IMPLEMENTING THE NATIONAL DEFENSE STRATEGY

HEARING

BEFORE THE

SUBCOMMITTEE ON PREVENTION OF NUCLEAR AND BIOLOGICAL ATTACK

OF THE

COMMITTEE ON HOMELAND SECURITY HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

JULY 28, 2005

Serial No. 109–38

Printed for the use of the Committee on Homeland Security

Available via the World Wide Web: http://www.gpoaccess.gov/congress/index.html

U.S. GOVERNMENT PRINTING OFFICE

28–655 PDF WASHINGTON : 2007

For sale by the Superintendent of Documents, U.S. Government Printing Office
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FOR THE RECORD

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IMPLEMENTING THE NATIONAL BIODEFENSE STRATEGY

Thursday, July 28, 2005

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
SUBCOMMITTEE ON PREVENTION OF NUCLEAR
AND BIOLOGICAL ATTACK,
Washington, DC.

The subcommittee met, pursuant to call, at 2:00 p.m., in Room 1309, Longworth House Office Building, Hon. John Linder [chairman of the subcommittee] presiding.

Present: Representatives Linder, Shays, Simmons, Jindal, McCaul, Langevin, Markey, Dicks, Harman, Norton, Christensen and Thompson.

Mr. LINDER. The hearing will come to order. Please be seated—our guests.

The Committee on Homeland Security, Subcommittee on the Prevention of Nuclear and Biological Attack is hearing today testimony of implementation of the National Biodefense Strategy. I want to welcome our guests and thank them for appearing this day. I look forward to hearing each of your unique contributions to implementing a National Biodefense Strategy and especially your efforts to prevent a bioterrorism event from occurring in the first place.

Throughout history, infectious diseases have been a constant for civilization. However, al-Qa'ida's intentions have added a decidedly sinister aspect to natural diseases and engineered organisms. The reason this subcommittee puts a premium on preventing a bioterrorism attack is simple. Even a limited attack would have tremendous human costs, not just in this country but around the world. And the social and economic disruption can be catastrophic to our way of life. One only has to look at the SARS outbreak to begin to appreciate this impact. Experts estimated the economic impact of the 6-month SARS epidemic on the Asia-Pacific region to be approximately $40 billion. In Canada, where 43 people lost their lives, the cost to the nation's economy was $419 million. The cost to the Ontario health system alone was $763 million. The SARS outbreak also had a substantial impact on the global airline industry. Flights in the Asian Pacific area decreased by 45 percent.

We are mindful of the recent bombings in London and Egypt, which clearly demonstrate the persistent intent of terrorists not just to harm us but also our key allies. Conventional means are low-hanging fruit for terrorists. However, as technology hurdles to acquiring and modifying biological agents continue to fall, we must

leverage this country's superior science and technological capabilities against bioterrorism.

The administration and Congress have responded forcefully to this threat by making biodefense a top homeland security priority. We have done so by creating a blueprint for a coordinated National Biodefense Program, dramatically increasing funding for biodefense, research, surveillance and response activities, and encouraging the development of new vaccines, drugs and medical devices to combat deadly pathogens. However, these priorities are a joint effort within the government. Bureaucracies find it much easier to reinvent the wheel instead of collaborating and sharing resources and information. Therefore, it is critical to the biodefense efforts that the programs that each of you represent be seamlessly leveraged to prevent and, if it does occur, maximize our recovery from a bioterrorist event. Otherwise, the consequence is not 3,000 deaths but 30,000 or more.

The wide range of possible biologic agents makes it impossible to anticipate every conceivable attack. And, as science advances and biotechnology spreads, the list of possible agents will continue to evolve. Both of these facts bring us to two irreducible points: people and intelligence. If we are to be successful in mounting a defense against bioterrorism, every aspect of our strategy must utilize to the maximum extent possible the capability of the intelligence community, and each of your efforts must be closely coordinated with the IC. Science, tools, reagents and technology may be ubiquitous; scientists, however, are not. We have to do a better job of keeping track of those individuals with skill sets that are attractive to potential terrorists.

The threat of terrorism and terrorists will remain with us for the foreseeable future. However, the civilized world outnumbers them. The capabilities that each of your programs represent must outsmart them. If we remain committed to sustaining our collaborations and building a defense that makes us safe from bioterrorism, we also build for this Nation an enduring scientific and medical preparedness capability.

Thank you again to our witnesses for being with us today. I look forward to hearing the progress each of your key agencies and programs have made to our Nation's biodefense.

And I now recognize my partner, the ranking member, Mr. Langevin.

PREPARED STATEMENT OF HON JOHN. LINDER

I would like to welcome and thank our distinguished panel of witnesses for appearing today before this Subcommittee. I look forward to hearing each of your unique contributions to implementing the National Biodefense Strategy and especially your efforts to prevent a bioterrorism event from occurring in the first place.

Throughout history, infectious diseases have been a constant for civilization. However, al-Qa'ida's intentions have added a decidedly sinister aspect to natural disease and engineered organisms. The reason this Subcommittee puts a premium on preventing a bioterrorism attack is simple—even a limited bio-attack would have tremendous human costs, not just in this country, but around the world, and the social and economic disruption can be catastrophic to our way of life.

One only has to look at the SARS outbreak to begin to appreciate this impact. Experts estimated the economic impact of the *six-month* SARS epidemic on the Asia-Pacific region to be approximately $40 billion. In Canada, where 43 people lost their lives, the cost to the nation's economy was $419 million. The cost to the Ontario health care system alone was $763 million. The SARS outbreak also had a substan-

tial impact on the global airline industry—flights in the Asia-Pacific area decreased by 45%.

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- creating a blueprint for a coordinated national biodefense program;
- dramatically increasing funding for biodefense research, surveillance, and response activities; and
- encouraging the development of new vaccines, drugs, and medical devices to combat deadly pathogens.

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Thank you again to our witnesses for being with us today. I look forward to hearing the progress that each of your key agencies and programs have made to our Nation's biodefense.

Mr. LANGEVIN. Thank you, Mr. Chairman, for holding this very important hearing addressing some critically important issues. I would like to take this opportunity to welcome our witnesses here today, and I look forward to hearing their testimony. I particularly want to welcome Dr. Gerberding back. It was great to visit you at the CDC, and I look forward to hearing what you have to say today.

This hearing is a continuation of one we had two weeks ago. During that hearing, we spoke to bioweapons experts about the materials needed and the technical expertise required to produce a biological weapon and to carry out an attack.

In contrast to the threat of nuclear terrorism, a topic for which this committee also has oversight responsibility, the solution to the biological threat is much less clear. To build a nuclear weapon, a would-be terrorist must acquire weapons-grade uranium or plutonium. If we deny them this crucial ingredient, no nuclear weapon can be built.

I hope, Mr. Chairman, that the work that this committee has done in that area will push those committees with jurisdiction over programs like Nunn-Lugar to further secure those materials more quickly.

However, the testimony we heard last week painted a much different picture regarding bioterror weapons. Our witnesses described the rapidly shifting landscape of many possible pathogens that can be obtained through legitimate channels. The situation we are facing is one in which the increased efficacy of the technology used in bioengineering has lowered the bar such that nonexperts now have the ability to build these weapons in home laboratories.

I would compare it to the improvements in computer technology. Ten years ago, you needed a computer expert to send or receive audio or video files across the Internet. Today, the technology does most of the work for you, and anyone can send these types of files.

The Centers for Disease Control has identified over 60 pathogens that they consider dangerous and for which they suggest the government procure and stockpile countermeasures. A good deal of the equipment needed to develop these weapons is readily available. Supplies such as DNA, growth media and other solutions can be simply ordered through the mail. The next step after creating the pathogen is putting it into a form where it can be used as a weapon and delivering the weapon to the target.

Now, according to the witnesses at the last hearing, it is not prohibitively technically difficult to bioengineer a weapon by modifying its genetic structure. This presents a three-fold problem: First, the natural pathogen can be made much more deadly by including genetic instructions to produce a deadly toxin. The result is a bioweapon with the infection capacity of the original organism but with the lethality of the toxin. The second problem they describe is with detection. As I understand it, biodetectors are built to look for specific sequences and characteristics that identify anthrax, for example. But if anthrax is slightly modified, the detector would not detect it. Finally, I save the worst for last, our vaccines won't work on the organism if they have been modified for vaccine resistance.

These problems are deadly serious, and we must move forward with a real sense of urgency. I want to thank the Chairman for holding such an important hearing, and I look forward to hearing from our panel.

And I want to thank you, and I yield back.

Mr. LINDER. Members are reminded that opening statements may be submitted for the record.

We are pleased to have a distinguished panel of witnesses before us today on this important topic. Dr. Julie Gerberding is the director at the Centers for Disease Control and Prevention at the Department of Health and Human Services; Dr. Anthony Fauci, director of National Institute of Allergy and Infectious Diseases at the National Institutes of Health for the Department of Health and Human Services; Brigadier General Eric Schoomaker, commanding general of the U.S. Army Medical Research and Materiel Command of the U.S. Department of Defense; and Dr. John Vitko, director of Biological Countermeasure Portfolio, Science and Technology Directorate at the Department of Homeland Security.

I would like to remind our witnesses that we have a limited time, and all of your prepared statements are made part of the record, without objection, and if you could summarize in 5 minutes, we would be grateful.

Dr. Gerberding.

STATEMENT OF DR. JULIE GERBERDING, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. GERBERDING. Thank you, Mr. Chairman. And I really appreciate your having this hearing, and I especially appreciate that you and the committee took time to come to Atlanta and really work with us in-depth on some of these issues. That was a great boon to our engagement and our appreciation for your support.

CDC is a very important component of our Nation's health protection. We have actually been in the business of bioterrorism since 1951 when our epidemic intelligence service was created in response to concerns about bioterrorism in the context of the Korean War. And since that time, we have exercised our threat detection, intervention and response capabilities more than 10,000 times across the United States and in about a thousand communities around the world.

But as you can see from this graphic, since 9/11, the intensity, the magnitude, and the impact of the threats that we have been addressing have grown substantially in this very global and connected world. And we have had a series of operations that have been significant enough, both natural and terrorist in nature, to require us to step up our emergency operations center. And for the record, I would like to make note that you have copies of our slides as well as a copy of our exposure report and a list of our preparedness goals for CDC.

In the context of threats this large, we are responsive to one of the failures documented in the 9/11 Commission Report, and that was the failure of imagination. People have trouble imagining things when they can't imagine how they can handle them. But our job at CDC and throughout the Federal Government is to really do that imagining, to imagine the unimaginable so that we can take steps to prevent the threat, or, when we can't prevent it, to take the steps necessary to prepare people.

And what we really have here at this table and across the Federal Government and state and local communities is a network of prevention and preparedness that has to work in a seamless fashion with a clear strategy. But each of us plays a very unique role. So I am going to just describe for you CDC's role in this, recognizing full well we are just one part of the Department of Health and Human Services and one part of the overall responsible workforce in this regard.

On the next graphic, I have listed the nine preparedness goals under which that CDC is operating. These goals were developed to prevent, detect, investigate, control, recover and improve our capability to deal with health threats, both terrorist as well as natural in nature. These goals drive the work done at CDC and throughout the state and local health systems. These goals have clear objectives, they have key performance measures, and we will be reporting on the progress toward achieving these goals over the next several months.

On the next graphic, I have depicted one of the most important core capacities that CDC brings to the table, and that is our sur-

veillance capacity. We do surveillance to detect emerging threats in all various content domains. But one that we are particularly engaged in right now is the capacity to develop real-time health protection data through communities across our country by tapping into health records. I am getting anonymous information about patients' utilization of services so that we can have the earliest possible warning of an emerging threat at the community level and we can have the fastest possible situation awareness about how that threat is progressing and how well we are managing it.

On the next graphic, I have listed another one of our very, very important capacities in this regard. I mentioned globalization, connectivity and speed as characteristics of threats. CDC has international staff deployed in 43 countries as we speak. These individuals form a very important backbone of threat detection throughout our global detection system. And that is on the next graphic.

You can see how we are linking our existing public health capabilities into a global health protection that takes advantage of our quarantine stations, our international field stations, our relationships with the business sector, our sentinel surveillance sites and a number of other assets to link our surveillance activities into the CDC bio-intelligence center and then to relay information from that system to Homeland Security and other intelligence centers so that it can be integrated.

On the last graphic, I would just like to point out another one of our very critical core capacities. That is certainly our laboratory capacity. Mr. Chairman, these are four of the buildings that will be opening at CDC on September 12 this year.

We thank you and the Georgia delegation as well as the Congress for their support of these buildings. But three of these buildings represent new state-of-the-art laboratories, bringing our total laboratory capacity to more than a million square feet. We have the national treasure for environmental health, the national treasure for biodefense, the national treasure for various laboratories related to smallpox as well as of course our capacity in SARS. These laboratories at CDC are part of our overall laboratory response network that again supports Homeland Security activities and other threat assessment and response capabilities, and I think really speaks to the fact that the science is behind everything that we do, and we are using that science not only to take threats off the table but also to detect, respond, and mitigate them as quickly as we possible can. So thank you for your support. And we look forward to your questions.

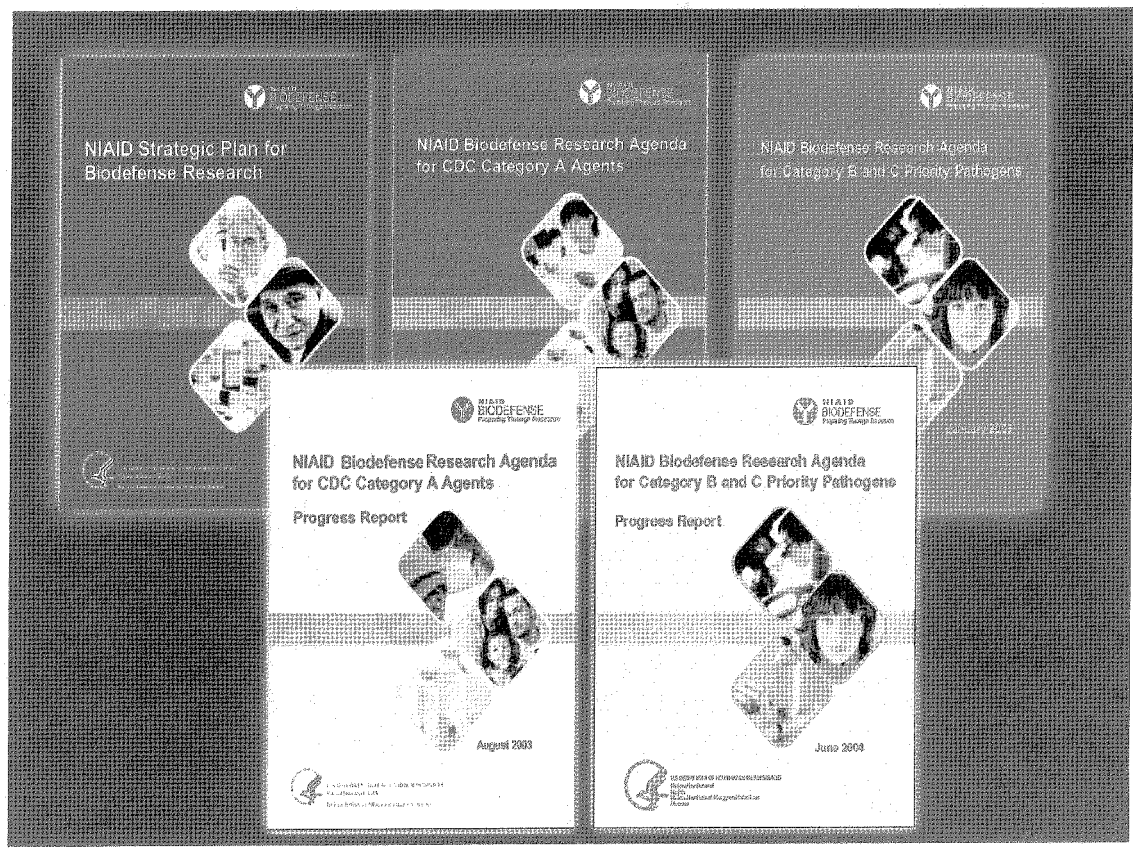
The NIH Biomedical Research Response to the Threat of Bioterrorism

U.S. House of Representatives
Committee on Homeland Security
Subcommittee on Prevention of Nuclear and Biological Attack

Dr. Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Department of Health and Human Services
July 28, 2005

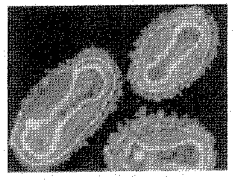
Homeland Security Presidential Directive-10 "Biodefense for the 21st Century"

- Threat Awareness
- Prevention and Protection
- Surveillance and Detection
- Response and Recovery
  - Response Planning
  - Mass Casualty Care
  - Risk Communication
  - Medical Countermeasure Development
  - Decontamination


NIAID Strategic Plan for Biodefense Research
NIAID Biodefense Research Agenda for CDC Category A Agents
NIAID Biodefense Research Agenda for Category B and C Priority Pathogens
NIAID BIODEFENSE
NIAID Biodefense Research Agenda for CDC Category A Agents
Progress Report
August 2003
NIAID BIODEFENSE
NIAID Biodefense Research Agenda for Category B and C Priority Pathogens
Progress Report
June 2004

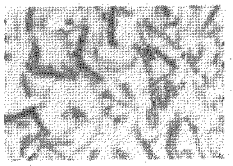
Biodefense Countermeasure Development: Key Achievements

Smallpox



- More than 300 million doses of smallpox vaccine now available
- "Next-generation" vaccine (MVA) in advanced testing
- Antiviral drug development, e.g. oral cidofovir

Anthrax

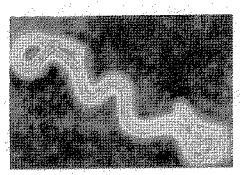


- New vaccine (rPA) tested and procured under Project Bioshield
- Development of novel antitoxins, e.g. monoclonal/polyclonal antibodies

Biodefense Countermeasure Development: Key Achievements

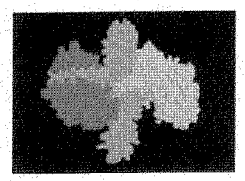
Ebola

- Vaccine in human trials at NIAID Vaccine Research Center



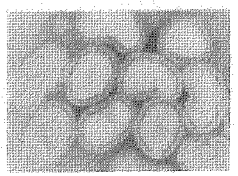
Botulinum Toxin

- Development of vaccine and monoclonal/polyclonal antibodies

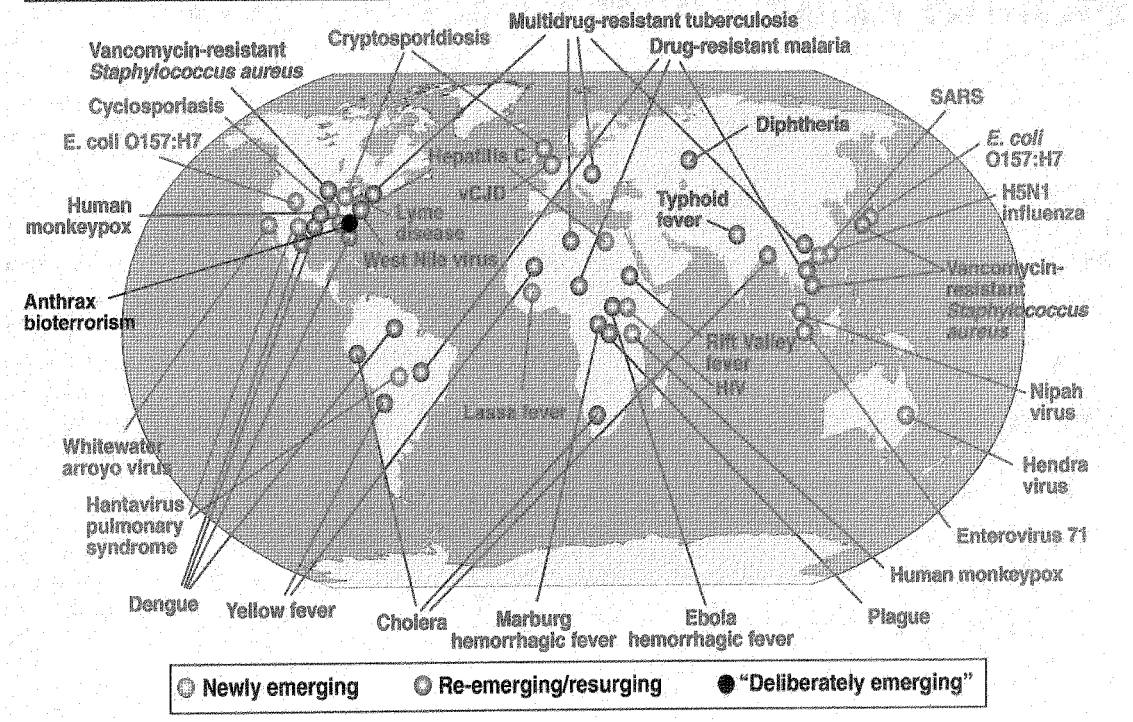


Influenza

- Development of vaccines against potential pandemic strains



Global Examples of Emerging and Re-Emerging Infectious Diseases



[The statement of Dr. Gerberding follows:]

PREPARED STATEMENT OF DR. JULIE L. GERBERDING

Good afternoon, Chairman Linder and Subcommittee members. I am Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). I appreciate the opportunity to share with you CDC's unique role and contributions to building national biodefense capacities, particularly with regard to *Biodefense for the 21st Century*.

The philosophy of public health during the 20th century has been to prevent natural outbreaks. In the 21st Century, however this is not enough. The threat of terrorism necessitates that we improve our public health and medical systems so that we can respond with greater flexibility, speed, and capacity to handle mass casualties and large-scale emergency response in coordination with our traditional emergency response partners as well as those at Department of Homeland Security (DHS) and Department of Defense (DoD).

HHS is responsible for leading Federal public health efforts to ensure an integrated and focused national effort to anticipate and respond to emerging biological and other weapons threats. HHS is also the principal Federal agency responsible for coordinating all Federal-level assets activated to support and augment the state and local medical and public health response to mass casualty events. Within HHS, CDC supports these activities through extensive coordination and collaboration with a number of federal departments and agencies.

T2CDC'S Strategic Preparedness Framework

The events of September and October 2001 made it very clear that terrorism is a serious threat to our Nation and the world. The Bush Administration and Congress responded forcefully to this threat by providing funding to strengthen our medical and public health capacities to protect our citizens from future attacks. To support HHS, CDC has made terrorism preparedness and emergency response one of two overarching agency goals and has built an infrastructure to catalyze and implement biodefense activities and collaborate with our Federal, state, and local government partners as well as with the private sector, non-governmental organizations, and tribal nations.

To do this effectively, CDC has established nine agency preparedness goals to strategically focus and efficiently direct CDC resources. For the purposes of this testimony each of the goals has been categorized according to the four essential components of our national biodefense program as identified in the HSPD–10.

1. Threat Awareness:
   - Decrease the time needed to classify health events as terrorism or naturally occurring in partnership with other agencies.
2. Prevention and Protection:
   - Increase the use and development of interventions known to prevent human illness from chemical, biological, radiological agents, and naturally occurring health threats.
3. Surveillance and Detection:
   - Decrease the time needed to detect and report chemical, biological, radiological agents in tissue, food or environmental samples that cause threats to the public's health.
   - Improve the timeliness and accuracy of information regarding threats to the public's health as reported by clinicians and through electronic early event detection, in real time, to those who need to know.
4. Response and Recovery:
   - Decrease the time to identify causes, risk factors, and appropriate interventions for those affected by threats to the public's health.
   - Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.
   - Decrease the time needed to restore health services and environmental safety to pre-event levels.
   - Increase the long-term follow-up provided to those affected by threats to the public's health.

In addition to these eight goals, CDC has a ninth goal under the heading of "Improvement" to decrease the time needed to implement recommendations from after action reports following threats to the public's health. Taken together these goals provide CDC a strategic framework from which to establish and implement preparedness programs with the goal of integrating our activities with those of our emergency response partners at all levels of government and the private sector.

Key Activities and Accomplishments

For the purposes of this testimony, I will now share with you CDC's unique blending of leadership and supporting roles under *Biodefense for the 21st Century highlighting three priority areas:*

- Laboratory Capacity
- Surveillance and Detection
- Response Capacity

For each of these areas, I will address CDC's activities and accomplishments toward building these capacities at the local, State and Federal levels.

LABORATORY CAPACITY

CDC is internationally recognized as a world leader for its premier clinical and chemical laboratories. To help strengthen our nation's laboratory capacity in responding to potential terrorism threats, we are aggressively moving forward on several fronts.

Laboratory Response Network Activities

The Laboratory Response Network (LRN) is a unified network of domestic and international laboratories that seeks to meet the needs for analysis of all specimen/sample types (e.g., clinical, environmental, food) and agent types (e.g., chemical, biological, radiological). The objective of the LRN is to ensure an effective laboratory response to bioterrorism by helping to improve the Nation's public health laboratory infrastructure, through uniform diagnostic standards and protocols. Currently, there are more than 150 laboratories, representing all 50 states which make up the LRN. In addition more than 10 Federal agencies or departments actively participate in supporting the LRN including CDC, Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Department of Energy (DOE), Environmental Protection Agency (EPA), DoD, Federal Bureau of Investigation (FBI), and DHS.

To further expand and improve national laboratory response to an event, the Interagency Consortium of Laboratory Networks (ICLN) is a network of networks which was established six months ago to promote collaboration, communication, and technical acuity throughout the government's overall response strategy. This DHS-led group includes representatives from HHS (including CDC), USDA, DoD, DOE, EPA, Department of Commerce, Department of the Interior, Department of Justice, and the State Department. Together, all of these lab networks cover the diverse biological, chemical, radiological and nuclear materials that may be detected in clinical, environmental or food samples. The ICLN envisions a US homeland security infrastructure with a coordinated and operational system of laboratory networks that provides timely, high quality, and interpretable results for early detection and effective consequence management to acts of terrorism and other events requiring an integrated laboratory response.

National Interagency Biodefense Campus Initiative

The National Interagency Biodefense Campus (NIBC) is standing up at Fort Detrick to leverage and expand key competencies to achieve productive and efficient interagency cooperation in support of Homeland Security Biodefense. The co-location and collaboration of partners from DoD, HHS, DHS, and USDA provides a unique opportunity for coordinating and synchronizing areas of common interest among the federal agencies involved in medical research and/or biotechnology related to biodefense. The confederation of members promotes federal interagency coordination in facilities planning, technology sharing, and sharing of expertise, while minimizing duplication of effort, technology, and facilities.

CDC's Environmental Health Laboratory

CDC and the Agecy for Toxic Substances and Disease Registry (ATSDR) is responsible for detecting, responding to, and preventing human illness caused by a chemical release. Highlights of our accomplishments include:

- Developing a Rapid Toxic Screen to analyze human blood and urine samples for 150 chemical agents likely to be used in chemical terrorism.
- Assisting local, state, and federal agencies during national and international chemical terrorism events, providing chemical and toxicologic expertise, etiologic chemical analysis, and clinical guidance.
- Helping to increase state and local chemical lab capacity through funding, technical assistance, training and the conduct of drills and exercises.
- Supporting surveillance for chemical terrorism events through the American Association of Poison Control Centers' Toxic Exposure Surveillance System (TESS), which monitors and analyzes real-time data from the nation's poison-control centers.

Select Agent & Toxins Program

Through the Select Agent and Toxins Program within CDC, HHS regulates the possession, use, and transfer of 39 biological agents and toxins that have the potential to pose a severe threat to public health and safety. The CDC Select Agent and Toxins Program oversees these activities and registers all laboratories and other entities in the United States that possess, use, or transfer a select agent or toxin.

Currently there are 333 entities registered with the Select Agent and Toxins Program including academic institutions; biomedical centers; commercial manufacturing (e.g., the pharmaceutical industry) or distribution facilities; federal, state, and local laboratories (including clinical and diagnostic laboratories); and research facilities.

Similarly, USDA has the responsibility of regulating pathogens that affect animals or animal products, plants or plant products. CDC collaborates with USDA to ensure that both regulations are harmonized and consistent.

SURVEILLANCE AND DETECTION

Historically, CDC has engaged in environmental and biological surveillance to track and respond to natural or unintentional man-made threats to the public's health. Because of this tradition, CDC has well-established partnerships with state, local and Federal agencies involved in bio-surveillance. These partnerships are being significantly expanded in the area of active reporting as well as exploring new methods of biologic threat detection domestically and globally.

BioWatch Preparedness and Response

A new system of providing around the clock detection capability is the BioWatch environmental surveillance program. This program utilizes automatic biohazard detection sensors placed strategically across the nation to detect potential threats to the public's health. CDC is working in tandem with the DHS, DOJ, and the EPA in the implementation of this program. These agencies have jointly developed draft guidance for BioWatch Preparedness and Response. This guidance is a three part tool that clearly articulates protocols and procedures for BioWatch-specific environmental sampling and response.

BioSense

BioSense is a significant expansion of information that CDC has traditionally collected from Federal, state and local reporting sources. It is a comprehensive public health data mining activity that integrates traditional and novel sources of public health data to enhance detection, quantification, and localization of possible bioterrorism attacks and outbreaks. In addition, it directly supports epidemiological investigation, event containment, and emergency response and recovery operations.

- BioSense also provides Early Event Detection (EED) and Situational Awareness (SA) capabilities to state and local public health departments, and specifically to cities where BioWatch sensors have been deployed. There are approximately 400 users enrolled representing 49 states, one territory, and 34 major metropolitan areas. Current data sources include DoD and Veterans Affairs (VA) ambulatory care data, laboratory test orders from Lab Corp Corporation, and BioWatch sensor results.
- BioSense continues to refine and expand this important data resource and is currently collaborating with the EPA on the potential use of water system testing data as another source for Early Event Detection as well as with DoD and the VA in strengthening their detection capacity through the utilization of BioSense data.

Biological Threat Characterization Program

CDC is an active participant in the Biological Threat Characterization Program (BTCP) which is a component center of the National Biodefense Analysis and Countermeasures Centers (NBACC) within DHS. A number of Federal agencies participate in this program including the FBI, CIA and DoD. BTCP has been tasked to provide bi-annual risk assessments for biological threat agents of concern. CDC subject matter experts are providing technical input to this process and will participate in the review of the final results.

Global Disease Detection

CDC is renowned as an international public health agency. Medical doctors, researchers, and epidemiologists from around the world contact CDC for advice on the evaluation and diagnosis of patients feared to have bioterrorism-associated or emerging infectious diseases. CDC staff are available twenty four hours a day, seven days a week to provide telephone and on-line consultations.

The Global Disease Detection initiative aims to recognize infectious disease outbreaks faster, to improve the ability to control and prevent outbreaks, and to detect emerging microbial threats. CDC will continue implementing a comprehensive system of surveillance by expanding the Emerging Infections Program and the Field

Epidemiology and Laboratory Training Program. This network is a phased approach that requires ongoing support for existing country/regional platforms while bringing a high level of focus and attention to develop new sites. An effective network will have a strategic presence across the globe with an information technology and laboratory infrastructure that would allow for the broadest possible detection and response capacities before a significant event occurs. Additional activities include improving early warning systems; researching new viral strains; aiding in collaborations with multinational organizations; and augmenting surveillance.

Recently CDC experts have assisted in ruling-out smallpox in a patient in Africa, and in providing injury checklists to help evaluate victims of the London terrorist bomb attacks.

CDC also has provided direct, in-country technical and operational support to large-scale international activities, such as the 2004 Summer Olympics in Athens, Greece.

RESPONSE CAPACITY

CDC is unique in its ability to rapidly mobilize pharmaceuticals and medical supplies to anywhere in the country within a 12 hour window from the decision to deploy these assets. In addition, our agency can bring to bear its formidable arsenal of scientific knowledge and subject matter expertise to assist in responding to and containing public health emergencies. Our goal is to increase this capacity even more with a priority focus on building response capacity at the state and local levels.

Preparedness and health security are a shared Federal, state and local responsibility. NIH is leading the way in the development of new medical countermeasures to threats we face. HHS has completed contract awards for the acquisition by the Strategic National Stockpile (SNS) of several new countermeasures, including the next-generation anthrax vaccine, under Project BioShield. CDC, meanwhile, is working closely with state and local health departments, federal agencies and departments including FDA, HRSA, DoD and other key stakeholders to create a seamless response network to ensure that these countermeasures can be delivered in a timely and effective fashion.

We have accomplished much but there is much more to be done. We continually explore options to strengthen the dispensing of countermeasures to save as many lives as possible in those first critical hours or days of a major emergency. HHS is working in concert with partners and stakeholders to advance the best strategies to ensure medical countermeasures are readily available to protect individuals in the event of a terrorist attack or naturally occurring health problem.

Cities Readiness Initiative

CRI is a multi-agency initiative spearheaded by HHS and DHS. Other participating agencies include DOJ, FBI, VA and the United States Postal Service. The intent of the Cities Readiness Initiative (CRI) pilot is to build capacity for catastrophic public health emergency response in densely populated areas. Specifically, the Cities Readiness Initiative is designed to significantly improve the operational capability of 21 large metropolitan areas to receive, distribute and dispense SNS assets. Each designated city should be able, in the wake of a bioterrorism event for which antibiotics are an appropriate countermeasure, to provide such prophylaxis to the known and potentially affected population within 48 hours of the time of the decision to do so.

Under this program, 20 cities and the District of Columbia receive direct assistance through CDC's Public Health Emergency Preparedness cooperative agreement. Participating cities include: Atlanta, Boston, Chicago, Cleveland, Dallas, Denver, Detroit, Houston, Las Vegas, Los Angeles, Miami, Minneapolis, New York City, Philadelphia, Phoenix, Pittsburgh, St. Louis, San Diego, San Francisco, Seattle, and the District of Columbia/National Capitol Region.

CDC's Division of Strategic National Stockpile (DSNS) supports this initiative with on-going technical assistance to ensure SNS assets are received and dispensed efficiently and effectively.

CDC conducted its own internal assessments in all 21 cities at baseline. These preliminary assessments showed initial improvement. CDC is currently working with partners and a research organization to externally validate CDC's rating tool.

State and Local Readiness Program

CDC administers the Public Health Emergency Preparedness cooperative agreement to assist State and local public health programs in building and improving their preparedness capacities. This includes overseeing their progress in completing activities that help address CDC's nine preparedness goals mentioned earlier in this testimony, by monitoring 34 measures that have been identified as good indicators

of public health emergency preparedness. As we learn more about effective methods of emergency preparedness, the development and refinement of these measures will be conducted in collaboration with state, local, territorial, and tribal public health input as well as with key partners including National Association of County and City Health Officials (NACCHO), Association of State and Territorial Health Officials (ASTHO), Council of State and Territorial Epidemiologists (CSTE), Association of Public Health Laboratories (APHL), DHS, and the Federal Emergency Management Agency. Note that these measures were initially refined through review of the *Target Capabilities* List from DHS which provides defines "nationally accepted preparedness levels of first responder capabilities" for state and local programs.

Risk Communication

HHS coordinates the development of Department-level training opportunities related to public health and medical emergency response, including providing training opportunities for its employees (civil service and uniformed) with the basic tools necessary to manage and operate during a public health emergency.

CDC has developed a preparedness education strategy that targets public health agencies, healthcare organizations, clinicians and laboratorians needed to collaborate to detect, investigate, respond to, and recover from a public health emergency.

One component of CDC's preparedness education strategy is directed to developing and providing information to public health workers and clinicians in advance of an emerging threat. This education is developed to prepare and alert clinicians and public health workers in advance and "just in case" of a potential threat in their community, to recognize symptoms, syndromes, or patterns of illness that require reporting and to improve their capacity to respond.

In addition, CDC has invested in the development of "just-in-time" educational materials, which are educational methods to provide prompt, emergent information as needed and as it becomes available. During an emergency event, CDC is able to rapidly provide new information to clinicians and public health professionals, as rapidly as possible, through web-based and live satellite broadcast educational programs and other communication channels, to improve response efforts.

Conclusion

CDC is working hard to meet the public health challenges of the 21st century. We are redefining our mission, restructuring the way we conduct business, and reorienting our goals. We are changing as an agency because we must respond faster and more efficiently as we protect our nation's health in today's world.

To succeed we rely on many partners including the medical community, federal, state and local governments, innovators and the highly talented CDC workforce. CDC's new business model allows us to be the nimble organization that we need to be to combat world threats to the public's health.

Thank you for the opportunity to be here today. I would be happy to address any questions that you may have.

U.S. House of Representatives

Committee on Homeland Security
Subcommittee o Prevention of
Nuclear and Biological Attack

July 28, 2005

21st Century Health Protection in the Time of Terror:
Globalization, Connectivity, & Speed!

CDC

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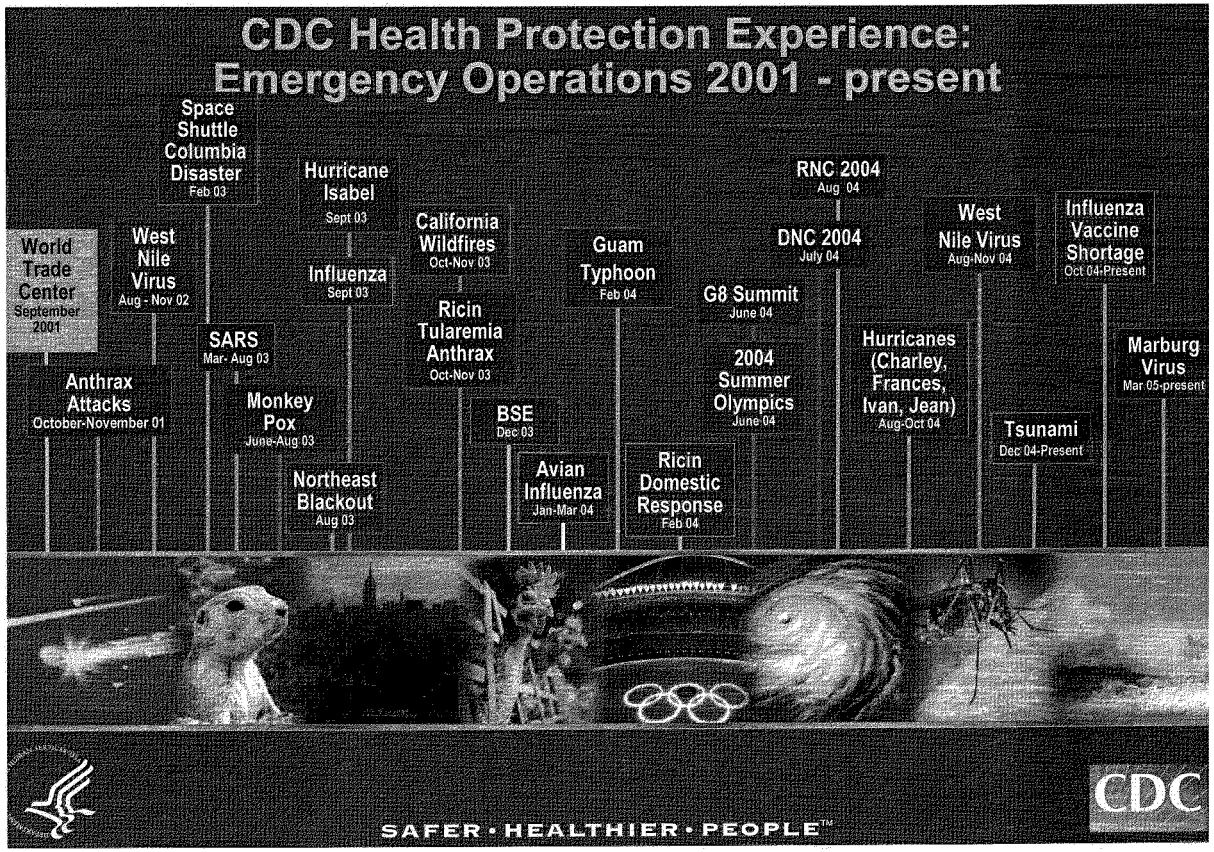
CDC Health Protection Experience:
Emergency Operations 2001 - present
World Trade Center September 2001
Anthrax Attacks October-November 01
West Nile Virus Aug - Nov 02
Space Shuttle Columbia Disaster Feb 03
SARS Mar- Aug 03
Monkey Pox June-Aug 03
Hurricane Isabel Sept 03
Influenza Sept 03
Northeast Blackout Aug 03
California Wildfires Oct-Nov 03
Ricin Tularemia Anthrax Oct-Nov 03
BSE Dec 03
Avian Influenza Jan-Mar 04
Guam Typhoon Feb 04
Ricin Domestic Response Feb 04
G8 Summit June 04
2004 Summer Olympics June 04
DNC 2004 July 04
RNC 2004 Aug 04
Hurricanes (Charley, Frances, Ivan, Jean) Aug-Oct 04
West Nile Virus Aug-Nov 04
Tsunami Dec 04-Present
Influenza Vaccine Shortage Oct 04-Present
Marburg Virus Mar 05-present
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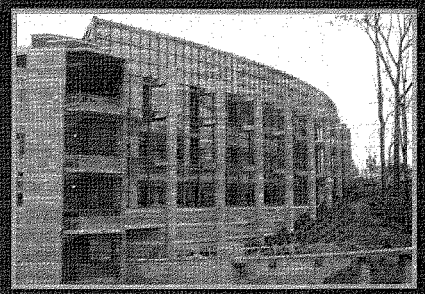
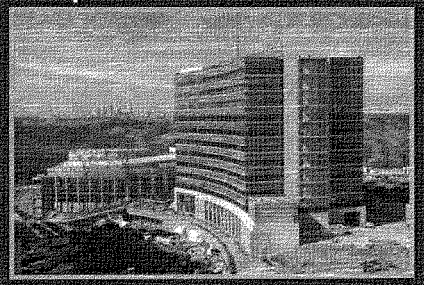
CDC's Health Protection Capabilities: Core Mission and New Enhancements

Emerging Infectious Diseases Laboratory

Global Communications Center



Headquarters and Emergency Operations Center



Environmental Toxicology Lab

CDC

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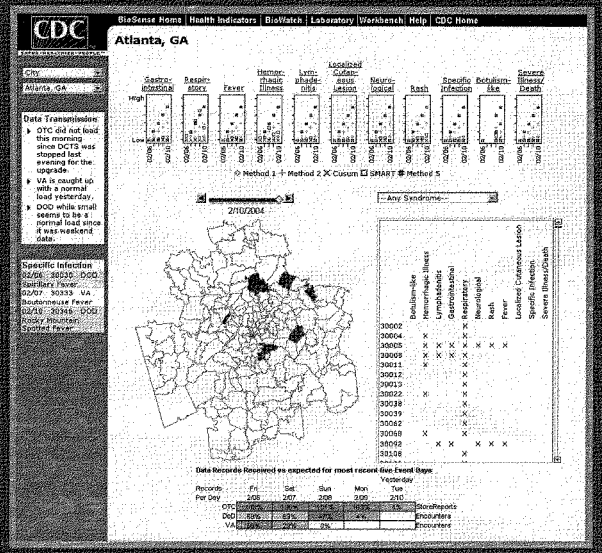
CDC's Preparedness Goals

Pre –Event	Event	Post-Event
Prevent 1) Increase the use and development of interventions known to prevent human illness from chemical, biological, radiological agents and naturally occurring health threats. 2) Decrease the time needed to classify health events as terrorism or naturally occurring in partnership with other agencies ***Detect and report*** 3) Decrease the time needed to detect chemical, biological, radiological agents in tissue, food or environmental sample that cause threats to the public's health. 4) Improve the timeliness and accuracy of information regarding threats to the public's health	***Investigate*** 5) Decrease the time to identify causes, risk factors, and appropriate interventions for those affected by threats to the public's health. ***Control*** 6) Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health	***Recover*** 7) Decrease the time needed to restore health services and environmental safety to pre-event levels. 8) Increase the long-term follow-up provided to those affected by threats to the public's health. ***Improve*** 9) Decrease the time needed to implement recommendations from after-action reports following threats to the public's health.

Biosense: Real-time Health Protection



(Demonstration Data)

- First appropriation this year
  - DoD and VA already strong BioSense partners
- Major target: real-time data from health care sector
- Health threat detection in major cities and all states
- Over 380 users nationally
- CDC BioIntelligence center – making information out of data
- Early event detection
- Situational management

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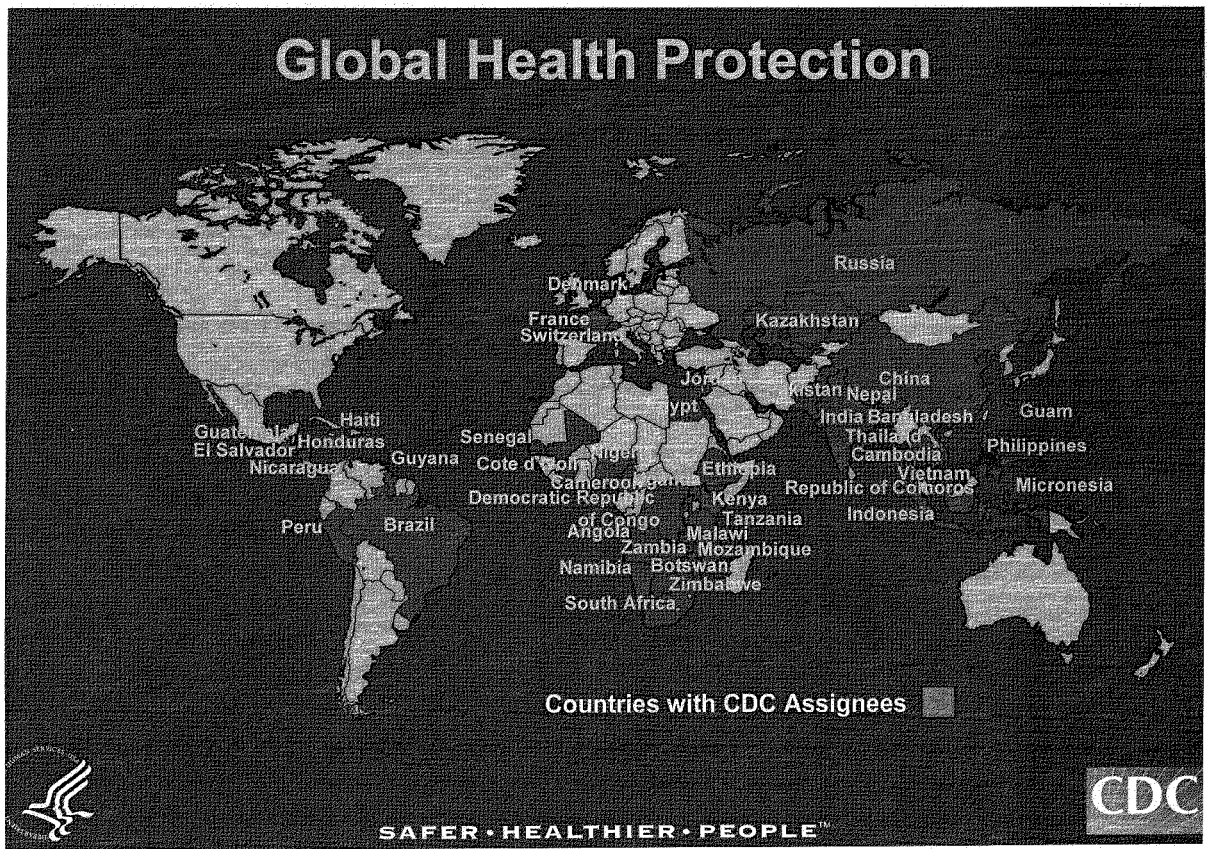
Global Health Protection
Russia
Denmark
France
Switzerland
Kazakhstan
China
Nepal
India
Guam
Philippines
Cambodia
Vietnam
Republic of Comoros
Micronesia
Indonesia
Haiti
Honduras
El Salvador
Nicaragua
Guyana
Senegal
Ethiopia
Kenya
Tanzania
Malawi
Mozambique
Zambia
Angola
Namibia
Botswana
Zimbabwe
South Africa
Peru
Brazil
Countries with CDC Assignees
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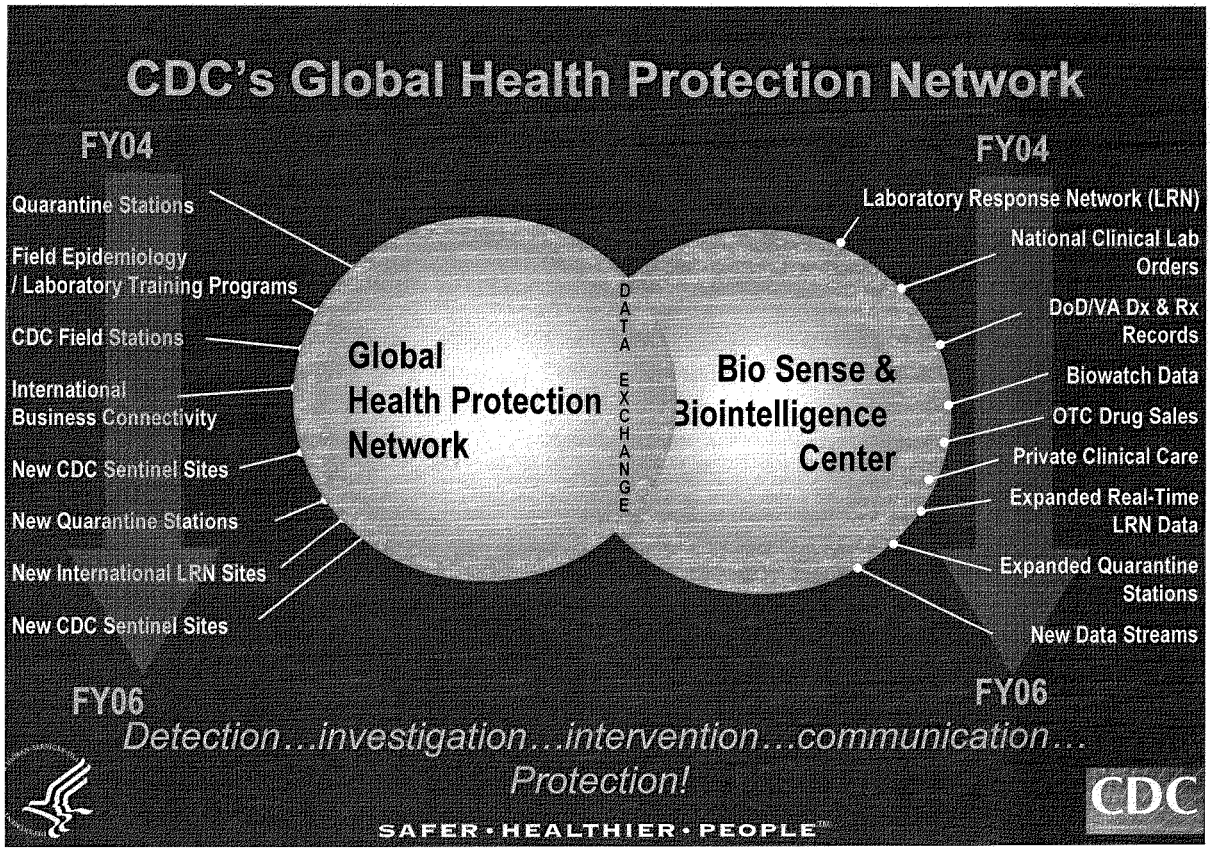
CDC


CDC's Global Health Protection Network
FY04
Quarantine Stations
Field Epidemiology / Laboratory Training Programs
CDC Field Stations
International Business Connectivity
New CDC Sentinel Sites
New Quarantine Stations
New International LRN Sites
New CDC Sentinel Sites
FY06
Global Health Protection Network
DATA EXCHANGE
Bio Sense & Biointelligence Center
FY04
Laboratory Response Network (LRN)
National Clinical Lab Orders
DoD/VA Dx & Rx Records
Biowatch Data
OTC Drug Sales
Private Clinical Care
Expanded Real-Time LRN Data
Expanded Quarantine Stations
New Data Streams
FY06
Detection…investigation…intervention…communication…
Protection!
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Mr. LINDER. Thank you, Dr. Gerberding.

Dr. Fauci.

STATEMENT OF TONY FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTES OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. FAUCI. Mr. Chairman, members of the committee, thank you for giving me the opportunity to discuss with you this afternoon the role of the NIH research endeavor in providing the fundamental and ultimately applied research that goes into the development of countermeasures against bioterror threats as well as threats that naturally occur. I would like to submit for the record these slides such that you might have them in front of you as I go through them.

Mr. LINDER. Without objection.

Dr. FAUCI. The Homeland Security Presidential Directive 10 entitled, Biodefense for the 21st Century, has multiple components. The NIH research effort is associated slightly with some of them, but very intensively with one in particular that I would like to spend a couple of minutes reviewing for you: the development of medical countermeasures for the response and recovery phase as well for the preparatory phase of diagnostics and vaccines.

Soon after the September 11, 2001, tragedy, followed by the anthrax attack on this city and New York City, we developed a strategic plan based on the anticipation of a considerable amount of resources that would be put into the preparedness and the research arena. So, in collaboration with our sister agencies, the CDC and the FDA and elsewhere, we took a look at how we can predict in some respects, and we use the CDC category A, B, and C agents, and respond in a countermeasure fashion to any of a number of threats. We developed a research agenda for these various categories, and over the past year, we have come out with progress reports. And I would like to very briefly give you a thumbnail sketch of some of the key achievements over the past couple of years.

First, with regard to smallpox. The President himself had asked us in the Department what kind of preparation we had very soon after the anthrax attacks in 2001 with regard to smallpox. We had 18 million vaccine doses with a population of 288 million. So smallpox vaccine was a serious problem that we needed to address immediately. We now have more than 300 million doses of smallpox vaccine; but since we know there are uncommon but nonetheless potentially very serious toxicities associated with that, we now are in the developmental phase of a much less adverse event-related smallpox vaccine, modified vaccinia Ankara.

Moving on to anthrax, we now have the next generation recombinant protective antigen which has been under procurement through the BioShield law and which in fact is now going through testing, showing protection against aerosolized challenge with anthrax. We have the first Ebola vaccine that has been tested in humans and have now gone on to the second-generation vaccine which has proved to be safe and in fact virtually 100 percent protective in monkeys.

Botulism toxin is another issue. We have monoclonal as well as polyclonal antibodies, and we are developing a more purified approach with monoclonal antibodies. And then finally on this list influenza a very important pathogen because it gives the link between naturally occurring pathogens and naturally occurring potential catastrophes and what we in the health community can do to link that to our preparedness to deliberately released microbes. And that is the preparation that we at the CDC and NIH and FDA are going through in preparedness for a potential influenza pandemic.

And on this last visual is a map of the world showing some sampling of the emerging and re-emerging infectious diseases that we have had to deal with over the past 25 to 30 years. We include deliberately emerging pathogens in that group for a very important reason: The preparedness that allows us to respond to a SARS or a West Nile or a pandemic flu fundamentally and in principle is the same sort of preparedness that will allow us to respond to deliberately released microbes in a very comprehensive way. And it is this joining together that I think will hold us in the best stead to be able to respond to the threats ahead.

I will be happy to answer any questions later on. Thank you, Mr. Chairman.

[The statement of Dr. Fauci follows:]

PREPARED STATEMENT OF ANTHONY S. FAUCI, M.D.

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to discuss with you today the research programs of National Institutes of Health (NIH) aimed at developing effective medical countermeasures against bioterror attacks. The terrible events of September 11, 2001, clearly exposed the vulnerability of the United States to brutal acts of terrorism. The anthrax attacks that followed just a few weeks later made it very clear that the threat of bioterrorism with pathogens or biological toxins represents a serious threat to our Nation and the world.

The Administration and Congress responded forcefully to this threat, and have made biodefense a top national security priority. After a comprehensive review of the Nation's biodefense activities, President Bush in April 2004 signed a Homeland Security Presidential Directive called "Biodefense for the 21st Century" that provides a detailed strategy for defending the Nation from biological attacks. This strategy has four pillars: Threat Awareness; Prevention and Protection; Surveillance and Detection; and Response and Recovery. The NIH was assigned the lead role in the development of medical countermeasures to biological attack, and in the conduct of research concerning potential agents of bioterrorism that directly affect human health. The National Institute of Allergy and Infectious Diseases (NIAID) is the NIH institute with primary responsibility for carrying out this assignment.

In my testimony today I will discuss the NIH biodefense research program, some recent accomplishments in NIH biodefense research, and the mechanisms by which NIH coordinates its activities with other Federal agencies. I will close with a brief discussion of biodefense research to counter possible future threats from engineered microbes, as well as research needed to counter naturally emerging and re-emerging infectious diseases such as influenza.

NIH Biodefense Strategic Plan and Research Agenda

The NIH biodefense research program is guided by a comprehensive strategic planning process. In February 2002, NIAID convened the Blue Ribbon Panel on Bioterrorism and Its Implications for Biomedical Research, whose members were distinguished experts from academic centers, private industry, civilian government agencies, and the military. Three key documents were developed based on this Panel's advice and on extensive discussions with other Federal agencies. These documents are: the *NIAID Strategic Plan for Biodefense Research,* the *NIAID Research Agenda for CDC Category A Agents,* and the *NIAID Research Agenda for CDC Category B and C Priority Pathogens.* Category A agents are the most dangerous microbes and toxins; these agents cause diseases that include anthrax, smallpox, plague, botulism, tularemia, and viral hemorrhagic fevers. These agents were given the highest pri-

ority because they: (a) are relatively easily disseminated or transmitted from person to person; (b) result in high mortality rates with the potential for major public health impact; (c) would likely cause significant social disruption; and (d) require special action for public health preparedness. Category B agents are in the second tier of priority. These are agents that: (a) are moderately easy to disseminate, (b) result in moderate morbidity and low mortality, and (c) require specific enhancements of national diagnostic capacity and disease surveillance systems. Category C Agents have the next highest priority. They include emerging pathogens that could be engineered for mass dissemination in the future because of their availability, ease of production and dissemination, and potential for high rates of morbidity and mortality and major health impact.

The Strategic Plan outlines three distinct priority areas for the biodefense research program: development of *infrastructure* needed to safely conduct research on dangerous pathogens; basic research on microbes and host immune defenses; and targeted, milestone-driven *medical countermeasure development* to create the vaccines, therapeutics, and diagnostics that we will need in the event of a bioterror attack. The two biodefense research agendas describe short-term, intermediate, and long-term goals for research on the wide variety of agents that could be used to conduct such an attack. Two recent progress reports describe the significant advances made toward the goals set forth in these research agendas. All these documents are available on the NIAID website at *http://www.niaid.nih.gov/biodefense.*

In addition to NIAID's efforts in biodefense research, in 2004, DHHS tasked the Institute with the development of a research program to accelerate the development and deployment of new medical countermeasures against ionizing radiation for the civilian population. NIAID developed and recently released *The NIH Strategic Plan and Research Agenda for Medical Countermeasures against Radiological and Nuclear Threats.* This *Strategic Research Plan* and Agenda is organized into four sections: (1) basic and translational research on the mechanisms of radiation injury, repair, and restoration that can lead to the identification and characterization of new therapeutics; (2) bioassays and tools for biodosimetry, which will aid in diagnosis; (3) immediate product development of promising therapies; and (4) infrastructure to support the necessary research. The document is intended to unify and strengthen the research community focused on these areas, promote collaboration, and facilitate transition from research to product development. NIH is working closely with DHHS to prioritize the research and development activities in this ambitious agenda within the resources available and as one component of the larger National medical countermeasures research agenda.

Recent Accomplishments

Basic research into the interactions between pathogens and their human hosts provides the foundation for medical countermeasure development. For example, a major NIAID basic biodefense research initiative moving rapidly forward is focused on the human innate immune system, which is comprised of broadly active "first responder" cells and other non-specific mechanisms that are the body's first line of defense against infection. The delineation of methods to boost innate immune responses could lead to the development of fast-acting countermeasures that would be effective against a wide variety of pathogens or toxins that might be used in an attack. In order to develop effective ways to increase innate responses, NIAID-supported scientists at Scripps Institute in La Jolla, CA, are mapping the mechanisms by which innate immunity operates and discerning how these responses are triggered.

NIH biodefense research is ultimately directed toward the development of new and effective medical countermeasures, including vaccines, therapeutics, and diagnostics against potential bioterror agents. Substantial progress in this area already has been achieved. In the area of therapeutics, for example, NIAID-supported scientists recently discovered that a poxvirus infection may be halted by a cancer drug aimed not at the virus, but at the human cellular machinery that the virus needs to spread from cell to cell. Although much work needs to be done on this concept, this research opens the possibility of providing a therapeutic approach to poxviruses such as smallpox and also of circumventing the problem of antiviral drug resistance. This approach might also be applicable to other viruses. Researchers supported by NIAID also are investigating the use of antibodies that can bind to and block the action of toxins produced by the anthrax and botulinum bacteria.

New and improved strategies for the development of vaccines against potential bioterror agents are being pursued vigorously. Our stockpile of usable smallpox vaccines has grown enormously since 2001, when only 90,000 doses were readily available for domestic use. Today, because of clinical research on the minimal dose required to produce immunity and due to an aggressive acquisition program, more

than 300 million doses are held in the Strategic National Stockpile (SNS). Moreover, NIAID-supported researchers are testing next-generation smallpox vaccines that may prove to be effective against the smallpox virus and safer than the current smallpox vaccines, thus potentially allowing them to be used by populations that have contraindications for currently available smallpox vaccines, including people with weakened immune systems. One of these vaccine candidates, modified vaccinia Ankara (MVA), is based on a strain of the vaccinia virus that causes fewer side effects than the traditional Dryvax vaccinia virus strain because it does not replicate effectively in human cells. Human trials of MVA vaccines are underway at NIH and elsewhere. Encouragingly, vaccine manufacturers Bavarian Nordic and Acambis announced this year that Phase I and Phase II trials have demonstrated MVA vaccine to be safe and immunogenic in human volunteers, complementing earlier studies by NIAID intramural scientists and their colleagues showing that MVA protects monkeys and mice from smallpox-like viruses. Additionally, NIAID supports a targeted research program to reduce the incidence and severity of eczema vaccinatum (EV), the most common life-threatening complication of smallpox immunization, and to protect individuals with atopic dermatitis from the adverse consequences of vaccinia exposure. The Atopic Dermatitis and Vaccinia Immunization Network conducts research that will identify and evaluate ways to reduce the risk of EV.

NIAID also has made progress in the development of a vaccine to protect against viral hemorrhagic fever viruses that could potentially be used as bioterror agents. For example, research scientists at the NIAID Vaccine Research Center have completed enrollment of a Phase I human trial of a DNA-based vaccine for Ebola. Thus far, the vaccine appears to be safe and immunogenic.

NIAID also has played a major role in the rapid development of the next-generation anthrax vaccine known as recombinant protective antigen, or rPA. The technology for creating this vaccine was developed at the United States Army Medical Research Institute for Infectious Diseases (USAMRIID), and NIAID has supported its advanced research and development. Clinical trials to evaluate rPA in healthy adults currently are underway. Preliminary unpublished data suggest that the immune responses elicited in humans are similar to those elicited in animal studies. Those animal studies have demonstrated that the rPA vaccine protected animals against aerosol challenge with anthrax spores. Last November, the Department of Health and Human Services (DHHS) awarded a contract for the acquisition of 75 million doses of rPA vaccine to be held in the SNS. NIAID's rPA product development initiatives were instrumental in making the initiative possible. Candidate vaccines for plague, botulinum toxin, and other agents are also under development.

In addition to conducting and supporting biodefense research initiatives, NIH has invested in several research infrastructure expansion programs. NIAID has established a nationwide network of Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCEs). These Centers are now conducting fundamental research on infectious diseases that could be used in bioterrorism; developing diagnostics, therapeutics and vaccines needed for biodefense; and providing training for future biodefense researchers. Two new RCE awards were announced on June 1, 2005, bringing to ten the total number of RCEs nationwide. NIAID also supports five Cooperative Centers for Translational Research on Human Immunology and Biodefense to characterize human immune responses to disease-causing organisms, develop technologies to measure these responses, and apply this knowledge to design therapies that strengthen host immunity. In addition, NIAID supports the construction of two National Biocontainment Laboratories (NBLs), built to Biosafety Level 4 standards and therefore capable of safely containing any known pathogen, and nine Regional Biocontainment Laboratories (RBLs) with Biosafety Level 3 facilities. NIAID also will support the construction of two additional RBLs this year. Together, these high-level research laboratories, some of which are already under construction, will provide the facilities needed to carry out the Nation's expanded biodefense research program with the highest degree of safety and security.

Coordination of NIH-Supported Medical Countermeasures Research

Although NIH is a leading agency in government-sponsored research to develop medical countermeasures against biological threats, it is by no means the only agency involved; the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), the Department of Homeland Security (DHS), the Department of Agriculture (USDA), and other governmental organizations also play important roles. Coordination among the various agencies involved is therefore extremely important. In broad terms, Federal medical countermeasures research is coordinated at three distinct levels: within NIH, within DHHS, and across the government as a whole.

Within NIH. Although NIAID is responsible for the majority of NIH-sponsored medical countermeasures research for infectious agents and toxins, other NIH Institutes and Centers make significant contributions. The focal point for trans-NIH coordination and planning of all medical countermeasure research activities in these areas is the NIH Biodefense Research Coordinating Committee. I am Chairman of this committee, which meets at least quarterly. It is administered by the NIAID Office of Biodefense Research, which also serves as the liaison office for NIH contacts with other Federal agencies such as DoD and DHS.

Within DHHS. Coordination of medical countermeasures research between the CDC, NIH, FDA, and other agencies within DHHS is the responsibility of the DHHS Office of Public Health Emergency Preparedness (OPHEP). The OPHEP Office of Research and Development Coordination holds periodic meetings with all governmental stakeholders in the development of medical countermeasures.

Across Federal Agencies. At the highest level, coordination of medical countermeasures research is carried out by the White House, and in particular, the Homeland Security Council, the National Security Council, and the Office of Science and Technology Policy. The focal point for interagency efforts to establish U.S. Government requirements and prioritize and coordinate medical countermeasures acquisition programs is the Weapons of Mass Destruction Medical Countermeasures (WMDMC) Subcommittee ("WMDMC Subcommittee"). This interagency subcommittee of the National Science and Technology Council is co-chaired by DHHS, DHS, and DoD and draws stakeholders from throughout the Federal government.

Although these three levels describe the structure through which biodefense research programs are formally coordinated, NIH collaborates daily with the other Federal agencies and is party to a large number of interagency programs, informal contacts, and communication mechanisms that significantly contribute to the efficiency and effectiveness with which medical countermeasures research is carried out across the U.S. Government. For example, my staff meets regularly with the Defense Threat Reduction Agency and the Defense Advanced Research Projects Agency, two important entities within the research infrastructure in the DOD. NIH biodefense staff also work closely with the research community at Fort Detrick and the United States Army Medical Research and Materiel Command. Moreover, NIH is a major participant in the National Interagency Biodefense Campus now under construction at Fort Detrick; once complete, this facility will foster improved coordination and synergy in Federal biodefense activities.

Emerging Engineered and Natural Threats

Looking toward the future, it is clear that as the power of biological science and technology continues to grow it will become increasingly possible that we will face an attack with a pathogen that has been deliberately engineered for increased virulence. This enhanced virulence could take the form of resistance to one of more antibiotic or antiviral drugs, increased infectiousness or pathogenicity, or, in the somewhat longer term, a new virulent pathogen made by combining genes from more than one organism. Ongoing research to counter these threats includes the development of new broad spectrum therapies, new vaccines with broad cross-reactivity, and immunomodulators to make drugs and vaccines more effective.

Threats arising from deliberate human action are not the only dangers we will confront, because naturally occurring infectious diseases such as HIV/AIDS, SARS, and West Nile virus emerge or re-emerge on a regular basis. A current example is the H5N1 avian influenza virus, which has killed millions of wild and domestic birds, as well as more than 50 people in four countries (Thailand, Vietnam, Cambodia, and Indonesia). There have been two likely cases of human-to-human transmission of the H5N1 virus, and it is possible that other such transmissions have occurred recently. It is also possible that the H5N1 virus, through genetic mutation or recombination with a human-adapted influenza virus, could become easily transmissible among people. Given the poor condition of public health systems in many underdeveloped regions and the speed of modern air travel, the consequences of such an event would be severe.

Although a pandemic alert has not yet been declared, NIAID has taken a number of steps to develop and clinically test vaccines against H5N1 influenza. In January 2004, researchers at St. Jude Children's Research Hospital obtained a clinical isolate of a highly virulent H5N1 virus and used a technique called reverse genetics to create an H5N1 vaccine candidate from this strain. NIAID then contracted with Sanofi-Pasteur and Chiron Corporation to manufacture pilot lots of eight and ten thousand vaccine doses, respectively. The inactivated H5N1 vaccines will be tested in Phase I and II clinical trials that will assess safety and the appropriate vaccine dosage to optimize immunogenicity, as well as provide information about how the immune system responds to this vaccine. The Sanofi-Pasteur trial, which began on

April 4 and is fully enrolled, is testing the vaccine in approximately 450 healthy adults. Trials of the Chiron-produced vaccines are expected to begin later this year.

In addition to these relatively small pilot lots, DHHS contracted with Sanofi-Pasteur to produce two million doses of its H5N1 vaccine, in order to ensure that the manufacturing techniques, procedures, and conditions that would be used for large-scale production will yield a satisfactory product. Moving to large-scale production of the vaccine in parallel with clinical testing of pilot lots is an unusual step, and an indication of the urgency with which we have determined that H5N1 vaccine development must be addressed. Waiting for the results of the initial clinical trials, which would be the normal procedure, would delay our ability to make large quantities of vaccine by at least six months. These doses, which have now been manufactured, could be used to vaccinate health care workers, researchers, and, if indicated, the public in affected areas.

Antiviral medications are an important counterpart to vaccines as a means of controlling influenza outbreaks, both to prevent illness after exposure and to treat infection after it occurs. Efforts are underway to test and improve antiviral drugs to prevent or treat H5N1 influenza. Researchers recently determined that H5N1 viruses are sensitive to oseltamivir, a neuraminidase inhibitor that is marketed as Tamiflu and is approved for individuals older than one year. DHHS has deposited approximately 2.3 million treatment courses of oseltamivir in the SNS, to which it is anticipated that more doses will be added. Scientists are planning to conduct studies to further characterize the safety profile of oseltamivir for very young children; other studies are in progress to evaluate novel drug targets, as well as long-acting next-generation neuraminidase inhibitors. In addition, development and testing in animals of a combination antiviral regimen against H5N1 and other potential pandemic influenza strains is underway.

NIAID also is developing vaccines that are potentially protective against SARS and West Nile virus. NIAID scientists at the Vaccine Research Center have completed enrollment for a Phase I trial of a recombinant SARS DNA vaccine, and have initiated a Phase I clinical trial of a DNA West Nile virus vaccine.

In conclusion, it is clear that defense against biological threats, whether natural or the result of deliberate human action, will of necessity continue to be a high national security priority for the foreseeable future. As per the President's Homeland Security Presidential Directive 10, "Biodefense in the 21st Century," NIH is taking the lead in the construction of a sustainable and comprehensive program to develop medical countermeasures for biological threat agents. The long institutional experience that NIAID has had with infectious disease research allowed us to rapidly take on a greatly expanded role in civilian biodefense after the terrorist attacks in the fall of 2001, and I am confident that we are making good progress.

I appreciate this opportunity to appear before you today, and I would be pleased to answer any questions that you may have.

Mr. LINDER. Thank you, Dr. Fauci.

General SCHOOMAKER.

STATEMENT OF BRIGADIER GENERAL ERIC B. SCHOOMAKER, COMMANDING GENERAL, U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND, FORT DETRICK, MARYLAND

General SCHOOMAKER. Mr. Chairman and members of the committee, thank you for this opportunity to discuss the role of the United States Army Medical Research and Materiel Command, or MRMC, in the implementation of the National Biodefense Strategy, focused around our interagency partnerships.

I am the commanding general of the MRMC and Fort Detrick. I am responsible for delivering the best medical solutions in the form of both expertise and products, such as vaccines and therapeutic agents to enhance, protect, and treat the warfighter on point for the Nation. Since the 2001 attacks on the United States, this mission has expanded to include providing assistance to other Federal partners in protecting the Nation.

In my short time in this position, I have been very impressed with the steps taken by our talented personnel and our interagency partners represented here by this panel to implement the National

Biodefense Strategy and congressional guidance. We are clearly on the road toward a vigorous and already productive interagency partnership that will ensure we meet the biomedical research and developmental goals of this strategy.

Army and DOD researchers have led the medical biodefense research and development for over 35 years. We have gifted people with unique expertise, facilities and capabilities and a proven track record. Laboratories within the MRMC are leaders in the biodefense effort particularly the United States Army Medical Research Institute for Infectious Diseases, or USAMRIID, which is located at Fort Detrick. Many of the Nation's biodefense experts work at, or have learned their skills from, USAMRIID. Many know USAMRIID as the home of the largest biosafety level 4 research capability and as the organization that has been repeatedly called upon and has responded to disease outbreaks such as the anthrax contaminated letters in 2001. A new USAMRIID facility is an essential element of implementing the National Biodefense Strategy.

The interagency partnership which I have been discussing, is embodied by the National Interagency Biodefense Campus, or NIBC, being planned at Fort Detrick, Maryland. Our challenge at Fort Detrick is to become the host of the NIBC, comprised of biodefense laboratories of the United States Army, the National Institutes of Allergy and Infectious Disease, or NIAID, the Department of Health and Human Services, or HHS, the National Institutes of Health, the Department of Homeland Security, the Department of Agriculture, and, in collaboration with the Centers for Disease Control and Prevention, or CDC, and others. Each NIBC partner will implement part of its agency's overall biodefense program. Collectively, the laboratories and partners will collaborate on developing a comprehensive understanding of biologic agent characteristics, elucidating disease processes, and developing products to reduce risks to human health and agricultural productivity. Additionally, the Frederick Campus of the National Cancer Institute of the HHS, or the NCI, which is already located on Fort Detrick, will collaborate with and provide biotechnology support for the NIBC partners. In summary, we are ensuring the congressionally directed laboratory colocation will become a vibrant interagency partnership to enhance the biodefense of the Nation.

While DOD must continue to prioritize our projects and dedicate our resources to protect and treat the warrior on point for the Nation, we see the NIBC as a unique opportunity. You have heard some of these mentioned already. We can develop a more effective military program by leveraging complementary efforts of multiple agencies to defend our military and our homeland against biowarfare and bioterrism. We anticipate that the colocation will compress the discovery cycle to accelerate the development and the approval of new medical countermeasures.

Together, the interagency partners are moving forward to ensure that the NIBC follows the National Biodefense Strategy by coupling our complementary efforts. We have already formed coordinating committees. We have already looked into our complementary capacities, and using the pillars of the President's strategy, and we are harnessing our capabilities on an interagency basis so

that we are not duplicative. Our mantra is "duplication by design and not by default."

Planning for the future is really already informing the present. Research collaborations between the Federal agencies and the private industry have already begun. For example, these three agencies have contributed to research and development of this new generation of U.S. anthrax vaccine.

We feel very good about this collaboration. We are not waiting for buildings; the interagency cooperation has begun already. We feel that this campus will also prepare us the bench of scientists and the critical mass of intellectual power that we require for the future to get those unanticipated agents there.

Mr. Chairman, this concludes my remarks. And I am pleased to answer any questions you might have.

[The statement of General Schoomaker follows:]

PREPARED STATEMENT OF BRIGADIER GENERAL ERIC B. SCHOOMAKER

Mr. Chairman and members of the committee, thank you for this opportunity to discuss the role of the U.S. Army Medical Research and Materiel Command, or MRMC, in the implementation of the National Biodefense Strategy focused around our interagency partnerships.

I am the Commanding General of the MRMC and Fort Detrick. I am responsible for delivering the best medical solutions—in the form of both expertise and products, such as vaccines and therapeutic agents—to enhance, protect, and treat the warfighter on point for the Nation. This responsibility includes protection against, and treatment for, intentional or natural biological threats. Since the 2001 attacks on the U.S., this mission has expanded to include providing assistance to the other Federal partners in the protection of the Nation.

In my short time in this position, I have been very impressed with the steps our talented personnel and our interagency partners have taken to implement the National Biodefense Strategy and Congressional guidance. I am proud to describe a partnership that goes beyond the Army and the Department of Defense, as we are clearly on the road toward a vigorous and already productive interagency partnership that will ensure we meet the biomedical research and development goals of the Strategy.

Army and DoD researchers have led medical biodefense research and development for over 35 years. We have gifted people with unique expertise, facilities, and capabilities—and a proven track record. Laboratories within the MRMC are leaders in the biodefense effort, particularly the U.S. Army Medical Research Institute of Infectious Diseases, or USAMRIID, which is located at Fort Detrick. Many of the Nation/s biodefense experts are at, or learned their skills from, USAMRIID. Many know USAMRIID as the home of largest biosafety level 4 research capability and as the organization that has repeatedly responded to disease outbreaks such as the anthrax-contaminated letters in 2001. A new USAMRIID facility is an essential element of implementing the National Biodefense Strategy.

The interagency partnership, which I have been discussing, can be embodied by the National Interagency Biodefense Campus, or NIBC, being planned for Fort Detrick, Maryland. Our challenge at Fort Detrick is to become the host of the NIBC comprised of biodefense laboratories of the the Army; the National Institute of Allergy and Infectious Diseases, or NIAID, of the Department of Health and Human Services (HHS) National Institutes of Health; the Department of Homeland Security; the Department of Agriculture; and in collaboration with the HHS Centers for Disease Control and Prevention, or CDC; and others."

Each NIBC partner will implement part of its agency's overall biodefense program. Collectively, the laboratories and partners will collaborate on developing a comprehensive understanding of biological agent characteristics, elucidating disease processes, and developing products to reduce risks to human health and agricultural productivity. Additionally, the Frederick Campus of the HHS National Cancer Institute, or the NCI, already located on Fort Detrick, will collaborate with and provide biotechnology support for the NIBC partners.

Using Congressional guidance, we took a proactive role and invited partner Federal agencies mentioned earlier to join us in an interagency campus that would build upon the foundation already present at Fort Detrick. We are providing Army

land and Army infrastructure, as well as facilitating the process of interagency leadership. In sum, we are ensuring the Congressionally-directed laboratory collocation will become a vibrant interagency partnership that will enhance the biodefense of the Nation.

While DoD must continue to prioritize our projects and dedicate our resources to protect and treat the warrior on point for the Nation, we see the NIBC as a unique opportunity. We can develop a more effective military program by leveraging complementary efforts of multiple agencies to defend our military and our homeland against biowarfare and bioterrorism. We anticipate that collocation will compress the discovery cycle to accelerate the development and approval of new medical countermeasures.

Together, the interagency partners are moving forward to ensure the NIBC follows the National Biodefense Strategy by coupling our complementary efforts. We have formed coordinating committees of scientists and others to ensure we address the four pillars of the Strategy (Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery). While harnessing our interagency capabilities we are avoiding unnecessary duplication and economizing efforts. Our mantra is "duplication by design and not by default."

Planning for the future is already informing the present. Research collaborations with Federal agencies and private industry have already begun. For example, three agencies have contributed to the research and development of the next generation U.S. anthrax vaccine. The technology was developed at USAMRIID, the initial production was accomplished at the NCI, and the final manufacture, licensure, and commercialization is being accomplished by the HHS NIAID and the HHS Office of the Assistant Secretary for Public Health Emergency Preparedness via contract with VaxGen, Inc. through Project BioShield. This serves as a model option, currently being followed for other countermeasures, for successful development of solutions for national defense.

The NIBC will enhance our responsiveness to natural public health threats as well as intentional bioterrorism; it is important to note that these initially may be indistinguishable. For example, interagency partnerships played a key role in developing diagnostic systems and evaluating antiviral drugs for Severe Acute Respiratory Syndrome, or SARS, during an outbreak in several countries. CDC and USAMRIID developed tests for this newly emerging disease entity. Additionally, NIAID and USAMRIID screened over one hundred thousand compounds against the SARS-associated virus and one promising candidate has entered into clinical trials sponsored by Intermune, a commercial partner.

You can see that we are not waiting for buildings; in fact, collaboration existed among interagency partners before the NIBC concept was developed and additional partnership activities have begun and are further planned. These and other examples demonstrate that we know we are more effective working together than alone.

One final key aspect of the NIBC is development of the bench by having a critical mass of personnel in partnership with the community of Frederick, MD, and academic and business partners. Through these measures, we will have the opportunity to improve the intellectual pipeline focused on the Nation's defense against bioterrorism.

We're making significant progress every day toward realizing the vision of the National Biodefense Strategy. Fort Detrick and the NIBC will be a collaborative center of biodefense medical research and development excellence for our Nation. All partners have established good working relationships and the Frederick community is extremely supportive.

We are excited to be part of this historic partnership. I want to thank Congress for its material support of the non-DoD NIBC partners and for its recognition of the MRMC and USAMRIID as pivotal elements of this interagency partnership.

Mr. Chairman, this concludes my remarks, and I will be pleased to answer your questions.

Mr. LINDER. Thank you, Dr. Schoomaker.

Dr. VITKO.

STATEMENT OF JOHN VITKO, JR., Ph.D., DIRECTOR, BIOLOGICAL COUNTERMEASURE PORTFOLIO, SCIENCE AND TECHNOLOGY DIRECTORATE, DEPARTMENT OF HOMELAND SECURITY

Mr. VITKO. Good afternoon, Chairman Linder, and Ranking Member Langevin and distinguished members of the committee. I

am pleased to appear before you today to discuss the role of the Department of Homeland Security in implementing the National Biodefense Strategy. This strategy outlines four essential pillars: Threat awareness, prevention and protection; surveillance and detection; response and recovery.

DHS plays a major role in each of these pillars, leading the efforts in risk and net assessments, critical infrastructure protection, coordination of attack warning, forensics analysis and support attribution, response planning, and coordinated risk communications. In each of these areas, we work closely with our partners such as HHS, DOD, USDA, EPA, Department of Justice, and the intelligence community.

Today I would like to focus on the activities within the Science and Technology Directorate, S&T. But, before doing so, it is important to note that other DHS directorates also have major roles in implementing the National Biodefense Strategy.

The emergency preparedness and response directorate and its partners have developed a national response plan and a national incident management system to guide coordinated Federal, State, local and international response to biological attack. The information analysis and infrastructure protection directorate coordinates the national infrastructure protection plan. And the public information office coordinates comprehensive risk communication strategies.

Now I will focus on the role of S&T biodefense activities which I direct in implementing the strategy.

Under threat awareness, the national strategy charges DHS with the lead responsibility for conducting threat assessments to help prioritize the Nation's biodefense activities. To this end, S&T is conducting threat assessments and material threat determinations to help prioritize BioShield acquisitions and inform the associated requirements. To date, the secretary of DHS has issued formal determinations for anthrax, smallpox, botulinum toxin, and for radiological and nuclear devices. Three more assessments are in final review, and depending on their outcomes may result in additional material threat determinations.

Second, we are in the midst of a broader set of forma risk assessments covering 29 agents with the results to be available in January 2006.

Third, we are conducting laboratory experiments to reduce the uncertainty in some of the key parameters that affect these assessments. These experiments are being conducted in an interim national biodefense analysis and countermeasure center, NBACC, pending the completion of the new facility on the Fort Detrick campus in 2008 as part of the NBIC that General Schoomaker just talked about. DHS has also worked closely with HHS in their lead to develop a strategy for addressing engineered threats.

In the area of prevention and protection, S&T's main role has been working on agro defense and, in particular, in the area of foreign animal diseases. In this, we work very closely with USDA. S&T owns and operates the Plum Island Animal Disease Center. Working with USDA, we have developed and are implementing a joint strategy for foreign animal diseases to expedite the transition of new vaccines and immunomodulators to National Veterinary

Stockpile and of new validated diagnostics to the National Animal Health Laboratory Network.

Recognizing the Plum Island facility is more than 50 years old, we have funded the conceptual design of the next generation facility, the National Bio and Agradefense Facility. S&T has also established two university centers of excellence in agricultural and food protection.

In the area of surveillance and detection, national strategy calls for creating a national bioawareness system to permit the recognition of attack at the earliest possible moment. To that end, S&T has partnered with EPA and CDC to deploy BioWatch, the Nation's first bio-aerosol monitoring system. This first-generation system has been operating for more than 2 years and has performed more than 1.5 million assays to date without a false positive. We are currently deploying a second-generation system which greatly increases the number of air samplers and the supporting analysis in the top threat cities. And we are in the midst of developing the next-generation detection system which will automatically analyze the air samples onsite rather than taking them to an off-site laboratory, thereby greatly reducing the cost and making biologics accessible to even more communities.

We have also taken several major actions to coordinate biodetection activities amongst the various departments. These include an interagency memorandum of understanding on coordinated monitoring of biological threat agents, a pilot demonstration of joint civilian and military concepts of operation for early detection and characterization of biological events, and a preliminary approach for making versions of the high sensitivity, high specificity assays developed by the United States Government available to the private sector for commercial development with suitable testing and quality control.

Biodefense for the 21st century also explicitly designates NBACC's, National Bioforensics Analysis Center, NBFAC, as the Nation's lead facility for technical forensic analysis to support attribution. Pending the completion of the new NBACC facility in fiscal year 2008, NBFAC has established interim capabilities at USAMRIID and is already conducting extensive casework supporting FBI investigations of biocrimes or bioterrorism.

In summary, DHS has been working closely with its interagency partners in fulfilling the important roles assigned to it in the National Biodefense Strategy and has already made major contributions to defending this Nation against attacks with biological agents.

Mr. Chairman, Ranking Member Langevin, and members of the committee, I thank you for the opportunity to appear before you, and I will be happy to answer any questions you may have.

[The statement of Mr. Vitko follows:]

FOR THE RECORD

PREPARED STATEMENT OF DR. JOHN VITKO, JR.

INTRODUCTION

Good afternoon, Chairman Linder, Ranking Member Langevin, and distinguished members of the Committee. I am pleased to appear before you today to discuss the role of the Department of Homeland Security (DHS) in the implementation strategy

and progress in executing the major provisions of **Biodefense for the 21st Century.**

Biological threats can take many forms and be distributed in many ways. Aerosolized anthrax, smallpox, foot and mouth disease, and bulk food contamination are among the threats that can have high consequences for humans and agriculture. Recognizing the natural availability of biological agents, their ease of production and use, infrastructure vulnerabilities, and need for a coordinated consequence management plan for a bioterrorist attack response, President Bush instructed Federal departments and agencies to review their efforts and find better ways to secure America from bioattacks.

In April 2004, this review culminated in approval of a joint strategy entitled *Biodefense for the 21st Century.* This strategy provides a comprehensive framework for our nation's biodefense. This directive builds upon past accomplishments, specifies agency roles and responsibilities, and integrates the programs and efforts of various communities—national security, medical, public health, intelligence, diplomatic, agricultural and law enforcement—into a sustained and focused effort against biological weapons threats.

The Department of Homeland Security (DHS) and the Science and Technology (S&T) Directorate have major responsibilities in this integrated national effort. In particular, I want to highlight our progress in implementing this comprehensive strategy and the effectiveness of our interagency collaborations with our key Federal partners, including those represented here today.

Mission and Objectives:

The presidential directive *Biodefense for the 21st Century* outlines four essential pillars of the nation's biodefense program and defines the responsibilities of the various Federal departments and agencies with respect to implementing this strategy. The four pillars with the designated lead agencies shown in parentheses are:

- **Threat Awareness,** which includes biological weapons-related intelligence (intelligence community), risk and net assessments (DHS), and anticipation of future threats (HHS).
- **Prevention and Protection,** which includes proactive prevention (Department of State, Department of Defense, Department of Justice and the Intelligence Community) and critical infrastructure protection (DHS).
- Surveillance and Detection, which includes attack warning (DHS) and attribution (DHS analysis in support of lead agency).
- Response and Recovery, which includes response planning (DHS), mass casualty care (HHS), risk communication (DHS), medical countermeasures (HHS), and decontamination (EPA).

MULTIPLE DHS ORGANIZATIONAL ELEMENTS HAVE MAJOR ROLES IN IMPLEMENTING THE NATIONAL BIODEFENSE STRATEGY

Before specifically addressing the activities of Science and Technology Directorate, it is important to note that several other DHS organizational elements have major roles and responsibilities in implementing the national biodefense strategy.

The Emergency Preparedness and Response Directorate (EPR) has the lead responsibility for working with other appropriate Federal departments and agencies, to develop comprehensive plans that provide for seamless, coordinated Federal, state, local, and international responses to a biological attack. To this end, EPR and its partners have developed the National Response Plan (NRP) and the National Incident Management System (NIMS). The NRP includes Emergency Support Functions (ESFs) to provide Federal resources during a response, including those for public health and medical services (ESF–8, HHS lead) and for agriculture and natural resources (ESF–11, USDA lead). EPR also operates the National Medical Disaster System (NMDS) and works closely with HHS in their lead for mass casualty care.

The Office of Domestic Preparedness/State and Local Government Coordination and Preparedness operates the Metropolitan Medical Response System (MMRS).

The Information Analysis and Infrastructure Protection (IAIP) Directorate has the lead for critical infrastructure protection (including agriculture and food); the S&T Directorate supports IAIP in this role. IAIP coordinates the National Infrastructure Protection Plan (NIPP) which includes shielding critical components of the nation's infrastructure and development of pre-event mitigation strategies. IAIP has the lead DHS role in outreach to the private sector through the interfaces provided by the various Sector Coordinating Councils and the Government Coordinating Councils. IAIP intelligence analysts also work closely with their counterparts in the National Counter-Terrorism Center (NCTC) the FBI, CIA and DIA in assessing the intent of the enemy, their capabilities, potential scenarios, and attack vectors. Working with counterterrorist experts in the Community, they develop link charts on potential as-

sociates here in the United States of operatives abroad who may have received training in weapons of mass destruction (WMD) capabilities or have knowledge of WMD programs.

The Public Information Office (PIO) works with other appropriate Federal departments and agencies to develop "comprehensive coordinated risk communication strategies to facilitate emergency preparedness for biological weapons attacks. This includes travel and citizen advisories, international coordination and communication, and response and recovery communications in the event of a large-scale biological attack."

S&T DIRECTORATE ROLES AND ACCOMPLISHMENTS

Within the S&T Directorate, the responsibilities for implementing the National Biodefense Strategy fall within Biological Countermeasures Portfolio, which I direct. The mission of this Portfolio is to provide the understanding, technologies, and systems needed to protect against biological attacks on the nation's population, agriculture, or infrastructure. Within this mission, the S&T Directorate has the lead role for decision support tools, risk assessments and support to intelligence, early detection and attack analysis, and bioforensics analysis.

DHS S&T also supports our partnering departments and agencies with their leads in other key areas of an integrated biodefense: the Department of Health and Human Services (HHS) on medical countermeasures and mass casualty response; the Department of Defense (DoD) on broad range of homeland security/homeland defense issues; the U.S. Department of Agriculture (USDA) on agriculture biosecurity; USDA and HHS on food defense; the HHS and Department of Veterans' Affairs (VA) on maintaining the Strategic National Stockpile and other pharmaceutical caches (antidotes, vaccines and ventilators); the Environmental Protection Agency (EPA) on response and recovery, including water safety; the Department of Justice on bioterrorism investigations; and the Intelligence Community on threat warnings.

Today I would like to focus on the technical progress of the Biological Countermeasures Portfolio as it relates to the pillars of defense outlined in *Biodefense for the 21st Century.*

THREAT AWARENESS

Under *Biodefense for the 21st Century,* DHS has the lead responsibility for conducting threats assessments to guide prioritization of the Nation's on-going investments in biodefense-related research, development, planning, and preparedness. To this end, the S&T Directorate is leading three major threat assessment activities:

- Material Threat Assessments and Determinations to support Project BioShield development of medical countermeasures;
- Formal periodic risk assessments of a broad range of biothreat agents to guide the broader range of bio-defense investments; and
- Laboratory based characterization of the threats to close key gaps in informing the above risk assessments.

The first of these activities is being led out of the S&T Directorate's Biodefense Knowledge Center and the latter two out of the BioThreat Characterization Center (BTCC) of the National Biodefense Countermeasures and Analysis Center (NBACC).

In addition to these lead roles, DHS has worked closely with HHS, in their lead role, to develop a strategy for addressing engineered threats.

Material Threat Assessments (MTAs) and Material Threat Determinations for BioShield

The Project BioShield Act of 2004 charges the Secretary of Homeland Security with the responsibility to determine which biological, chemical, radiological or nuclear threats constitute a Material Threat to our Nation's security. To fulfill this responsibility, the S&T Directorate , in partnership with the IAIP Protection Directorate, has been conducting formal threat assessments of the agents of greatest concern to establish plausible high consequence scenarios. These assessments combine intelligence information with technical assessments of the feasibility of a terrorist to produce and disseminate the agent to provide an indication of the number of exposed individuals, the geographical extent of the exposure, and other collateral effects. If these consequences are of such a magnitude to be of significant concern to our national security or public health, the Secretary of DHS then issues a formal Material Threat Determination to the Secretary of HHS, which initiates the BioShield process. Subsequently, HHS, assisted by the interagency Weapons of Mass Destruction Medical Countermeasures subcommittee, determines the need for, and requirements of, any new medical countermeasures.

To date, the Secretary of DHS has issued Material Threat Determinations for anthrax, smallpox, botulinum toxin and radiological/nuclear devices. Assessments are nearly complete for plague, tularemia, and chemical nerve agents, and an assess-

ment of viral hemorrhagic fevers will be initiated in August. Based on the outcomes of these assessments, the Secretary of DHS may issue additional Material Threat Determinations.

Risk Assessments across a Broader Range of Biological Threats

As part of its responsibility in the President's National Biodefense Strategy, DHS is required to conduct periodic, formal risk assessments of a much broader set of biological agents to help prioritize the nation's ongoing biodefense activities. These risk assessments provide a systematic evaluation of the development and deployment of a broad range of biological threats, the vulnerability of different portions of our society to those threats, and the resulting consequences of any such attacks.

The first such formal risk assessment is due in January of 2006, with subsequent assessments due every two years. The scope, process, and timescale for this first assessment have been presented to and agreed to by the interagency Biodefense Policy Coordinating Committee co-chaired by the Homeland Security Council and the National Security Council. This risk assessment is addressing 29 biological agents and is being conducted in partnership with the Intelligence Community, HHS, DoD, USDA, EPA, the IAIP Directorate and others. Two advisory boards, one a Government Stakeholders Advisory Board and the other an Independent Risk Assessment Expert Review Board (academia, industry, and government), have been established to provide input and advice.

A Strategy for Addressing Emerging Threats

Much of the biodefense efforts to date have focused on protecting against attacks with bioterrorism agents that can be (or used to be) found in nature. However, rapid advances in biotechnology demand that we also consider the possibility and impact of emerging or engineered agents, for example, modifications to organisms that increase their resistance to medical countermeasure or make them more difficult to detect. The President's *Biodefense for the 21st Century* assigns HHS the lead in anticipating such future threats. The S&T Directorate is partnering with HHS and others in formulating and implementing a strategy for anticipating and responding to such threats.

Based on intelligence information, available literature and expert judgment, we have developed an informed estimate of the types of emerging threats that might be within the ability of a terrorist organization to develop over the near (1–3 years), mid (4–10 years), and longer-terms (10 yrs). In this analysis, four elements stand out as essential to an effective defense against emerging threats:

- Threat, vulnerability and risk assessments to prioritize these threats in terms of the difficulty of their development and deployment, as well as their potential consequences;
- Surveillance and detection capabilities to rapidly detect and characterize engineered agents in environmental and clinical samples so as to provide timely guidance in the selection of the appropriate medical countermeasure;
- An expanded range of safe and effective medical countermeasures and an infrastructure to support rapid research, development, test, and evaluation (RDT&E) of new medical countermeasures; and
- Integrated concepts of operation (CONOPS) for the identification and response to emerging threats.

Scientific research to better inform these threat and risk assessments

The threat and risk assessments described above are performed with the best available information. However, there are large uncertainties, sometimes factors of ten to a hundred, in some of the key parameters and hence in the associated risks. One of the major functions of the threat and risk assessments is to identify these critical knowledge gaps, which can differ for different threat scenarios—in one case it may be the minimum amount of agent needed to infect a person; in another case it may be the time that such an agent remains viable (capable of causing an infection) in the air, food or water; and in a third it may be the effect of food processing or water treatment on the agent's viability. Conducting the laboratory experiments to close the critical knowledge gaps is a primary function of DHS's National Biodefense Analysis and Countermeasures Center (NBACC).

Congress has appropriated a total of $128M for design and construction of NBACC with the necessary biocontainment laboratory space and support infrastructure to conduct these and other experiments. NBACC will be built on the National Interagency Biodefense Campus (NIBC) at Ft. Detrick, MD, in close physical proximity to the DoD's United States Army Medical Research Institute of Infectious Diseases (USAMRIID), the HHS National Institutes of Health's's Integrated Research Facility and the USDA's Foreign Disease-Weed Science Research Unit. NBACC is also collaborating with the HHS Centers for Disease Control and Prevention, a new

member of the NIBC, to further address the critical knowledge gaps. The Record of Decision for NBACC's Final Environmental Impact Statement was signed in January 2005. Design of the facility began in March 2005, with construction scheduled to begin in FY 2006 and be complete by the fourth quarter of FY 2008.

Currently, interim capabilities for both NBACC's biological threat awareness and bioforensic analysis functions have been established with other government and private laboratories to allow vital work in these areas to occur during the NBACC facility's construction

PREVENTION AND PROTECTION: CRITICAL INFRASTRUCTURE PROTECTION: AGRO-DEFENSE

Biodefense for the 21st Century tasks DHS with leading efforts to protect critical infrastructures from biological attack. HSPD–9 further details these responsibilities for protecting agriculture and food. Significant S&T Directorate roles include:

- Acceleration and expansion of the development of current and new veterinary countermeasures;
- Developing with USDA a plan to provide facilities for research and diagnostic capabilities for foreign animal and zoonotic diseases; and
- Establishing new university centers of excellence for agriculture and food security.

In 2003, the S&T Directorate and USDA (Agricultural Research Service [ARS], and Animal and Plant Health Inspection Service [APHIS]) began developing a joint strategy for foreign animal disease. One of the first goals of the strategy is to develop veterinary countermeasures for foot and mouth disease. Following the process laid out in the strategy, ARS has the lead for basic research and early development of vaccines and immunomodulators (antivirals). Potential candidates are then transitioned to DHS for continued development with industry. Once appropriate products are developed, APHIS supplies them to the National Veterinary Stockpile. Interagency coordinating meetings were held as recently as May 2005 to review progress on the joint strategy.

As part of the integrated biodefense complex, the S&T Directorate operates the Plum Island Animal Disease Center (PIADC) and two Homeland Security (HS) Centers of Excellence in agricultural security described below.

Plum Island Animal Disease Center

PIADC is a critical national asset in the strategy for addressing foreign animal diseases. This strategy includes programs on:

- Net assessment of the foreign animal disease threat;
- Vaccines and therapeutics:
  - Improved current vaccines (onset of immunity, adjuvants);
  - Development of next-generation vaccines and immunomodulators; and
  - Transition of promising candidates to industry partners for full product development.
- Assays and diagnostics:
  - National and international validation;
  - Enhanced diagnostics capability and surge capacity; and
  - A new bioforensics capability.

The overall goal of this strategy is to expedite the transition of new vaccines and immunomodulators to the USDA National Veterinary Stockpile and of new validated diagnostics to the USDA National Animal Health Laboratory Network (NAHLN), as well as increasing surge capacity at critical nodes of the response infrastructure.

In addition to these research and diagnostics programs, the S&T Directorate has responsibility for the maintenance and operations of the PIADC facilities, including necessary upgrades and enhancements of facilities and security.

To facilitate overall coordination of these programs at PIADC, a Board of Directors has been established, chaired by the S&T Directorate and including the administrators of both ARS and APHIS. In addition, the Office of Science and Technology Policy's National Science and Technology Council recently established a new Subcommittee on Foreign Animal Disease Threats which is co-chaired by USDA and the S&T Directorate and provides a valuable new interagency forum for cooperation.

NATIONAL BIO AND AGRODEFENSE FACILITY

PIADC is a unique and critical facility for the nation's foreign animal disease defense and celebrated its 50th anniversary in 2004. Thus, the facility is now well beyond its originally planned life span, and is in need of recapitalization.

In FY 2005 the S&T Directorate is funding a conceptual design study for a next-generation facility, the National Bio and Agrodefense Facility (NBAF). The goal of this study is to determine the programmatic drivers for the necessary size and scope

of the facility and the research and development to be conducted there. Three major programmatic themes are being considered:

- The historical PIADC mission for foreign animal disease research in livestock, with needs anticipated over the lifetime of the new facility (approximately 40 years);
- The study of zoonotic diseases, including associated requirements for specific biosafety levels of containment; and
- Testing and evaluation required for approval of medical countermeasures by the Food and Drug Administration (FDA) in HHS.

DHS is working closely with its interagency partners throughout this planning process, including USDA and HHS.

The proposed FY 2006 budget for DHS includes $23M for the architectural and engineering design and pre-construction costs of the NBAF.

University Centers of Excellence

In addition, the S&T Directorate has established two University Centers of Excellence explicitly focused on agricultural and food protection. Texas A&M University and its partners from the University of Texas Medical Branch, University of California at Davis, and the University of Southern California have formed the National Center for Foreign Animal and Zoonotic Disease Defense. They are working closely with partners in academia, industry, and government to address potential threats to animal agriculture, including Foot and Mouth Disease (FMD), Rift Valley fever, avian influenza, and brucellosis. The University of Minnesota and its partners, Michigan State University, University of Wisconsin at Madison, North Dakota State University, Georgia Institute of Technology, and the University of Tennessee at Knoxville have formed the National Center for Food Protection and Defense. They are addressing food issues related to post-harvest food protection, including developing a prototype food event modeling system, new risk communication approaches to minimize the potential impact of food contamination events, and realistic decontamination scenarios involving surrogate agents and food matrices.

SURVEILLANCE AND DETECTION: ATTACK WARNING

Biodefense for the 21st Century calls for "creating a national bioawareness system (that) will permit the recognition of a biological attack at the earliest possible moment and permit initiation of a robust response to prevent unnecessary loss of life, economic losses, and social disruption." Some of the key S&T Directorate activities in support of this are:

- Development and upgrading of a BioWatch, an urban bioaerosol monitoring system currently operating in more than 30 cities;
- Coordination of interagency biodetection activities; and
- Design of the National Biosurveillance Integration System (NBIS).

BioWatch

In early 2003, DHS, in partnership with the EPA and CDC, deployed the BioWatch environmental monitoring system to protect our nation's cities from the threat and ramifications of a bioterrorist attack This first generation system (Gen 1 BioWatch) uses air samplers distributed throughout a city, with filters retrieved daily or more frequently and brought to a nearby Laboratory Response Network (LRN) laboratory for genetic (PCR) analysis. Results are available within 12 hours of filter retrieval. This system has been operating for more than two years and has performed greater than 1.5 million assays without a false positive.

We are now in the midst of deploying a second generation system (Gen 2 BioWatch), which increases the number of collectors in the top ten or so threat cities two to four-fold thereby decreasing the minimum size attack that can be detected and increasing the probability of detection.

Because Gen 1 and Gen 2 systems involve the manual collection of filters and analysis by laboratory staff, labor costs account for about 75% of the operational costs associated with these systems and hence limit both the number of collectors deployed and the frequency with which filters are retrieved. To overcome these limitations advanced next generation detection platforms are currently under development which will automatically perform the detection analysis at the air sampling sites and wirelessly transmit any positives to the LRN laboratory for human confirmation of the signal interpretation. These systems will allow much more frequent sample analysis and address an expanded range of agents. Laboratory tests will be completed in FY 2006 and field tests in FY 2007. The system will then be piloted in an existing BioWatch city (FY 2008) before initiating full scale deployment in FY 2009. The autonomous nature of this Gen 3 system and its low operational cost should allow us to greatly expand the coverage provided by BioWatch.

We are also developing a Biological Warning and Incident Characterization (BWIC) System to assist the local decision makers in determining the public health significance of any BioWatch positive and also to assist in reconstructing the event to guide the response. To accomplish this BWIC integrates BioWatch data with plume and disease modeling and with medical surveillance data (e.g. from CDC's BioSense system) to provide an improved understanding about the possible origin and extent of the release and some estimate of its possible impact. BWIC is currently being piloted in in two cities, and upon completion of the pilots will begin a phased deployment to other BioWatch cities.

Coordination of interagency bio-monitoring and biodetection activities

Since the initiation of BioWatch, the United States Postal System (USPS) has initiated the Biohazard Detection System for the monitoring of mail distribution centers and the DoD has initiated its Installation Protection Program Guardian for monitoring of military bases. In addition, multiple agencies are involved in the testing of 'white powders' from various sources. Recognizing the needed for a more coordinated and integrated approach to such biomonitoring, the S&T Directorate has initiated several programs to improve interagency coordination in this area.

BioNet is a DHS funded, DoD executed program to pilot an integrated civilian and military concept of operations for the early detection and characterization of biological events. The pilot is currently taking place in San Diego, CA, and will be completed this fiscal year. It will provide common (or similar) architectures, operational protocols and communication processes to link existing/projected civilian and military biological detection systems.

Bio-monitoring MOU: An interagency Memorandum of Understanding (MOU) on Coordinated Monitoring of Biological Threat Agents has been signed by DHS, HHS, DoD, DoJ/FBI and USPS and is currently being implemented. The MOU calls for a written plan for coordinated air monitoring; protocols and timelines for shared prompt notification; determining the "equivalency" of biothreat agent testing performed by the participating agencies; and a joint technology roadmap to better leverage Federal investments. In addition the MOU also contains the initial steps in extending this approach to other biodetection measurements. This MOU seeks to address the issues relevant to biological agent detection and characterization necessary to make public health or national security decisions. It does not address subsequent responses which would be addressed by other arrangements and mechanisms.

Public Health Actionable Assays: In coordination with CDC and DoD, we are formulating an approach for working with the private sector to make very high quality, extremely low false alarm rate assays available to them for use in commercial detection technologies. In this approach, the U.S. Government would provide industry with the appropriate signatures to be tested on their detection platforms using their protocols but tested by a U.S. designated independent laboratory. If the combination of signatures, protocols, and platform meet the equivalency requirements established under the MOU then the combination (called an assay) would be designated a "USG—Public Health Actionable Assay" meaning that any positive results would not have to be retested in a government laboratory prior to alerting the Public Health Community. This approach will be piloted in FY 2006.

Development of the National Biosurveillance Integration System (NBIS)

There are many other biosurveillance activities being undertaken by various Federal Departments and agencies. For example, CDC is developing an electronic medical surveillance system (BioSense) to look for early medical indicators of a possible biological attack, and USDA and HHS are developing the laboratory network for detecting and responding to possible food contamination. It is important that the information from all these sector specific biosurveillance systems be brought together to form a comprehensive biosurveillance situation awareness or common operating picture. To that end, the S&T Directorate has worked with the various Federal Departments and with industry to design the National Biosurveillance Integration System (NBIS). NBIS will integrate information on the state of health of people, animals and plants with bio-monitoring of air and water, with results from regulatory testing of food, and with real-time threat information so as to provide the earliest possible detection and characterization of a possible bio-attack. The initial design was completed in early FY 2005 and has been transferred to the IAIP Directorate for implementation.

SURVEILLANCE AND DETECTION: ATTRIBUTION

Biodefense for the 21st Century specifically names the National Bioforensics Analysis Center (NBFAC) of the National Biodefense Analysis and Countermeasures Center (NBACC) as the lead Federal facility to conduct and facilitate the technical

forensic analysis and interpretation of materials recovered following a biological attack in support of the appropriate lead Federal agency. As noted above, a new NBACC facility will be constructed on the National Interagency Biodefense Campus (NIBC) at Ft. Detrick, MD. Pending completion of that facility in FY 2008, an interim NBFAC capability has been established in leased biocontainment space at USAMRIID also located at Ft. Detrick. This leased space was totally renovated to provide a contamination-free environment for ultra high sensitivity forensic work. In a short span of only 12 months, NBFAC has become operational and is now conducting casework supporting on-going FBI investigations of biocrimes or acts of bioterrorism. To date, NBFAC is already processing over a hundred samples per month. All evidence receipt, accessioning and processing are being conducted in secure, contamination free, biocontainment space within the interim NBFAC laboratory. This is a capability that was non-existent at the time of the anthrax attacks in the fall 2001.

To further bolster the admissibility and validity of biological evidence analytical results used in court proceedings, NBFAC will obtain the International Organization of Standardization (ISO) 17025 certification as a reference analytical laboratory in 2005–06. To meet stringent ISO certification requirements, NBFAC has established a stand-alone Safety and Biosurety Program, Quality/Accreditation Program, and received select agent handling certification from Centers for Disease Control and Prevention (CDC) for all laboratory staff and facilities. Standard operating procedures and protocols are in place for evidence handling and analytical flow processes.

To provide reference microbiological material against which to compare suspect samples, the NBFAC has established a National Bioforensic Repository Collection (NBRC). The repository is developing and implementing a comprehensive management plan and acquisition strategy in FY 2005 and will continue implementation throughout FY 2006.

NBFAC has also taken several major steps to extend its analytical capabilities. It has implemented interagency agreements with other federal laboratories to provide capability for specialized analysis and surge requirements and it has implemented a robust research and development (R&D) initiative to develop next generation forensic tools. The R&D program focuses on: developing improved protocols for sample collection, preparation, and extraction; validating new genotyping approaches for more precise and rapid identification of suspect samples; and implementing novel methods for analyzing of the physical and chemical signatures of biothreat agents and their associated matrices to look for differences in the processes used to grow, harvest, process and deliver agents.

RESPONSE AND RECOVERY

Attack with a biological agent can cause widespread contamination of large outdoor urban areas and the included facilities and critical infrastructure that are beyond the scope of current protocols and procedures to address in a timely and cost effective manner. Recognizing the importance of the addressing these issues, *Biodefense for the 21st Century* has charged EPA, in coordination with other Federal departments, to develop strategies, guidelines and plans for decontamination of persons, equipment and facilities and has charged DHS with the lead in developing decontamination methodologies for critical infrastructures.

To support these responsibilities, the S&T Directorate has focused on providing systems solutions through the use of so called domestic demonstrations and applications programs (DDAPs) which bring together users, technologies and procedures to demonstrate in integrated solution to a problem. This approach has been used successfully in the past to develop urban monitoring systems which later became BioWatch and detection and response systems in transit facilities (PROTECT) currently operating in several metropolitan subway systems. Two DDAPs are currently underway on the protection of critical infrastructures, using airports as a model system. The first of these, the PROACT program, has developed "Guidelines to Improve Airport Preparedness against Chemical and Biological Terrorism" that have been provided to the Transportation Security Administration(TSA) and the Federal Aviation Administration (FAA) for review and distribution to airports around the nation. The second of these, the Restoration DDAP, is focused on the recovery of an airport following a biological attack. This program in being conducted in collaboration with the San Francisco International Airport (SFO), the EPA, and CDC (NIOSH) and is focused on developing tools and protocols to significantly reduce the time it currently takes to decontaminate a facility. The major deliverable, due in FY 2006, is a pre-reviewed (by EPA) decontamination plan for SFO that can serve as a template/guideline for other airports in the nation and which will have been dem-

onstrated in concert with the operational user/facility, responders and other federal partners to provide a systems solution to the problem.

The S&T Directorate also co-chairs with EPA the Subcommittee of Decontamination Standards and Technology, assembled by the Committee on Homeland and National Security of the National Science and Technology Council. The objectives of the Subcommittee are to facilitate the development of consistent guidelines, testing protocols, certification methods, and reassessment strategies to address incidents involving biological and chemical agents. The Subcommittee will examine current barriers to standardization and interoperability between agencies and recommend strategies to remove such barriers. A technology gap analysis will be performed to develop a research initiative as well as addressing Human Decontamination issues.

CONCLUSION

The Department of Homeland Security and the S&T Directorate's Biological Countermeasures Portfolio fully support the national biodefense program as stated in *Biodefense for the 21st Century,* and other Homeland Security Presidential Directives. Moreover, these programs are conducted in an active collaboration with other Federal departments and agencies having a role in meeting this national priority, and are focused on reducing the threat of a biological attack against this nation's population and its agriculture and food critical infrastructures, and supports a science-based forensics and attribution capability.

This concludes my prepared statement. With the Committee's permission, I request my formal statement be submitted for the record. Mr. Chairman, Ranking Member Langevin, and Members of the Committee, I thank you for the opportunity to appear before you and I will be happy to answer any questions that you may have.

Mr. LINDER. Thank you, Dr. Vitko.

Thank you all. Each of you is involved in, it seems to me, anticipating something and responding to it. Is anybody involved in finding how the intelligence community can intersect with the biological community to find the bad actors and prevent their actions?

Dr. Gerberding?

Dr. GERBERDING. We have limited intersection in that regard right now. One of our most important domains currently is the recognition that CDC itself is a threat. And so, in cooperation with other agencies, we have come to grips with the fact that our own internal security and the security of the CDC is something that requires a much greater effort, so the guns and the guards and the other security measures that have been part of our portfolio of investments since 9/11 are there in part to deal with that component of prevention. But on a more global scale, as we learn about what are the signatures of people who are planning threats or what is the signature of someone who is working with a biological agent, these are areas where I think we have opportunities to expand and enhance our intersection with other intelligence agencies.

Mr. LINDER. Thank you.

Mr. VITKO. Mr. Chairman, DHS's information analysis and infrastructure protection directorate has a significant effort in that area. Our intelligence

Mr. LINDER. Dr. Vitko, you spend less than 2 percent of your budget on intelligence.

Mr. VITKO. DHS does?

Mr. LINDER. Yes. Less than 2 percent.

Dr. Fauci, does the vaccination for Ebola deal also with Marburg, or is it specific to Ebola?

Dr. FAUCI. We have two vaccines that we are testing, Mr. Chairman. One is a specific for Ebola. The hemorrhagic fevers in general with Lassa Marburg and Ebola are the ones we are worried about. The first one we have tested now that is shown to be safe and

immunogenic in monkeys is specific for Ebola. We have a second-generation one that has been developed in collaboration with the Department of Defense, and that is one in which you have both Marburg and Ebola in the same construct. So we are working towards having a protection against the threats of hemorrhagic fevers.

Mr. LINDER. Is it time for us to start thinking about classes of drugs as opposed to one drug for one bug?

Dr. FAUCI. That is an extraordinarily good point, and in fact, that is the thinking right now of how we are approaching classes of microbes. We use the terminology, but I want to make sure we do that with a caveat, because it is not going to be all-encompassing—rather a little bit less than universal vaccination and antimicrobials. An example of that was recently noted in a nonbioterror microbe group B streptococcus, which is an infection that fundamentally infects pregnant women, who risk passing it on to their newborn infants. There has been a recent important breakthrough conceptually of being able to develop, by expressing all the genes of a particular group of subtypes, those overlapping antigens that in one vaccine could allow you to essentially have a vaccine against all the different types. So that is a first step towards the concept of universality, particularly within subtypes of a microbe. So we are working in that direction, Mr. Chairman.

Mr. LINDER. There have been several articles and TV shows lately talking about the risk of avian flu. How does a terrorist take advantage of that?

Dr. Gerberding?

Dr. GERBERDING. Well, in this case, Mother Nature herself is a very effective terrorist, and we are respectful of her. But we recognize that influenza has some of the important characteristics of an excellent threat agent. It is easily transmissible. It is relatively easy to produce, and it is easy to modify or engineer. So it does have characteristics that, if a person were intent on modifying or creating an even worse influenza isolate, it is not beyond our imagination to consider that as part of our preparedness efforts.

Mr. LINDER. Dr. Vitko, you mentioned briefly an actual bioterrorism and countermeasure center.

Mr. VITKO. Yes.

Mr. LINDER. The first time that was presented to us, it was going to be four labs. Then it was going to be three labs, and now it is two labs. What is the most recent iteration of that?

Mr. VITKO. There are two main centers in there, the BioThreat Characterization Center, which does the laboratory experiments to reduce the uncertainties in known parameters about the threat and improve the assessments; and the second one is the National BioForensics Analysis Center, NBFAC, and that does the technical forensic analysis. The concept you had heard before, there is a broader—NBACC refers both to the center and to the hub programs. And so the other thing you probably heard in that context is the BioDefense Knowledge Center, which is in fact in Livermore Valley, California.

Mr. LINDER. I hope we have time for another round of questions. My time has expired. Mr. Langevin.

Mr. LANGEVIN. Thank you very much.

Dr. Fauci, you touched on an issue that I wanted to address. This subcommittee had a hearing 2 weeks ago where we heard testimony from bioweapons experts, including Dr. Ken Alibek. And the chief concern they all expressed was that we are not ready to rapidly respond to new pathogens, and that known pathogens such as anthrax can be easily bioengineered to be resistant to known vaccines that we have in stockpile. Dr. Roger Brent, another one of the witnesses, compared the stockpiling of the vaccine to the Maginot line, a defense that can be defeated simply by going around it.

What more can we do and are we doing enough to ensure that we could rapidly respond to new pathogens? Is BioShield the way to go? Some have suggested that, instead, we focus on developing the rapid bug-to-drug capability focused on the ability for rapid DNA sequencing of pathogens and quick development and deployment of countermeasures. So can you address that?

Dr. FAUCI. Yes, I would be happy to, Mr. Langevin. First of all, there is a weakness in the stockpiling of a particular countermeasure, a vaccine or an antibiotic, because of the potential capability of engineering around that. But it would be folly to not do that at all. To say that someone has the potential of engineering a smallpox virus that could elude antivirals—and we don't have a good antiviral—or that could divert the immune response away and, therefore, not stockpile a standard smallpox vaccine I think would be not a good idea at all.

Having said that, we should be and are aware of the fact that you have to have countermeasures that would address the ability to divert bioweapons away from the countermeasures that we have already developed. And that is the reason why we are pursuing two areas and a third area that answers your last question, and that is, multiple antibiotics and antivirals that are against different targets. It is extremely difficult to engineer a microbe in which you divert away from virtually every target of an antimicrobial or an antiviral without mutating the microbe out of existence. It is not impossible, but it is very, very difficult to do. So the more different targets you have as the target of your countermeasure, the better off that you are. So there is no question about that.

But the other issue of whether or not we should be looking at genomes—this is one of the major efforts at NIH in collaboration with CDC of sequencing the genomes of virtually all of the target agents, the agents that are suspect of being potential bioterror agents, and to literally be able to examine all the vulnerable points from both an antimicrobial standpoint as well as multiple overlapping antigens. So I believe that we have to do somewhat of a golden mean: We need to stockpile the things that are obvious, but don't rely just on one vaccine, one bug-or-one drug, one bug, but think in terms of the cross-reactivity and the more universal approaches.

Mr. LANGEVIN. Dr. Gerberding, obviously our ability to respond to potential bioweapons attack is going to be largely dependent on not only countermeasures but how quickly we are aware of such an attack. And we rely heavily on the—in addition to sensors, also the public health system. At our visit to the CDC, I had asked you about your confidence in real-time information getting to the CDC or other government entities in terms of being aware of these po-

tential threats or attacks; and you said we had really more work to do in the sense that you didn't give me a feeling that there was a high confidence or a robust system in place. Can you share with the committee your thoughts on our ability to communicate real-time with the public health system and our ability to respond?

Dr. GERBERDING. Thank you. In terms of detection, there is variability across the various agents. We have many smallpox false alarms now, and our system is very sensitive to the potential for a smallpox attack in an individual with a rash or a fever that is suspicious. For some other conditions, it is much more difficult because their initial presentation can be subtle, and this is where the BioSense system becomes very important. This is our first year of funding for BioSense, and by the end of this year, we will have sentinel hospitals and emergency rooms, intensive care units, and laboratories connected from some of the cities involved in our Cities Readiness Initiative that are linked to the BioWatch Environmental Protection Program. And, if all goes well by the end of next year, we will have all of those facilities and those catchments connected up in real-time so that if someone visits the emergency room with something that could be inhalation anthrax, we will have that in our system in real-time.

Internationally, we have a bigger problem. We have seen even with the cases of avian influenza that are emerging out of Asia now, that sometimes we are seeing a lag of up to 30 days before we are aware that a case has occurred. So we have a very, very big effort under way to try to decrease that lag time in the international arena.

Mr. LANGEVIN. And your interaction with pharmacies, you had raised the issue that you used to have good reporting from the pharmacy network, and now that is not as robust. Could you share that with the committee?

Dr. GERBERDING. Yes. For a while, we were able to receive information I think from about 80 percent market share across the country of over-the-counter purchases for certain conditions like influenza. That system has become more expensive than we can afford, so we are replacing it with a different mechanism for getting information about purchases. We believe that our ability to collect them through billing records and through other pharmaceutical resources is going to improve.

We also currently—I want to acknowledge our Department of Defense partners here, because right now today we are getting real-time information from the Department of Defense and the VA medical facilities around the country that includes visits, procedures, diagnoses, and other critical indicators. Because those facilities are so geographically distributed, they are already providing somewhat of a sentinel map that proved to perform very well during last year's flu vaccine shortage.

Mr. LANGEVIN. Is there something you need from this Congress with respect to pharmacies and the reporting that they could do to you?

Dr. GERBERDING. Let me get updated on that this week, and I will get back to you for the record. Thank you.

Mr. LANGEVIN. I see my time has expired, but I want to thank you all for your testimony.

Dr. GERBERDING. Thank you.

Mr. LINDER. Mr. Shays is recognized for 5 minutes.

Mr. SHAYS. Thank you, Mr. Chairman.

In the work that I do in my national security subcommittee that we have oversight of Defense, State Department and Homeland Security, and all agencies that interact on terrorism, we had a hearing with noted medical scholars, and one ran a major medical magazine. And he concluded the hearing by saying—and this was pre-9/11—he concluded the hearing by saying: Congressman, I wanted to share my biggest concern. His biggest concern was, he said in so many words, that a small group of dedicated scientists could create an altered biological agent that could wipe out humanity as we know it.

I want you each to react to that statement in these terms: Is it something that concerns you? Is it something that is a fear without justification? And so on.

Dr. GERBERDING. I think you are asking us to imagine the unimaginable. Technically, we know it is relatively easy these days to engineer and reengineer agents. So the technical obstacles are relatively trivial. What is challenging is the distribution of those agents in manners that would bypass our capacity to recognize and intervene effectively. And I think we are still somewhat confident that, for many of the pathogens, the capability of causing mass destruction is limited because of the nature of the agent and the limitations of distribution. However, as we said when we were concerned about smallpox preparedness, there are certainly opportunities to distribute or reengineer a smallpox virus that could certainly cause terror. It doesn't take very many casualties to upset our economy and to cause major disruption in our society.

So I think these are things that we as Federal agencies need to and are imagining, and we are doing all of the things that we as scientists can do to try to stay one step ahead of the terrorists in this regard. It is a big challenge.

Dr. FAUCI. My response, Mr. Shays, is not significantly different at all from Dr. Gerberding's. Technically speaking, you can do almost anything with a microbe. The real question is, will you end up with a microbe that functionally can do the things that the concerned person that you are hearing said, namely, essentially wipe out everyone from the face of the earth? Again, that is conceivable—anything is possible. However, it would be very, very difficult to do that, extraordinarily difficult, even in the best of hands to not only do the engineering to get a microbe that has the characteristics, but be able to spread it in a way in which it has virulence, transmissibility, and the ability to spread in a sustained, transmissible way. Not impossible, but very, very difficult to do.

General SCHOOMAKER. Sir, first of all, I would be foolish to try to elaborate on what my distinguished colleagues who are really experts in this area have said already.

Mr. SHAYS. But do you basically agree with their points?

General SCHOOMAKER. Yes, sir. I would add that the U.S. military has always been concerned conceptually about this notion—to draw on something that Dr. Gerberding talked about already, that nature is doing on a continuous basis to us, and that we have to be prepared in our military role to be able to respond or to antici-

pate virtually any bio-event that is out there that Soldiers, Sailors, Airmen, Marines, and Coast Guard might encounter. So we go back to reinforcing I think the whole interagency cooperation and need to understand the immune system, to understand the biology of these bugs, and to have a rapidly responsive method of handling that.

Mr. VITKO. I basically agree with the statements made prior to me, especially those of Dr. Fauci, on the real difficulty of functionally engineering an organism to accomplish what you want in a radical way.

With that said, there are smaller steps that can be done in engineering organisms. And the question is, how big a step are you trying to make? And in the case that we worked out the strategy with HHS and DOD for engineered threats we tried to build in our best guesses, estimates, at the difficulty of engineering in certain traits and a strategy for getting there. So, for example, antibiotic resistance to a single drug is much more easy to introduce than antibiotic resistance to multiple drugs than making a total de novo kind of pathogen that has a desired set of properties.

Mr. SHAYS. My time has clearly run out, but let me just say for the next round of questions when we get there: Going through the Soviet Union, you would see pathogens that they would store, whether they were threats to animals or humans, they would justify in some cases by saying we don't know, when the perma-frost goes, what kind of biological agents we will deal with.

But having said that, I would like to in next round ask you to respond to all the potential viruses and so on that are stored by colleges and research firms that we may not even have a good sense of. So that will be in my second round.

Mr. LINDER. Dr. Christensen is recognized for 5 minutes.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. And I very much appreciate your having this hearing, and I hope that we will leave here with a clearer understanding of who does what and be able to get some answers to our concerns, with so many agencies involved and research for biologic countermeasures and our preparedness for bioterrorism, as to why we are moving still so slowly, it seems to me.

I guess I would start my questioning with General Schoomaker, and but others can answer. If I went through the testimony correctly, there are four new labs coming on line at CDC, maybe two at NIH, and then the one at Fort Detrick. What I want to know is which lab does what? Are we duplicating efforts here? Do we need a new lab, given that we have labs at CDC and NIH and they are creating more—which, what is the responsibility of each of these labs, and are we duplicating effort?

General SCHOOMAKER. No, ma'am. I think that is a legitimate concern, and it is one that has been expressed. I would say that every one of the labs, as I think has been outlined, has a different role in this chain of custody of both understanding the basic science and of the immune system of the human and potential host, as well as the microbes that we are dealing with, and then moving those good ideas and that basic laboratory science through a test and evaluation system which tests safety and efficacy to production. And, between threat analysis and anticipating what agents are out

there to the science that is required to understand these agents better and the immune system of the host, to test and evaluation, that for USAMRIID is one of our core competencies, the ability—

Mrs. CHRISTENSEN. So you do test and evaluation of the basic science that is developed at NIH?

General SCHOOMAKER. In the context of what we are talking here, ma'am, in the protection of the public, U.S. public against these hazards, I would say, yes. We have basic scientists that are addressing militarily relevant concerns. But for this, one of our major contributions at USAMRIID is that we are a large laboratory with a great experience, expertise, as well as facilities to test aerosolized agents and to test the effectiveness of vaccines or other agents that would be used to ameliorate those.

Mrs. CHRISTENSEN. Dr. Fauci?

Dr. FAUCI. I just might add that we certainly don't need an unlimited amount of BSL4s. I think the plans we have now will likely meet the needs for the foreseeable future. The NIH does not have a BSL4 on its campus. The NIH is building a BSL4 up in Fort Detrick in order to do the kinds of research that are part of our expanded plan of research. And literally, the time needed in that facility would not be able to accommodate what we were doing at the same time as what the Department of Defense is doing up there. The BSL4 that is being built in Hamilton, Montana in a laboratory is going to meet the needs of the critical mass of scientists who are now working on biodefense there, and then obviously there is a very important facility at the CDC which Dr. Gerberding will address.

Mrs. CHRISTENSEN. Dr. Gerberding, could I ask you a question so that I can get it in and you can answer both? You say that in your statement that, after the decision is made, the supplies that treat the countermeasures can get to any location in our country within 12 hours. In the intervening 12 hours, between the event and the time the supplies get there, what level of preparedness is the public health system at right now in terms of containing whatever the event is, treating the immediate effects, controlling the spread, and then to distributing or applying whatever is sent from the stockpiles?

Dr. GERBERDING. Let me speak to the laboratory question first. One of those buildings that I showed you is housing for BSL laboratories that CDC has desperately needed. Right now we can't simultaneously work on Ebola and smallpox, but we need to be working on those and some other agents that need those labs. But what is exciting about the Fort Detrick campus is not just the agencies coming together and co-locating; it is the scientific synergy that can be created by bringing people with the variety of expert capabilities together to work collaboratively. This is the era of big science, and getting the right critical mass of the very best minds in the country together to contribute their unique capabilities to these problems is, in my opinion, essential. I mean, it has also allowed us to look at some gaps. For example, CDC's role in this campus is to be focusing in on environmental microbiology, which speaks to the question you asked, your second question about what happens in the first 12 hours. If we have a contaminated environment like occurred here in Congress in 2001, the science around: How do you

define the extent of contamination, and how do you ameliorate that contaminant, and how do you know you have done it, and how clean is clean, and when is it clean enough? Those are questions that we desperately need scientific answers to, and these are the kind of things that we think, by taking advantage of the aerosol lab and the forensics capabilities that Homeland is building and CDC's unique microbiologic science capabilities, we ought to be able to get to those answers faster. That also is predicated under the assumption that we will engage the EPA and the other agencies that have primary leadership in these areas.

Mr. LINDER. Mr. Simmons, you are recognized for five minutes.

Mr. SIMMONS. Thank you, Mr. Chairman.

And I thank the distinguished panel made up of medical doctors and Ph.D.s—I think all four of you have at least your Ph.D. or your medical degree, so congratulations, even the general, yes, indeed.

The chairman made the comment earlier about prevention; there is a lot of talk about identifying problems and responding to them in a proper way, and that is entirely appropriate. As the Chairman of the Intelligence and Information Sharing Subcommittee of this committee, my interest is in identifying the threat capabilities, and then trying to prevent these attacks from taking place in the first place.

Clearly, the United States intelligence community plays a role in this, certainly in threat assessment, in determining capabilities, but then more importantly, and perhaps more difficult, determining what the plans and intentions may be.

My first question goes to the issue, do each of you or all of you, in your current capacity, provide requirements to and get products back from the U.S. Intelligence Community at a classified level that is useful to you in attempting to determine the threat and to prevent an attack? And I will follow that with a second question while you consider the first.

The al-Qa'ida handbook, which is a translation of an al-Qa'ida document that was taken in Manchester, England a couple years ago, makes reference to public sources. And the al-Qa'ida guidance is, use public sources openly and without resorting to illegal means. It is possible to gather at least 80 percent of information about the enemy from public sources. They go on to mention books, magazines, newspapers, periodicals, official publications and broadcasts.

It occurs to me that open sources of information lend themselves particularly to this area, because so much of what we know about research and development in medicine is shared through professional journals and books. And let me give you an example.

Pfizer Corporation is currently looking into the use of aerosols for diabetes treatments so you don't take a shot through the skin, you use an aerosol, but the vaporization is critically important for the system to work. It is my understanding that the same vaporization, or the technology of that vaporization, can be used in a biological weapon that would be airborne, and perhaps dispatched in a theater, a building's air conditioning system, subway system, train or any close space.

To what extent do any of your agencies go into the open source with a red team mindset to see what, in fact, the bad guys might be looking at to use to develop and spread biological agents; to

what extent are you using open sources to develop your intelligence assessments?

Dr. GERBERDING. Let me address your first question first, and then I guess come around again.

CDC is linked into the intelligence community in several ways. We have more than one FBI agent who is permanently stationed at CDC, and we are very closely allied with the regional FBI Center in Atlanta. We have reciprocal training. We have trained more than 8,000 local public health and law enforcement officials through our combined forensic epidemiology program so that we can investigate at the local level.

But we also have analysts at CDC. We are coming online with a data stream so that we will have primary source information, and we are also working with the Department of Defense on being a note in the medical intelligence information that the Department of Defense is creating.

So we have a number of systems that are likely to be operational when we move into our new headquarters building on September 12th. That is one of our deadlines for getting these systems interoperable.

Dr. FAUCI. Just to amplify a bit, at the NIH, which does a lot of the research involved, we have several taps into intelligence that help us direct development of countermeasures. We are in close collaboration with the CDC and their plug into the intelligence community. We rely heavily on the material threat assessments that come from the Department of Homeland Security. And we all have top secret security clearance and get briefed on a relatively regular basis by the CIA and the FBI.

General SCHOOMAKER. Sir, one linkage to the intelligence community, as these others have said, the Medical Research and Material Command, in fact, the whole of the DoD is linked with the DIA, Defense Intelligence Agency, as well as the Armed Forces Medical Intelligence Center, which is a joint command. It is collocated at Fort Detrick with MRMC. In fact, to go back to a theme that Dr. Gerberding brought up, the critical mass of people working on these and sharing information, the design of this campus is, in fact, especially made so that it shares information. We do have a very close linkage with the Armed Forces Medical Center.

As far as aerosolization is concerned, and the risk, our people at USAMRIID are national, international experts on aerosols, I would like to take your question for the record and get back to you on that.

Mr. SIMMONS. Thank you.

Mr. VITKO. Our information analysis analysts work very closely, as you have heard in previous testimony, with the FBI, CIA, NCTC and other agencies. They have constructed a multi-agency intelligence team to support the risk assessments when doing material threat assessments. We make use of both that formal intelligence information, and we provide them cues and products to look for from the bioterror characterization activities that we do, but we make extensive use of open source information in doing the material threat assessments that we undertake. So we think it is a very important source.

Mr. SIMMONS. I thank the Chair.

Mr. LINDER. Mr. Dicks is recognized for 5 minutes.

Mr. DICKS. Thank you very much, Mr. Chairman.

Mr. Vitko, can you walk us through the process of developing a material threat assessment?

Mr. VITKO. It would be my pleasure, Congressman.

Material threat assessment starts with selecting agents that might be of significant concern. The next piece that you do is you try to—it is intelligence in form, that is, what do we understand about potential adversaries and their capabilities, but then it moves on to the scientific process of trying to establish the feasibility of a terrorist constructing a weapon.

So we start asking questions about how would they obtain an organism, to what level could they grow it out, what resources would it take, is it storable; how would you disseminate it; what are the potential scenarios; how long does that agent then survive in the environment or the food processing or water processing kinds of system it goes through, and it takes that through to the consequence end.

Throughout that, in each of those stages, we involve the appropriate experts. So typically in a material threat assessment, there are 40 to 50 experts involved. There are typically, again, two interim reviews, and then a final review and vetting at both an unclassified level and a classified level.

Mr. DICKS. Do any of these entities represented here by Dr. Fauci, Dr. Gerberding and General Schoomaker, are they involved in this, or is this your people—

Mr. VITKO. Absolutely.

Mr. DICKS. So do you have a collaborative—

Mr. VITKO. This is not only multi-agency, it involves the academic community, it involves the entire—

Mr. DICKS. Is that why it takes so long? We have only done four of these. I am told that there are about 60 possibilities for material threat assessments. Is that correct, is the list that long?

Mr. VITKO. Well, the 60 agents that you told about are the CDC's category A, B and C list. Clearly some of those are higher priority concern than others, that is why they are—

Mr. DICKS. I assume you are doing the higher priority first?

Mr. VITKO. We are doing the higher ones, and we have essentially finished the category A agents. The reason it takes so long is because, if you look at each of these—and there are typically, as I described, 30 to 40 parameters in trying to assess the consequences of this kind of event, if I am off even by a factor of two in each of those, I can have large uncertainties in what comes out in the end. We try to pinpoint that down as well as we can—there are still uncertainties—and we try to reduce that and to develop a consensus understanding in the community around that.

Mr. DICKS. Now, one of the things we heard at our last hearing was that, because it is becoming so easy to bioengineer pathogens for vaccine resistance, that stockpiling of vaccines may not be the right approach. One of our witnesses likened the vaccine stockpile to the Maginot Line of World War II, which the German Army simply went around. They suggested that we focus on developing bug to drug capability. What advice do you have for us on this? I mean, we have been upset that maybe you are not getting these material

threat assessments over to DHS, and then they can't use the money in the BioShield Fund to go out and get various drugs as countermeasures.

Some people suggest that that may not be the right approach. What can you tell us about this?

Dr. FAUCI. I think we need a balance of multiple approaches, which we are implementing, Mr. Dicks. We certainly need to stockpile vaccines for the obvious threats, and smallpox is one of them. We are also keenly aware of the theoretical possibility of being able to engineer a microbe to evade vaccine, linked to a mechanism, for example, of suppressing the body's immune system.

So to say one or the other I think would not be the appropriate response, but to do a reasonable amount of stockpiles for the obvious, but don't think that you are now totally protected, but direct your research to be able to circumvent attempts to get around the—

Mr. DICKS. Dr. Fauci, you have a lot of experience and people have a lot of confidence in you. Are you concerned about the pace of getting these material threat assessments done and getting commitments made out of the BioShield Fund? Does this worry you, or do you think we are on a reasonable pace here?

Dr. FAUCI. I am not satisfied, Mr. Dicks. I am aware of how difficult it is, as articulated by Dr. Vitko about getting them out, and I think we will soon be getting significantly more out. But I agree with you that there is concern about getting it so that we can then steer our research and development efforts—

Mr. DICKS. The companies are particularly concerned, one about liability, one, that the bigger companies won't be involved because they can make more money doing other things—we watch those every night on television—and that they are concerned about the pace of the commitments made by DHS, and they are basically pointing the finger at Dr. Vitko and his people and saying they are not getting these material threat assessments done.

Until DHS gets it, they can't take any steps. In fact, there was one on radiological that I am told that went over there and was sent back. And there was a lot of confusion about where it stood.

So this is worrisome to us because we don't have the same kind of resources here that we had in Nunn-Lugar and some other things, and somehow we have to encourage and move the process a little more rapidly.

Dr. FAUCI. I agree, Mr. Dicks. There are a couple of issues that you brought up, I will very briefly address them.

I agree there is a concern, and we need to move faster and do better about getting them out, and DHS is clearly addressing that. They are very well aware of that.

The other is—

Mr. DICKS. I should have said HHS, excuse me, they are the ones that have to spend the money out of the Biofund.

Dr. FAUCI. We have to spend the money out of the BioShield. That is my concern because we want to get it out there and get those countermeasures out.

But the point you made about the big companies is something that we at the Department, particularly Secretary Leavitt, are concerned about, and are trying to address: how do we better

incentivize the larger companies to get involved? The mechanism we have in place now has been helpful, but we really need to do better to get them involved. Liability is clearly one of them that you mentioned, and this is an issue of very intensive discussion at the present time.

Mr. DICKS. Even the smaller companies are worried about liability.

Dr. FAUCI. Everybody is, but if you want to get the big players in, they have much more to lose than the others. They don't want to step on ground that is going to endanger a large enterprise.

Mr. LINDER. The time of the gentleman has expired.

The gentleman from Texas is recognized for 5 minutes.

Mr. MCCAUL. Thank you, Mr. Chairman. This is really a follow-up to Mr. Dicks' question.

Four of the 60 material threat assessments have been done. What is your timetable for completing the 60, and would do you favor, as he mentioned, immunity from liability for the big pharmaceutical companies to get them incentivized to participate?

Mr. VITKO. I will speak to the timetable. We have done material threat assessments, three more assessments are in their final review. We will have done 29 agents by January of 2006 in terms of risk assessments. Those are not full material threat assessments, those are risk assessments, so in some cases there may be additional details to be pursued, and that is where the pace of that is.

Mr. MCCAUL. Do you need additional resources to speed up the process?

Mr. VITKO. Actually, we have the financial resources. This is a question of having the right people and the time it takes to do that, but thank you very much for the offer.

MR. McCaul. I don't know if it is an offer—

Dr. FAUCI. The debate for liability protection is up for some considerable discussion, you can go all the way to one side, have complete indemnification for everything—that I think would be a hard one to sell—but better than we are doing now with regard to liability. I think there is universal agreement that we need to address the liability issue better than it being addressed currently.

MR. McCaul. There is more out of curiosity. I assume most of you read the Hot Zone way back when. I read it again about a year ago, and the first couple of chapters are really a page turner, and scary. The person comes down with the Ebola virus, it is a Marburg strain, I think, and begins hemorrhaging on the airplane. When are we going to have a material threat assessments for that agent?

And secondly, have we ever weaponized—has it ever been weaponized, either by us or the Soviets? And I don't know if you can answer it in open hearing. And is there an airborne strain to that virus that we know of today?

Mr. VITKO. I will speak to the first part—

Mr. LINDER. Let's not have the answer in open session.

Mr. MCCAUL. I will withdraw the question. Perhaps I can get that information in a closed hearing.

Then lastly, we passed the faster and smarter funding bill in the House, and that provided grants for First Responders. But as I understand it, DHS does not have—or HHS, I should say, does not

have a similar mechanism for bioterrorism grants. My State of Texas always ranks dead last per capita, along with New York and California on that type of funding. Would you recommend—what are your thoughts on changing that formula to a risk-based formula for bioterrorism grants? And perhaps, Dr. Gerberding, maybe your expertise.

Dr. GERBERDING. Thank you. It is a dilemma to assure that we have a network of protection in every location in the country and yet pay attention to the places where the risk may or may not be greater but the impact is large. And certainly in urban areas like New York City, we know that the impact factor is huge.

I always harken back to anthrax when I remember the night that I stayed up all night with the City of Fort Collins, Colorado when there was a white powder in their post office. That is probably not a city that would rank high on the threat assessment scale, but it was a community that had exactly the same requirements as any other anthrax-exposed community.

I think one of the things that we have done this year through the City Readiness Initiative is to dedicate some—more than $30 million to a set of 20 cities plus the D.C. area to invest in much more depth in countermeasure delivery and some of the additional linkages between the environmental assessment capabilities, the laboratory and our ability to deliver countermeasures. So that's a step towards focusing on higher threat environments. And I know Secretary Leavitt is looking very closely, working with the stakeholders in these communities to determine what is the right balance between a seamless network and yet assuring where people would be experiencing the most impact that we have the best preparedness possible.

Mr. MCCAUL. Okay, thank you. I will yield the balance of my time. Thank you.

Mr. LINDER. The gentleman from Mississippi is recognized for 5 minutes.

Mr. THOMPSON. Thank you very much, Mr. Chairman.

Dr. Fauci, I am looking at a document relative to biodefense countermeasures, and I see anthrax is listed on here; and it says that we have a new vaccine tested and procured under the project BioShield; is that correct?

Dr. FAUCI. That is correct. The contract was signed for procurement. The payment for that is upon delivery to the Strategic National Stockpile. The work that is going on with the recombinant protective antigen, which is the next generation of anthrax vaccine, is safety studies in phase one, and now going into phase two, as well as work in an animal model, to determine if you can protect with your vaccine against an aerosolized challenge.

Mr. THOMPSON. Can you tell me, how old is that contract right now?

Dr. FAUCI. The contract was signed within this past year, so it was in 2005 that it was signed.

Mr. THOMPSON. Can you tell me the rationale for giving the contract to a company that had never produced the vaccine?

Dr. FAUCI. This was a decision at the Department, but I would be happy to—that was not my decision, but I would be happy to address it.

The rationale is that this is under a typical classical contract bid procedure where the proposals and response to Request For Proposals are examined and rated and prioritized, and the contract is let on the basis of a rating and ranking among the competing entities that put contract proposals in.

We are dealing with a very unusual situation, Mr. Thompson. If we were to exclude now any company that would engage in a BioShield procurement who has not developed a vaccine, we would exclude most everyone who would be interested in doing that.

Mr. THOMPSON. Well, then I understand there are a number of companies who have produced this anthrax vaccine that we didn't select. So using your rationale, if we have companies who do it, why would we choose a company that has never produced a vaccine?

Dr. FAUCI. That gets into the contract law of prioritization and the decision that is made on what the factors are in having a procurement officer decide that one is better than the other, and I don't think it would be appropriate for me to address why one got it versus the other, that gets into contract law that I am a little bit concerned about making a statement about why—

Mr. THOMPSON. Let me tell you why; because in the process of awarding the contract, we went out and bought some vaccine from another company just to have some around.

Dr. FAUCI. Right.

Mr. THOMPSON. And I am trying to figure out the logic of going out and buying some vaccine from one company and ordering some from other company that has never produced it.

Dr. FAUCI. Right. I cannot give you the precise answer for that, but I can create a scenario that is very compatible with what you just described.

You have a vaccine that you want to improve upon, and you sign a contract for the development of a vaccine that you could have in your stockpile that is better than the current vaccine, but during the developmental process of that new vaccine, there is a gap of not having enough on hand of a vaccine that may not be the optimal vaccine, but at least it is a vaccine that you could use as a stop gap. That could have been the rationale that the Department used. And as I mentioned, that was not my decision because I do the research, I don't do the procurement.

Mr. THOMPSON. Well, you produced a document saying it was done, and that is why I raised the question.

Dr. FAUCI. I appreciate that, Mr. Thompson, but I am trying to explain how that got in there.

Mr. THOMPSON. Do you know of any other vaccines that have been similarly situated?

Dr. FAUCI. When you say similar situation, you mean—

Mr. THOMPSON. That we have had to go out and procure a vaccine from another source and we contracted with another source to produce it.

Dr. FAUCI. Well, what we are dealing with right now in the biodefense arena does not lend itself to vaccines that have already been made for a particular microbe. The other one that is amenable to vaccine protection would be smallpox, that is the other example with anthrax. We had a smallpox vaccine, we had an anthrax vac-

cine. We were down to virtually no doses, 18 million doses of smallpox vaccine. The companies that originally made it were long out of the business of making smallpox vaccines, so that would be the other example, so there are really only two.

I would might also add, Mr. Thompson, that the rPA vaccine and the AVA vaccine for anthrax are really two different vaccines, they are not the same. One is the supernatant of the anthrax which contains all of the antigens. The rPA was the purified component. We wanted to go with the more purified component. One, it was very likely it would require less immunization doses to get us where we wanted to be, and the other, there was the concern about issues, be they verified or not, about the baggage associated with the safety of the original anthrax vaccine.

Mr. THOMPSON. Thank you, Mr. Chairman.

Mr. LINDER. The chairman recognizes the gentleman from Louisiana for 5 minutes.

Mr. JINDAL. Thank you, Mr. Chairman, thank you for calling this hearing.

I want to thank the witnesses. I have had the privilege of working with at least two of them before, so I want to thank you for taking the time to come and talk to us today.

I had three broad areas that I wanted to ask questions in, we may not have time to get to each of them, but I want to share with you the three questions and give you each a chance to respond.

The first was, on one of his last days as working as the Secretary of Health and Human Services, Secretary Thompson talked about the fact that he was somewhat surprised we haven't yet to see an attack on our food supply chain, given the vulnerabilities. I would like your response to that assessment, whether you think we have taken steps, significant and enough steps since September 11, 2001 to secure our food safety from a by bioterrorist attack.

The second is—and I know they are not mutually exclusive, but the second is, how do we set priorities when it comes to preparing our public health infrastructure from the threat of a bioterrorist, a man-made attack, versus a naturally-occurring pandemic, and which do you think is more likely to actually occur in a short-term horizon over the next few years?

And again, I know they are not mutually exclusive. The ideal answer is it would take and build defenses there to protect our Nation from both.

Third, and finally, I remember all too well how we didn't have a robust, comprehensive surveillance system on 9/11 for a bioterrorist attack, how we had many local county health units that didn't have 24-hour, seven-day-a-week communications ability, and I know we have come a long way since then.

I would like your assessment, given BioWatch, the Global Disease Detection Initiative and some of these other things, and I know CDC is involved with many of these things, how close are we to getting real-time information? And within that, if you could comment on the fact, the development of sensors that could give us real-time data instead of just 24 hour data.

And again, I know I have asked a lot of questions, and I would appreciate your comments on any part of those three during the time that we have got.

Dr. GERBERDING. I will try to give short answers and if you need more detail we can get back to you for the record.

With respect to food safety, I will speak from the CDC perspective. Our role is primarily the surveillance of events potentially related to food-borne problems; and second, obviously safe food handling, the so-called Farm-To-Table initiatives on which we collaborate with FDA and USDA.

We have made a lot of progress in food safety. The FDA could tell you about the enhanced food inspection systems, the food laboratory system that is now part of the linkage into the Laboratory Response Network.

At CDC, we have a system called Pulse Net, and we have been able to decrease the time from contaminated food to detection and public health response sequentially over the last several years by using methodologies that are based on fingerprinting of the agent and comparing those in the database of CDC, so that if there is a hamburger problem and the case is in Colorado and there is a case in New Hampshire, we have the fingerprints collected centrally and can immediately say that shouldn't happen, there must be a point source outbreak going on here.

With respect to the likelihood of bioterror versus mother terror—mother nature as a terrorist—I think the fact is we have to prepare for both. And one of the things I have the most confidence in right now is, from a CDC perspective, the investments that we are making in terrorism preparedness are serving us very well across the State and local health system for ordinary threats.

This past year I visited Orange County Health Department. They described to me in very explicit terms how helpful the smallpox preparedness planning process was in dealing with the flu vaccine shortage this year. In Pennsylvania, we heard stories about how preparedness efforts have led to a much more rapid immunization program when there was a food-borne hepatitis A outbreak detected in a community. And on and on again, the public health benefits from these investments are paying off every day for people from ordinary health problems, but each one of those is also an exercise, and every time we use these capacities to deal with a health threat, we have the opportunity to improve. And that is part of, I think, the answer to your last question, which is that preparedness isn't all or none, it is a process. Just when we achieve milestones, we have the responsibility to imagine the next challenge and to continue to move in that direction.

So our Biosense program, the real-time surveillance capacity is doing just that this year, creating the linkages to the health system so that we are not talking about a daily or weekly, or worse, handwritten reports of events, we are getting them as they occur and as people seek medical attention or through the BioWatch system, before human exposure occurs and we are still dealing with it at the environmental or the prehealth threat stage.

A lot of work, these investments have made a big difference, but they require sustainability, and we have a lot more work to do. So we are making progress, but there is more on our plate.

Dr. FAUCI. Just very briefly, with regard to the food supply, many of the food-borne pathogens are part of the category B and

category C of the CDC agents. So on our research agenda, we do address those with countermeasures.

If you would note on my last slide, the map I show is global examples of emerging and reemerging diseases. I agree completely with Dr. Gerberding, we don't consider separately deliberately emerging and naturally occurring. And in our infrastructure, our intellectual capital and the research we do, our regional centers of excellence are called Regional Centers of Excellence For BioDefense and Emerging Infectious Diseases. So we think it just makes total sense to consider them as a group. We worry about both of them and we address them in very similar manners.

Mr. JINDAL. My time is expired, but I just want to thank the witnesses for your service, and thank you for appearing here today.

Mr. LINDER. The gentlelady from California is recognized for 5 minutes.

Ms. HARMAN. Thank you, Mr. Chairman.

This is a very capable panel. It gives me great comfort—and I worry a lot about potential attacks on our country, it gives me great comfort to hear them and to know the progress that they are making, individually and collectively.

You and I and several others went to Atlanta about a month after 9/11 to a dilapidated old place called the Centers For Disease Control. What a dump, it reminded me of my public high school in Los Angeles, World War II bungalows, wiring on the outside, police tape across rooms where the ceiling had caved in, refrigerators in the hallways, I mean, just a mess. And I am thrilled to see the reinvention of CDC, which is clearly, to me, the tip of the spear in the effort to fight and get a handle on bioterror. If the CDC doesn't work, we are never going to make all this work.

But I want to congratulate Dr. Gerberding and also thank her for making a visit very early in her tenure to Harbor-UCLA in California, a public health service hospital, which is one of the premiere trauma centers in Los Angeles County, but also one of the premiere teaching hospitals in the country, and I really appreciated that.

I want to continue where Dr. Christensen left off. She was asking about the public health network. And it seems to me, as good as you all are and as much as you can find out, if we don't have treatment centers and research centers and centers that can identify diseases when they walk in the door or arise nearby, we still don't have the capability we need. So my question is about our public health network and how good is it, what other help does it need, what should we be doing, and how does it mesh with the cutting edge research that all of you do.

Dr. GERBERDING. Thank you. I think it is important to emphasize that our network is only as strong as its weakest link. And we started in the hole. It wasn't just the CDC that was dilapidated, we are dealing with a public health system that, for many decades, had been woefully neglected, and it is going to take a long and sustained effort to bring it up to contemporary 2001 standards. Global connectivity and speed are the requirements of our thinking these days.

I will, however, say that the progress has been incredible. I think we have health departments that have been revitalized. We are

learning a lot from success stories. I visited the State of Nebraska, they have an exemplary preparedness program there which deals both with the rural as well as the urban issues.

One of the things we learned there was that leadership from the top in the State is essential to success. If the governor is engaged and you have competent people at the various positions that our agencies all represent, you have a much greater chance of having a good network in that community. So our job is to try to identify what is the performance. And with our new grant that we are just starting this year, we will have, for the first time ever, a performance-based approach to measuring what is working, what is not working, not to blame or name or shame, but for us to say there is a problem here, this place is not able to perform this level of preparedness, it is CDC's job to go in and diagnose the problem and offer treatment and assistance and technical support.

So I can't show you the results of the performance-based approach yet because we are just at the very beginning phases of it, but I think this is going to help you and this committee and others at the State and local level understand what is going well, what isn't going well, where should we preprioritize, but also get those lessons learned to move outside of the jurisdiction.

I think we made a mistake in some of these areas of investing in some things 50 times. There were some things that probably could have done better in a regional or centralized manner with less investment and more expeditious dissemination, and we are trying to find those things and reallocate those investments in ways that are more helpful so that the local and state governments can concentrate on the things that are uniquely problematic for them, or where unique local and state solutions are imperative.

It is a tremendous compendium of progress, but it is also a very sobering reflection of where we need to go next.

Ms. HARMAN. Any other answers? My time is just about up, but I appreciate it.

General SCHOOMAKER. I will just make one comment.

For most of what we talked about today, the Department of Defense and my command is in support of main efforts that our interagency partners obviously are leading in. But in this one regard of public health, it should be important to remind people that the Department of Defense has responsibility for 8.6 million beneficiaries of healthcare, both as Soldiers, Sailors, Airmen, Marines, and Coast Guard, but also their families and retirees. And we are making every effort that you have heard here today to do real-time surveillance to look out for the public health.

And I think in the last decade we have made tremendous inroads by substituting, just as military does, we have an expression we substitute knowledge for mass on the battlefield, and we are substituting knowledge for mass on the battlefield of public health as well through the electronic medical record, rapid information exchange, and the like.

Ms. HARMAN. Thank you. Thank you, Mr. Chairman.

Mr. LINDER. The gentlelady from the District of Columbia, you are recognized for 5 minutes.

Ms. NORTON. Thank you very much, Mr. Chairman.

Dr. Fauci, you spoke, I think appropriately, of being prepared for the obvious threats first. We know there are all kinds of next generation threats BioShield will have to deal with and the rest. I am very concerned about obvious threats. Of course, this is a city that had to deal with large numbers of people who were threatened with and died from anthrax, where this very campus was the central focus of the only large-scale attack of its kind in our country.

I draw some comfort from knowing—I learned even at another hearing—of the work being done on anthrax. My concern, very frankly, is whether we are really—are we getting ahead of ourselves? We, in another committee, for example, had to deal with—Dr. Gerberding knows about this, the shortage of flu vaccine. This is a matter we have lived with for decades. You talk about being unprepared, the notion of being unprepared for something as obvious as what to do if something goes down, that happened to us in the flu vaccine. It did not inspire my confidence, as I sat in yet another committee and thought, really not about the flu, but thought about BioShield, about anthrax, about smallpox.

I want to ask two questions, one goes to anthrax. You mentioned, Dr. Fauci, obvious threats, and the other goes to smallpox. I want to know whether or not, with the drugs you have now, given the fact that we have already had an anthrax attack, whether you believe we would be prepared to disseminate drugs and deal with an anthrax attack. Particularly, I am interested in closed areas, such as the Metro.

Then I want to ask about smallpox. Who can forget the brouhaha with which the administration announced that, beginning with health care workers, we are going to make sure that people were vaccined against smallpox, it was a very real danger, big announcement. I never saw anything stop in its tracks more quickly than that, I can't find traces of what is happening. I need to know about that because in your testimony, Dr. Fauci, you talk about increases in the usable smallpox vaccines since 2001, aggressive acquisition program, more than 300 million doses.

Now we have got all these doses, there was this huge announcement by the administration of a program, what is the use of getting doses, announcing a program, and at least I can't find the link between what you say now exists and the program that was announced a couple of years ago. So I would like to ask about those two obvious threats, and how close we are to being able to do something about them in an event of an attack—not a futuristic attack, not a next generation attack, but perhaps the most obvious threat that we face today.

Dr. FAUCI. Thank you, Ms. Norton, and I will try to address that, and I think it is important to distinguish between smallpox vaccine that is available in anticipation of an event in which you try to get a certain relative proportion of individuals who might be first responders vaccined.

You recall correctly that what the Department had originally put out was a goal that we did not reach, but a degree—

Ms. NORTON. We never got past the first responders, in fact, we never got through the first responders.

Dr. FAUCI. Right. And Dr. Gerberding will answer that aspect of it. But before I hand it over to her, I just want to mention that

when you think in terms of having doses available, were there a disseminated smallpox attack, you would likely have not seen any reluctance of people getting vaccined, which gets to the research point of the modified vaccinia Ankara. The next-generation smallpox vaccine , which thus far was considerably experienced in safety, has very few, if any, adverse events associated with that.

So what we are doing, as I mentioned in my statement, we are moving to get stores of that, as the next generation, at the same time having enough smallpox vaccine in the strategic national stockpile, were there an event to be able to vaccinate everybody.

The response of preparedness I will hand over to Dr. Gerberding.

Dr. GERBERDING. Thank you. I will try to be quick on this.

If you remember the smallpox preparedness program, it wasn't just about vaccinating people, it was about getting laboratories able to diagnose, it was about educating several million clinicians on how to detect a case, and several other elements of preparedness that were quite successfully achieved. One of the lessons that we learned from that is that when you are dealing with something that is at low but not zero risk, but really high consequence, you have to help people understand more effectively what is the rationale for it. Why would we invest—and particularly in this case, when our very careful monitoring determined some risks from this vaccine that had never been picked up before, despite all the decades that we used it to protect our kids in the past.

So when you are engaging in the Pre-event Immunization Program that has hazards, the balance has to be very carefully articulated, and I think we could have improved our ability of engaging clinicians in the public in this process before we went forward.

We immunized almost 50,000 people. Since that time, we have invested about $37 million in key cities, including the District, to try to make sure if we had a smallpox attack, we have a system that can get that vaccine that is in your stockpile to the arms of the people within 48 hours, and that is what we are working on right now. D.C. is not there yet, I can tell you right now, but we are working very hard with these investments. CDC just assigned a senior manager to the health department in Washington, D.C. to help improve our ability to handle our—

Ms. NORTON. When do you envision you will start again to try to enlist first responders, nurses, doctors and the like?

Dr. GERBERDING. Each community, including the District, makes its own decisions about what is the plan for administering vaccines, how many people need to be vaccinated, who should they be, and it is really their decision based on their distribution plan in the community, how many pre-event, how many during event and how many post event.

The Secretary and all of us in the Department right now are working on plans to augment our ability to do that so that the Federal Government can help and not expect each community to carry the full burden.

Ms. NORTON. I thank you, Mr. Chairman.

I just want to say that if you think that local jurisdictions on their own are going to proceed, even given the educational effort, without considerable prodding from the Federal Government to go ahead, if you think they should be ready now, I am here to tell you

that I think without some reassurance from you at CDC that now is the time to go ahead, this program is not going to start—

Dr. GERBERDING. No, I agree with you. That is part of the investment and the reason we are putting the money there because we think that sends a message which is important. That is why we have performance measures so that we can verify whether performance has improved. And it is why, in the case of the D.C. area, we are specifically assigning one of our best managers to come in locally and really help get this on the road because we recognize this is a high threat community.

But I agree with you completely. We can't sit in Atlanta and Washington and make pronouncements, we have to get out there—

Ms. NORTON. Nor can you say that each local jurisdiction go ahead when you want to; you have to push it.

Mr. LINDER. The time of the gentlelady is expired.

Mr. Markey is recognized for 5 minutes.

Mr. MARKEY. Thank you, Mr. Chairman. Welcome.

In April of 2005, I wrote to both CDC and the Department of Homeland Security about the accidental shipment of the H2N2 flu virus to thousands of laboratories and health care facilities. The H2N2 virus was the flu virus that caused the worldwide flu epidemic, pandemic that killed 1 million to 4 million people between 1957 and 1958.

While all the samples have reportedly been accounted for, the responses provided by CDC and DHS raised some serious questions regarding both policy and the degree to which CDC and DHS are coordinating their efforts.

When I asked the Department of Homeland Security whether the H2N2 flu samples could be used as a biological weapon, the Department of Homeland Security stated that "if these materials fell into the hands of terrorists, they could be used as a biological weapon." When I asked the Department of Homeland Security whether they had evaluated their laboratories and screened the individuals that have access to this virus, DHS stated that this job belonged to the CDC select agent program, the program for Ebola, the program for the most serious virus.

But CDC's response to my question stated that CDC decided not to include the H2N2 flu strain on the select agent list in the first place.

My first question, Dr. Gerberding, do you agree with the Department of Homeland Security's conclusion that H2N2 could be used as a biological weapon?

Dr. GERBERDING. Our opinion is that virtually any infectious disease could be used as a biological weapon. Influenza was not on the select agent list, that was a decision made by a group of experts who were looking at not just can something cause disease, but can it be weaponized and does it meet the other criteria—

Mr. MARKEY. What was your conclusion?

Dr. GERBERDING. The conclusion at that time was not. One of the things that is not commonly recognized about H2N2 is that the H2 is new, but the N2 is something that we have been experiencing for the last several years. So, in fact, the true threat associated with that particular experience was probably not nearly as great as we had been describing in our anticipation of making sure that we

absolutely had recovered it because we have population immunity to the N2 component.

Mr. MARKEY. When the CDC is evaluating whether to include something on the select agent list, is potential use as a biological weapon considered?

Dr. GERBERDING. CDC does not make the decision about what is on the select agent list, that is a decision that is made by an interagency working group of the Federal Government, which includes the U.S. Department of Agriculture and NIH and the CDC—

Mr. MARKEY. When the CDC is making its recommendation, does it include as part of its recommendation whether or not it can be used as a biological weapon?

Dr. GERBERDING. That is the criteria for a select agent.

Mr. MARKEY. So is there a disagreement between the Department of Homeland Security and CDC on its inclusion?

Dr. GERBERDING. I would defer to Dr. Vitko, because I don't know what the Homeland Security position was on that committee.

Mr. VITKO. I wasn't around for the committee. The point is, we believe that—I don't have the detailed response that you have in your hand—but I believe there is another paragraph on there that also states that it is a question of quantity and the way it is released, so yes.

Mr. MARKEY. Well, in the Department of Homeland Security response to my letter on the H2N2 virus, the Department of Homeland Security repeatedly stated that the CDC Select Agent Office was responsible for monitoring those who have access to the virus and other matters. Did you know that H2N2 wasn't even on the select agent list in the first place? And if so, why did your agency continually refer me to the office in charge of regulating the select agents back at CDC?

Mr. VITKO. It must have been an error.

Mr. MARKEY. Well, it appears that there is a regulatory black hole that sits right in the middle of these agencies on this issue, that is, that on something that is so contemporary, this flu virus, and so potentially dangerous if it could be used, that there should be, at this point, given the fact that it is now 4 months since I wrote the letter, that some kind of a resolution of the issue was reached, and some kind of coordination that was established between Homeland Security and CDC over a subject where there appears to be a difference of opinion in terms of how this agent could be used on bioterrorist organization.

Dr. GERBERDING. I can't speak for what was in the Homeland Security letter, but the process that Congress has defined for us in making these decisions is to, first of all, make a determination that a pathogen belongs to a select agent list using a set of criteria. Once an agent is on the list, it is CDC's job to do the appropriate steps to assure that people who are using that agent have security clearance and are using the appropriate containment procedures in their laboratory. So had this virus been on that list, CDC would have been responsible for the laboratories that were used it as a—

Mr. MARKEY. I understand that, but getting it on the list now is obviously something that is difficult to comprehend because of this regulatory black hole that exists. For example, the Bird Flu Virus,

or SARS, or any other highly infectious virus, have they been added to the being select agent list?

Dr. GERBERDING. Highly pathogenic avian influenza viruses are on the select agent list as defined by the USDA list of select agents.

Mr. MARKEY. They are on the select agents.

Dr. GERBERDING. The viruses that are capable of causing pandemics and fall into the avian group are on the list.

Mr. MARKEY. Have you solicited the Department of Homeland Security's views on whether these viruses—

Dr. GERBERDING. The Department of Homeland Security is represented on an expert committee that makes the determination, as are the other Federal agencies that have a stake on this.

Mr. MARKEY Thank you.

Mr. LINDER. We would like to get a few more questions, if the panel can stay around for a few more questions. I think we will vote in about 15 minutes. I just have a couple of questions.

Going back to the labs, how many level 4 labs are there in the country?

Mr. VITKO. Level 4 labs in the country? I actually don't have that answer. I will defer to Dr. Fauci on that. We did a survey on 3 and 4, we issued a biocontainment report in which there are several hundred at the 3 or 4 level, but only a dozen or so at the level 4 level. Not even that, less than that.

Mr. LINDER. Are we building more?

Dr. FAUCI. Currently there is the CDC, there is the BSL4 at USAMRIID. There is a BSL4 in Galveston. So those are three. There is one that is being constructed at Rocky Mountain Labs in Hamilton, Montana. There is one that is being constructed at Fort Detrick at the NIH in conjunction with the United States Army. And then there are planned BSL4s, one in Galveston and one in Boston, and they have not begun yet. The one in Galveston just broke ground in May of 2005, the one in Boston is scheduled to break ground in December of 2005.

Mr. LINDER. But at what point do we build enough labs that they start to cannibalize the other labs they have because of limited scientific knowledge we have in this country.

Dr. FAUCI. I am sorry?

Mr. LINDER. At what point do we begin to cannibalize the other labs that currently exist because of the limited number of scientists at this level in the country?

Dr. FAUCI. You say the other laboratories—

Mr. LINDER. New labs will wind up taking scientists from the old labs.

Dr. FAUCI. Yes, okay. I understand. I didn't quite get it the first time, I apologize.

The question is a reasonable question. If you have scientists that are involved in biodefense, are you drawing them out from other areas of research that are important to the Nation? And the answer is, whenever you are gearing up in a new area that requires scientific expertise, certainly there is a draw off to some extent. But in other experiences we have had, such as with HIV/AIDS in which we had to draw from the microbiological and infectious diseases community, it really turns out that it normalizes reasonably

quickly, where you get more people involved in a field, and although initially there may be some drawing off of people who would otherwise have been working on something else and now working on biodefense, at the end of the day it tends to equalize itself because you get quantitatively more people in the field as opposed to just diverting from one to the other.

So there is the initial component of what you are talking about, but what we hope to do is enhance the amount of intellectual capital involved in all emerging and reemerging infectious diseases with the ability to go back and forth between deliberately emerged or bioterror agents or agents that we absolutely still need more people for where they are naturally occurring.

General SCHOOMAKER. It might also be worth just clarifying that a BSL4 lab is not necessarily a BSL4 lab, there are distinctions within the community of BSL4s that have expertise and capacities. For example, aerosolized testing evaluation, that is a subset of BSL4. So it sounds highly redundant, or maybe competing with one another, but there are specialties and specialization within the BSL4.

Mr. LINDER. Dr. Gerberding, in a private conversation you and I had we talked about sources of intelligence around the world, and you mentioned the use of some of these international corporations. I would like you to expand on that for the record and for this committee.

Dr. GERBERDING. I think that what we are talking about is making use of any available information, particularly in the areas that don't have robust public health systems or don't have data systems that allow health information or event information to come in through traditional means. The United States Government has a large stake in the health status of these areas because we have workers and citizens and businesses that are operational there. People on the business sector have a stake in the health of their workers and in the health of the communities in which they are working.

So it is very possible that there are health events that could unfold in an area where the business community may be the first to recognize that there is a problem, and might be in a position to give us a heads-up or to give the local minister of health a heads-up that there is something amiss in the community.

We have no proof that this is a successful strategy, but we have strong interests on the parts of several corporations to think about, is there a way that this kind of shared interest in health status, not just terrorism, but any kind of health event could benefit the community, could help be an element of protection for the business and could serve as another input or a resource for information here. It is a little bit like the open source method of mining things that appear on the Internet or reading local reports in newspapers and the local press about things unfolding at the community level.

Again, I have no proof that this is going to be successful, but it is something that we want to explore carefully because we certainly don't want to compromise the business interest or send a message to their customers in that region of the world that they are there for anything other than business purposes. But we live in a global

community, and there are potential situations where this could be a win-win for all parties concerned.

Mr. LINDER. Mr. Langevin.

Mr. LANGEVIN. Thank you, Mr. Chairman.

If I could, I know Dr. Christensen touched on this, but so I have a more clear understanding, Dr. Fauci, the work that you do at NIH and the work that is done at CDC, who does what? Is there a duplication of effort between NIH and CDC in this respect?

Dr. FAUCI. No, there is not, Mr. Langevin. There is a certain degree of complementarity, but there certainly is not a duplication of efforts at all. In fact, we very closely coordinate what we do on a real-time basis almost constantly, so I really cannot think of any examples at all where there is duplication without a purpose of complementary nature to it.

Dr. GERBERDING. I couldn't agree more. I feel that we have a collaborative relationship. Dr. Fauci and I are often at the witness table together for that very reason. But one very specific example is that some joint research proposals that CDC had a small amount of extra research money that Dr. Fauci's institute embedded in their larger research portfolio, so when the investigator applied for bioterrorism infectious resources, it was an NIH grant, but the CDC got some of its priority work done through their mechanism. So we think that is a good model for demonstrating that we are collaborating and not redundant, and at the same time the investigators who cue up to apply for these resources have the imprimatur of an NIH grant. So it is a win-win.

Mr. LANGEVIN. That is good to hear.

Now, one of the stated goals of HSPD–10 is decontamination recovery from a chemical or biological attack. Who is the lead agency on this, and how is it done? And what types of attacks do you feel that we can successfully decontaminate right now?

And related to this is the issue of quarantining, and what authority do we have to quarantine and who has the ultimate authority on that kind of activity?

Mr. VITKO. The HSPD–10 in the section on response and recovery gives EPA the overall lead for determining the decontamination technology standard and systems approaches to the cleanup.

In the section on prevention and protection in the critical infrastructures, it lists DHS as the lead for decontamination methodologies for critical infrastructures. So those are the two agencies, with the EPA having an overall responsibility.

Mr. LANGEVIN. And another question. Last winter we experienced a great shortage of flu vaccine which clearly demonstrated a weakness in our public health practices, namely that we rely too heavily on one flu vaccine maker. Do you have sufficient flu vaccine to inoculate the public this coming winter? And on a related point, are there lessons learned from this that you will find useful in procurement of other vaccines?

Dr. GERBERDING. Let me first say many lessons were learned, I think, by FDA, CDC and NIH and the rest of the stakeholders in last year's flu vaccine shortage. We will not know how many doses of flu vaccine we have until the season is completed because the manufacturing process starts imminently and the vaccine rolls off the assembly line throughout the season. If everything goes well,

we will have the expected supply from Sanofi Pasteur. We are hoping Chiron will be able to resume their production, although, again, until they actually start producing vaccine, we are not counting on it.

Dr. GERBERDING. And we are still working on the international sources. We expect a third manufacturer to be newly licensed this year for sales in the United States in time for flu season.

But the lesson we learned, I think the biggest lesson overall is, don't count your chickens until they are hatched. And so we are not planning to blast out at the beginning of the season with optimism that all of these sources will come through as we are expecting. We are going to emphasize immunization of the high-risk groups first so that we are sure the people who need the protection the most don't have to stand in line to receive it.

Mr. LANGEVIN. I see my time has about expired, so I yield back.

Mr. LINDER. Mr. Shays.

Mr. SHAYS. Thank you, Mr. Chairman. And thank you all for staying for additional time. Mr. Chairman, if this had been my committee, they would have been here at 10:00, still here, so don't spoil them, because we are learning so much.

You are an awesome panel. You are very articulate and you are very helpful. And I agree with my colleague Ms. Jane Harman that it gives me some comfort to know you are doing what you are doing.

I had asked the question about what is in the refrigerators in the Soviet Union, the stuff that they are working on. I have seen it. They have strings with wax attached, very poor security, and so on.

But forget them for a second. I would like you to comment—and since I would like to ask a few questions, if you all agree, then we will just go to the next question. But the question I have is, should we be concerned about some of the viruses, pathogens, whatever that may be in research labs, locked up, not properly identified in colleges and so on?

Dr. GERBERDING. I am concerned. I think that the academic culture traditionally has been very open, very collegial, and very focused on research. And we are asking for somewhat of a culture change. We are asking our academic partners to be mindful of the fact that some of the agents that they are working with are potentially threat agents or, in the wrong hands, could be used or developed as a threat agent, as part of the importance of the select agent process, so that people who are working with the select agents are registered, inspected, and their security background is checked.

It is not a fail-safe system. And, you know, the trust that has been built up over many, many years of successful engagement in these infectious disease research activities—and I should say, probably also applies to chem and biothreats in a different realm—is one that has worked very, very well when you consider the possibilities. But we need to have a stronger network now. And it is not 100 percent known what is in the freezer.

Mr. SHAYS. Does anyone disagree with the answer there?

Dr. FAUCI. Agree, and that the National Science Advisory Board for BioDefense is trying to create just what Dr. Gerberding said,

that culture of responsibility among the people who might have these agents.

Mr. SHAYS. The culture is important, but do we have laws that back it up? Can people be sent to jail if they don't properly label and secure these vaccines?

Dr. GERBERDING. Absolutely. That is the purpose of the select agent process. There is the law enforcement component to that through the Department of Justice.

Mr. SHAYS. Just as briefly as you can, give me some comfort, in addition to what you said so far, that we are utilizing the resources that are already available at every hospital that takes in patients. How good is the network, not of new—you know, just within the existing facilities? Does every hospital in every State have to file information every day to a centralized location in the State? And then do you have access every day on, you know, a "now" basis to get that information?

Dr. GERBERDING. No. The only information we currently get from the health care delivery system every day is what we get from the Department of Defense and the VA. But we will, through the Secretary's health information technology initiative, which is a major, major, major priority of our administration. As electronic medical records become available we are creating opportunities to have the de-identified information of public health interest automatically forwarded to CDC through our biosense mechanisms so that we have that real-time, everywhere, everybody, everyday kind of access to health events in our communities.

Mr. SHAYS. General, you want to answer, but let me make sure that you incorporate some kind of answer as to whether there are deadlines.

General.

General SCHOOMAKER. Sir, I just want to add to that I think we are in our relative infancy in this, the connectivity of the different elements of the health care delivery system. The Department of Defense has shared its expertise and its technology with the CDC and continues to do that. We use a program based on syndromic events, that is, the recognition of syndromes that are associated with known agents that are infectious illnesses, but that I think we would all agree right now is still again in its infancy. It is wired in with Johns Hopkins University in a program called essence. There are improvements coming, and are forthcoming right now.

Mr. SHAYS. When do you think we are going to see a system that just, we have instant data from almost every hospital, health care center? When we will have such a system?

Dr. GERBERDING. For the most useful information, I would say we are in a 5-year horizon for being able to do that ubiquitously. By the end of this year, we will have that information from critical hospitals in most of our major cities; and by the end of next year, we will have it from all of the hospitals in those major cities.

Mr. SHAYS. Fairly instant data? I am sorry.

Dr. GERBERDING. Real-time data. As the transaction occurs in the ER, it will be appearing in our system.

Mr. SHAYS. Thank you.

Mr. LINDER. Dr. Christensen.

Mrs. CHRISTENSEN. Thank you. I think I am going to try to follow my colleague Mr. Jindal's lead. I am going to try to get a couple questions in.

One, where does the new chief medical officer of the Department of Homeland Security fit into all of this?

Two, I am glad to hear about some of the research, Dr. Fauci, on the agents with broad application. But we had a hearing where we heard of some others that seemed to be very promising and would be worthwhile considering, such as those that treat radiation sickness or stop bleeding. And I wanted to know maybe from Dr. Vitko, how do you get them entered into consideration and maybe into the stockpile?

And Dr. Gerberding, just the cuts in your budget, I am still concerned that we are going to find that some of the core functions, the infrastructure that has to be there every day, is going to suffer while we have the demands on CDC to deal with bioterrorism.

Mr. VITKO. Okay. I will begin with answering the question on the chief medical officer.

As you heard from me, the portion that I represent in S&T is the bioportfolio that basically does the research and development aspects, but we have very little operational responsibility. The chief medical officer will come in and have overall responsibility for being the medical interface with the other agencies, with HHS, USDA. DHS does have some operational assets in that sense in the National Disaster Medical System and in the medical—Metropolitan Medical Response System and in coordinating those kinds of activities. So the chief medical officer will be the overall interface for the agencies.

Dr. FAUCI. Countermeasures such as those for radiation sickness. We just completed our strategic plan and research agenda for radiation, for the money that is coming from the Department in 2005, $47 million. A very high priority is how one treats radiation exposure, and in fact, we have been in communication with the company that I believe you are referring to.

Mr. VITKO. And we have done the material threat assessments on both the radiological devices and a special study on nuclear weapons, fissile weapons, used in that kind of context, and provided that to the WMD medical countermeasures committee, and they are using that in their requirements process.

Dr. GERBERDING. And with respect to the proposed 2006 budget for CDC, our overall preparedness budget has actually increased in the proposed budget. What has been cut from our budget are some very specific programs. The House mark and the Senate mark, of course, are not resolved yet, so we are not really clear where that budget will ultimately reside.

While I think every agency head at this table and any other table would always think of good ways to use budget increases, we also can do a lot with the budget that we have, and we have got to make every one of these preparedness dollars go as far as we can. That is why we are putting emphasis on the performance-based investments this year, so we know what we are getting and where we need to either invest more or do more to get that network seamless.

Mr. LINDER. Mr. Simmons.

Mr. SIMMONS. Thank you, Mr. Chairman.

And, again, thanks to the panel. A quick question focusing on Dr. Vitko's testimony.

Pages 7 and 8, he refers to the Plum Island Animal Disease Center. The Plum Island Animal Disease Center is located in New York on Plum Island in Long Island Sound, but most of its professional personnel actually reside in Connecticut and go out to the facility on a daily basis by ferry boat—well, all working days of the year and all working weeks—under all sorts of interesting and challenging conditions.

I understand from your testimony that there is a recapitalization program under way for a next-generation facility, the National Bio and Agro Defense Facility. It doesn't indicate in your testimony whether this facility is planned as an upgrade to Plum Island or for some other location. And ever since Plum Island left USDA and went into Homeland Security, there were rumors that it might close and those activities might be moved elsewhere.

The facility is not a new facility from the standpoint of its installation; it has been around, I think, for 50 or 60 years. But, in fact, investments have been made; I have been out to the island several times, and it is relatively modern in many of its aspects.

My question is, in the planning for the upgrades, is that for Plum Island or is that for some other location?

Mr. VITKO. And the answer is, the siting decisions haven't been made on it yet. We are first formulating the programmatic requirements of what we want to accomplish, see whether it can be accomplished within the existing footprint and traded off, and look at other options.

Mr. SIMMONS. And when might we be brought up to date on some of those activities?

Mr. VITKO. The conceptual design studies that are formulating those program requirements are just now being initiated, and somewhere in mid-2006 we should have the programmatic requirements and the pros and cons of different siting strategies available at that time.

Mr. SIMMONS. Okay. I thank you for that. I mean, I will simply say that the people that I have met that work out there are highly qualified, very capable, an extraordinary asset and that, of course, relocating creates losses. And I hope the people doing the planning are aware of that.

Mr. VITKO. We echo the fact that the Plum Island Animal Disease Center is making major contributions, has and continues to make major contributions; the personnel are excellent. And we are making progress; right now, even within the existing footprint, we are constrained with the space that we have there about how much progress we can make on foreign animal diseases just because of the facilities. It is possible that it could be expanded there; it is possible that we will need to look elsewhere. Those are the options that are on the table.

Mr. SIMMONS. I thank the panel. And I thank the chairman for going for the second round.

Mr. LINDER. We have a 15-minute vote starting. Ms. Norton, we still have time for your questions.

Ms. NORTON. Thank you very much, Mr. Chairman. I just have one question. This is a question for Dr. Gerberding. Again, it is anthrax, an obvious threat.

I wrote you a letter in—several months ago after a false alarm here involving what you may remember to be postal facilities in Virginia where they thought there was an anthrax attack. I learned for the first time that my own first responders and first responders throughout this region are using biological field detection nonlaboratory equipment.

I have not received a response to this letter. If I could just say to all you, when a Member of Congress writes, you just well answer, because any good member will cite this to you as part of her questions. And it is not a very good thing not to answer when some—if you don't know the answer, tell them.

I was really concerned because I found these things being used all around. And I said, Well, you get this thing. Who regulates these things? Which ones are good? Which ones are bad? And I learned after making some inquiries that nobody does anything, they just go out and get them if you don't—people don't do what they have to do if the government doesn't give them any guidance.

Now, I learned, however, that you had—you, CDC, had given some recommendations to the U.S. Postal Service—of course, perhaps, in light of the fact that they had suffered an attack once—on the use of these autonomous handheld devices. I don't know that the devices were good or bad during this or had anything to do, frankly, with this false alarm. What I do know, or have learned since, is that they are being used throughout the country.

We know that, of course, your certified laboratory response network is the only way to know if there has been an anthrax attack. But so do these people know that; and they said to me, Well, in coordination with them—and we will always send it to them anyway—we are going to use these things.

Disturbingly, Dr. Kati Kelley, who is now the President of the Association of Public Health Laboratories, testified before the Government Reform Committee—and I am quoting here, and I did in my letter—"CDC's minimal supply of materials to allow testing"—she talked about her concerns about CDC's minimal supply of materials to allow testing for biological terrorism substances. She said that you simply didn't have the—there was a shortage of the critical testing kits at CDC.

I asked about that, and I asked whether you could do something about the proliferation of these handheld devices. I am not suggesting that they are good or bad. I am suggesting that if the government sits back and says—and here, in this case, you actually recommended against the use of these biological field detection autonomous nonlaboratory equipment; if you are going to recommend against it and if you were not a regulatory agency that is going to offer no guidance and they are going to proliferate, leaving it to the wonderful free market sector, when they don't hear you saying anything, they just all produce whatever ones they want to and they market to our first responders, then I am left to ask, Well, who in the world will—and help us out here.

If it wasn't for you to do, particularly after I wrote directly to you April 29, I don't know why—perhaps it was Mr. Vitko—this stands

unanswered. And more seriously unanswered is the opinion or the view expressed to the Government Reform Committee in April that you, yourself, are very short of critical testing kits, which leaves me wondering what would happen here if we had another attack and all we had were these hand-held devices which nobody has tested or given any guidance or any recommendations concerning.

So I would like to know those two things: Whether you yourself could handle someone sending to you directly from, let us say, various parts of the country, particularly in the event of a simultaneous attack. And why you haven't given some guidance yourself or gone to whoever you think is appropriate to offer guidance.

And, finally, why didn't you answer my letter?

Dr. GERBERDING. Ms. Norton, I can see that people are getting ready to vote, so let me try to get the most important.

Ms. NORTON. I don't have to vote.

Dr. GERBERDING. I am trying to answer what I think is your most important question. I apologize for being nonresponsive to your letter; I will look into why that happened. We generally have a good track record of response, as we take congressional letters very seriously; and I am personally very sorry that you didn't get good customer service from CDC on this issue.

With respect to the shortage of reagents for the last—I can assure you that, first of all, that played absolutely no role in the situation in the postal facilities here. We do not have a current shortage, but we are worried that we are able to keep up the supply as reagents expire over time. So the planned request in our 2006 budget appropriation is to correct that. And assuming that our budget is, as we anticipate from the current marks in the House and the Senate, we will have the resources we need to deal with the reagent issues in the future at CDC.

So that is not a current issue across the United States; it is a predicted issue if we didn't take steps to fix it in the future.

With respect to what the Postal Service is doing to monitor the quality of the air in the postal facilities, I can assure you that the USPS has used an extremely thoughtful process. They have evaluated these systems very carefully. And I believe it is the Department of Homeland Security that they are working with.

There are three sets of these systems in major play that we can talk about comfortably in public. There are some other applications that would best be discussed out of the public record. One is the BioWatch system that you have heard about in our cities; one is the system in play in our postal facilities, at the decision of the U.S. Postal Service with consultation from DHS and CDC; and a third is the system that I believe the military is using in certain applications that I again don't want to—

Ms. NORTON. I am talking about handheld devices. Are you talking about?

Dr. GERBERDING. I am talking about the circumstances of the scenario that you are describing these past several months. With respect to handheld or so-called "smart ticket" types of devices, that is an area where CDC explicitly has recommended against their use, other than for ruling out a true positive, because they are not specific. They are very often misused; we have had numerous false positives with them.

Ms. NORTON. They say it is an extra layer and they are going to send it to you anyway. And they want to use them.

You may be right. What bothers me is, nobody tells—they are buying them because you don't give them any guidance one way or the other.

Dr. GERBERDING. I would disagree. We do provide guidance to the Postal Service.

Mr. LINDER. The time of the gentlelady has expired.

Mr. VITKO. Let me also join the answer, if I may.

First of all, CDC has provided that guidance advising against them. Second of all, DHS sponsored jointly with NIST a test of handheld devices, specifically around anthrax testing the "smart tickets," in which five companies participated, independently run by the American Association of Analytical Chemists, that were done explicitly for this purpose, to provide an independent evaluation of the product to see whether it could perform—and these handheld detectors might be useful against powders, not against testing surface contamination or hemispheric contamination, but against powders—and to test their validity.

And the test results of that are available. And so a process has been set up with an independent third-party agency, this respected testing agency to do that.

Third is, I mentioned to you that these joint five agencies have joined on this coordinated biomonitoring memorandum of understanding, and part of that, they are establishing equivalency processes. And we have also begun a discussion with industry for an approach to make available for them the high accuracy—more importantly, high specificity—assays.

The real issue with the handheld assays or with anything that you use in a commercial device is, does it have the specificity to say that this is a threat and not light up on everything else and start the whole system ringing? And we are in the process of working that with the—there is an industry consortium called the—

Mr. LINDER. Dr. Vitko, I actually do have to vote. And if you have more to say to her, you can send her a letter. I want to thank our witnesses for their expert testimony. It has been very, very helpful. This is new ground for us, and we are grateful.

And, without objection, the hearing is adjourned.

[Whereupon, at 4:18 p.m., the subcommittee was adjourned.]

FOR THE RECORD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

AUG 9 2005

The Honorable John Linder
Chairman, House Committee on Homeland Security
Subcommittee on Prevention of Nuclear
and Biological Attack
U.S. House of Representatives
202 Adams Building
Washington, D.C. 20515

Dear Chairman Linder:

Thank you for giving me the opportunity to correct the record of the hearing you held on Thursday, July 28, 2005, on biodefense.

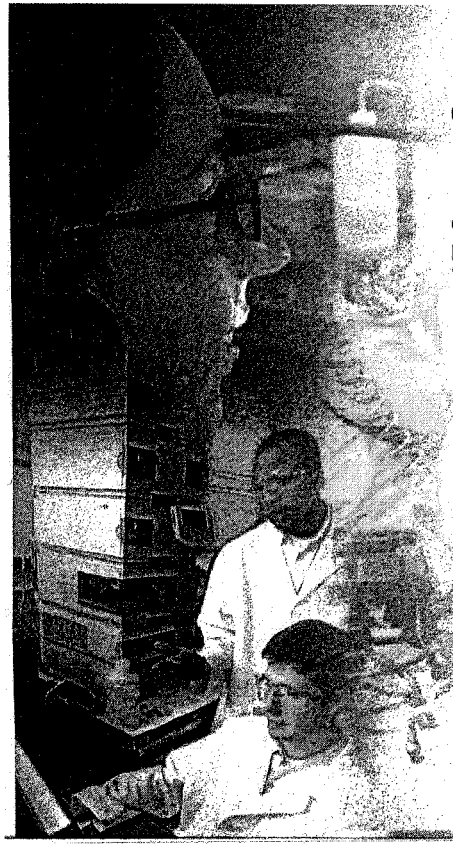
I would like the following additional information added to clarify a question Delegate Eleanor Holmes Norton asked during the hearing regarding a letter to which she had not received a response from the Centers for Disease Control and Prevention (CDC).

Dr. Julie Gerberding:
To further clarify a question asked by Delegate Norton regarding the CDC Guidance on handheld anthrax detection devices, we now understand that there was a miscommunication regarding this letter. CDC did not receive the letter Delegate Norton referenced, and we now understand that the letter was intended for the Department of Homeland Security (DHS), not CDC. Finally, Delegate Norton's office said that the responses of CDC and DHS at the hearing addressed her concerns.

Thank you again for this opportunity to clarify this miscommunication for the official record of the hearing.

Sincerely,

Julie Louise Gerberding, M.D., M.P.H.
Director



CDC Mission: To promote health and quality of life by preventing and controlling disease, injury, and disability.

CDC's daily work is essential to the health of America, and the world. Because of CDC, people are healthier...safer...more productive,..and happier. Six strategic imperatives are the foundation of all our efforts.

1. **Health Impact Focus:** Align CDC's strategies, goals, and performance to have the maximum impact on people's health and safety.
2. **Customer-centricity:** Market what people want and need to choose health.
3. **Public Health Research:** Create and disseminate the knowledge and innovations that people need to protect their health now and in the future.
4. **Leadership:** Leverage our unique capabilities, partnerships, and networks to improve the health system.
5. **Global Health Impact:** Extend our knowledge and tools to promote health protection around the world.
6. **Accountability:** Sustain people's trust and confidence by making the most efficient and effective use of their investments in us.

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1-800-CDC-INFO

CDC
Environmental Health

Third National Report on Human Exposure to Environmental Chemicals

The most extensive assessment ever made of the exposure of the U.S. population to chemicals in our environment.

Better exposure information means that we can make better decisions to protect our health.

Background

The *National Report on Human Exposure to Environmental Chemicals* is a report of the ongoing assessment of the exposure of the U.S. population to environmental chemicals using biomonitoring. The *Second National Report on Human Exposure to Environmental Chemicals* (*Second Report*) was released in 2003 and presented biomonitoring exposure data for 116 environmental chemicals for the civilian, noninstitutionalized U.S. population over the 2-year period from 1999 to 2000. This *Third Report* presents similar exposure data for the U.S. population for 148 environmental chemicals over the period from 2001 to 2002. The *Third Report* also includes the data from the *Second Report*, that is, data for 1999-2000.

The Environmental Health Laboratory measured chemicals or their metabolites in blood and urine samples from a random sample of participants from the National Health and Nutrition Examination Survey (NHANES) that is conducted by CDC's National Center for Health Statistics. NHANES is a series of surveys that in 1999 began continuous operation to provide results for a survey sample of the U.S. population every 2 years.

For this *Report*, an environmental chemical means a chemical compound or chemical element present in air, water, food, soil, dust, or other environmental media (for example, consumer products). Biomonitoring may measure the chemical or its metabolite in blood or urine. A metabolite is a substance produced when body tissues chemically alter the original compound. Blood and urine levels reflect the amount of the chemical that actually gets into the body from the environment.

The chemicals covered in the *Third Report* that were not covered in previous versions of the *Report* are as follows:

- pyrethroid insecticides
- additional polycyclic aromatic hydrocarbons (including benzo-[a]-pyrene)
- aldrin, endrin, and dieldrin
- additional phthalate metabolites
- additional pesticides and herbicides
- additional dioxins, furans, and polychlorinated biphenyls (PCBs)

Public Health Uses of the *Report*

The *Report* provides unique exposure information to scientists, physicians, and health officials to help prevent disease that results from exposure to environmental chemicals. Specific public health uses of the exposure information in the *Third Report* are

- to determine which chemicals get into Americans and at what concentrations;
- for chemicals with a known toxicity level, to determine the proportion of the population with levels above those associated with adverse health effects;
- to establish reference ranges that can be used by physicians and scientists to determine whether a person or group has an unusually high exposure;
- to assess the effectiveness of public health efforts to reduce exposure of Americans to specific chemicals;
- to determine whether exposure levels are higher among minorities, children, women of childbearing age, or other vulnerable groups;
- to track, over time, trends in levels of exposure of the population; and
- to set priorities for research on human health effects of exposure.

Interpreting the Data

Just because people have an environmental chemical in their blood or urine does not mean that the chemical causes disease. The toxicity of a chemical is related to its dose or concentration in addition to a person's individual susceptibility. Small amounts may be of no health consequence, whereas larger amounts may cause adverse health effects. Research studies, separate from the *Report*, are required to determine which levels of a chemical may cause health effects and which levels are not a significant health concern. For some chemicals, such as lead, research studies provide a good understanding of health risks associated with various blood levels. For most of the environmental chemicals for which information is presented in the *Report*, more research is needed to determine whether exposure at levels reported here is a cause for health concern. CDC conducts and provides biomonitoring measurements for this type of research in collaboration with other agencies and institutions.

The *Third Report* presents data collected to provide estimates of exposure for the civilian, noninstitutionalized U.S. population. The current survey design does not permit CDC to estimate exposure on a state-by-state or city-by-city basis. For example, CDC cannot extract a subset of data and examine levels of blood lead that represent a state population.

More information available online at www.cdc.gov/exposurereport
Includes a fully indexed, searchable PDF version of the *Report*, executive summary, fact sheets, and more.

Key Highlights and Findings

First-Time Exposure Information for the U.S. Population for 38 of the 148 Chemicals Included in the *Report*
These 38 chemicals are pyrethroid insecticides; the organochlorine pesticides aldrin, endrin, and dieldrin; additional polycyclic aromatic hydrocarbons (including benzo-[a]-pyrene); additional phthalate metabolites; additional dioxins, furans, and polychlorinated biphenyls; and additional pesticides and herbicides. As a result of measuring these chemicals, population "reference ranges" for blood and urine concentrations of the chemicals, including 95th percentiles, are available for the first time. The 95th percentile level means that 95% of the samples of serum, blood, or urine from the population have concentrations below that level. Public health officials use the reference ranges to determine whether groups of people are experiencing an exposure that is unusual compared with an exposure experienced by the rest of the population.

Continued Progress in Reducing Blood Lead Levels in Children
New data on blood lead levels in children aged 1 to 5 years enable estimates of the number of children with elevated levels (that is, levels greater than or equal to 10 µg/dL). For the period 1999–2002, 1.6% of children aged 1 to 5 years had elevated blood lead levels. This percentage has decreased from 4.4% in the early 1990s.

These data document that public health efforts to reduce the number of children with elevated blood lead levels in the general population continue to be successful. However, other data show that special populations of children at high risk for lead exposure (for example, children living in homes containing lead-based paint or lead-contaminated dust) have higher rates of elevated blood lead levels and remain a major public health concern. Since no safe blood lead level in children has been identified, emphasis should be placed on efforts to control or eliminate lead in children's environment before children are exposed.

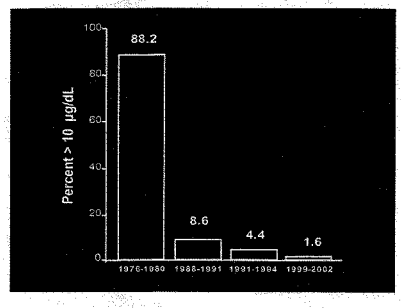


Figure 1. Percentage of children 1-5 years old in the U.S. population with elevated blood lead levels (≥ 10 µg/dL)

Exposure to Cadmium
Recent research studies have shown that urine cadmium levels a low as 1 µg per gram of creatinine in people may be associated with subtle kidney injury (that is, injury that may not be readily apparent) and with an increased risk for low bone-mineral densit CDC is not establishing a new level of health concern in this *Report*, but is noting how population urine cadmium levels compare with results of recent research. The *Third Report* show that about 5% of the U.S. population aged 20 years and older ha urinary cadmium levels at or near these levels. Cigarette smokin is the most likely source for these higher cadmium levels. These cadmium findings should promote further research on the public health consequences of cadmium in people.

Encouraging Findings About Exposure to the Organochlorin Pesticides Aldrin, Endrin, and Dieldrin
These three pesticides are similar and were once widely used insecticides in agricultural applications, particularly for cotton a corn. Agricultural uses of aldrin and dieldrin were discontinued the United States in 1970, and termite control ended in 1987. Production and use of endrin was discontinued in 1986. Althoug these pesticides are no longer used in the United States, they are still used in other countries. Results from the *Third Report* show undetectable or very low serum levels of each of these organochlorine pesticides.

Better Human Exposure Data for Dioxin-like Compounds
The *Third Report* provides data for 29 dioxins, furans, and dioxi like polychlorinated biphenyls that now have generally lower limits of detection than they did previously. Results for three of these chemicals are presented for the first time in this *Report*. Th new exposure information for dioxins and related compounds wi substantively improve risk assessments currently in progress to determine health risks to the U.S. population from exposure to this family of chemicals.

Mercury Exposure Among Women of Childbearing Age (16–49 Years)
Most of the mercury in blood comes from food. The mercury in food comes from consumption of fish and shellfish which accumulate methylmercury from water and soil. Mercury exposure is important to monitor in women of childbearing age because mercury can cause adverse neurodevelopmental effects the developing fetus at blood levels potentially attainable throug dietary sources. Data from the *Third Report* for the period 1999-2002 show that all women of childbearing age had levels below 58 µg per liter (µg/L), a concentration associated with neurodevelopmental effects in the fetus.

However, mercury levels in these women continue to merit clos monitoring because 5.7% of women of childbearing age had levels within a factor of 10 of those associated with neurodevelopmental effects. Defining safe levels of mercury in blood continues to be an active research area.

Key Highlights and Findings (continued)

Exposure to Environmental Tobacco Smoke

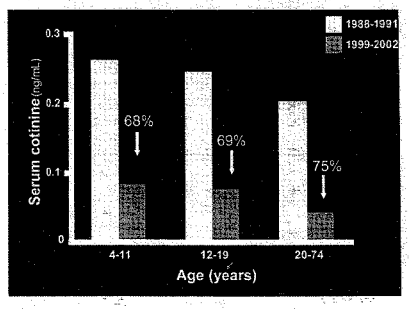
Cotinine is a metabolite of nicotine, and levels of cotinine in blood track exposure to environmental tobacco smoke (ETS) in people who do not smoke. Higher cotinine levels indicate more exposure to ETS, which has been identified as a human carcinogen. Data on blood cotinine levels for the U.S. population are available for 1988–1991 from previous work at CDC. With this *Third Report,* data are now available for the period 1999-2002.

Compared with results from the period 1988–1991, the 1999–2002 data show that median cotinine levels in nonsmokers have decreased 68% for children, 69% for adolescents, and about 75% for adults. Non-Hispanic blacks have levels more than twice those of Mexican Americans and non-Hispanic whites. Children's levels are more than twice those of adults. Efforts to reduce ETS exposure in the population show significant progress, but ETS exposure remains a major public health concern.

Improved Markers for Phthalate Exposure

Phthalates are "plasticizers," the name given to a group of chemicals that soften and increase the flexibility of plastics and vinyl. Exposure to these plasticizers is widespread. Newly identified markers give a better indication of exposure. Animal studies have demonstrated reproductive toxicity and other effects of phthalates. Currently, very limited scientific information is available on potential human health effects of phthalates at levels presented for the U.S. population in the *Report.*

Figure 2. Serum cotinine levels tracking exposure to secondhand smoke in the non-smoking U.S. population



New Measures for Some of the Widely Used Pyrethroid Insecticides

Pyrethroids are a group of synthetic insecticides that are now the most commonly used insecticides applied around the home. The *Third Report* presents first-time exposure information for five commonly used pyrethroid insecticides. The findings suggest widespread exposure to pyrethroid insecticides, since 3-phenoxybenzoic acid, a common metabolite of several pyrethroi insecticides, was found in much of the U.S. population. Currently, very limited scientific information is available on potential human health effects of pyrethroid insecticides at level presented for the U.S. population in the *Report.*

Selection of Chemicals Included in the *Report*

Chemicals for which data were collected and information presented in the *Report* were selected on the basis of scientific data that suggested exposure in the U.S. population; the seriousness of health effects known or suspected to result from exposure; the need to assess the efficacy of public health actions to reduce exposure to a chemical; the availability of a biomonitoring analytical method with adequate accuracy, precision, sensitivity, specificity, and speed; the availability of sufficient quantity of blood or urine samples; and the cost of analysis for the chemical.

In October 2002, CDC solicited nominations from the public for candidate chemicals or categories of chemicals for possible inclusion ir future *Reports* (*Federal Register*, Vol. 67, No. 194, October 7, 2002) and received nominations for hundreds of chemicals. Details on th nomination process and the list of the nominated chemicals are available at www.cdc.gov/exposurereport/chemical_nominations.htm.

Plans for Future *Reports*

CDC plans to release future *Reports* of exposure of the U.S. population that cover 2-year periods (for example, 2003–2004, 2005–2006, and 2007–2008). These *Reports* will include data on more chemicals and additional information on exposure in population groups defin by age, sex, and race or ethnicity.

About CDC's Environmental Health Laboratory

Using advanced laboratory science and innovative techniques, the Environmental Health Laboratory at the National Center for Environmental Health (NCEH) at the Centers for Disease Control and Prevention (CDC) has been in the forefront of efforts to assess people's exposure to environmental chemicals. CDC's highly trained laboratory scientists have built on more than three decades of experience in measuring chemicals directly in people's blood or urine, a process known as biomonitoring. Biomonitoring measurements are the most health-relevant assessments of exposure because they measure the amount of the chemical that actually gets into people fro all environmental sources (e.g., air, soil, water, dust, or food) combined. With a few exceptions, it is the concentration of the chemical in people that provides the best exposure information to evaluate the potential for adverse health effects.

Chemicals in the *Report*

Metals
Antimony
Barium
Beryllium
Cadmium
Cesium
Cobalt
Lead
Mercury
Molybdenum
Platinum
Tungsten
Thallium
Uranium

Tobacco Smoke
Cotinine

Phytoestrogens
Daidzein
Enterodiol
Enterolactone
Equol
Genistein
O-Desmethylangolensin

Polycyclic Aromatic Hydrocarbons
1-Hydroxybenz[a]anthracene
3- and 9-Hydroxybenz[a]anthracene
1-Hydroxybenzo[c]phenanthrene
2-Hydroxybenzo[c]phenanthrene
3-Hydroxybenzo[c]phenanthrene
1-Hydroxychrysene
2-Hydroxychrysene
3-Hydroxychrysene
4-Hydroxychrysene
6-Hydroxychrysene
3-Hydroxyfluoranthene*
2-Hydroxyfluorene
3-Hydroxyfluorene
9-Hydroxyfluorene
1-Hydroxyphenanthrene
2-Hydroxyphenanthrene
3-Hydroxyphenanthrene
4-Hydroxyphenanthrene
9-Hydroxyphenanthrene
1-Hydroxypyrene
3-Hydroxybenzo[a]pyrene
1-Hydroxynapthalene
2-Hydroxynapthalene

Phthalates
Mono-methyl phthalate
Mono-ethyl phthalate
Mono-n-butyl phthalate
Mono-isobutyl phthalate
Mono-benzyl phthalate
Mono-cyclohexyl phthalate
Mono-2-ethylhexyl phthalate
Mono-(2-ethyl-5-oxohexyl) phthalate
Mono-(2-ethyl-5-hydroxyhexyl) phthalate
Mono-n-octyl phthalate
Mono-(3-carboxypropyl) phthalate
Mono-isononyl phthalate

Organophosphate Insecticides: Dialkyl Phosphate Metabolites
Dimethylphosphate
Dimethylthiophosphate
Dimethyldithiophosphate
Diethylphosphate
Diethylthiophosphate
Diethyldithiophosphate

Organophosphate Insecticides: Specific Metabolites
Malathion dicarboxylic acid*
para-Nitrophenol
3,5,6-Trichloro-2-pyridinol
2-Isopropyl-4-methyl-6-hydroxypyrimidine
2-(Diethylamino)-6-methylpyrimidin-4-ol/one
3-Chloro-7-hydroxy-4-methyl-2H-chromen-2-one/ol

Herbicides
2,4,5-Trichlorophenoxyacetic acid
2,4-Dichlorophenoxyacetic acid
2,4-Dichlorophenol
Alachlor mercapturate*
Atrazine mercapturate
Acetochlor mercapturate
Metolachlor mercapturate

Pyrethroid Pesticides
4-Fluoro-3-phenoxybenzoic acid
***cis*-3-(2,2-Dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid**
***trans*-3-(2,2-Dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid**
***cis*-3-(2,2-Dibromovinyl)-2,2-dimethylcyclopropane carboxylic acid**
3-Phenoxybenzoic acid

Other Pesticides
N,N-Diethyl-3-methylbenzamide
ortho-Phenylphenol
2,5-Dichlorophenol

Carbamate Pesticides
2-Isopropoxyphenol
Carbofuranphenol

Organochlorine Pesticides
Hexachlorobenzene
Beta-hexachlorocyclohexane
Gamma-hexachlorocyclohexane
Pentachlorophenol
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
p,p'-DDT
p,p'-DDE
o,p'-DDT
Oxychlordane
trans-Nonachlor
Heptachlor epoxide
Mirex
Aldrin
Dieldrin
Endrin

Polychlorinated Dibenzo-p-dioxins, Dibenzofurans, Coplanar and Mono-Ortho-Substituted Biphenyls
1,2,3,4,6,7,8,9-Octachlorodibenzo-p-dioxin (OCDD)
1,2,3,4,6,7,8-Heptachlorodibenzo-p-dioxin (HpCDD)
1,2,3,4,7,8-Hexachlorodibenzo-p-dioxin (HxCDD)
1,2,3,6,7,8-Hexachlorodibenzo-p-dioxin (HxCDD)
1,2,3,7,8,9-Hexachlorodibenzo-p-dioxin (HxCDD)
1,2,3,7,8-Pentachlorodibenzo-p-dioxin (PeCDD)
2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD)
1,2,3,4,6,7,8,9-Octachlorodibenzofuran (OCDF)
1,2,3,4,6,7,8-Heptachlorodibenzofuran (HpCDF)
1,2,3,4,7,8,9-Heptachlorodibenzofuran (HpCDF)
1,2,3,4,7,8-Hexachlorodibenzofuran (HxCDF)
1,2,3,6,7,8-Hexachlorodibenzofuran (HxCDF)
1,2,3,7,8,9-Hexachlorodibenzofuran (HxCDF)
1,2,3,7,8-Pentachlorodibenzofuran (PeCDF)
2,3,4,6,7,8-Hexachlorodibenzofuran (HxCDF)
2,3,4,7,8-Pentachlorodibenzofuran (PeCDF)
2,3,7,8-Tetrachlorodibenzofuran (TCDF)
2,4,4'-Trichlorobiphenyl (PCB 28)*
2,3',4,4'-Tetrachlorobiphenyl (PCB 66)
2,4,4',5-Tetrachlorobiphenyl (PCB 74)
3,4,4',5-Tetrachlorobiphenyl (PCB 81)
2,3,3',4,4'-Pentachlorobiphenyl (PCB 105)
2,3',4,4',5-Pentachlorobiphenyl (PCB 118)
3,3',4,4',5-Pentachlorobiphenyl (PCB 126)
2,3,3',4,4',5-Hexachlorobiphenyl (PCB 156)
2,3,3',4,4',5'-Hexachlorobiphenyl (PCB 157)
2,3',4,4',5,5'-Hexachlorobiphenyl (PCB 167)
3,3',4,4',5,5'-Hexachlorobiphenyl (PCB 169)
2,3,3',4,4',5,5'-Heptachlorobiphenyl (PCB 189)

Non-dioxin-like Polychlorinated Biphenyls
2,2',5,5'-Tetrachlorobiphenyl (PCB 52)
2,2',3,4,5'-Pentachlorobiphenyl (PCB 87)
2,2',4,4',5-Pentachlorobiphenyl (PCB 99)
2,2',4,5,5'-Pentachlorobiphenyl (PCB 101)
2,3,3',4',6-Pentachlorobiphenyl (PCB 110)
2,2',3,3',4,4'-Hexachlorobiphenyl (PCB 128)
2,2',3,4,4',5' and 2,3,3',4,4',6-Hexachlorobiphenyl (PCB 138 & 158)
2,2',3,4',5,5'-Hexachlorobiphenyl (PCB 146)
2,2',3,4',5',6'-Hexachlorobiphenyl (PCB 149)
2,2',3,5,5',6-Hexachlorobiphenyl (PCB 151)
2,2',4,4',5,5'-Hexachlorobiphenyl (PCB 153)
2,2',3,3',4,4',5-Heptachlorobiphenyl (PCB 170)
2,2',3,3',4,5,5'-Heptachlorobiphenyl (PCB 172)
2,2',3,3',4,5',6'-Heptachlorobiphenyl (PCB 177)
2,2',3,3',5,5',6-Heptachlorobiphenyl (PCB 178)
2,2',3,4,4',5,5'-Heptachlorobiphenyl (PCB 180)
2,2',3,4,4',5',6-Heptachlorobiphenyl (PCB 183)
2,2',3,4',5,5',6-Heptachlorobiphenyl (PCB 187)
2,2',3,3',4,4',5,5'-Octachlorobiphenyl (PCB 194)
2,2',3,3',4,4',5,6-Octachlorobiphenyl (PCB 195)
2,2',3,3',4,4',5,6' and 2,2',3,4,4',5,5',6-Octachlorobiphen (PCB 196 & 203)
2,2',3,3',4,5,5',6-Octachlorobiphenyl (PCB 199)
2,2',3,3',4,4',5,5',6'-Nonachlorobiphenyl (PCB 206)

First-time data on chemicals in **bold**.
*Results available for 1999-2000 only.

Sample table

Table 190. Mono-ethyl phthalate

Geometric mean and selected percentiles of urine concentrations (in µg/L) for the U.S. population aged 6 years and older, National Health and Nutrition Examination Survey, 1999-2002.

	Survey years	Geometric mean (95% conf. interval)	Selected percentiles (95% confidence interval) 50th	75th	90th	95th	Sample size
Total, age 6 and older	99-00	178 (150-204)	164 (138-191)	429 (370-538)	1288 (1010-1486)	2840 (2150-3275)	2596
	01-02	178 (159-199)	169 (141-196)	465 (415-527)	1238 (1040-1442)	2500 (1900-3281)	2762
Age group							
6-11 years	99-00	91.3 (74.6-111)	74.7 (62.1-93.7)	197 (129-245)	378 (295-730)	756 (379-1070)	381
	01-02	83.1 (71.3-102)	71.5 (61.3-92.3)	181 (143-217)	444 (315-634)	868 (573-1093)	393
12-19 years	99-00	211 (169-278)	193 (141-256)	558 (416-814)	1818 (1150-2133)	3269 (1900-4425)	752
	01-02	187 (159-243)	184 (148-227)	479 (387-561)	1300 (883-1480)	2961 (1470-3638)	742
20 years and over	99-00	190 (164-215)	181 (140-220)	482 (395-586)	1348 (1010-1660)	3482 (2230-4648)	1456
	01-02	191 (171-214)	181 (152-212)	498 (441-587)	1352 (1060-1660)	2720 (2160-3070)	1547
Gender							
Male	99-00	178 (149-215)	154 (119-187)	523 (372-650)	1439 (1020-2259)	3489 (2130-4960)	1214
	01-02	182 (157-211)	171 (129-199)	392 (418-600)	1452 (1090-2110)	3050 (2110-3300)	1371
Female	99-00	178 (154-206)	174 (138-210)	428 (350-505)	877 (800-1233)	2236 (1370-3860)	1382
	01-02	174 (150-198)	167 (135-194)	427 (347-496)	1052 (870-1318)	1840 (1460-2520)	1411
Race/ethnicity							
Mexican American	99-00	191 (157-229)	174 (145-210)	441 (299-541)	1250 (851-1515)	1720 (1460-2139)	813
	01-02	238 (195-283)	226 (190-264)	536 (444-662)	1456 (1350-2113)	2596 (1540-4853)	577
Other Hispanic	99-00	322 (270-377)	305 (256-355)	769 (652-845)	1880 (1410-2221)	3680 (1130-4649)	663
	01-02	352 (324-384)	357 (296-407)	836 (705-956)	2169 (1635-2679)	3540 (2810-5970)	703
Non-Hispanic white	99-00	152 (133-172)	133 (108-157)	365 (287-482)	977 (786-1242)	2470 (1530-3885)	968
	01-02	158 (141-176)	147 (119-177)	413 (365-515)	1220 (905-1529)	2310 (1590-2725)	1216

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