the current and future needs of the warfighter;

Second, I will outline current programs that address the biological threat, including how we are drawing upon the scientific community; and

Third, I will outline some current and planned efforts and processes by which the Department coordinates with the scientific community to ensure that cutting edge technologies to counter bioterrorist threats are evaluated and incorporated into the Department's research, development, and acquisition (RDA) efforts.

DEPARTMENT OF DEFENSE THREAT, REQUIREMENTS, AND PROGRAMS PROCESS

Following Desert Storm, there was a need to coordinate chemical and biological defense efforts among the Armed Services in order to better address lessons learned from the Gulf War. In 1994, the Department established the Joint Service Chemical and Biological Defense Program. The vision of this program is to ensure U.S. military personnel are the best equipped and best prepared force in the world for operating in future battlespaces that may feature chemical or biological contamination. The events of the past few months have demonstrated that our concept of future battlespaces is changing from the battlefield to include greater emphasis on homeland security.

The customer for the DoD's Chemical and Biological Defense Program is the warfighter. The customer, through the Joint Staff and the combatant commanders, identifies requirements that form the basis of programs for the RDA community. In order to identify capabilities needed in the far term, the Services prepare a document entitled "Joint Future Operational Capabilities," which provides direction to the science and technology community.

In addition to warfighter requirements, identification of current and emerging threats by the Intelligence Community provides a principal means for the definition of program needs for biological defense. The Defense Intelligence Agency provides validated biological and chemical threat assessments. These reports assess the effects of weapons on how we fight, and in turn are used by the warfighter to generate the requirements to resolve materiel shortcomings. Together, assessments of operational needs, adversarial threats, and vulnerabilities form the basis of Mission Needs Statements and Operational Requirement Documents. The result is that our programs and technologies are driven by validated threat assessments and user mission requirements, not by technologies.

The Department of Defense has established a set of requirements for the successful completion of military operations in chemical and biological environments. We submit an Annual Report to Congress documenting our progress in meeting these requirements. The Chemical and Biological Defense Program consists of all DoD RDA efforts that develop and procure systems designed to provide U.S. Forces with the ability to operate effectively in the presence of chemical and biological agents. Joint and Service unique RDA efforts are structured to support the framework of the three mission areas of chemical and biological defense: contamination avoidance (detection, identification, warning, reporting, reconnaissance, and battle management), protection (individual, collective and medical support), and decontamination. The programs affect all joint warfighting capabilities, while providing an integrated system of systems on the battlefield. It is essential to view all chemical and biological defense programs as an integrated system, with each mission area important to joint forces' survival. Our forces need the full spectrum of defensive equipment to survive, fight, and win in a contaminated environment. For example, protective clothing may be of little value if we don't provide the appropriate detection and warning systems.

CURRENT DOD RESEARCH DEVELOPMENT AND ACQUISITION TO ADDRESS BIOTERRORISM

The process I described roughly outlines how the Department conducts business during peacetime. Since September 11th, we have been at war against terrorism of global reach, and the DoD RDA community has been fully engaged in supporting both combat operations overseas and homeland defense. I must point out to the committee that DoD is not charged with lead Federal agent responsibilities as described in the Federal Response Plan for response to incidents of domestic terrorism. However, because of the Department's specialized expertise in chemical and biological defense and many unique research facilities and capabilities, the Department plays a key role in addressing bioterrorism.

DoD Biological Defense Funding Summary

In Fiscal Year 2002, the budget request for the Department of Defense Chemical and Biological Defense Program was approximately $856 million, which includes ap-

proximately $507 million for research and development and $348 million for procurement. Science and technology efforts included approximately $86 million for the Medical Biological Defense Research Program and approximately $32 million for biological detection. Some of the remaining budget includes dual purpose projects (such as decontamination and masks) that provide protection against both chemical and biological threats. In addition, the Defense Advanced Research Projects Agency (DARPA) separately requested $140 million for exploratory research efforts for biological warfare defense.

DoD Biological Defense Selected Project Description Summary

Following is a brief summary of key biological defense efforts.

Detection of Biological Agents

The Department of Defense has fielded the following detection capabilities:

- *Biological Integrated Detection System (BIDS)* is a vehicle-mounted biological detection and identification capability. Until recently, BIDS units were deployed around the Pentagon.
- *Portal Shield* is a network sensor system that provides automated biological point detection capability to protect high value fixed sites against BW attacks. This system was deployed at the NATO 50th Anniversary, and Presidential Nomination Convention.
- *Biological Weapons Agent Sampling Kit* provides a low cost, disposable assay ticket which can provide rapid detection using environmental samples.
- *Joint Biological Point Detection System* which would provide automated point and mobile biodetection, with reduced size, weight, and power requirements compared to existing systems. The JBPDS is currently fielded at high value military sites.

Research activities include automation of biological sample preparation, methods for detection of biological agents in water, and modeling and simulation of agents to assist in hazard warning.

Medical Biological Defense

Today, the medical treatment for individuals exposed to biological agents requires a response tailored to each specific threat. A critical capability for effective treatment includes training to diagnose and treat biological threats through such courses as "Medical Management of Biological Casualties," which is available on the internet at *www.biomedtraining.org.*

Technology advances are being pursued in the research, development and manufacturing of vaccines and pharmaceuticals that prevent the lethal or incapacitating effects of biological warfare agents. Therapies that improve survival and reduce the time for recovery have been developed by private industry and tested against specific biological warfare agent threats by the DoD. These include commercially available antibiotics such as ciprofloxacin, doxycycline, and tetracycline. Rapid portable diagnostics enabling quick medical response for exposed warfighters are being pursued. Currently fielded diagnostics rely on immunological response assays. The Joint Biological Agent Identification and Diagnosis System currently under development is based on the use of polymerase chain reaction (PCR) technology to provide more rapid and accurate diagnosis. DoD has been working with the Food and Drug Administration (FDA) to obtain approval for therapies and diagnostics that are not yet FDA approved. DoD is working with FDA and the National Institutes of Health to identify candidate therapies that could be tested in animal models for select biological agents. DoD is also working with the Centers for Disease Control and Prevention and the Department of Energy National Laboratories in the development of genetic primers.

Decontamination of Biological Agents

Decontamination supports post-attack restoration of forces and operations to a near normal capability. Decontamination is organized into three categories that reflect operational urgency: immediate, operational, and thorough decontamination. Decontamination also entails special considerations for patients, sensitive equipment, aircraft, fixed sites, and the retrograde of equipment. DoD doctrine addresses consequence management decontamination operations, which uses civilian standard operating procedures, including hypochlorite solutions, and soap and water solutions. Some of the existing systems include the M291 Skin Decontaminating Kit, the M295 Individual Equipment Decontaminating Kit, and the sorbent decontaminating system, which is replacing the existing decontaminant with a non-aqueous and less caustic decontaminant. Development efforts include the Joint Service Sensitive Equipment Decontamination, for items such as electronics, and the Joint Service Fixed Site Decontamination System, which will provide a family of decontaminants and applicators to provide the capability to decontaminate ports, airfield, and rear-

area supply depots. Currently, military requirements support a combined decontaminant that is effective against chemical and biological agents.

Leveraging the Private Sector

The efforts described above highlight key biological defense capabilities that are fielded or are planned to be fielded in the near-term. This does not include the numerous research efforts to exploit cutting edge science and technology advances to ensure continuous improvement in our protection and response capabilities. Through the Department's science and technology efforts, the state-of-the-art in basic and applied research is being explored. An excellent example of the DoD leveraging cutting edge science and technology developed by America's scientists is the Biological Agent Warning System (BAWS) technology developed by MIT Lincoln Laboratory. The BAWS technology integrated into the JBPDS not only improved overall system performance for biological warfare agent detection, but also significantly reduced operation and support costs of the most advanced U.S. point biological detection capability.

Research and Development Opportunities

Through the execution of the Chemical and Biological Defense Program, the private sector, academia, and other Federal Government agencies are invited to apply their knowledge and skills to solve warfighter materiel needs. Executing agencies post Broad Agency Announcements, Requests for Proposals, and Requests for Quotation in accordance with the Federal Acquisition Regulation to provide a structure for fair competition of concepts and ideas. Interested parties may submit their proposals for review and award of contract. These procedures can be shortened in time of need, but remain the preferred method for the government to leverage private sector innovation.

The Chemical Biological Defense Small Business Innovative Research (SBIR) program is an effort by the Department to incorporate emerging scientific and technical capabilities of America's scientists and private sector. The overall objective of the SBIR program is to improve the transfer of innovative scientific and technical efforts that, in our case, will maximize a strong chemical and biological defense posture. Examples of innovative capabilities tapped by the SBIR program include biological detection technology, modeling and simulation, contamination avoidance, and individual protection.

The Military Departments and Defense Agencies retain the responsibility to manage and execute the various individual projects. Frequent requests are made to review new technologies and concepts to incorporate into chemical and biological defense efforts. Solicited proposals may be submitted in response to requests for proposals (RFPs) or requests for quotations (RFQs) published in Federal Business Opportunities (known as "FedBizOpps"), the government's designated point of entry on the Internet for providing public access to notices of procurement actions over $25,000. FedBizOpps may be found at *http://www.fedbizopps.gov.*

The appropriate addressee for submitting unsolicited proposals is with the Military Departments and Defense Agencies. There are several organizations participating in the DoD management of chemical and biological defense programs to whom unsolicited proposals might be submitted. Many of these organizations provide information on the processes for submitting proposals through Broad Agency Announcements (BAAs) or similar instructions. Following is a partial list of organizations, and internet addresses, with information on submitting unsolicited proposals. This information may be updated occasionally, and thus should be checked for updates.

- U.S. Army Soldier Biological and Chemical Command—*http://www.sbccom.apgea.army.mil/RDA/baa0l.htm*
- U.S. Army Medical Research and Materiel Command—*http://mrmc-www.army mil/*
- Air Force Research Laboratories—*http://extra.afrl.afmil/bus-op shtm*
- Naval Surface Warfare Center—*http://www.nswe.nav.mil/dahl.htm*
- Marine Corps Systems Command—*http://www.marcorsyscom.usmc.mil/BusOpps.htm*
- Joint Program Office for Biological Defense—*http://www.jpobd.net/default.htm*
- Defense Advanced Research Projects Agency—*http://www.darpa.mil*
- Technical Support Working Group—*http://www.tswg.gov*

In response to the September 11 attacks, the Department also established a BAA to accept proposals from all sources on how to respond to the terrorist threats. Thousands of proposals were submitted. Hundreds of these applied to the biological terrorist threat.

Finally, there are numerous conferences annually in which the Department's chemical and biological defense science and technology needs are presented to academia and industry organizations, thereby providing yet further opportunities for scientists and the private sector to become aware of how they can contribute to America's chemical and biological defense posture.

CONCLUSION

The anthrax attacks late last year pointed out the real dangers of biological weapons. While these attacks have increased the priority of our efforts, the Department has been drawing upon our Nation's scientific expertise to develop and field an effective defense capability to protect our forces and Nation from adversaries at home and overseas. Continuing advances in genetic engineering, biotechnology, and related scientific areas will require our continued vigilance to ensure that we are prepared for the threat and not caught by technological surprise. My comments today highlight just some of the numerous scientific efforts the Department is supporting. I thank you for the opportunity to speak today and welcome any questions you may have.

Senator WYDEN. Thank you.

Dr. Simpson.

STATEMENT OF DR. LISA A. SIMPSON, M.B., B.Ch., M.P.H., DEPUTY DIRECTOR, AGENCY FOR HEALTH CARE RESEARCH AND QUALITY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. SIMPSON. Good afternoon, Mr. Chairman. I am very pleased to be here today to discuss an exciting new effort at the Department of Health and Human Services that will give us an opportunity to learn how to respond to what the private sector is doing to improve the security, safety, and quality of our health care system.

We, too, have been frustrated and have heard from the companies and the issues and concerns that the first panel detailed for us, because we have recognized that it is difficult sometimes for them to find the right place in government for their products and ideas to be considered.

Alleviating this frustration and forging a strong collaboration between government and industry is especially important as the Nation comes together to improve the security in the face of the recent bioterrorist attacks.

To that end, on December 6, 2001, Secretary Thompson established the Council on Private Sector Initiatives to improve the security, safety, and quality of health care. The council, as we call it, will help us to manage in a fair, systematic, and consistent manner the requests that the Department is receiving from individuals and firms seeking review of their innovative ideas and products. In essence, the council offered something we heard about this morning, the one-stop shopping concept for companies seeking to present their ideas to the Department of Health and Human Services.

I would now like to describe the council to you, focusing specifically on its charge, its composition, the process for submitting requests, and its current activities. Secretary Thompson laid out a clear mission for the council with five very specific charges.

First, to triage the requests from individuals and firms seeking HHS review of their ideas to improve the security, safety, and quality of the health care delivery system.

Second, to ensure that HHS responds systematically and consistently to these requests, providing constructive feedback as appropriate.

Third, to ensure that our focus on public health preparedness is complemented by careful attention to the preparedness of our health care delivery system.

Fourth, to provide the private sector with a single point of entry to the Department of Health and Human Services for these initiatives, and finally, to report to the Secretary periodically to ensure accountability for these efforts.

Recognizing the breadth of expertise to properly evaluate the private sector requests and the need to foster interagency and even interdepartmental collaboration, as we have heard this morning, the Secretary has invited a wide array of HHS agencies and departments to serve on this council. As necessary, the council can also be expanded beyond these original members.

The current members of the council are the heads or their designees of the following agencies of the Department of Health and Human Services, and I will use acronyms for the purposes of time, the CDC, the FDA, the NIH, CMS, ARC, the Assistant Secretary for Health, the Assistant Secretary for Planning and Evaluation, and the Director of the Office of Public Health Preparedness.

In addition, the council also includes the heads or their designees from the Department of Defense, the Department of Veterans Affairs, and the Federal Bureau of Investigation. We have also extended invitations to the Environmental Protection Agency and the Department of Energy to ensure appropriate coordination across other relevant departments. Equitable access and consideration is a key principle for this council.

The requests received to date by the Department of Health and Human Services represent a broad range of private sector entrepreneurs, ranging from a major pharmaceutical manufacturer to a recently disabled man whose company consists of him and his wife, and whose letter presented an idea for a compact respirator. The council will help level the playing field between these large and small companies and these innovations in the private sector.

To help ensure that all of them are treated in a fair, systematic, and consistent manner, we have set out a clear process to triage the requests, refer them to the appropriate agency or department, and to follow up on their disposition.

The council held its first meeting on January 23 of this year, and has already started its work. Since its formation, the council's staff has reviewed requests from 18 companies. Member agencies have already met with three of these companies, and the remaining requests are being currently reviewed.

We have already established a website, the name of which, the URL is *www.cpsi.ahrq.gov,* for Council and Private Sector Initiatives. This website will give companies instructions on how to submit a request, as well as enable access to the contact persons within the council who can provide further information on their respective agencies.

We hope that this council will provide opportunities for the Department of Health and Human Services, all of our agencies, and our fellow Federal departments to learn from this innovation and

energy in the private sector. Further, we also hope that the council will reduce the frustration and burdens that private sector companies have so eloquently detailed for us, and have faced in bringing their ideas and products to us.

This concludes my prepared remarks. I am happy to answer any questions from you.

[The prepared statement of Dr. Simpson follows:]

PREPARED STATEMENT OF LISA A. SIMPSON, M.B., B.CH., M.P.H., DEPUTY DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning, I am very pleased to be here today to discuss an exciting new effort at the Department of Health and Human Services which will give the Federal Government an opportunity to learn what the private sector is doing that could enhance the security, safety, and quality of the Nation's health care system.

We have heard from private-sector companies that they are frustrated because it is difficult for them to find the right place in government for their products and ideas to be considered. Alleviating this frustration—and forging a strong collaboration between government and industry—is especially important as the Nation comes together to improve security in the face of recent bioterrorist attacks.

To that end, on December 6, 2001, Secretary Thompson established the Council on Private Sector Initiatives to Improve Security, Safety, and Quality of Health Care. CPSI, or the Council as we call it, will help us to manage in a fair, systematic, and consistent manner the requests the Department has received from individuals and firms seeking review of their innovative ideas and products.

In a memo creating the Council, Secretary Thompson noted, "The Council will ensure that our focus on public health preparedness is complemented by careful attention to the preparedness of our health care delivery system. This Council will also enhance our responsiveness to innovation by providing the private sector with a single point of contact at the Department."

In essence, the Council offers "one stop shopping" for companies seeking to present their ideas to HHS. Requests will be reviewed and sent to the appropriate Federal Agency or Department for action in coordination with the department performing similar functions. However, we do recognize that not all requests can be met fully because they are outside the scope of what HHS and other government agencies can do. Our goal is to reduce the time and potential duplication of effort that companies may face in bringing their ideas to experts within Government who have the knowledge to evaluate them.

I would now like to describe the CPSI to you, focusing specifically on its charge, its composition, the process for submitting request, and its current activities.

CHARGE

Secretary Thompson laid out a mission for the Council with five very specific charges:

1. Triage requests from individuals and firms seeking HHS review of their ideas for improving the security, safety, and quality of our health care delivery system.
2. Ensure that HHS responds systematically and consistently to these requests, providing constructive feedback as appropriate.
3. Ensure that our focus on public health preparedness is complemented by careful attention to the preparedness of our health care delivery system.
4. Provide the private sector with a single point of contact at the Department of Health and Human Services for these initiatives.
5. Report to the Secretary periodically on the nature of the requests received; the timeliness with which they are handled, their disposition, and the opportunities they present for supporting new and existing Secretarial initiatives.

In addition to reporting to the Secretary, CPSI will provide feedback to the agencies and Departments so that they can see the progress of other requests, examine the reporting of their own activities, and avoid the processing of duplicate requests within their own organizations.

COMPOSITION

Recognizing the breadth of expertise required to evaluate the private-sector requests and the need to foster interagency and even interdepartmental collaboration, the Secretary invited a a wide array of Federal Agencies and Departments to serve

on the Council. As necessary, the Council can be expanded beyond these original members.

The current members of CPSI are heads, or their designees, of the following agencies of the Department of Health and Human Services:

- Centers for Disease Control and Prevention;
- Food and Drug Administration;
- National Institutes of Health;
- Centers for Medicare and Medicaid Services;
- Agency for Healthcare Research and Quality;
- Assistant Secretary for Health;
- Assistant Secretary for Planning and Evaluation; and
- Director of the Office of Public Health Preparedness.

In addition, the Council also includes the heads or their designees, from the:

- Department of Defense;
- Department of Veterans Affairs; and
- Federal Bureau of Investigation.

Invitations are being extended to the Environmental Protection Agency and the Department of Energy to ensure appropriate coordination across other relevant departments.

The CPSI is being chaired by John M. Eisenberg, M.D., Director of the Agency for Healthcare Research and Quality.

PROCESS

Equitable access and consideration is a key principle of the Council. The requests received to date by the Department of Health Human Services comprise a broad range of private sector entrepreneurs ranging from a major pharmaceutical manufacturer offering their production capabilities to a letter from a recently disabled man, whose company consists of only him and his wife, presenting an idea for a compact respirator.

Many large companies have learned how to gain entry to the government; many small companies do not have the resources and the knowledge to even know where to begin. The HHS Council will help level this playing field. To help ensure that all are treated in a fair, systematic, and consistent manner, we have set out clear process to triage requests, refer them to the proper Agency or Department, and follow up on the disposition.

Once received, requests are reviewed by Council staff to determine the purview of which Departments or Agencies the content falls. Requests that fall under a single Agency or Department are forwarded to a designated contact who will take whatever action is deemed appropriate. Requests that involve multiple Departments or Agencies may be invited to a meeting where representatives of those agencies are present. This fosters collaboration among the agencies and reduces the burden that private sector companies face in trying to gain access to multiple agencies or offices separately.

After the referral and contact are completed, Agencies and Offices report their actions back to the Council for tracking and reporting purposes. Since the Council is newly formed, this process will be evaluated and refined as we gain more experience.

CURRENT ACTIVITIES

Less than 2 weeks ago, on January 23, 2002, the Council held its first meeting at the Hubert H. Humphrey Building. The goal of this meeting was to ensure that the HHS agencies and our sister Federal Departments involved in the Council had an opportunity to provide input into the formation of the Council, its structure, and processes.

To date, we have received requests from approximately 18 companies. Although, the Council is newly established, we have already started work. The Council already has met with 3 companies, and we have scheduled meetings with an additional 8. Another 5 are being referred to specific agencies. Two are in the process of consideration.

Having attended some of the meetings myself, I found it exciting to learn about what is being done in the private sector which can extend and strengthen current public sector investments.

We have also established a website—*www.cpsi.ahrq.gov*—that will give companies instructions on how to submit a request as well as provide access to the contact persons within the Council who can provide further information.

We hope the Council will provide opportunities for the Department of Health and Human Services, our Agencies, and our fellow Federal Departments to learn from

innovation in the private sector. Further, we also hope that the Council will reduce the frustration and burdens that private-sector companies have faced in bringing their ideas and products to us.

This concludes my prepared statement. At this time, I would be happy to answer questions from you and other Members of the Subcommittee.

Senator WYDEN. Thank you very much, and again you both, and your departments, have been very cooperative, and we appreciate it.

I think what I am concerned about at this point, and it sort of sparked out of a comment that you made, Dr. Simpson, because the department is going to have one-stop shopping in the Department of Health and Human Services, but it strikes me that for the entrepreneurs, that what that raises is the question of one stop out of 20 that Dr. Ryan may have to make as she and her colleagues work through the Federal Government. As I understand it, you all are going to try, if an entrepreneur is in touch with you, you are going to try and walk them all the way through the system in terms of other agencies and the like.

Let us say, for example, that somebody brings you a product that might involve a communications focus, or even an energy or environmental kind of concern, are you going to walk them—the Health and Human Service staff—are you going to walk them through all the potential agencies so that the hypothetical Dr. Ryan does not have to say, "Thank you, Dr. Simpson," and then start traipsing to all the other 19?

Dr. SIMPSON. Well, within the Department of Health and Human Services, our goal is to appropriately and in a timely manner refer them to either the one agency, if their product or idea is clearly linked to just the one agency, or if there are multiple agencies, to do that at the same time in a coordinated fashion, and then built into this an accountability and feedback to the council staff, and hence to the Secretary. A clear charge from the Secretary is to find out how were those requests handled, and what was the final decision.

Now, in the specific example you just gave us, if the idea or innovation really crosses departments and goes to the Department of Defense or Environmental Protection, we would then refer them to our contact through the council and rely on those departments to continue the coordination they have already established within their departments, and periodically to give feedback to us on how effective has our process been in getting the information they need to them, and vice versa. So we are trying to learn as we go, with this new council, to really improve the communication, both internal and external as well.

As we see the process of our referrals, the process is that we send it to one agency, but all the other agencies will see who has been referred where, and they can say, "hey, that is a product we may have a role in here, let us also do that."

Senator WYDEN. I think that is certainly a step in the right direction. What I am concerned about is, I want the first person that an entrepreneur with a promising idea meets at the Federal level, I want that person to walk them all the way through the system, and I think that what you describe certainly is a constructive step, and as I say, I talked with the Secretary about it, and I know that he is committed to doing this. That is not what is in question.

What I am concerned about is the possibility, even under the scenario that you describe, that someone spends a lot of time at the Department of Health and Human Services, and your people are plenty useful, but then they decide that it is something with the Department of Energy or Commerce, and then our entrepreneur starts all over again at that department, and they decide it is somebody else, and by that time everybody has started all over multiple times.

We do not need to belabor this. I think that you all have clearly taken a step in the right direction. I think what my interest is, and I may ask your associate to touch on the same kind of question, I would like one set of rules for those entrepreneurs, one set of rules so that they understand what the kind of general parameters are, and then one advocate to sort of take them all the way through the system, and what we are talking about still today leaves us with the possibility of lots of different rules coming from lots of different agencies, and then having to start over.

Please go back to your departments and let Secretary Thompson and Secretary Rumsfeld know that this is not some sort of an attack on them. They have been very helpful, and we are going to work with you, and I think those are the general parameters of what I am interested in.

Ma'am, would you like to comment and pick up on the same sort of thing, because I think it really frames where we want to go with this. I think the case of the Department of Defense, it perhaps has been even more baffling to the entrepreneurs, again not because somebody is trying to be malicious or difficult. It is that the lines blur.

I serve on the Senate Intelligence Committee, as Senator Rockefeller does, an intelligence area that I have sort of been very interested in, and sort of the lines are blurred between what you all are doing and DARPA. I have had entrepreneurs come to me and say, I read about this announcement, and I read about it 2 weeks after it closed, and then I read a story that there were 13,000 applications, and perhaps if you could take the same point that I touched on with Dr. Johnson and put it in connection particularly with the agencies that are most relevant for you, and I think it is particularly—not just DOD but the CIA. I think that would be helpful, to the extent you could in a public forum.

Dr. JOHNSON-WINEGAR. Well, you are absolutely right that the Department of Defense is very, very complex, and probably bewildering to many folks. First of all, they are not sure whether they should talk to the Army, the Navy, the Air Force, or the Department of Defense or to DARPA, or to some other components of the Department of Defense, and they are not really sure that all of those individual components re talking to each other, much less to other agencies with which we have very similar efforts.

As Dr. Simpson mentioned in her comments, between the Department of Defense and the Department of Health and Human Services we share a lot of ongoing work and initiatives on the medical countermeasures for bioterrorists, whether that be vaccines, or drugs, or therapy, or diagnostic devices, and so I would certainly characterize the relationship between our two departments as con-

stantly improving and increasing interchange of ideas and thoughts between the two of us. Similarly, in other areas.

For example, in the area of decontamination we are working very closely with EPA, who was given the lead role for decontaminating the Senate building here. They did not really have any hands-on expertise in working with anthrax, so who do they come to? The Department of Defense. Likewise, a number of other agencies. The Department of Energy has a number of other efforts for biological detection, as do we, and so I think that between the Federal agencies our coordination and communication has improved.

However, I do admit and recognize that that is probably not clear enough to the small companies, the entrepreneurs and the private business, as to where to start. We get numerous requests on a daily basis. We try to identify the appropriate agency if we feel that is not appropriate for something that the Department of Defense wants to pursue. We do not have all of the information that we need to make that an easy road for those individuals to travel. I think we realize we have some improving to do in that area, but I am certainly willing to admit we are not there today.

Senator WYDEN. Well, extra points for candor, and I appreciate that. That has clearly got to be one of the priorities in all of this, both as it relates to what we are trying to do, and then as I put on my other hat on the defense intelligence side as well.

Let me ask you one other question that has been of interest to me in my service in the Congress, and that is whether you have any suggestions on how we can improve the tech transfer effort in this area.

As you know, there is a very significant statute, the Bayh-Dole Act, which my sense is has again been a very useful law, but there have been a number of changes since it was originally conceived. Today, from essentially all of the parties, universities who are eager to participate in these joint efforts, certainly entrepreneurs who would like to tap into these technologies, and then taxpayers who want to see a rate of return on licensed products and the like, there may be areas where we could strengthen this law and improve it. Are there efforts underway in your departments to look at the Bayh-Dole law and, if so, what can you tell us about those?

Dr. SIMPSON. Well, first, let me just state again, and I think it is something you alluded to, which is Secretary Thompson's commitment to this partnership with the private sector, and he has challenged each of us, each of our agencies, to come up with new and better ways to be open and to be responsive. To the extent that looking at this act in ways that it needs to be modified, I think he would be open. I personally would need to go back to the department—and I am now being told, Senator that the Office of the Inspector General has done work in this area, and we would actually be happy to provide that information, but I think at the heart of this is a real commitment on our part and the Secretary to be responsive, and be more efficient in our operations.

Senator WYDEN. I would like to see any work that is going on at the department. I am not sure if the Bayh-Dole work is primarily on pharmaceuticals which would be useful, taxpayer-funded medicine, which is something the Secretary has been helpful to me

on as well, but what I am talking about is basic research, particularly in the fight against bioterrorism.

My sense is that the taxpayers put up billions and billions of dollars in various government-funded laboratories, and I think we ought to be looking at ways to transfer more of that federally-funded basic research to the private sector, and that, of course, was the purpose of Bayh-Dole, and why I have made an effort to see how it is being carried out, and I would hope we would look for ways, again on a bipartisan basis in conjunction with the Administration, to strengthen that.

Doctor, did you want to add anything to that?

Dr. JOHNSON-WINEGAR. I would just echo her comments and say I cannot give you any specifics today, but I certainly will take that for the record and get back to you with any information the department can provide.

Senator WYDEN. Let us do this. If both of you could give us a little report, say within 30 days, on how your agency is carrying out Bayh-Dole, particularly as it relates to terrorism and what, if any, ideas you have for strengthening it, and I would be particularly interested in ideas that could be achieved quickly through the administrative route, rather than through the need to pass a law.

Well, you two have been very, very helpful, and exceptionally patient. Is there anything either of you two would like to add?

Dr. SIMPSON. No. Just thank you for having us here, and we look forward to working with you and your Subcommittee in responding to this very important national priority.

Dr. JOHNSON-WINEGAR. I would just like to add that, clearly from the Department of Defense point of view, we recognize the terrific contributions that both industry and academia can make. Having been a scientist once myself, even though it was quite sometime ago, I do realize that perhaps we do not often recognize and appreciate the contributions they make, and I think it is incumbent on all of us to do things to focus those energies and talents on this problem which is facing all of us today.

Senator WYDEN. We will be calling on you often, and certainly be soliciting your input as we go forward with this draft legislative proposal, and with that, the hearing is adjourned.

[Whereupon, at 1:25 p.m., the hearing was adjourned.]

A P P E N D I X

COLLEGE OF AMERICAN PATHOLOGISTS, DIVISION OF GOVERNMENT AND PROFESSIONAL AFFAIRS, STATEMENT FOR THE RECORD

The College of American Pathologists (CAP) appreciates the opportunity to comment on the critically important issue of ensuring that all needed technologies are available to the government to prepare, respond and prevent a biological weapons attack. The College represents more than 16,000 pathologists who serve as medical directors of the Nation's clinical laboratories. Combating and preparing for the threat of bioterorrism is important to the College from multiple perspectives: that of our pathologist membership, in our role as a private accreditation organization and, of particular interest to this hearing, as a leader in providing cutting-edge bioinformatics technology.

The U.S. health care information system is challenged as never before by the need to link disparate pieces of data from numerous emergency rooms, pathology laboratories and physician offices into a network of ongoing bioterrorism disease surveillance. The College oversees the strategic direction and scientific maintenance of the Systematized Nomenclature of Medicine, better known as SNOMED. SNOMED's concept-based clinical language provides a validated technology to help health care workers and government officials quickly identify and respond to biological and chemical threats. With extensive content relating to such potential threats as anthrax and smallpox, SNOMED helps ensure that consistent, reliable information can be instantaneously shared and understood by clinicians, hospitals, the Centers for Disease Control and Prevention (CDC) and other Federal authorities that coordinate surveillance activities.

SNOMED Reference Terminology provides the framework to encode and integrate clinical data, from symptoms to definitive diagnoses, and creates a common language essential to identifying and ensuring a rapid response to bioterrorism. College members played a key role in identifying the Nation's first case of anthrax in Florida and are concerned, because of the lack of an electronic surveillance network, with the potential for delays in the reporting of new cases. CAP believes that if all labs used a uniform terminology, such as SNOMED, the detection, diagnosis and response to bioterrorism agents would occur much more quickly and efficiently. Further, because SNOMED and other new technologies offer significant value to multiple government agencies and applications, the College believes the government would be well served to create a central point for information and evaluation to ensure all appropriate agencies know about and have access to valuable resources, tools and technologies. Similarly, the private sector would be well served by a central point of entry to the Federal Government for bioterrorism capabilities. With an "information central," the private sector could more easily share its technological knowledge governmentwide—enhancing coordination at the Federal level.

On another front, the College performs accreditation inspections for more than 6,000 clinical laboratories and provides quality assurance testing materials to more than 30,000 labs. Therefore, the College's Laboratory Accreditation Program network provides a significant conduit for communication with the private laboratory sector and an opportunity for education and awareness on this issue. On October 12, the College was pleased to respond to a CDC request to ask clinical labs to familiarize themselves with CDC anthrax protocols and procedures to follow should they suspect a case or isolate. Within 5 hours of CDC's request, the College, using a combination of fax and e-mail, sent the CDC alert to 30,000 clinical labs and to all its 16,000 members, and placed the alert on the CAP Web page. We stand ready to assist the CDC, Congress and other public health and government entities in anyway we can. Such private sector resources, if better understood and known by the government, could help coordinate and improve the ability of our Nation's laboratories to respond to bioterrorism.

Bills have been introduced in both the House and the Senate to better prepare for biological and chemical attacks by strengthening our public health and medical infrastructure and improving response efforts at the Federal, State and local levels.

These bills highlight the need to boost funding for hospitals, laboratories, clinics, information networks and public health services in the event of a bioterrorism attack. Of particular interest, the final version of the "Public Health Security and Bioterrorism Response Act" (H.R. 3448) includes provisions that provide additional Federal grants and funding for the development of materials for the recognition and identification (including proficiency testing) of potential bioweapons and other agents that may create a public health emergency, and for the care of victims of such emergencies. The College urges support of this provision which seeks to utilize important private sector resources.

Finally, the College has a four-point approach to enhance the understanding of laboratory pathologists in preparing their facilities and educating their colleagues about the eventuality of a bioterrorist attack. These include:

- Provide multimedia education to our member pathologists and laboratory technicians in the proper identification, handling and transport of bioterrorism agents. In that regard, the College has on its Web site, *www.cap.org*, instituted a current and updated information site on Bioterrorism Preparedness.
- Educate clinicians so they can effectively use laboratory techniques and procedures that will detect and combat suspect bioterrorist agents.
- Continue to work with the CDC to provide information to the private clinical sector about the laboratory response network and other government programs to ensure laboratory preparedness.
- Explore the need to expand the microbiological proficiency testing program to include regular challenges of strains of potential bioterrorism agents—in a form nontoxic to lab personnel.

The College will continue to reach out to both government policymakers and professional groups as the Nation, and laboratories, respond to the growing threat of biological and chemical attacks. Thank you again for the opportunity to comment.