AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 107–452

BIOTERRORISM, 2001

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

SPECIAL HEARINGS

OCTOBER 3, 2001—WASHINGTON, DC
OCTOBER 28, 2001—WASHINGTON, DC
NOVEMBER 2, 2001—WASHINGTON, DC
NOVEMBER 29, 2001—WASHINGTON, DC

Printed for the use of the Committee on Appropriations

Available via the World Wide Web: http://www.access.gpo.gov/congress/senate

U.S. GOVERNMENT PRINTING OFFICE

77–048 PDF WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON APPROPRIATIONS

ROBERT C. BYRD, West Virginia, *Chairman*

DANIEL K. INOUYE, Hawaii
ERNEST F. HOLLINGS, South Carolina
PATRICK J. LEAHY, Vermont
TOM HARKIN, Iowa
BARBARA A. MIKULSKI, Maryland
HARRY REID, Nevada
HERB KOHL, Wisconsin
PATTY MURRAY, Washington
BYRON L. DORGAN, North Dakota
DIANNE FEINSTEIN, California
RICHARD J. DURBIN, Illinois
TIM JOHNSON, South Dakota
MARY L. LANDRIEU, Louisiana
JACK REED, Rhode Island

TED STEVENS, Alaska
THAD COCHRAN, Mississippi
ARLEN SPECTER, Pennsylvania
PETE V. DOMENICI, New Mexico
CHRISTOPHER S. BOND, Missouri
MITCH McCONNELL, Kentucky
CONRAD BURNS, Montana
RICHARD C. SHELBY, Alabama
JUDD GREGG, New Hampshire
ROBERT F. BENNETT, Utah
BEN NIGHTHORSE CAMPBELL, Colorado
LARRY CRAIG, Idaho
KAY BAILEY HUTCHISON, Texas
MIKE DeWINE, Ohio

TERRENCE E. SAUVAIN, *Staff Director*
CHARLES KIEFFER, *Deputy Staff Director*
STEVEN J. CORTESE, *Minority Staff Director*
LISA SUTHERLAND, *Deputy Minority Staff Director*

SUBCOMMITTEE ON DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES

TOM HARKIN, Iowa, *Chairman*

ERNEST F. HOLLINGS, South Carolina
DANIEL K. INOUYE, Hawaii
HARRY REID, Nevada
HERB KOHL, Wisconsin
PATTY MURRAY, Washington
MARY L. LANDRIEU, Louisiana
ROBERT C. BYRD, West Virginia

ARLEN SPECTER, Pennsylvania
THAD COCHRAN, Mississippi
JUDD GREGG, New Hampshire
LARRY CRAIG, Idaho
KAY BAILEY HUTCHISON, Texas
TED STEVENS, Alaska
MIKE DeWINE, Ohio

Professional Staff
ELLEN MURRAY
JIM SOURWINE
MARK LAISCH
ADRIENNE HALLETT
ERIK FATEMI
ADAM GLUCK
BETTILOU TAYLOR *(Minority)*
MARY DIETRICH *(Minority)*
SUDIP SHRIKANT PARIKH *(Minority)*

Administrative Support
CAROLE GEAGLEY
EMMA ASHBURN *(Minority)*

CONTENTS

WEDNESDAY, OCTOBER 3, 2001

	Page
Opening statement of Senator Tom Harkin	1
Prepared statement of the American Pharmaceutical Association	3
Prepared statement of the American Society of Clinical Pathologists	5
Prepared statement of the Commissioned Officers Association of the U.S. Public Health Service	6
Prepared statement of the Association of State and Territorial Health Officials	
Opening statement of Senator Arlen Specter	13
Opening statement of Senator Robert C. Byrd	14
Statement of Hon. Edward M. Kennedy, U.S. Senator from Massachusetts	16
Prepared statement	19
Statement of Hon. Bill Frist, U.S. Senator from Tennessee	20
Prepared statement	23
Statement of Hon. Chuck Hagel, U.S. Senator from Nebraska	28
Statement of Hon. John R. Edwards, U.S. Senator from North Carolina	29
Statement of Hon. Tommy G. Thompson, Secretary, Department of Health and Human Services	32
Prepared statement	36
Opening statement of Senator Mike DeWine	46
Opening statement of Senator Richard J. Durbin	46
Opening statement of Senator Judd Gregg	48
Opening statement of Senator Herb Kohl	49
Statement of Jonathan Tucker, Ph.D., director, Chemical & Biological Weapons Nonproliferation Program, Monterey Institute of International Studies	52
Prepared statement	55
Statement of Stephen Cantrill, M.D., associate director, Department of Emergency Medicine, Denver Health Medical Center	62
Prepared statement	64
Statement of Jerome M. Hauer, managing director, Crisis and Consequences Management, Kroll Associates	66
Statement of Patricia Quinlisk, M.D., M.P.H., medical director and State epidemiologist, Iowa Department of Health	68
Prepared statement	71
Statement of Rex Archer, M.D., M.P.H., director, Kansas City Health Department	79
Prepared statement	81

TUESDAY, OCTOBER 23, 2001

Opening statement of Senator Tom Harkin	93
Opening statement of Senator Arlen Specter	95
Statement of Jeffrey P. Koplan, M.D., M.P.H., Director, Centers for Disease Control and Prevention, Department of Health and Human Services	98
Prepared statement	104
Statement of James T. Caruso, Deputy Assistant Director, Counterterrorism Division, Federal Bureau of Investigation, Department of Justice	109
Statement of Bob Kramer, president and chief operating officer, Bioport Corporation	123
Prepared statement	125
Statement of Mary Kuhn, vice president of operations, Bayer Corporation	129
Prepared statement	131

Page

Statement of Barbara Hunt, R.N., M.P.A., district health officer, Washoe County Health Department, Reno, Nevada 133
Prepared statement 135
Statement of Hilary Koprowski, M.D., president, Biotechnology Foundation, Inc., Philadelphia, PA, professor, Department of Microbiology and Immunology, director, Center of Neurovirology and Biotechnology Foundation Laboratories at Thomas Jefferson University 136
Prepared statement 137
Statement of Thomas P. Monath, M.D., vice president for Research and Medical Affairs, Acambia, Inc. 138
Prepared statement 140
Statement of Mary J.R. Gilchrist, Ph.D., director, University of Iowa Hygienic Laboratory 141
Prepared statement 143

FRIDAY, NOVEMBER 2, 2001

Opening statement of Senator Tom Harkin 155
Opening statement of Senator Arlen Specter 156
Opening statement of Senator Robert C. Byrd 157
Opening statement of Senator Ted Stevens 160
Statement of Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services 160
Prepared statement 162
Statement of James W. LeDuc, Ph.D., Acting Director, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Department of Health and Human Services 164
Prepared statement 165
Statement of Michael Friedman, M.D., chief medical officer for biomedical preparedness, Pharmaceutical Research and Manufacturers of America 171
Prepared statement 172
Statement of M. Anita Barry, M.D., M.P.H., director, Communicable Disease Control, Boston Public Health Commission, and member, National Association of County and City Health Officials 177
Prepared statement 179

THURSDAY, NOVEMBER 29, 2001

Opening statement of Senator Tom Harkin 201
Opening statement of Senator Arlen Specter 202
Opening statement of Senator Ted Stevens 204
Statement of Jeffrey P. Koplan, M.D., M.P.H., Director, Centers for Disease Control and Prevention, Department of Health and Human Services 205
Prepared statement 207
Statement of Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health 210
Prepared statement 211
Opening statement of Senator Herb Kohl 218
Opening statement of Senator Mary L. Landrieu 224
Prepared statement 226
Statement of Ken Alibek, M.D., president, Advanced Biosystems, Inc. 229
Prepared statement 231
Statement of Joseph Barbera, M.D., associate professor and co-director, Institute for Crisis, Disaster, and Risk Management, the George Washington University 233
Prepared statement 235
Statement of Joseph LeValley, senior vice president for planning and systems development, Mercy Medical Center of Des Moines, Des Moines, Iowa 237
Prepared statement 239

BIOTERRORISM

WEDNESDAY, OCTOBER 3, 2001

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:35 a.m., in room 216, Hart Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Byrd, Kohl, Murray, Durbin, Landrieu, Specter, Gregg, and DeWine.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Good morning. The hearing of the Appropriations Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies, will come to order.

History will note that on September 11, 2001, our freedom was attacked. These attacks have made us realize that a free America must be a vigilant America. Vigilance requires that we prepare to meet the likely threats posed by our enemies. While I do not want to overstate its likelihood, or incite unnecessary panic, we must take a hard look at the threat posed by biological weapons and our Nation's preparedness to meet that threat.

This is not science fiction fantasy. Iraq had a biological weapons program, although we have no evidence that it was successful. They had already shown a willingness to use chemical weapons on combat against their own citizens. I believe we are not far from the day when a nation or organization will possess both biological weapons and chemical weapons and the will to use them, so the time for us to prepare is now.

Preparedness requires an investment in our public health infrastructure on the local, State, and Federal level. They must have the resources and expertise needed to respond to an array of terrorist actions. It is no longer a matter of public health, it is a matter of national defense.

Imagine how we would meet a biological attack, given our Nation's current state of readiness. On May 20, a western State's department of public health begins receiving reports that increasing numbers of people are seeking medical attention at a city's area hospital for coughing and fever during the previous evening. By early afternoon on May 20, 500 persons with these symptoms have received medical care, and 25 have died.

The State declares a public health emergency. Hospitals and clinics around the area who just days before were dealing with what

appeared to be just an unusual case of influenza are recalling staffs, but hospital staffs are beginning to call in sick. More and more people and resources are scarce. The State's Governor then restricts travel, including bus, rail, and air travel into and out of the affected area. All antibiotics that can be used to prevent or treat the plague are commandeered. Citizens are told to seek treatment at a medical facility if they're feeling ill. By the end of that day, 783 cases of pneumonic plague have occurred, and 123 people have died.

On day 2, May 21, a cable news network reports that a national crash effort is underway to move large quantities of antibiotics to the region. A push pack of needed medical supplies from the National Pharmaceutical Stockpile arrives in the city, but there are great difficulties moving antibiotics from the stockpile delivery point to the persons who need it for treatment. Out-of-State cases now begin to be reported. The CDC notifies bordering States of the epidemic.

On day 3, May 22, hospitals cannot manage the influx of sick patients. By noon, there are 3,060 United States and international cases of the plague and 795 have died.

On the day 4, May 23, there are conflicting reports of the number of sick and dead. Some reports show an estimated 3,700 cases of pneumonic plague, with 950 deaths. Others are reporting over 4,000 cases, and more than 2,000 deaths.

The good news from this? This was an exercise, just an exercise. In this scenario, an aerosol of plague, (Y. pestis) bacilli was released at the Denver Performing Arts Center, and we can see the results of this. Clearly, we are not sufficiently prepared, but we have made some progress.

Several years ago, this subcommittee, under the leadership of Senator Specter from Pennsylvania, began to put more and more effort into protecting us from bioterrorism. Over the past 2 years, we have appropriated $545 million to the Center for Disease Control for this purpose. That investment has improved the detection, treatment, and containment of a potential bioterrorist attack by strengthening the Federal, State, and local partnerships that are the first and even second lines of defense. In addition, two of our distinguished witnesses, Senators Kennedy and Frist, led the effort to pass the Public Health Threats and Emergencies Act. That legislation will further strengthen our efforts.

In the near term, we will put forward a plan on how to allocate the $20 billion in anti-terrorism funds we approved 2 weeks ago. It is my hope that this hearing will help us focus on how a portion of those funds can be used to combat bioterrorism. Should the unthinkable happen, our local public health departments will be the first line of defense. Unlike a conventional or chemical weapons attack, a biological weapon can be launched and can strike without even a sound.

It will be our emergency room personnel and urgent care providers who will recognize the attack and counter it. That requires training and effective surveillance systems that can put pieces of information together in a meaningful plan. That is how public health threats are tracked and contained.

For example, in New York, a doctor who had recently attended a public health seminar on the importance of this type of tracking and reporting had the presence of mind to report two unusual cases of encephalitis to the public health department. That information led to the identification of the West Nile virus outbreak.

In the case of biological weapons, we will require trained personnel and equipment to first detect the attack, the ability to treat a large number of exposed individuals, and immediate access to the necessary pharmaceuticals, whether it be vaccines, antibiotics, or something else.

We have made some progress in meeting the threat, but how much further do we need to go to protect Americans from a biological attack? That is the question we must address today.

We have a very distinguished and knowledgeable panel of witnesses, who I know will add a great deal to this hearing, and I want to thank them for joining us. Before we begin with our first distinguished panel, I would ask unanimous consent that a number of statements from various experts who asked to testify today, but who were unable to be accommodated, be inserted into the record.

[The statements follow:]

PREPARED STATEMENT OF THE AMERICAN PHARMACEUTICAL ASSOCIATION

The American Pharmaceutical Association (APhA), the national professional society of pharmacists, is pleased that the Committee is addressing the important issue of bioterrorism and ways to prepare for and provide a response to a biological or chemical terrorist attack. APhA is the first established and largest professional association of pharmacists in the United States. APhA's 50,000 members include practicing pharmacists, pharmaceutical scientists, pharmacy students, pharmacy technicians, and others interested in advancing the profession. Pharmacy is the third largest health profession in America. The Association is extremely proud of the role our pharmacist members played in meeting the needs of individuals who, in the aftermath of the terrorist attacks, were stranded away from home or working on rescue efforts and were in need of medications or other healthcare needs.

The roots of pharmacy's involvement with public health initiatives go back well over a century. Pharmacists have served as local, decentralized extenders of public health departments, playing a major role in the distribution and administration of vital vaccines, medications, supplies and health care services.[1] The nation's pharmacists have demonstrated a serious commitment to preventing disease and stand ready to serve the needs of our nation in the event of a biological or chemical attack. Indeed, the profession recognizes the deadly threat that an attack of this nature would pose with the population of our nation at risk of fatal infection with little notice. When an attack occurs, time will be short to mount a preventive program to preserve the public's health. Pharmacists' accessibility in every community provides an excellent opportunity to reach individuals in need of preventive care, healthcare services, medications and supplies, vaccines, and information. Pharmacists want to actively participate in whatever response or preventive plan is implemented, and are available to assist in preparedness efforts and response to bioterrorism. APhA pledges its services and communications vehicles to help mobilize this vital resource.

Pharmacists' contributions to such efforts can include: Monitoring for and surveillance of signs and symptoms of a possible biological or chemical attack. Pharmacists are a trusted source of health care information for the public. Patients often seek the advice of pharmacists, even before going to a physician, when they require health information. The initial symptoms presented by several potential biological agents that could be utilized against our citizenry resemble those of the flu. Many patients may attempt to self medicate and will seek a remedy from their local pharmacy shelf before going to the physician's office or hospital. As one of the most accessible health care professionals, pharmacists are in an excellent position to assist in monitoring any patterns of symptoms or diseases reported by patients. Phar-

[1] Pharmacy in History, American Institute of the History of Pharmacy; Vol. 41, pgs. 137–149, 1999.

macists' involvement in this area can help to serve as an early warning that a bioterrorism attack has occurred.

The pharmacist is an expert in medication use, both prescription and over-the-counter. This expertise is invaluable in determining which pharmaceuticals should be stored and which can be used as second and third line agents if the supply of first line agents is limited.[2]

The resources and talents of the nation's pharmacists may be extended beyond dispensing necessary medications and working with patients to make those medications work. For example, pharmacists in 31 states may administer vaccines and provide general support for immunization programs. There is substantial evidence that pharmacists are readily accessible, trusted professionals who can motivate the public to be vaccinated and enhance vaccine delivery. These capabilities will be helpful in a national infectious disease emergency. Here are some of the practical ways pharmacists could help:

Community pharmacists at more than 52,000 neighborhood pharmacies can educate the public and, in 31 states, actually immunize them. In many rural areas, a pharmacist is the only health professional conveniently located to patients. The nation's community pharmacies could serve as 52,000 bases of operation and communication for immunization programs coordinated by state health departments.

Pharmacists in hospitals and other health systems can educate, motivate, support, and immunize inpatients and outpatients in these settings. As medication experts, pharmacists link the clinical, logistic, and administrative functions of hospitals and health systems.

Consultant pharmacists can enhance immunization delivery to residents of nursing homes and other institutions. Consultant pharmacists review residents' drug regimens monthly and are already integral contributors to health quality in these settings.

Pharmacists are trained to take any of three roles in support of the national preparedness plan. These three roles are:

Motivating: Pharmacists can distribute literature, display posters, perform one-on-one counseling, speak to local civic groups, and similar activities. Scientific studies demonstrate that 50 percent to 94 percent of the people to whom a pharmacist recommends immunization accept this recommendation.[3] In the confusion and uncertainty possible in any national immunization campaign, pharmacists can be voices of reason and sources of factual information and advice.

Hosting: In 1997, more than 5 million doses of influenza vaccine were administered at more than 15,000 pharmacies across the country, more than one-quarter of all pharmacies. Even in the pharmacies where pharmacists are not yet trained to immunize, nurses or other vaccine providers could administer vaccines or establish vaccine supply depots. These sites are equipped to store refrigerated medications, are widely dispersed in urban, suburban, and rural settings, near population centers of diverse sizes. Most are open long hours and have large parking lots that could accommodate large patient flows. Further, given that more than 95 percent of pharmacies already have electronic communications capabilities, pharmacies could serve as communication centers for sending and receiving instructions and data between state health authorities and field workers during a pandemic. In addition, pharmacists can serve as information resources to consumers, media, and other health care professionals.

Immunizing: Estimates are that there are currently more than 3,000 immunizing pharmacists, delivering more than 300,000 doses of vaccine to adults during recent flu seasons. Pharmacists are authorized to administer drugs in 31 states, corresponding to a population of over 135 million people. Additional states are considering empowering pharmacists with this authority to advance the public health. Pharmacists could be enlisted to administer vaccine dose(s) during bioterrorism events, reporting to state authorities, as well as providing areas for vaccine and medication storage and distribution.

APhA has made available to its members educational programming focusing on bioterrorism at Association annual meetings. Additionally, a bioterrorism resource center located on APhA's homepage (www.aphanet.org) was developed to assist pharmacists and consumers with education about and preparing for a bioterrorism attack.

All of these actions will be greatly facilitated by having Congress express interest in including the nation's pharmacists in plans to defend the nation against these threats.

---

[2] Supplement to the Journal of the American Pharmaceutical Association, September/October 2000.

[3] Spruill et al., 1982; Grabenstein et al., 1986; Morton et al., 1988; Grabenstein et al., 1990.

Thank you for the opportunity to provide comments on this important issue. The American Pharmaceutical Association and its members stand ready to assist the government in any way possible to prepare for and respond to bioterrorism.

Contact information: American Pharmaceutical Association 2215 Constitution Avenue, NW Washington, DC 20037 (202) 429–7575.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

In light of the tragic events of September 11, 2001, we appreciate you holding this hearing to address the issue of bioterrorism. We hope the following comments will provide you with some specific suggestions on how to improve the public health infrastructure and prepare for potential biological and chemical attacks.

As the world's largest organization representing laboratory personnel, the American Society of Clinical Pathologists' 75,000 board certified pathologists, clinical scientists, certified technologists and technicians, are the individuals most likely to first receive patient specimens for etiologic agents that are likely to be used in bioterrorism and toxins that may be used as chemical weapons. These professionals must provide prompt and accurate laboratory test results so that a potential outbreak can be detected, provide support for hospitals and clinics caring for affected patients, and assist in the development of an integrated epidemiologic network, especially for law enforcement purposes.

Bioterrorist events will likely present as outbreaks of acute febrile illnesses or as unusual infectious diseases with no readily apparent point source. Therefore, clinicians will rely heavily upon laboratory tests for diagnostic clues as to the etiologic agent. Laboratory professionals must be trained to identify microbial pathogens likely to be used for bioterrorism, to safely collect, transport, and process specimens containing biological agents associated with bioterrorist acts, to follow chain of custody and other legal requirements, and to have familiarity with needs of mass disaster support services.

Unfortunately, there is growing concern over the serious shortage of medical laboratory personnel in our nation's health care system. In the United States, vacancy rates for seven of ten key laboratory medicine positions are at an all time high. Since the early 1980s, the number of accredited educational programs for laboratory positions has decreased significantly, and laboratory professionals who entered the workforce in the 1960s and 1970s will be retiring soon.

To assist in reversing this shortage, we respectfully request two amendments to the legislation offering appropriations for the Public Health Improvement Act, Public Law 106–505. Specifically, we ask that the legislation allow schools and programs of allied health to qualify for grants. The "Public Health Threats and Emergencies; Education of Medical and Public Health Personnel" program already allows grants to be given to state or local public health agencies to train laboratory personnel in the recognition or identification of resistance in pathogens. Similarly, we ask that schools and programs be eligible for grants in order to train medical laboratory personnel in disciplines that recognize or identify a potential biological agent. The "Public Health Threats and Emergencies; Public Health Countermeasures to a Bioterrorist Attack" program allows states, hospitals, clinics, or primary care facilities to qualify for grants to enhance the ability of personnel to recognize the symptoms and epidemiological characteristics of exposure to a potential weapon. The Centers for Disease Control and Prevention should implement these training initiatives, and provide grants to schools and programs that train medical laboratory personnel and to other public or private non-profit entities. We suggest appropriating $25 million for education training grants. The Association of Public Health Laboratories concurs with this approach.

Also, in order to protect the health of the citizens of the United States from bioterrorism, emerging infectious diseases, foodborne diseases, and environmentally associated diseases, it is imperative to establish a national system of laboratories to help detect, coordinate, and control these threats. A national laboratory system is where public health, hospital and independent laboratories throughout the United States would build a collaborative infrastructure, to assure that timely and accurate laboratory information can be shared. The Centers for Disease Control and Prevention has determined that "maintaining and developing a national laboratory system that is efficient at detecting and timely in reporting is critical to minimize the negative impact of disease or other adverse public health events in the community." A national laboratory system is intended to assure the availability of consistent public health laboratory capacity regardless of the location.

Development of a national laboratory system is already underway with the establishment of four demonstration projects in Nebraska, Minnesota, Michigan and

Washington state, but much more needs to be accomplished to weave an effective national system, and quickly. A national laboratory system would permit partnership building among clinical laboratories, public health laboratories, and the government. It would assess staffing and capacity needs, provide guidance for training in bioterrorism specimens, and create voluntary standards for the public health infrastructure.

To carry out this function, we respectfully request $50 million for the national laboratory system. To maintain the system, an additional $50 million should be authorized for future years.

The American Society of Clinical Pathologists also supports funding the Centers for Disease Control and Prevention at $500 million for building and upgrading state and local public health capacity.

Thank you for the opportunity to comment on this critical public health concern. If you have questions or need additional information, please contact the American Society of Clinical Pathologists at (202) 347–4450.

PREPARED STATEMENT OF THE COMMISSIONED OFFICERS ASSOCIATION OF THE U.S. PUBLIC HEALTH SERVICE

INTRODUCTION

The Commissioned Officers Association (COA) of the U.S. Public Health Service appreciates the interest of this Subcommittee in the very important issue of bioterrorism. We are pleased that this Subcommittee recognizes the vulnerability of the nation to acts of bioterrorism by fringe groups and rogue nations, and is willing to take a leadership role in seeing to it that the various governmental agencies (local, state and federal) are asking the necessary questions and taking the necessary steps to ensure the nation is prepared if the unthinkable should occur.

COA believes the threat of bioterrorism is a serious one, and the Federal Government must have a clear, coherent and coordinated plan to deal with potential incidents that could impact upon the safety and health of large numbers of Americans. COA also strongly supports the enhancement of the Nation's public health infrastructure at all levels of government. In our view, such an effort is necessary irrespective of the magnitude of the bioterrorism threat we may face. Too often the bulk of Federal health funds has been expended for direct health care costs or to support biomedical research, while Federal expenditures for public health programs have lagged far behind. Consequently, we would urge this Subcommittee to examine not only the ability of our public health agencies to respond to bioterrorism, but also to review their ability to meet the current demands being placed upon them.

THE COMMISSIONED CORPS OF THE U.S. PUBLIC HEALTH SERVICE

In our view any planning that takes place with regard to response to an incident of bioterrorism "must" take into consideration the capabilities of the Commissioned Corps of the U.S. Public Health Service. This view has been supported on a number of occasions, most recently by Secretary Thompson in testimony before the Senate Appropriations Committee, Subcommittee on Commerce, Justice, State, and the Judiciary this past May 9th. In that hearing he stated:

"In order to advance an orderly and comprehensive approach to the many issues involved in such preparation (for a bioterrorism event), I will appoint a special assistant within the Immediate Office of the Secretary to lead the department's bioterrorism initiative. This person will report to me directly. I plan to call a national meeting of HHS agencies to evaluate the status of bioterrorism activities and report back to Congress on our efforts. In addition, the new special assistant will support the Surgeon General's efforts to revitalize the Public Health Service Commissioned Corps and its Readiness Force. Let me assure you that this is a top priority for me and for my entire department."

Congress has also noted that the Commissioned Corps has much to offer in the area of bioterrorism. In 1998 the Senate Armed Services Committee, in the Committee Report that accompanied the Department of Defense Authorization Act for fiscal year 1999, observed: "The Committee notes the efforts underway within the Department of Defense to develop the means to respond to acts of terrorism involving weapons of mass destruction. In this regard, the committee directs the Secretary of Defense to ensure the assessment of needs and capabilities includes an analysis of the capabilities that exist within the Commissioned Officer Corps of the U.S. Public Health Service, who, as members of the uniformed services, might be easily inte-

grated into Department of Defense plans to respond to emergencies involving weapons of mass destruction."

The Commissioned Corps has a history of deploying with the military that goes well beyond mobilization in times of war. In such instances the uniform and rank structure of the Commissioned Corps, as noted by the Senate Armed Services Committee, has indeed facilitated the relationship among the services.

This Committee came to a similar conclusion. In the report accompanying the Appropriations Bill for the Departments of Labor, HHS and Education for fiscal year 1999, the Committee stated: "In developing plans for bioterrorism countermeasures, the Committee notes the standing personnel and reserves of the Public Health Service are a valuable resource that ought to be well-integrated."

The Commissioned Corps, as a uniformed service, brings some unique capabilities to the public health and emergency response arenas, making these officers especially well-suited for the public health response required in the aftermath of a bioterrorism incident. As noted in a February 1998 Report prepared by a Special Advisory Committee of esteemed public health professionals headed by Former Surgeon General C. Everett Koop, ". . . expertise which is resident in the Corps to deal with biological and chemical agents is a critical resource that can be called upon in the event of terrorist attack." Tab A briefly describes some of the important characteristics of the Commissioned Corps, among them:

—public health training and experience;
—on call 24 hours a day, like their military counterparts;
—available for assignment to accommodate changing public health needs and priorities;
—an exceptional track record in the area of emergency response;
—presence in 49 of 50 states, with large concentrations of officers in nearly every region of the country, thereby allowing for an expedited response.

The Commissioned Corps is also a rich source of epidemiologists whose expertise will be critical as part of a bioterrorist response.

In August 1997 Minnesota's former governor, Arne H. Carlson sent a letter to then-DHHS Secretary Shalala praising the outstanding assistance provided by Commissioned Corps task forces to the citizens of Minnesota in the aftermath of the devastating spring floods. Governor Carlson noted that one of the lesser publicized, but serious impacts of the flooding was an estimated 2500 flooded private wells, requiring the restoration of safe water supplies for many of Minnesota's citizens. He observed that "(t)he three task forces entered the state fully equipped and thoroughly organized to operate with a minimum of state involvement", and they brought the long, dirty and sometimes dangerous work to a successful conclusion in six weeks. Tab B further details the emergency response capability of the Commissioned Corps based upon actual experience since the late 1980's.

One special component of the Commissioned Corps (cited by Secretary Thompson in his May 9th testimony before the Senate Appropriations Committee, Subcommittee on Commerce, Justice, State, and the Judiciary) is the Commissioned Corps Readiness Force (CCRF), which was created by the Office of the Surgeon General in 1994 to improve the DHHS ability to respond to public health emergencies. The CCRF is a cadre of nearly 1500 PHS active duty officers who are uniquely qualified by virtue of their education, skills and experience to respond to public health emergencies, and who can be mobilized quickly for this purpose.

The Commissioned Corps is also a vital part of the Nation's emergency response capacity through its role with Disaster Medical Assistance Teams (DMATs), which consist of both federal and private sector personnel. One of these DMATs (PHS–1) is comprised primarily of Commissioned Corps Officers (approximately 80 percent). This team has been stationed at high profile national events to provide the initial public health response in the event of a bioterrorism incident.

In 1999 the first *National Symposium on Medical and Public Health Response to Bioterrorism* was held in Arlington, VA. During a panel discussion of a smallpox scenario, Mr. Jerome H. Hauer, then Director, Office of Emergency Management, New York City, stated that in the event of a smallpox outbreak in New York, he would require hundreds of investigators in the metropolitan area. In addition, he noted the requirement for personnel to provide smallpox vaccinations, observing that the vaccination process is complex, and the average health care provider is not trained in this area.

Mr. Hauer's needs can most certainly be met by the Commissioned Corps. With hundreds of public health professionals stationed within a short drive of New York City, a rapid response can be achieved. The variety of locations nationwide where Commissioned Corps officers are stationed permits the mobilization of a large number of Commissioned Corps officers anywhere in the country in a very short period of time. Furthermore, with some improvements to the administration and training

of the inactive reserve component of the Commissioned Corps (discussed below), an additional response capacity, or a backfill capacity, as circumstances require can be made available. The medical expertise also resides within the Commissioned Corps to staff alternate care facilities as needed (e.g. hospitals to handle small pox cases).

While the Commissioned Corps is currently the best available source of public health expertise, a few modest initiatives will make it even better. Some of the initiatives may require legislation, while others may simply require policy changes within the Department of Health and Human Services. Clearly, however, oversight from this Committee is crucial to ensure that the necessary steps are taken. The following are some of the actions that would enhance the ability of the Commissioned Corps to respond to a bioterrorism incident:

—*Clarification of the ability to mobilize the Commissioned Corps under a single operational control in the event of an incident involving a weapon of mass destruction.*—The Surgeon General, the uniformed leader of the Commissioned Corps, administers the Corps and as such is responsible for formulating Commissioned Corps policy. However, Commissioned Officers are assigned to agencies both within and outside the Department of Health and Human Services. This diversity in assignments is a clear advantage, and one of the great strengths of the Commissioned Corps. However, those agencies to which officers are assigned retain significant control over the work performed by their officers. There should be no question that the Surgeon General has authority to direct all PHS officers to respond to a bioterrorism incident, regardless of the agency to which the officers are assigned.

—*Provide additional training.*—The public health background these officers bring to the bioterrorism scenario is a significant advantage. However, it is important that, as in any specialized area, the officers receive ongoing training to develop/maintain their expertise.

—*Formalize the Inactive Reserve program.*—This issue was touched upon above. Unlike the inactive reserve components of the other services, the Commissioned Corps program has been run on an informal basis, with a somewhat loose affiliation by the members. Nearly all members of the PHS inactive reserve have served at least two years on active duty and thus are familiar with Federal programs and procedures. The potential of this program has been recognized by many in Congress, including the House Appropriations Committee that directed a study to ascertain the viability of establishing an Office of Reserve Coordination to administer the program. Without question the inactive reserve program, and public health in general, could be dramatically enhanced if even modest resources were committed to the maintenance of the reserve program and to the training and utilization of inactive reserve officers.

Once again, the Commissioned Officers Association very much appreciates this opportunity to submit its views to this distinguished Subcommittee. We look forward to addressing further details of these and other issues with you and the Subcommittee staff.

PREPARED STATEMENT OF THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

The Association of State and Territorial Health Officials (ASTHO) appreciates this opportunity to provide comments to the U.S. Senate Subcommittee on Labor, Health and Human Services, and Education Appropriations on public health preparedness particularly for potential terrorist attacks using biological or chemical agents.

ASTHO represents the state and territorial public health agencies of the U.S. states, the U.S. territories, and the District of Columbia. ASTHO's members are the chief executive officers of the health agencies of these jurisdictions. In response to the tragic events of September 11, ASTHO has established an Anti- terrorism Preparedness Task Force to provide expert information and advice on relevant preparedness policy and programmatic, and legislative priorities.

For years, public health professionals have identified the need for strengthening the United States' public health infrastructure as a major national issue. Public health surveillance capabilities provide an early warning system for our nation. However, challenges such as emerging infectious diseases continue to tax this system. The terrorist events of September 11 have further shown that disaster preparedness and strengthening the public health system's ability to identify and respond to such disasters must be a top national priority.

Within the past few days, members of Congress have proposed appropriations in excess of $1.6 billion to improve the nation's bioterrorism preparedness, with a major portion of those funds devoted to critical public health response programs

through state and local health agencies. We fully endorse this proposed allocation as a critical down payment for future vigilance against a tragic threat that is here to stay.

Ten days after the September 11th tragedies, ASTHO produced a special closed circuit satellite telecast to discuss public health infrastructure in the context of emergency preparedness. The conference, moderated by ASTHO's President Dr. Georges Benjamin of Maryland, featured presentations from state health commissioners in several of the affected states (E. Anne Peterson, MD, MPH, Virginia; George T. DiFernando, Jr., MD, MPH, New Jersey; and Robert S. Zimmerman, Jr., Pennsylvania); HHS Deputy Secretary Claude Allen; Jeffrey Koplan, MD, MPH, Director of the Centers for Disease Control and Prevention (CDC); and Elizabeth M. Duke, Ph.D., Acting Administrator of the Health Resources and Services Administration (HRSA). The discussion focused on the public health response to the terrorist events: the successes, challenges, and unresolved issues. Dr. Koplan listed seven critical areas of public health capacity that must be strengthened to ensure national preparedness against a biological or chemical threat:

(1) public health workforce;
(2) laboratory capacity;
(3) epidemiology and surveillance;
(4) secure and accessible information systems;
(5) communication;
(6) effective policy and evaluation; and
(7) preparedness and response capacity.

We believe these key areas are absolutely essential to preparedness planning and require additional resources to assure their availability. States are at different stages of preparedness in each of these seven critical areas. Therefore the states will have different priority needs.

In addition, resources and leadership are needed at the federal level to support state planning and coordination and development of a national strategy for preparedness. We encourage Congress to utilize and build upon the expertise, experience, and leadership that CDC has demonstrated in recent years in developing our nation's public health response to bioterrorism.

CRITICAL RESPONSE AREAS

Public health workforce

A well-trained, fully prepared public health workforce is the foundation of our public health system. The public health workforce includes a range of disciplines such as physicians, nurses, dentists, social workers, nutritionists, environmental health specialists, epidemiologists, veterinarians, laboratorians, health educators, disease investigators, and outreach workers. These professionals work to improve the public's health through prevention, education, research, and policy development.

The current public health workforce is not sufficiently trained to meet the growing needs of emerging infectious diseases, new vaccines, and more far-reaching prevention efforts, in addition to planning for potential threats of terrorism or emergencies such as a global pandemic influenza. A Status Report recently prepared by CDC on the Public Health's Infrastructure indicates that as of 1997, 78 percent of local health officers did not have graduate degrees in public health.[1] Moreover, many public health professionals lack opportunities for continuing education in their fields due to insufficient budgets, staff shortages, and proximity to education and training programs.[2] If we are to be fully prepared to respond, these trends must be reversed.

The Status Report also shows that the governmental portion of the public health workforce includes nearly 500,000 professionals deployed at the local, state, and national levels. With the increasingly complex patterns of disease, interventions, technology and partnerships; advanced education and training are becoming increasingly important.[3] At the same time, hiring freezes and low salaries have hindered the ability of health agencies to recruit and retain talented public health officials. The average tenure of a state health official is less than two years.

Laboratory capacity

Active surveillance depends on the ability of the public health laboratory to rapidly and accurately analyze and identify samples submitted to them for analysis. For example, in 1997, the Colorado State Public Health Laboratory was responsible

[1] A Status Report, "Public Health's Infrastructure" prepared for the Appropriations Committee of the United States Senate by the Department of Health and Human Services and the Centers for Disease Control and Prevention, 2000.
[2] Ibid.
[3] Ibid.

for determining that an outbreak of E. coli O157: H7 had occurred and that contaminated hamburger patties were the source of infection. Their rapid response prevented serious cases of hemolytic uremic syndrome that frequently result from this infection from occurring across the nation as a result of the largest recall of contaminated meat products in our nation's history.

Public health laboratories are ideally suited for the critical role of identifying biological agents. Unfortunately, some state public health laboratories are not equipped to detect the most likely biological agents such as anthrax and smallpox. State laboratory facilities need to be upgraded with appropriate equipment and trained personnel.

Laboratory personnel in all 50 states and territories should have access to advanced training in both the identification of bioterrorist agents, using the newest detection techniques, and in handling the agents safely. Responding to these issues is not a short-term proposition. Laboratory support for public health programs requires ongoing investment in new techniques, new equipment, methods development and documentation, staff training, and quality assurance procedures.

Another related issue pertains to the need to train hospital and private clinical laboratory personnel to recognize an unusual pathogen, a critical public health role in emergency preparedness. The importance of timely detection cannot be overemphasized. In the case of many biologic agents, the time lag between exposure to the pathogen and the onset of symptoms may vary from hours to weeks. An effective response will depend jointly on the ability of the clinician to identify and accurately diagnose an uncommon disease or toxic response and on a surveillance system for collecting and organizing information from clinicians and laboratories.

Three excellent programs currently exist within CDC to enhance laboratory capacity and coordination but not all states receive funding to support these efforts. ASTHO recommends enhancement of these programs: the Laboratory Response Network, the National Laboratory System, and the development of a Chemical Terrorism Preparedness program to include all states.

Epidemiology and surveillance

Epidemiology and surveillance programs of state health agencies detect outbreaks of common diseases or rare occurrences of unusual diseases. Epidemiological investigation determines when and where the exposure took place and whether cases are still occurring. To conduct such surveillance, state health agencies need adequate numbers of epidemiologists trained to recognize both natural and intentional events and to institute appropriate measures to control them.

In additional to trained personnel, there is also a need for electronic reporting capabilities. An electronic disease reporting system enhances state and local surveillance partnerships which are critical throughout the detection and response process. An electronic system would connect reporting entities, such as hospitals, private laboratories, physician offices and local health agencies with state and national public health officials. Such systems require not only technology but also support in the areas of technical support persons, hardware, and software.

Secure and accessible information systems

The ability to rapidly communicate with state and local health agencies is critical in responding to bioterrorist and infectious disease outbreaks. Rapid communication was an essential component of the coordinated response to the September 11 attacks in Virginia, New York, and Pennsylvania.

All states need state of the art computer systems with high speed Internet access. Satellites for distance learning are essential and videoconference capability is also greatly needed to improve the ability to disseminate information routinely and in the event of an emergency. Information is only as reliable as the data management that supports it. Upgrading information systems is an ongoing challenge. Many states' analyses of their data systems show major gaps in infrastructure. Weaknesses exist particularly in linking databases, in assuring the security necessary to increasing web applications, and in interactions with the provider community, the source of much public health data. Three systems have been developed by CDC to begin to address the aforementioned gaps; however, these systems are not fully implemented.

The first of these three systems, the Epidemic Information Exchange (Epi-X), was designed to instantly notify public health practitioners of urgent public health events and request assistance from CDC on- line. Epi-X assists bioterrorism preparedness efforts by providing a secure communication channel for public health officials. Future enhancements of the system include providing secure communications for multi-state outbreak-response teams, links between disease surveillance pro-

grams and the Health Alert Network, and improved software to automate the recognition of similar disease outbreaks across jurisdictions.

The National Electronic Disease Surveillance System (NEDSS) assists in the management of surveillance systems and allows the public health community to respond more quickly to public health threats. When completed, NEDSS will electronically integrate and link together a wide variety of surveillance activities and will facilitate more accurate and timely reporting of disease information to CDC and state and local health agencies. To accelerate NEDSS deployment, additional resources are needed to strengthen state data security infrastructure, fast-track the availability of the NEDSS Base System, and enhance NEDSS functionality at the state level.

The Health Alert Network serves as the backbone for the public health communication strategy developed by CDC. This network will ensure communications capacity at all local and state health agencies. The Health Alert Network was operational 24 hours per day, seven days per week during September 11 to September 28 to provide critical information to state and local health agencies about the response and recovery activities associated with the terrorist attacks. Additional resources are needed to accelerate the development, coordination, and full implementation of these systems.

Communication

The importance of effective communication in times of emergencies cannot be overstated. Just as states and local health agencies need effective information systems, they also need up to date information and appropriate messages to share. Health officials are on the front lines and their message and communication approach will not only coordinate response, but will also reassure a fearful public.

Communication channels must be established before an emergency takes place, and must be inclusive of all partners involved in the response. Rapid, reliable information and communication among federal, state, and local public heath authorities, health care delivery systems, police, firefighters, emergency management services (EMS), emergency personnel, and others is essential.

Effective policy and evaluation

The events of September 11 have served to increase our understanding of the need for sound public health policy. Issues of conflicting legislative and regulatory provisions across state lines could impede the ability of public health to respond to critical health needs in the event of a bioterrorist event. The ASTHO Task Force on Anti-terrorism Preparedness will help identify many of the specific issues encountered during the days after the tragic events and will be prepared to make recommendations as to policy and even legislative needs in this regard in the near future.

CDC, in partnership with ASTHO, the National Association of County and City Health Officials (NACCHO), the National Association of Local Boards of Health, the Public Health Foundation and the American Public Health Association, has developed the National Public Health Performance Standards Program. Three assessment tools have been designed specifically for state and local health agencies and local boards of health. These assessment tools provide performance measures by which the public health system, including public and private partners who contribute to the public's health, can be evaluated.

Specific to bioterrorism preparedness evaluation, the Bioterrorism Preparedness and Response Core Capacity Project, which is co-chaired by CDC, ASTHO and NACCHO, is in the process of identifying core capacities for bioterrorism and emergency response preparedness.

States also have taken steps to evaluate their public health systems. For example, Washington State has begun to assess how well prepared its public health system is to respond to a major public health threat or emergency. The state has developed and tested performance standards for the public health system, evaluating how well its 34 local health jurisdictions and state department of health can perform in five key areas of public health practice. The state has also established a baseline assessment of county-level preparedness capacities examining the processes, procedures, and relationships necessary to effectively detect and respond to public health emergencies. This is typical of the types of exercises underway in other states.

Preparedness and response

Successful preparation for weapons of mass destruction emergencies will depend on the development of a well-orchestrated plan to be used in responding to an event. The implementation of that plan will vary, depending on the nature of the attack. If the incident involves biological agents, public health officials as well as emergency room personnel and critical care unit personnel will be key players and first re-

sponders. If the incident involves chemical or explosive agents, public health officials would be complementary to the management of the emergency. Regardless of the nature of the attack, the responsibilities of public health officials will include identification of existing assets and assessment of needs, resource allocation for preparedness, stockpiling of supplies, medical training for treatment, and communication with the public.

Planning and coordination

Planning and coordination go hand in hand with all areas previously mentioned. If the response to a biological threat or chemical attack has not been well planned, it carries the potential of being ineffective. States are currently working to better define and test the roles of various entities, including local health agencies, state laboratories, emergency responders, hospitals, and others to establish policy to address unexpected events. Pre-emergency response planning forges better communications between public health and emergency response sectors, which in many states operate independently. Improvements in infrastructure made now to address the major elements of emergency preparedness planning can have immediate and lasting benefits.

Emergency planning for bioterrorism requires special emphasis on certain functions not normally included in disaster plans. Examples include special surveillance operations, delivery of vaccines and antimicrobial agents, and other mitigation efforts. The widespread nature of adverse health effects due to the disruption of critical human infrastructure will require the expansion of the typical disaster management team. Public health officials bring essential contributions to such strategic planning teams.

National strategy

There is sufficient crossover and concurrence in each of these seven areas to necessitate appropriate coordination at the national level. In the event of a bioterrorist event, the magnitude of the problem, essential treatment and prevention measures, and environmental impact are continually assessed. If an infectious agent is involved, public health officials may have to house ill individuals in isolation units in hospitals, or in make-shift facilities, attended by medical personnel who are protected by specialized clothing, or who have received advance immunization. Public health officials may also be forced to place a large number of individuals in quarantine and temporarily close large public gathering places and transport centers. Massive distribution of stockpiled vaccine and medical treatments such as antibiotics will also be necessary. Assurance of safe food and water supplies will be especially critical. These are just a few of the many issues that require a strong national strategy.

Addressing the threat of smallpox and anthrax

The threat of a terrorist attack using smallpox remains unlikely, but health officials recognize that it is prudent to be prepared. It is important to move as rapidly as possible to accelerate production of smallpox vaccine. In addition, a plan should be developed outlining the appropriate course of action in the event of a smallpox attack, including the use of vaccine. Planning and resource allocation must be undertaken to ensure that vaccine delivery and administration and other appropriate actions are immediate, efficient, and effective.

ASTHO makes this recommendation on the basis of the following assessments: (a) while the probability of such an event appears low, a smallpox attack by terrorists is nonetheless a credible possibility; (b) the threat of smallpox is a threat that we do have the ability to substantially mitigate or even abrogate through effective use of vaccine; (c) smallpox is a threat for which there are really no good alternatives to vaccination for effective response; and (d) smallpox is a threat that carries the potential for great harm and global spread if there is not an effective response.

ASTHO also encourages expeditious exploration of methods to provide protection to civilian populations in the event of terrorist use of anthrax. ASTHO encourages CDC to develop rational, reasonable, and balanced communications tools concerning smallpox and anthrax which are suitable for the general public and can be shared with all state health agencies. ASTHO encourages Congress to provide additional resources as needed to support these recommended activities.

Conclusions and closing recommendations

The Department of Health and Human Services, through CDC, has been leading the effort to upgrade national public health capabilities to address any potential bioterrorist event. CDC has initiated a cooperative agreement program for state and major local health agencies to help upgrade their capabilities. Eligible applicants can request support under the following five focus areas: Preparedness Planning

and Readiness Assessment; Surveillance and Epidemiology Capacity; Laboratory Capacity-Biologic Agents; Laboratory Capacity-Chemical Agents; and the Health Alert Network. These funds have enabled state and local health agencies to link and integrate their preparedness activities and local and county preparations for crisis and consequence management of a terrorist event. ASTHO commends the Congress for making these resources available. However, all states are not funded in all areas and additional resources are urgently needed to address the concerns outlined in this document.

ASTHO urges the Subcommittee to assure that:

—The federal government assumes an appropriate leadership role in strengthening the national public health infrastructure and capacity;

—The federal government makes the necessary resources available for public health workforce training, preparedness planning, and readiness assessment at the state and local health agency level to assist in the development and implementation of plans to address public health issues following a biologic or chemical terrorist attack;

—Public health agencies at the local, state and federal levels are sufficiently enhanced to detect, monitor, and contain disease outbreaks. Rapid detection of a biological attack can prevent a local epidemic from becoming a national epidemic;

—Sufficient resources are provided to develop medical counter-measures against a bioterrorist attack, including funding to speed up vaccine production and to stockpile antibiotics; and

—Our nation's hospitals are properly equipped and health professionals are properly trained to respond to bioterrorism.

The public health system is the vital link in our ability to preserve and protect human life when disaster strikes. Services we all count on must be present in the event of a major epidemic, a bioterrorism incident, exposure to a chemical hazard, radiological release or contamination of food and water supplies. We thank the Subcommittee for its understanding of the vital importance of a national policy and appropriate resources to strengthen public health's capacity to identify and respond to bioterrorist events, and its recognition that by doing so, public health's overall capacity to protect our nation's health and well-being will be enhanced.

We look forward to working with the Subcommittee to assure the availability of the critical funding needed to address each of these urgent issues.

Senator HARKIN. Before I turn to our first panel, I will yield to our distinguished ranking member, Senator Specter, for his opening remarks.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you very much, Mr. Chairman, and thank you for convening this important hearing, and for your leadership in this important field.

Earlier this week, I held town meetings at Cheney and Lincoln Universities in Pennsylvania, and one of the key topics on the minds of the students and faculty there was what would happen in the case of an attack by biological weapons or chemical weapons. It is obvious that there is great concern in America today with the potential for weapons of mass destruction.

When we have seen what the terrorists did on September 11, there is no doubt that they have the capacity and the evil to render unlimited damage on America to the maximum extent of their capabilities, and there is obvious concern that, as well-financed as they are, and as sophisticated as they are, that they may have biological and chemical weapons and other weapons of mass destruction, so this is a matter of the utmost urgency.

The issue is joined today with contrasting viewpoints, with Secretary of Health and Human Services Thompson being quoted earlier this week that the administration was: "very confident that we could act and react to any kind of bioterrorist breakout," and Sec-

retary Thompson insisting that the Government: "can handle any contingency right now."

One of our witnesses today is Dr. Steven Cantrill, of the Department of Emergency Medicine of the Denver Health Medical Center, who categorically disagrees, saying: "an additional concern is the illusion shared by many that our health care system could adequately deal with a significant weapons of mass destruction incident."

In this area, I must respectfully disagree with Secretary Thompson, and Dr. Cantrill goes on to say: "this problem would only be partially alleviated by dispatching Federal resources to a specific locale, and could be of no help if terrorism opted to involve dozens of metropolitan areas simultaneously."

This subcommittee has responded with almost doubling the funding for bioterrorism from 1999 through the projections for the year 2002. We find that there is again a fragmentation of our efforts among the Department of Health and Human Services, the Department of Justice, the Department of Energy, the EPA, and emergency response.

We now have a new leader coming into the field later this week, Governor Tom Ridge, announced as being the Secretary of Homeland Security, and now there are issues raised as to the scope of his authority, and a number of us are drafting legislation to try to put a number of the agencies and resources under his control, like Border Patrol, Coast Guard, Immigration, and Naturalization, and a significant hand in intelligence.

Just having an agency in the Federal Government analogous to the National Security Advisor raises very serious questions as to whether that is enough authority on this very, very important matter. In a testimonial to the importance of this issue, we have four distinguished U.S. Senators here today. That is the most Senators this subcommittee has drawn in the 21 years that I have been here, so we know, ipso facto, this is an important subject.

Mr. Chairman, while we are having this hearing, down the hall there is a Subcommittee on Constitutional Law hearing on terrorism legislation which is probably of equal importance to what we are hearing today, so I am going to be shuttling back and forth, but I do welcome our colleagues here today, Senators Kennedy, Frist, Hagel, and Edwards, and look forward to their testimony.

Thank you.

Senator HARKIN. Thank you. Now I would recognize the distinguished chairman of the full Appropriations Committee, Senator Byrd.

OPENING STATEMENT OF SENATOR ROBERT C. BYRD

Senator BYRD. Thank you, Mr. Chairman. Thank you for holding this hearing. This is a very important hearing. I have been saying in the Armed Services Committee for a long time that we had better be thinking about chemical and biological weapons being used against us. While I think that debate was with respect to a nuclear attack and how a missile shield is important, this is as important, if not more so. So I congratulate you on holding this hearing, and I congratulate the ranking member, and these four eminent Sen-

ators who are on authorizing committees that are very important in this battle.

I was just sitting here thinking about the nine plagues of Egypt. You recall, Moses sought to get the pharaoh to let our people go, and pharaoh was hard-nosed about it, so God threw Moses and these plagues upon Egypt. There were nine of them. Let me see if I can remember them in sequence. First was blood, the rivers turned to blood—you can write it down and check me.

Blood, frogs, lice, flies, cattle, boils, hail, locusts, and darkness, nine plagues, so to translate that into today's language, and into today's modern life, that would be, I suppose, biological warfare in that day.

I am concerned about biological warfare. Unlike an explosion, a cloud of microbes released from a small plane would not trigger alarm like dropping a bomb. Many of the initial symptoms in humans could first be mistaken as an ordinary cold or the flu.

Most public health departments don't even have computers to track diseases, and yet several of the most dangerous biological warfare agents, plague, anthrax, and others, respond to antibiotics, so quick detection of an outbreak and rapid availability of drugs could save numerous lives. It is critical that adequate supplies of drugs be available, and that plans exist for their efficient distribution.

Are we ready? We might ask the Secretary when he comes. I may not be here at that time. I am trying to get these appropriations bills moving, Senator Kennedy. It is like moving a stone uphill, but Sisyphus kept trying, and so I will continue to try.

Unfortunately, public health experts believe that the Nation is currently tens of millions of vaccine doses short to effectively defend against a biological attack, and stockpiles of antibiotics and other medicine are inadequate. Just go over to Fairfax Hospital and look at the emergency room. I took my wife over there just a while back. She had pneumonia—we did not know it was pneumonia—then atrial fibrillation. She was in that emergency room all day, and I was right there with her. They cannot handle it. We do not have the infrastructure to handle the crowds that come to these hospitals.

Fairfax Hospital is a great hospital. But they do not have the infrastructure. Hospitals have reduced in-patient care in recent years. They are unprepared to handle large numbers of critically ill patients. If you have not been there, go over to Fairfax Hospital or any of the other hospitals in the area. Go to the emergency rooms. That is where we are likely to go, those of us who are past 80. You have got a long time to wait.

But the administration's belief is that Osama bin Laden and his Al Qaeda network may already have the means to use chemical and biological agents as terror weapons. A Department of Defense report released in January of 2001 indicated that Iraq, Iran, Syria, Sudan, and Libya all have active chemical or biological weapons programs.

Now, Mr. Chairman, that completes my statement. Thank you for conducting this exercise. We're both on appropriations, and so is Mr. Specter, and the Senators here who are on the authorizing committees will be talking with us about appropriating. There is no

more important problem facing us as appropriators, or as authorizers, than this one. Enough said.

Thank you.

Senator HARKIN. Mr. Chairman, you really put it succinctly, and we appreciate you being here and thank you for your leadership on the full committee in this effort. I know I can speak from having served on this committee now for 17 years, that I know we can look to you for the guidance and the leadership necessary to put the funds out there to make sure we meet this emerging national threat, and we thank you for your leadership in this area.

As our chairman said, as appropriators we look to our authorizers for guidance on how we spend this money. Regarding the $20 billion, we look to our authorizers to give us guidance and direction. We turn now to our distinguished first panel with those authorizers, and first I would recognize Senator Kennedy from Massachusetts.

Senator Kennedy, along with Senator Frist, introduced the legislation last year which was the Public Health Threats and Emergencies Act. It was passed and signed into law, and basically was the first step to building up our first line of defense and our basic infrastructure. Senator Kennedy and Senator Frist, I want to applaud both of you for being way ahead of the curve on this. You had the foresight to do it.

So Senator Byrd, I would just say we do have some basic legislation right now, thanks to Senator Kennedy and Senator Frist, to which we can look for the guidance on where we would want to put this money to build up that basic infrastructure.

With that, I want to thank both of you, and we will go in order of seniority, and I will recognize Senator Kennedy first.

STATEMENT OF HON. EDWARD M. KENNEDY, U.S. SENATOR FROM MASSACHUSETTS

Senator KENNEDY. Thank you very much, Mr. Chairman. If I could I'd like to submit my full statement in the record. I know the committee has a full schedule, so we will not take an undue amount of time.

First of all, I want to thank this committee for their superb statements that have been made this morning. This is a committee that has responsibility for allocating resources, and it is quite clear, not only from the statements this morning but also the actions that have been taken in the past, particularly in terms of the support for the research and the development of various vaccines and antibiotics, that this committee has been ahead of the curve. That is why we particularly appreciate the chance to work with the committee in terms of ensuring that we are going to have adequate resources to try and meet our responsibilities to the American people.

I want to first of all thank my colleague, Senator Frist, and my other colleagues as well, Senators Edwards and Hagel. Senator Frist and I embarked on a series of hearings in 1998 on this subject matter, and into 1999, and developed the legislation in 1999, and then passed it last year, and we have worked very closely together. It represented our best judgment and the judgment of the committee, and I enjoyed working with him.

While we worked very closely on this legislation and will continue to do so, I thank Senator Edwards and Senator Hagel. They have given with their legislation an additional component in dealing with the agricultural challenge. That was not dealt with in our committee. We did not include it, but we noted it, and it is an extremely important aspect which they will speak to, as well as to their sense of the importance of the legislation.

I want to also thank Secretary Thompson. He has been designated as the principal lead person for the administration. I have spent time with Secretary Thompson. He is very familiar with the General Accounting Office review, as well as other reviews about the inadequacies of our system, and the GAO has pointed out that there needed to be a great deal more coordination. There was fragmentation between the various agencies. He is addressing that issue. You will have more of a chance to get into that question. Also the GAO talks about the various gaps in our system, and I know you will hear from him on this issue. We address a number of those components that have been outlined in the GAO report, and that is why we are glad to be here.

As has been mentioned here, the September 11 terrorist attack indicates that we may very well face a different kind of attack in the future, and we are here to mention very briefly at least how we believe the focus and attention of resources ought to be focused.

First of all, we want to emphasize the area of prevention. The best way to assure the health and well-being of our citizens is to prevent a bioterrorist attack. That is going to be done as part of the administration's overall efforts in terms of the intelligence-gathering, information-gathering, the penetration of these various cells, as well as penetrating the free flow of resources that are going to various terrorist activity. That kind of aspect is underway at the present time, and it is something that is outside of what we are going to talk about, but it is of enormous importance.

Second, we take note that as there has been the development of weapons of mass destruction, both biological and chemical, the principal source of the storage of this material is in the former Soviet Union. As we have made important progress with the former Soviet Union in terms of the storage of nuclear material, we are very hopeful that the administration is working on assuring that we are going to have adequate storage in the former Soviet Union with regards to biological weapons. Also the scientists and researchers that are very much involved in the development of that program, and a similar kind of a program that has been worked on in the Nunn-Lugar proposal, could also have application here. Those are issues for another time, but they are, we believe, of importance.

The three items that I want to mention is, first, the issues of detection, second, the issues of treatment, and third, the issues of containment. This chart, which is difficult to read, Mr. Chairman, and then my colleague, Senator Frist, will go into greater details regarding how these particular features can be addressed in terms of the appropriations.

The first item, in order to have detection of any attack, is improving the State and local disease surveillance. This is primarily the public health system. You will see that reflected in the high

priorities we give to the public health system. That has been also a deficient area which has been identified by the GAO.

We have not addressed again the issue of food safety. Secretary Thompson will. Again, we have a small part of food safety in our committee. Most of that is in the Agriculture Committee. The chairman of the committee is very familiar with this issue, but that is an important part of it.

Next is the upgrading of the capacity of laboratories to identify biological weapons. There has to be an upgrading at the local level in terms of detection. That can be done in some parts of our country. Where it is being done, they have the ultimate in terms of the cutting edge technologies. We ought to make sure that those kinds of technologies are going to be available to communities all over the country.

The first line of defense is going to be in our public health system. Our proposal, then, is to improve the detection of an attack.

Second, our proposal will improve the treatment for victims of an attack. This comes by improving the ability of our hospitals to increase their emergency capacity. As Senator Byrd and others have pointed out, we have seen a contraction in the number of hospitals. That has been true in urban areas, it has been true in rural areas. We have gone in my own State of Massachusetts from 132 hospitals to 84 hospitals over the period of the last 5 years, and we know that in many of the urban areas people wait out in the corridors, even to go into the emergency rooms.

This is going to be called upon as the first order of priority. There are a number of different ways that their assets can be extended. There is good planning in a number of our great medical centers about how to do that. We ought to share that information, but we ought to now have the kind of investment that permits them to do this in very short order. That is a feature of our proposal.

Next is the development and enhancing of local and Federal medical response. This also includes training. Senator Frist, and many of us have heard him speak on this, will mention that in all the times he has been a doctor, in 25 years, he has not been able to detect smallpox, or has not had smallpox in front of him. We have to make sure we are going to have the training for the personnel to be able to detect this. This is training health professionals to diagnose and treat the victims of a bioterrorist attack.

Finally, our proposal will improve the containment of an attack by providing better vaccines to limit the spread of infection, by improving the national pharmaceutical stockpile, and by increasing research in medications. You will have an opportunity to hear from the top of our research community. They can give you different guidance as to what needs help and support, and there are a variety of different undertakings even at the present time, but as we understand right at the outset, most of those products do not have a private market. It is going to take an investment by the Federal Government, and the Federal Government is going to have to invest in terms of stockpiling those products.

Finally, I would like to just say, Mr. Chairman, the administration has approximately $350 to $400 million in their budget. Our budget recommendation is for an additional $1.4 billion. That

comes to about $1.8 billion. In terms of our recommendations this amounts now to about a sixfold increase. Money is not the answer to everything. We think that this is a prudent and reasonable kind of investment that can at least start us down the road to meet our first responsibilities.

The final point I would like to mention, Mr. Chairman, I would hope as a Nation that we are not going to be frightened by this prospect. I think that that would be very, very dangerous. We know that there are individuals that are taking action, as has been pointed out. This is a national responsibility, and we would hope that you are going to deal with it in a responsible way, a serious way, and a way that underlines the importance of preparation.

PREPARED STATEMENT

Some steps have been taken, other steps are needed, more steps are needed, a greater investment is needed, but the American people ought to understand this is serious. It is dangerous, but at least we have an understanding about what needs to be done in the very early stages of it, and that hopefully this committee and the Congress are prepared to make the kind of investment that is going to be a meaningful down payment to give the kind of protection the American people deserve.

[The statement follows:]

PREPARED STATEMENT OF SENATOR EDWARD M. KENNEDY

Thank you, Senator Harkin, and thank you also Senator Specter for holding today's hearing on this topic of special importance—improving the nation's preparedness for bioterrorism. Your own leadership in providing resources for public health and medical research has already done a great deal to strengthen the nation's preparedness to meet this challenge. It's a privilege to be here today with Senator Frist.

September 11th was a turning point in America's history. For two centuries, the continental United States was spared from foreign attack. The vicious air attacks of September 11th shattered that security. In the aftermath, we must clearly strengthen our ability to defend the American people against all forms of terrorist attacks.

One of the most destructive ways an enemy could attack the nation would be to use a biological weapon. The difficulty of mounting a biological attack has given the nation a reprieve—but none of us knows how long that reprieve will last.

Over the past two years, Senator Frist and I have held hearings on the dangers of bioterrorism. As we learned at those hearings, a biological weapon could unleash destruction on a very broad scale, and we need to be better prepared. A substantially increased investment must be a major part of the nation's response, and I am confident this committee will provide it. This investment is a sound price to pay for the greater security it will bring to every American and every community in the nation.

Our first priority must be to prevent an attack from ever occurring, and we are moving quickly to strengthen our intelligence capacity and take other needed steps to do so.

We also need to work with nations that have stocks of dangerous biological agents to ensure that they do not fall into the hands of terrorists. Russia currently holds the largest supply of potential biological weapons. I've spoken with Secretary Thompson about the situation in Russia, and I believe there's a real opportunity to make progress in securing and destroying these dangerous biological materials. We've worked with Russia on containing nuclear weapons. Now we must work together on preventing the spread of biological weapons.

But we must also enhance our preparedness for a bioterrorist attack. Americans need not live their lives in fear of a biological attack, but building strong defenses is the right thing to do.

If a bioterrorist attack does occur, the keys to responding effectively lie in three key concepts: immediate detection, immediate treatment and immediate containment.

Unlike the assaults on New York and Washington, a biological attack would not be accompanied by explosions and police sirens. Instead, terrorists could release a lethal bioweapon in a crowded shopping mall or subway station. They might expose millions to the deadly microbes by spraying a biological weapon over a city.

In the days that followed, victims of emergency room, complaining of mild fevers, aches in the joints or perhaps a sore throat. Doctors need to be well aware of the symptoms of a bioterrorist attack, or precious hours will be lost as doctors try to diagnose their patients.

In Boston, a recently installed electronic communication system would allow physicians to report unusual symptoms rapidly to local health officials so that an epidemic could be identified quickly. Too often, however, as a CDC report has stated: "Global travel and commerce can move microbes around the world at jet speed, yet our public health surveillance systems still rely on a 'Pony Express' system of paper-based reporting and telephone calls."

In addition, public health laboratories need the training, the equipment and the personnel to identify anthrax, plague, smallpox or other potential biological weapons as quickly as possible.

Emergency care facilities will also be essential. Boston, New York and a few other communities have plans to convert National Guard armories and other public buildings into temporary medical facilities, and other communities need to be well prepared too. Even cities with extensive plans need more resources to ensure that those plans will be effective when they are needed.

It has been an honor to work with Senator Frist on legislation to enhance the country's preparedness for bioterrorism. Congress enacted that initial legislation last November, and it has already served one of its intended purposes. That legislation gave the Secretary of HHS the authority to act decisively to protect the public health during a bioterrorist attack or other health emergency. Secretary Thompson used this new authority wisely to send medical supplies and personnel to New York, where they were so urgently needed, and I commend him for his prompt and effective action.

To improve detection, treatment and containment of a bioterrorist attack at the state and local level, the legislation authorized investments in disease surveillance, food safety, and new research initiatives to diagnose such attacks. The Act also called for new investments in hospital preparedness, so that medical facilities will have the planning and resources needed to assist victims. To improve containment, the legislation called for federal supplies of vaccines and antibiotics to be available quickly to assist local public health officials in containing an epidemic. Federal stockpiles of vaccines and antibiotics will be essential to contain any outbreak and save lives.

Under the leadership of Secretary Thompson and Secretary Shalala, much has been done to improve the nation's readiness. We are better prepared now, but we need to be even more prepared. Senator Frist and I look forward to working with our colleagues on this committee and in Congress to achieve these extremely important goals.

Senator HARKIN. Senator Kennedy, thank you for your very, very strong statement, and thank you for your leadership on this issue in getting the legislation passed last year.

Now we turn to the cosponsor of that legislation, who has been a great source of information and guidance for all of us here in the Senate because of his strong medical background, and that is Senator Frist from Tennessee.

STATEMENT OF HON. BILL FRIST, U.S. SENATOR FROM TENNESSEE

Senator FRIST. Thank you, Senators Harkin, Specter, and colleagues for holding this hearing on what is a pressing challenge for us all, and one of the most disturbing issues of our time, given the events of September 11, and that is the threat of germ weapons being used by terrorists.

Let me open by saying we are all walking a fine line in terms of both the potential for being alarmist, and at the same time lay-

ing out the information that is important for us to recognize in terms of our vulnerability as a Nation and as a people. The threat is real. There is no question about that. The overall probability is low. Nobody can give a number. There is uncertainty around the number, but it is low, yet is increasing. Given the events of September 11, I believe that it is increasing quite dramatically.

Bioweapons, germ weapons have huge consequence, much, much further than anything than we have ever seen in recent humanity, where we are talking about the potential destruction of millions, not thousands, not hundreds, not tens, and we are highly vulnerable. Again that is where we have to be very careful in terms of saying how vulnerable are we, but we are vulnerable not because we are unprepared today, and we will hear over the course of the day that in many ways we are very, very prepared, and have made tremendous progress, but that we are underprepared, and that there are certain gaps that we have a responsibility at this juncture to address.

We will hear a lot from respected experts a little bit later in the subsequent panels, but I think the message that I would like to leave is the following, and that is that as Nation, with respect to germ weapons in the hands of terrorists whose stated goal, and we know that today, and we did not know that quite as well a year ago, whose stated goal is to cripple the United States of America, that we are vulnerable not because we are unprepared, but because we are underprepared, and it is our responsibility to identify those gaps and to fill those gaps, to reduce that vulnerability.

Now, if our goal is to eliminate those gaps, it is important for this particular committee to address which gaps are significant, and in doing that, I would encourage you to look at least at what we started with in 1999, as Senator Kennedy laid out, and that is the Public Health Threats and Emergencies Act of 2000, because our specific purpose at that point in time was to develop a strategy and a framework that reflects coherency and comprehensiveness in terms of a national defense policy.

It does this in addressing three different areas. One is prevention. Senator Kennedy spoke to the importance of that. The second is preparedness, how ready are we, and what is the responsibility there, and then the response, and these can be looked at discretely, but clearly work in an interrelated fashion.

Why do I say the threat is increasing? Why do we act now, and why do we put such figures as $1.4 billion in addition now? The threat is increasing. If we look, Osama bin Laden has had public pronouncements that acquisition of biological and biochemical weapons of mass destruction are a religious duty of his. We know that now. We have not focused on it, but we know that now.

Coupled with that is that just 3 weeks ago he used something we had never thought about as a weapons of mass destruction, and that is an airplane loaded with fuel. He has the money, again something new. We know that he has money, and we know that technology is out there, available.

Senator Kennedy mentioned that during the 1980's the Soviet Union for that whole decade has more than 7,000 scientists working full-time on developing bio weapons that could be used for destructive purposes.

Second, the threat has increased because of technology, and you will hear different people in the third panel talking about the technology there. Let me just say, from a hospital standpoint we use nebulizers all the time—we did not have them 15 years ago—to aerosolize sprays. Perfumes are being aerosolized all the time. We know that from department stores. The aerosolization is just an example of how increasing technology has made it possible to distribute and deliver these biochemical, biological weapons, these germs in a way that just was not possible 10 years ago or 15 years ago.

The third issue is that issue which Senator Kennedy mentioned, is that the expertise is out there, there is no question about it. Even since the 1980's the science, in terms of genetic recombinant issues, genetic engineering, it is there today, and if it is not there today, it will be there within 6 months or a year. In certain areas the expertise is out there. It is out there probably to the highest bidder.

What we have done is propose an additional $1.4 billion specifically, not to cover everything, but when you look at some of the list you will say, you are all over the place. But look at the original framework of prevention, preparedness, and response, and you will see that we are really putting that increased funding where gaps have been identified.

We will hear again differing opinions about how prepared are we at the Federal level. In certain areas, we are very prepared, but without that local front line surge capacity at the hospitals, physicians who can recognize that rash which they have never seen, or never been trained to recognize before, or that cough, or that flu illness coming in being presented, out of the last thousand cases you have seen zero pneumonic plague, or pneumonic anthrax, to raise that bar up, if you cannot recognize it and detect it in an expeditious way, no matter how good the Federal response is, no matter how much money is spent at the Federal level, unless you have this vertical integration of Federal, State, and local coordination, it does not do any good. It does not do any good.

Now, very quickly—and again, we do not need to go through what we have done overall, but regarding prevention, there are three areas. First, regarding intelligence, we have got to know who has access to things such as smallpox, anthrax, the more naturally occurring things like tularemia, and the nerve toxins that are out there.

The issue of food has been mentioned and must be mentioned once again, and there are many people who think, we all know, we have underinvested in food safety. We have fewer than 1,000 inspectors, 56,000 sites out there where we need to be doing inspections. We only inspect about 1 percent of the food that is imported into this country. We have underinvested in the past, and you will hear more about that today. It absolutely must be addressed.

The third area as we look at prevention is this whole area of research. If we do not have a cure for smallpox, and smallpox has a 40 percent mortality rate today, and if we do not have a cure for that, we do have to invest in research so that we will have antiviral therapy. Anthrax has a 100 percent mortality rate if untreated, and as Senator Byrd pointed out, it has to be treated in

the first 24 hours, so you have to be able to detect it—after 24 hours. We don't know that the vaccines that we have today are going to be entirely as good as we think, and we need a second generation that will have the advantages that we know will protect.

The second issue of preparedness, again I do not need to go into too much, because we hear a lot about it at the Federal level. At the Federal level we are doing very well, I think, compared to 3 years ago. We can clearly do more. Most of the bulk of the funding of the more than $1 billion that we are saying should be put into the system is at the State and local level of preparedness, looking at medical surveillance, looking at medical epidemiology, addressing the issues of fax machines, Internet connections, so when one public health institution or unit identifies a rash which they suspect to be something, they can at least communicate broadly.

The last area—and we will hear more about stockpiling, I want to mention is this issue of stockpiling again. We have done very well. We hear about how well we have done, but clearly we have a long way to go in terms of having an adequate response at the stockpiling level. We have specific funding in for that stockpiling, and to improve that stockpiling so we can really give the security to the American people that they deserve.

In closing, let me just say that I think our most significant failure in this country as we look at this coherent strategy of prevention, of preparedness and response, is the lack of investment in our public health infrastructure. Our public health infrastructure is the front line. Without the front line, nothing else can click. Nothing else can work. That is the huge gap that we have underinvested in.

The good news about it, it is dual use. If we do not ever, and I pray that we do not ever see a chemical or bioterrorist attack in the United States, if we never see that, it is dual use investment, because at the same time you are investing in that public health infrastructure you are addressing the potential for a flu outbreak, a flu epidemic, better treatment for HIV and AIDS, and the other viral illnesses are out there.

PREPARED STATEMENT

Mr. Chairman, we sort of laid a template in the bill that we put forth last year that is now the law of the land. I would encourage this committee to use that as part of a coherent strategy as we go forward, in view of what I would argue is an increased threat of a bioterrorist attack. I think that we now need to identify those peculiar gaps that are out there, mainly at the State and at the local level, fill those gaps, and by doing that we will move from our underprepared state to a prepared state.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF SENATOR BILL FRIST

Thank you, Senators Harkin and Specter, for calling today's hearing on one of the most pressing and disturbing issues of our time—the threat of germ weapons used by terrorists. That threat is real. Although the threat has low probability, I would argue strongly that there is an increasing probability—with huge consequences. Today, we remain highly vulnerable.

You will hear from respected experts on these particular issues shortly. I will focus my comments on the following simple message: As a nation, with respect to biological weapons, we remain highly vulnerable, not because we are unprepared, but because we are under-prepared.

You will hear shortly from Secretary Thompson about the tremendous advances made by the Department of Health and Human Services over the past three years. Although we have made significant progress, there are still large gaps in our current approach. Our goal should be to eliminate these gaps and reduce the risk to our nation and our people.

Part of the progress that has been made is tied to crucial legislation—the Frist-Kennedy "Public Health Threats and Emergencies Act of 2000," a law which provides the strategy and framework for a coherent national biodefense policy. This bill addresses bioterrorism from three discrete but interdependent vantage points—prevention, maximizing our preparedness, and response.

With this framework in place, we can identify shortcomings within our ability to prevent, to prepare, and to respond. As a critical first step, Senator Kennedy and I are strongly recommending today that Congress work together with the Administration to provide sufficient funding for the priorities specifically established in the Public Health Threats and Emergencies Act. Just a few months ago, Senator Kennedy and I wrote the members of this Committee earlier this year, requesting full funding for our legislation. Today, we outline what additional steps should be taken in light of the September 11 attacks.

The threat of a bioterrorist attack is still remote, but it is higher today for a variety of reasons. First, Osama bin Laden has publicly pronounced that it is his religious duty to acquire weapons of mass destruction, including chemical and biological weapons. He has shown his disregard of human life, using weapons of mass destruction that we had never envisioned. Furthermore, he has the resources and motivation to use germ warfare.

Additionally, the threat is increased because of the recent scientific and technological advances. Rapid advances in agent delivery technology such as aerosolization have made weaponization of germs, such as anthrax, much easier. Finally, the expertise of scientists expert in germ warfare is available. Through the 1980s, over 7,000 scientists in the Soviet Union were part of a committed program to create and maximize the effectiveness of bioweapons. With the fall of the Soviet Union, these experts are unemployed and soliciting their expertise around the world.

Now that we are all aware of this potential threat, we must concentrate on our response and invest approximately $1.4 billion specifically to fill the gaps in our current biodefense and surveillance system. We must take necessary actions to prevent the use of bioweapons, prepare our communities, and improve our capacity to respond. We have shared these documents with the subcommittee and I ask that these documents be included in the record following my statement.

PREVENTION

Our first national priority must be enhanced on-the-ground intelligence to know who has access to and is capable of deploying biochemical agents, which will require increased investment for general intelligence capabilities. Much of that work is already being done within the Department of Defense, in an effort to significantly increase our human intelligence capabilities. Within the Department of Health and Human Services, however, we must increase international surveillance and cooperation activities. With this investment, we can enhance our intelligence capabilities to monitor other country's bioterrorism capabilities; improve coordination of international surveillance activities; and reduce threats posed by the former Soviet Union.

Bioterrorism has been successfully used only one time in our country and that was in 1984 in Oregon—and the method of delivery was food. We have under-invested in food safety. Less than 1 percent of all food imports are properly inspected. We have fewer than a thousand food inspectors expected to oversee 56,000 food sites. Given that two of the major biochemical agents—anthrax and tularemia—as well as a large number of disease-producing organisms may be transmitted through the food supply, we absolutely must do more to ensure the safety of our food.

Finally, for those likely bioterrorist agents for which we have no treatment and for those infections for which we have inadequate vaccines, we must invest in research. Specifically, we need anti-viral therapies for smallpox and newer, improved and more powerful versions of an anthrax vaccine.

PREPAREDNESS

Even if we do all that we can to prevent a bioterrorism attack, our preparedness will ultimately define the impact if such an attack were to occur. Therefore, our proposal to bolster preparedness includes what we must do, and if implemented properly, will ensure that we are perched and ready to respond at every level—federal, state and local.

As GAO reported last week, we must strengthen and better coordinate our federal bio- response program. As Secretary Thompson has stated, the federal government has already done a lot. We have a rapid response team of over 7000 health care providers for medical emergencies. We can deploy truckloads of therapeutics and medical supplies in "12 Hour Push Packages"—the key component of the National Pharmaceutical Stockpile. However, we must do more to strengthen our resources. Currently, the stockpile has enough antibiotics to give complete prophylaxis to 2 million people after an anthrax exposure, but that number is not large enough. To expand the contents and number of the push packages as well as increase our drug and vaccine inventories, we are asking for a doubling of the amount currently being spent to supply and support the national stockpile.

However, the federal preparedness is not sufficient unless our state and local agencies are also prepared. Unfortunately, our local preparedness is severely lacking today because it is inadequately underfunded. We have allowed our public health system—the front line of our defense—to deteriorate over the past 20 years. We must buttress our local response by upgrading local and state medical surveillance epidemiology; assuring adequate staffing and training of health professionals to diagnose and care for victims of bioterrorism; and improving our public health laboratories, many of which simply are not equipped to efficiently diagnose infections and other diseases associated with biochemical weapons. Finally, we must ensure that local entities are prepared to cope with the early situation—from recognition through diagnosis and initiation of treatment, until federal assistance in the form of push packages and other assistance can arrive.

For all of these reasons, most of the funding in our proposal almost $1 billion—is directed to improve our state and local responsiveness, and this investment will take a few years to fully implement.

RESPONSE

Once preparedness is maximized, the key to response and mitigation of disaster rests principally with coordination and seamless crisis management. Therefore, our proposal ensures that we have the plans and resources developed for an appropriate response by ensuring adequate health care personnel and hospital preparedness. We must improve our disaster response medical systems, including strengthening the National Disaster Medical System, the Metropolitan Medical Response System, and the Epidemic Intelligence Service.

Hospitals will be the natural destination for those who are victims of a bioterrorist attack and for those who seek relief from fear. However, only one in five hospitals have developed a plan for such a calamity. They are ill-prepared for the resulting surge capacity. We must ensure that local hospitals are equipped to provide appropriate crisis management structures—by ensuring that every hospital not only has a plan for dealing with a bioterrorist attack but also has appropriate surge capacity, decontamination units, and necessary supplies for the immediate needs. With all of the proposed preparation, we will be able to respond by implementing our detailed plans of action, deploying appropriately trained health care professionals and resources to care for thousands of individuals who will seek care, and providing up-to-date information regarding risk reduction.

One of the marvelous things about this particular investment is its dual use—not just preparing for a rapid response to in the event of germ warfare but also strengthening a system that every single day contributes to the improved health of all Americans. Now is the time to strengthen our public health system and ensure that we can adequately prepare for and respond to potential bioterrorist attacks, natural infectious disease outbreaks, or other challenges to the public health.

I commend the Administration for taking steps to address bioterrorism by not only increasing funding before the attacks of September 11, but also assigning Governor Ridge as the primary federal coordinator of such activities.

The Frist-Kennedy Public Health Threats and Emergencies Act provides the appropriate framework for a comprehensive biodefense plan. Now is the time to fund this authorizing legislation. In view of the increased risks of a bioterrorist attack, we must act now to fill the gaps we have identified—gaps that if allowed to persist debilitate our response—and to move us from the under-prepared to the appropriately prepared state.

Senator HARKIN. Thank you very much, Senator Frist, and Senator Kennedy.

Just as a postscript, Senator Frist, I was back home this last weekend, and a friend of mine who is a doctor in Des Moines came up to me and said, how am I supposed to recognize it? He said, I have never been trained to recognize anthrax. He said, we need help out here to start to recognize it. That is one of the points you just made there. We need to get that information out and training out at the local level, so I appreciate your comments. This just happened to me this last weekend.

I am now going to move to Senator Hagel and Senator Edwards, who just introduced new legislation, and I recognize the time constraints and how busy our Senators are, Senator Kennedy, Senator Frist, and please stay if you would like, but if you would like to leave, we would excuse you at this time.

Senator BYRD. Mr. Chairman, in the event that these two Senators need to leave, they mentioned a figure of $1.4 billion. How did you arrive at the $1.4 billion? How do you break that down, and how much of that needs to be appropriated immediately? Can it be broken down into phases that would help us to better understand it? I do not know how we can spend $1.4 billion better than in this very exercise here.

Senator KENNEDY. Quickly, Senator, half of it is, as Senator Frist pointed out, for our public health services. Those resources will be invested in the States. That is the front line. That is on the basis of figures estimated by the public health service, and the particular organizations, the Public Health Laboratories, for example. This is basically how we got it, and it was rather a lean budget on that.

You will find about another quarter or so of it is for the hospitals in terms of developing outreach programs, and the remaining third are listed here, and cover a number of the different kinds of programs that Senator Frist pointed out in terms of surveillance, the development of various vaccines, and the storage and purchase of those programs. This breakdown which is a part of our testimony is an activity sheet where we give the figures, the allocations of the $1.4 billion to each of probably 10 different initiatives, and we will be glad to submit to the committee the additional kinds of support for each of those.

There are some provisions that are not on there. Food protection is not on here. The agricultural aspects are not on here. There is not a program on here, although the Secretary will probably talk about it, like the Nunn-Lugar programs, in order to try to do something over in the former Soviet Union in terms of the employment of some of those scientists, so those elements are not on here and probably may have to be added. but this is really the public health aspect of the program, and we have submitted it, and we will be glad to work with the staffs of the committee to give the particular justification.

Senator FRIST. Mr. Chairman, could I just add to that very briefly? The documents from this chart should be made a part of the record, and should be before you. There are certain elements up here, and you see that $635 million of the $1.4 billion is for State and local preparedness capabilities. We absolutely must address that particular issue. Some of the $635 million could be multiyear.

It needs to be made available now, but it could be multiyear in terms of the way it is carried forth.

What we have done is looked at what is needed and backed it forward, recognizing that we see this increased risk. If you go down that list, the second area, improving hospital response capabilities, the $295 million, it is important that it be addressed. We would recommend that it be provided this year. To carry out that program fully will take 2 to 3 years. Our staff will be working with the committee staff, because as you go down that list there are a few things on there that could be multiyear. It does not have to all be right now. If it is right now, we will obviously be able to go from an unprepared to a prepared state.

Senator BYRD. Thank you.

Senator HARKIN. Mr. Chairman, since I have got your attention on this, we mentioned food safety, and I would like to just give you these figures. You might think about them, and you can write them down.

Senator BYRD. My problem is, I cannot write. I cannot read my own writing after I get it down.

Senator HARKIN. I have the same problem.

Senator BYRD. That is why I do not play the violin any more.

Senator HARKIN. That is a loss, because I have heard you play the violin in the past. But I want to give you these figures about food safety, and I have been harping on this for sometime. Last year, USDA received $712 million to inspect 6,000 meat, poultry, egg product and import establishments. So they got $712 million to inspect 6,000 establishments. FDA received $260 million, one-third as much, to inspect 57,000 food establishments and over 9,000 animal, drug and feed establishments, as well as a majority of food imported into the United States.

Of the 7,000 food-borne illnesses that we detected, 85 percent were linked to foods regulated by FDA. We have a gaping hole out there in our food safety, especially in terms of the importation of foods into this country. We just have a big, gaping hole there, and we have got to fill that. I would hope that we would look at some of that $1.4 billion in terms of that, and getting to the FDA and giving them the resources they need to do these inspections.

Senator DURBIN. Mr. Chairman, if I could just comment on that very briefly, one issue that I have been focused on is putting together one science-driven food safety inspection agency. We now have 12 different Federal agencies involved in food safety inspection, and 35 different laws. Senator Frist and Senator Kennedy, thanks for raising this issue.

Next week, on October 10, we are going to have a hearing in the Government Affairs Committee that is going to focus on food safety and security. Believe me, this is a big undertaking, to finally harmonize this, and I look forward to working with you in trying to make sure we do the right thing.

Senator HARKIN. You have a been a leader on that, and we appreciate it, and we do need one central food agency. It is all spread out now. We need one agency to look at food safety in this country, and we need to combine those that are in USDA and FDA some how.

Again, I thank the Senators, and please stay or leave as you so desire.

Now I turn to Senator Edwards and Senator Hagel, who have introduced the Biological and Chemical Weapons Preparedness Act of 2001, and going down the line of seniority I would recognize my good friend and my neighbor from across the Missouri, Senator Hagel of Nebraska.

STATEMENT OF HON. CHUCK HAGEL, U.S. SENATOR FROM NEBRASKA

Senator HAGEL. Mr. Chairman, thank you, and to you and to our Ranking Member, Senator Specter, we are very appreciative that you would put the focus on this, as has already been established this morning, because of its most critical nature, and to Chairman Byrd, thank you, because you will play a rather important role in all of this, and to our colleagues Senators Kennedy and Frist, I, too, would add my appreciation for their leadership and commitment to, in fact, as much as anyone could have, stay ahead of this issue.

I am reminded, Mr. Chairman, when Wayne Gretzky, the great hockey player, was asked why was he so great, he responded by saying, well, I am not sure I was that great, but if there was anything I tried to do, it is that I tried to skate not where the puck was, but where I thought the puck would be. Certainly Senators Kennedy and Frist have skated to where they thought the puck would be, and they were right.

In the interests of time, Mr. Chairman, I will submit a statement for the record. My colleague, Senator Edwards, has taken a very significant lead role on this issue through his committee assignments and his own interest in something very important, as one of the great challenges of our time, and I appreciate working with him. This issue has been referred to this morning by those who have spoken. It is a critical, integral part of our long-term war on terrorism.

It is about, as we have heard, preparation, prevention, and defense, but, as Senators Kennedy and Frist have laid out, all the components of this now must come together. I hope that what Senator Edwards and I have done by introducing our legislation, which he will speak to in a more framed way, I suspect, is to move forward what is critically important to coordinate the local, State, and Federal responses, meaning that this coordination is going to be absolutely essential. It is going to require resources that it now does not possess. It is going to require infrastructure which we do not now have. It is going to require thinking that we have not applied before.

So what Senators Kennedy and Frist have done is laid down a very important baseline. Senator Kennedy mentioned, as you did, Mr. Chairman of the Agriculture Committee, the need to deal with the agriculture piece here, and this is an area that Senator Edwards and I felt that we could contribute to by adding onto what Senators Kennedy and Frist have already done. We have done that, and we will be prepared to answer any questions.

As to where we think some of this money should go, our overall number is $1.6 billion. We have that broken down, and we would be glad to share that with you whenever you would like.

I would summarize my thoughts on this by saying, Mr. Chairman, as both Senators Frist and Kennedy have noted, that it is important that we not panic the American public. It is important that we speak plainly, directly, clearly, and honestly to the American public, as the President is doing, and as Secretary Thompson is doing. But we need to keep this in proportion, so that the American people can be assured, and as we continue our efforts here they will be assured, that we are dealing with this and they should have a high degree of confidence in what we are doing.

As you all know, and many of you have been around here a lot longer than I have and have provided leadership to this great country, we are now confronted with the great challenge of our time. Not since World War II has our Nation been confronted with such enormity in the completeness of this challenge. I believe our country is up to it. I believe our leadership is up to it. I think we have seen some testament to that over the last 3 weeks in how our House and Senate, and our Democrats and Republicans have worked together on this. This certainly seems to be, regarding this area that we are dealing with this morning, a very clear example of how that is coming together.

There is one last point I would make, which I think says it all, Mr. Chairman. You probably have seen the cover of Time Magazine this week. Time Magazine's cover, and a very, very good story about this issue, does not say it all, but it says an awful lot. It asks: How real is this threat? That is what we are talking about this morning. We all agree the threat is very real.

Mr. Chairman, thank you.

Senator HARKIN. Thank you. I brought Newsweek, which asks: How scared should we be?

It is almost the same cover.

Well, thank you for your leadership in this area, Senator Hagel.

Now I turn to Senator Edwards. Senator Edwards, I know you have spoken to me a number of times about this issue and your concern about it, and your focus on working with Senator Hagel to develop this legislation. So we do appreciate that, and we thank you for your leadership, and thank you for being here this morning.

STATEMENT OF HON. JOHN R. EDWARDS, U.S. SENATOR FROM NORTH CAROLINA

Senator EDWARDS. Mr. Chairman, thank you very much, and Senator Byrd, we thank you for your critical time on this issue. I think what this hearing shows, Mr. Chairman, is that the Senate is prepared to deal with not just the terrorist attacks of the past, but also the potential terrorist attacks of the future. I want to begin, as Senator Hagel did, by commending my colleagues Senators Kennedy and Frist, who have been leaders along with members of this subcommittee on this issue for years.

We fully endorse their request for additional resources. I do believe, though, Mr. Chairman, in addition to additional resources, we are also going to need to see some changes in our policies to deal with the national security threat to our country.

Let me start, Mr. Chairman, if I could, by asking you and others to picture in your mind's eye what a biological attack would look like. First, there would be no explosion. There would be no plane

crash. There would be no catastrophic event of any type. Instead, it would be a silent attack. It may not be seen for days, or even weeks, and it would first show up, as Senator Byrd described, as a case that looked very much like a bad cold or the flu in a hospital on one side of town. Then you would have another case with a child on the other side of town, and then you would have a case out in the county somewhere at a hospital, or seen by a primary care provider.

The critical question is, how much time passes before we recognize that there is something more than a cold or the flu going on, and the only people who can make that determination are your local emergency room personnel, the local health care providers, primary care physicians, and local nurses. Those are the people. They are our first line of defense in any kind of biological attack, and they are the key.

We could have all the teams in the world with extraordinary expertise gathered together in Washington, DC, but if these people who are on the front lines of providing health care across the country are not ready, it is very difficult for us as a Nation to be ready. Senator Frist talked about how few, if any, of these people have ever seen a case of anthrax or smallpox. They do not know what to look for, what the symptoms are, and they also do not know how to react.

That is the reason, Mr. Chairman, we are not adequately prepared, but all of us are here to say to the American people, we will be, and we are committed to being completely prepared. It is not flashy, it is not high tech, but it is the key to getting us ready to respond to the potential for a serious biological attack on our country.

I want to also commend Secretary Thompson for the work he has done. He knows from being Governor how critical these primary care providers are, and how critical they are to our response.

Senator Hagel mentioned he and I have offered legislation in addition to complementing the work that has been done by Senators Kennedy and Frist. There are two components of our legislation that we hope builds on the work that they have done.

One component is that we have a significant amount of money, $555 million, specifically in the form of block grants that go to State and local agencies, so that we do not have the money staying in Washington, DC, but we in fact get it to the front lines, to those people that we have all talked about this morning that are so critical in any sort of response on a national level to a biological attack, to get them trained, get them educated, get them prepared to put a disease surveillance system in place so that they could communicate the information among themselves to the people who need to know.

The second area that we have added is the issue of agriterrorism, of which both Senators Kennedy and Frist have made mention. Everyone recognizes this is a serious issue. We have $100 million in the form of block grants for agricultural terrorism, and $350 million for food safety, and also in the area of Federal Government programs for agricultural terrorism.

So we are working with our colleagues. All of us are committed to do what is necessary. The work that Senators Kennedy and Frist

have done and have shown extraordinary leadership on, along with the work of this subcommittee, has been critical. The work that Senator Hagel and I have done I think builds on that, first, by getting money directly to the people who we believe need it most, the people who are going to have to recognize that a biological attack has occurred and coordinate the response to that biological attack, and second, by dealing with the specific issue of agriterrorism and food safety, which all of us are concerned about and recognize is a serious national threat.

So Mr. Chairman, what I would say, and I think all of us would say to the American people, while we may not be fully prepared at this moment to respond, we are committed to being completely and totally prepared very quickly.

Thank you, Mr. Chairman.

Senator HARKIN. Senator Edwards, thank you for a great statement. Thank you for your leadership on this issue in light of what has been happening lately, and for working with Senator Hagel and all of us to move this forward.

Senator BYRD. Mr. Chairman, may I ask a quick question? You asked for $1.6 billion. Senator Frist and Senator Kennedy are talking about $1.4 billion. How does your $350 million, your $100 million, and your $555 million square with similar items in their requests?

Senator EDWARDS. Senator Byrd, I think we have worked with Senators Kennedy and Frist in coming up with these numbers. I think it is a matter of how we describe the figures. In fact, the additional money that is in our bill, in addition to what Senators Kennedy and Frist are proposing, is primarily aimed at agricultural terrorism, which is not something that is specifically addressed in their request. I believe, though, that our numbers are very much in line, because we have been working with them.

Senator BYRD. And your initial request, let us say it could be appropriated this year, what would it be, the initial portion of the $1.6 billion?

Senator EDWARDS. I think it is a 1-year appropriation request, Senator.

Senator BYRD. The $1.6 billion?

Senator EDWARDS. Yes, sir.

Senator BYRD. Then is that the case, Dr. Frist, with yours?

Senator FRIST. Conceptually, about .4 of the $1.4 billion needs to be for filling these gaps, and is ultimately going to need to be factored into a baseline as we go forward. There are just huge gaps in public health infrastructure and the like. Conceptually, about $1 billion of that is in response to the emergency money that needs to come in now. I do not know if it would come out of the $20 billion that was mentioned. That depends on how you determine it.

Of that $1 billion, just big picture overall, about 50 percent of that could be over a 2- to 3-year period.

Senator HAGEL. Senator Byrd, our percentages are not unlike what Senator Frist has said, too. We all recognize that, as Senator Frist said, the infrastructure is not in place now to be able to absorb that much resources coming within a 12-month period.

Senator BYRD. Thank you. Thank you very much.

Senator HARKIN. Thank you all very much. I thank Senators Kennedy, Frist, Hagel, and Edwards for being here.

Now we will turn to Secretary Thompson, Secretary of Health and Human Services, who we welcome. I want to welcome you, Secretary Thompson, and commend you and your Department for its rapid and professional response to September 11.

I understand, Mr. Secretary, you personally supervised HHS's response to the attack, sending health officials to New York to provide expertise and assistance in deploying Push Packages of emergency materials, including pharmaceuticals, that arrived in New York in under 7 hours. You are to be commended for HHS's level of preparedness, and your calm and speedy response to the crisis.

And with that, Secretary Thompson, your full statement will be made a part of the record. I know that you are under some time constraints. Welcome again to the subcommittee, and please proceed as you so desire.

STATEMENT OF HON. TOMMY G. THOMPSON, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

ACCOMPANIED BY DR. SCOTT LILLIBRIDGE

Secretary THOMPSON. Thank you very much, Mr. Chairman, Senator Specter, other distinguished members of the subcommittee. I appreciate very much this opportunity to appear in front of you. I also want to thank Senators Kennedy and Frist and Hagel and Edwards for their tremendous support and their tremendous introduction of legislation that can be very helpful.

I would like to thank you, Mr. Chairman, for your attention to a subject that has long been of very much interest to me, and has become a concern of all Americans since the terrorist attacks.

The Department of Health and Human Services is responsible for the public health responses to any biological or chemical attack, as well as for disease surveillance and medical preparedness. In the wake of September 11, there are questions about how prepared our Nation is to respond to a biological attack, and rightfully so.

Let me characterize our status this way. We are prepared to respond, but there is much more that can and should be done to strengthen that response. We have needs in the short term and in the long term. At HHS we are aggressively pursuing those needs so that we can build the strongest, most coordinated response possible to a biological attack.

Let me outline for you this morning what steps have been taken, what we are doing currently, and what our most pressing needs really are. We made great strides in our preparedness in the past 8 months, because the President and his administration have made it a priority, designating Vice President Cheney to lead a task force on this and just recently nominating Governor Tom Ridge, an outstanding Governor, to head up the national security.

For me, bioterrorism has been a concern for years. In fact, after being nominated for this position last December, the first briefing I received while still back in Wisconsin was on bioterrorism, when we moved rapidly to make sure the Department was improving its ability to respond. We began by making sure we were better coordinated, not only within our Department and the administration, but

within the State and local partners who depend so much on a strong and efficient response.

I moved bioterrorism into my immediate office, appointing Dr. Scott Lillibridge, who is with me today, who is a doctor, and at CDC as my Special Assistant for Bioterrorism. Dr. Scott Lillibridge is one of the country's most respected bioterrorism experts, and I charged him with making sure that the Department was working in a coordinated and aggressive manner to strengthen its capabilities. We sent a strong message to our Department that this issue is a priority, and that we will be ready.

We have also reached out to work more closely with the State and local governments, but a lot more needs to be done in that area. We have taken steps to improve our pharmaceutical stockpiles, and made investments in research in our public health infrastructure. In fact, this week we sent another $10 million out to 25 cities through the metropolitan medical response system to go from 97 cities to 122 cities that have the expertise to handle bioterrorism, and just this past week, we accelerated the production of a new smallpox vaccine.

We brought together CDC, NIH, FDA, manufacturers, and some outside consultants, and we have developed an accelerated plan that would produce the new smallpox vaccine by mid to late next year, and 40 million doses were to be delivered in the year 2005. Now it will be delivered in the year 2002. This shows how aggressively we are striving to strengthen our readiness and our response, but my confidence in our ability to respond comes from how our Department performed on September 11.

We had two major cities, as all of us know, that were simultaneously hit with terrorist attacks. When we began to respond that morning, we did not know if there was bioterrorism involved, and we did not know how many injuries or casualties there would be, and yet we immediately implemented our health alert system at the Centers for Disease Control. We contacted all the State health departments and put tham on alert, saying that if you see something suspicious, please contact us. This immediately put State and local health departments on alert for anything unusual or mysterious in terms of illness.

We also put 81 health laboratories across America on alert so that they could analyze any blood samples or any tissue samples that came in.

We then activated our national disaster medical system, which comprises 90 DMAT teams, or 7,000 medical professionals across America. We ended up that day sending five of these DMAT teams in to the City of New York, teams of doctors and nurses, over 200 individuals, as well as EMT's, and four to the Pentagon within hours on that first day. These medical teams were on the ground, supplementing the local health care system.

In addition, we sent mortuary teams to New York, Virginia, and Pennsylvania to assist with identification and with the fatalities. Within the first 24 hours, we sent from CDC a group of 35 epidemiologists. Now that has been increased to 55, to also help supplement local medical needs. These highly trained experts were in New York hospitals looking for any signs of bioterrorism, or the potential for any outbreak of disease as a result of the damage.

For the first time ever, we sent a Push Pack containing 50 tons of medical supplies to New York City. We have eight of these packs strategically located throughout the country, and they are supposed to arrive at any location within 12 hours. We were able to deliver that Push Pack to the City of New York within 7 hours.

This is the first time our emergency response system had been tested at this extreme level, and they responded without a hitch. Granted, we did not find any signs of bioterrorism, but we were there quickly. We had experts looking for any problems, and we were prepared to move rapidly to contain and treat any problematic disease. That response encouraged me, I believe it should encourage this committee and the Congress, and it should encourage the American public that we do have the ability to respond.

Now, I by no means contend that our system is perfect or without weaknesses. We have gaps. We can, indeed, make our responses stronger, and it is imperative, ladies and gentlemen, that we do so. We must continue to accelerate our preparedness efforts, and that is going to require a strong partnership with this committee and with Congress.

Frankly, bioterrorism preparedness has not been the highest fiscal priority in the past, as it competed with other public needs. My hope is that this will change as a result of greater awareness of our needs. Here are the areas in which we need to move more aggressively. You heard a lot about it today, and the first one, and by far it surpasses anything else, is our local public health infrastructure. Without question, this is our greatest need.

We must continue working with State and local public health systems to make sure that they are strong and prepared. This is going to include developing response and contingency plans, making sure that they have the tools to respond in educating their medical community. A strong and coordinated response between Federal, State, and local Governments is absolutely essential and fundamental to our ability to respond effectively and in an emergency. We must continue to strengthen that partnership.

We also need to make sure that doctors and medical professionals are able to get the continuing education and training that they will need to be astute in the area of identifying diseases from a biological attack. To supplement this effort, we plan to hold a bioterrorism conference every year for emergency medical professionals, the Nation's best experts and scientists will keep them up to speed with the latest in preparing for, identifying, and treating diseases from biological warfare.

We would also benefit from expanding the number of slots—I know that is something Senator Specter has been very interested in, and I applaud him for it—and that is in the CDC Epidemic and Intelligence Service, so we have moved highly trained experts in the field of identifying diseases. In fact, I would recommend to this committee that the Federal Government consider paying and placing more EIS graduates in State health departments. Currently, there are 42 EIS experts in the States, but we must make sure that every State has at least one of these EIS epidemiology specialists in their health departments, and we should add more to the States that could use the extra resources.

This program, ladies and gentlemen, would put uniquely trained individuals on the ground in each State who can be a valuable resource for public health departments in educating and training their medical community, as well as helping to identify anything suspicious or unusual.

Also in regard to public infrastructure I have created an advisory committee of public health experts, and I have asked Dr. D. A. Henderson, who is the doctor that led the eradication of smallpox, to lead that, including State and local officials. They are going to help us and assist us in devising the most effective and rapid ways to strengthen our local preparedness, and I have asked the Nation's Governors, public health agencies, public health industries—I met with the American Medical Association, the American Health Association last week and asked them to convene a summit with the Department in order to discuss bioterrorism.

I have spent the past few weeks meeting with leaders in the biotech, the medical device, the pharmaceutical insurance industries, as well as the major medical societies. They agreed that we need to work more closely together in the public and private sectors to make sure there are no weaknesses in our biodefense. We must continue investing in our local health care systems so that we are ready to respond in a very effective and coordinated manner in the event of a catastrophe.

The second area, pharmaceuticals, we must continue to accelerate the production of vaccines and antibiotics, invest in the research, bolster our stockpiles and more Push Packs. I would like this committee and Congress to add two more Push Packs to our arsenal, making more emergency medical supplies available throughout the country. After our New York experience in deploying a Push Pack for the first time, we are doing a review of the packages and their contents. The packages performed well, and yet we expect to further strengthen the Push Packages by better organizing them in terms of contents.

For example, we are in the process of developing a Push Package specifically for a chemical attack, and one specifically for a biological attack. We want to continue planning for tomorrow by making sure that the stockpile and the Push Packs are as up-to-date as possible. The third area—and Senator Harkin, this has been one of yours and Senator Durbin's and my real passions, and that is food safety.

We need more inspectors. We have 750 inspectors in FDA to ensure the safety of our food supply and to inspect 55,000 different sites. The FDA can use more help in monitoring our food, for this is one area in which we are lacking, and which we must be much more vigilant. We are aggressively working with the food industry as well to make sure that their awareness is appropriately heightened, and I thank you, Senator Harkin, for your leadership, and they are taking the necessary steps to secure the production and delivery of food.

Security, finally, we need continued help with improving security of all of our facilities and the resources those facilities hold. Public health is a national security issue. It must be treated as such, especially in these times. Therefore, we must not only make sure that we could respond to a crisis, but that we are secure in defending

our stockpiles, our institutions, and our products, and throughout the past 3 weeks I have spent a great deal of time meeting with Members of Congress, the Senate and the House. We have discussed our preparedness, our response, and our needs. I appreciate all of your attention to this issue.

While I am personally confident in our ability to respond because of the strides we have made in the past few months and years, I appreciate this committee reaching out to determine what we can do better, and what resources we need to become stronger. This endeavor must be pursued in partnership not just in this city, but within cities all across America. As a Nation, we must deal with this sensitive issue in a rational manner. People, Americans should not be scared, and believe that they need to be gas-masked, and people should not be frightened in using medicine and food. There is nothing that we know of that would warrant such actions.

People should be vigilant, should be aware and alert. A biological attack is certainly possible, but as President Bush has said, we must not be intimidated. We must get back to living our lives. Yes, we need to do more on bioterrorism, but we are prepared to respond. The mission now is to accelerate the efforts to strengthen that response and make sure that our local public health systems are able to respond as well.

PREPARED STATEMENT

We are doing today what this country once thought it could put off until tomorrow, and I applaud you. As always, I am confident that you, this Congress and all Americans, will rise to the challenge.

[The statement follows:]

PREPARED STATEMENT OF TOMMY G. THOMPSON

Mr. Chairman and Members of the Subcommittee, thank you for inviting me here today to discuss the Department of Health and Human Services (HHS) preparedness to respond to acts of terrorism involving biological agents.

Among weapons of mass destruction, bioterrorism features several characteristics that set it apart from other acts of terrorism involving, for example, explosives or chemical agents. While explosions or chemical attacks cause immediate and visible casualties, an intentional release of a biological weapon would unfold over the course of days or weeks, culminating potentially in a major epidemic. Until sufficient numbers of people arrive in emergency rooms, doctors' offices and health clinics with similar illnesses, there may be no sign that a bioterrorist attack has taken place.

Three important points must be considered in bioterrorism preparations. First, biological agents are easy to conceal. A small amount may be sufficient to harm large populations and cause epidemics over a broad geographic region. Second, the contagious nature of some infectious diseases means that once persons are exposed and infected they can continue to spread the disease to others. Third, in the most worrisome scenario of a surreptitious attack, the first responders are likely to be health professionals in emergency rooms, physician offices, outpatient clinics, public health settings, and other health-care activities rather than the traditional first responders. The longer the terrorist-induced epidemic goes unrecognized and undiagnosed, the longer the delay in initiating treatment and other control efforts to prevent further infectious outbreaks.

The broad goals of a national response to bioterrorism, or any epidemic involving a large population will be to detect the problem, control the epidemic's spread and treat the victims. HHS's approach to this challenge has been to strengthen public health infrastructure to deal more effectively with epidemics and other emergencies, and to hone our emergency health and medical response capacities at the federal, state and local level. HHS has also worked to forge new partnerships with organizations related to national security.

What has HHS been doing to prepare for this kind of event? Our efforts are focused on improving the nation's public health surveillance network to quickly detect and identify the biological agent that has been released; strengthening the capacities for medical response, especially at the local level; expanding the stockpile of pharmaceuticals for use if needed; expanding research on disease agents that might be released; developing new and more rapid methods for identifying biological agents and improved treatments and vaccines; improving information and communications systems; and preventing bioterrorism by regulation of the shipment of hazardous biological agents or toxins.

Several HHS agencies play a key role in our preparedness for terrorist events, including the Office of Emergency Preparedness (OEP), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes for Health (NIH).

In order to advance an orderly and comprehensive approach to the many issues involved in such preparation, in July of this year I appointed a special assistant within the Immediate Office of the Secretary to lead the Department's bioterrorism initiative. I have directed this individual, Dr. Scott Lillibridge, to begin creating a unified HHS preparedness and response system to deal with these important issues. Under my direction, Dr. Lillibridge will provide executive leadership and organizational direction for HHS budget, policy, and program implementation on terrorism preparedness issues. Let me assure you that this is a top priority for me and for my entire Department.

We are striving at HHS to strengthen our readiness and response, and our ability to respond has been greatly improved over the last several years. The system is not perfect, however, and we must continue to accelerate our preparedness efforts.

IMPROVED SURVEILLANCE IS KEY TO DETECTION

If a terrorist used a biological or chemical weapon against the civilian population, how quickly the outbreak is detected, analyzed, understood and addressed would be the responsibility of state and local public health jurisdictions and the Centers for Disease Control and Prevention.

The CDC has used funds provided by the past several congresses to begin the process of improving the expertise, facilities and procedures of state and local health departments and within CDC itself related to bioterrorism. CDC has established a Bioterrorism Preparedness and Response Program within its National Center for Infectious Diseases to direct and coordinate their activities. CDC has a dedicated anti-bioterrorism staff of more than 100 full-time professionals comprising expertise in epidemiology, surveillance, and laboratory diagnostics.

Over the last three years, the agency has awarded more than $130 million in cooperative agreements to 50 states, one territory and four major metropolitan health departments to support,

(1) Preparedness planning and readiness assessment;

(2) Epidemiology and surveillance;

(3) Laboratory capacity for biological or chemical agents; and

(4) The Health Alert Network (a nationwide, integrated, electronic communications system).

The CDC has launched an effort to improve public health laboratories that likely would be called upon to identify a biological or chemical attack. The Laboratory Response Network (LRN), a partnership among the Association of Public Health Laboratories (APHL), CDC, FBI, State Public Health Laboratories, DOD and the Nation's clinical laboratories, will help ensure that the highest level of containment and expertise in the identification of rare and lethal biological agents is available in an emergency event. The LRN also includes the Rapid Response and Advanced Technology Laboratory at CDC, which has the sole responsibility of providing rapid and accurate triage and subsequent analysis of biological agents suspected of being terrorist weapons.

The CDC is also working to provide coordinated communications in the public health system, between federal agencies and between public health officials and the public itself. To this end, CDC has the "Epidemic Information Exchange (EPI-X)." The EPI-X is a secure, Web-based communications network that will strengthen bioterrorism preparedness efforts by facilitating the sharing of preliminary information about disease outbreaks and other health events among officials across jurisdictions and provide experience in the use of a secure communications system.

CDC has invested $90 million in the Health Alert Network (HAN), a nationwide system that will distribute health advisories, prevention guidelines, distance learning, national disease surveillance information, laboratory findings and other information relevant to state and local readiness for handling disease outbreaks. HAN

provides high-speed Internet connections for local health officials; rapid communications with first responder agencies and others; transmission of surveillance, laboratory and other sensitive data; and on-line, Internet- and satellite-based distance learning. With the addition of several recent awards, CDC has provided HAN funding and technical assistance to 50 state health agencies, Guam, the District of Columbia, three metropolitan health departments and three exemplar Centers for Public Health Preparedness.

CDC also manages the National Pharmaceutical Stockpile (NPS), which provides us with the ability to rapidly respond to a domestic biological or chemical terrorist event with antibiotics, antidotes, vaccines and medical materiel to help save lives and prevent further spread of disease resulting from the terrorist threat agent. The NPS Program provides an initial, broad-based response within 12 hours of the federal authorization to deploy, followed by a prompt and more targeted response as dictated by the specific nature of the biological or chemical agent that is used. The first emergency deployment of the NPS occurred in response to the tragedy in New York city.

Because food may be a likely medium for spreading infectious diseases, FDA as well as CDC have enhanced their surveillance activities with respect to diseases caused by foodborne pathogens. PulseNet, a national network of public health laboratories created, administered and coordinated by CDC in collaboration with FDA and USDA, enables the comparison of bacteria isolated from patients from widespread locations, from foods and from food production facilities. This type of rapid comparison allows public health officials to connect what may appear to be unrelated clusters of illnesses, thus facilitating the identification of the source of an outbreak caused by intentional or unintentional contamination of foods.

BIOTERRORISM PREPAREDNESS AND RESPONSE

HHS coordinates and provides health leadership to the National Disaster Medical System (NDMS), which is a partnership that brings together HHS, DOD, FEMA, and the Department of Veterans Affairs (VA). The NDMS provides medical response, patient evacuation, and definitive medical care for mass casualty events. This system addresses both disaster situations and military contingencies. More than 7,000 private citizens across the country volunteer their time and expertise as members of response teams to support this effort. This system also includes approximately 2,000 participating non-federal hospitals. VA and DOD's expertise and resources are critical to many key aspects of NDMS response, and I would note that these Departments have distinguished themselves on many occasions.

In most localized disasters, including the scurrilous attacks on the World Trade Centers in New York and the Pentagon here in Washington, HHS organizes its medical field response through the Office of Emergency Preparedness using a team structure. Teams can include Disaster Medical Assistance Teams, specialty medical teams (such as burn and pediatric), and Disaster Mortuary Teams. In addition, National Medical Response Teams are able to deploy to sites anywhere in the country with a supply of specialized pharmaceuticals to treat up to 5,000 patients. Currently, HHS can draw on 27 such teams that can be federalized and deployed to assist victims. Such teams have been sent to many areas in the aftermath of disasters in support of FEMA-coordinated relief activities.

HHS, through OEP, has the capability to mobilize NDMS resources, the Public Health Service's Commissioned Corps Readiness Force, as well as enlist the support of other federal agencies, such as DOD and VA, to help provide needed medical and public health services to treat disaster victims. In the last few years, these assets were deployed to New York, Florida, Texas, Louisiana, Alabama, Mississippi, the Virgin Islands and Puerto Rico in the aftermath of hurricanes and tropical storms, and to New York and Virginia in response to the events of September 11, 2001.

However, regional or national response to a health emergency involving bioterrorism will also require that additional capacities be in place at the state and local level before the disaster strikes. HHS, primarily through CDC, is supporting state and local governments to strengthen their surveillance, epidemiological investigation and laboratory detection capabilities, as well as continuing development of a national stockpile of critical pharmaceuticals and vaccines to supplement local and state resources.

The Office of Emergency Preparedness is working on a number of fronts to assist local hospitals and medical practitioners to deal with the effects of bioterrorism and other terrorist acts. Since fiscal year 1995, for example, OEP has been developing local Metropolitan Medical Response Systems (MMRS). Through contractual relationships, the MMRS uses existing emergency response systems—emergency management, medical and mental health providers, public health departments, law en-

forcement, fire departments, EMS and the National Guard—to provide an integrated, unified response to a mass casualty event. As of September 30, 2001, OEP will has contracted with 97 municipalities to develop MMRSs. The fiscal year 2002 budget includes funding for an additional 25 MMRSs (for a total of 122).

MMRS contracts require the development of local capability for mass immunization/prophylaxis for the first 24 hours following an identified disease outbreak; distribution of materiel deployed to the local site from the National Pharmaceutical Stockpile; local capability for mass patient care, including procedures to augment existing care facilities; local medical staff trained to recognize disease symptoms so that they can initiate treatment; and local capability to manage the remains of the deceased.

TRAINING

HHS has used classroom training, distance learning, and hands-on training activities to prepare the health and medical community for contingencies such as bioterrorism and other terrorism events. For example, in fiscal year 1999, Congress appropriated funds for OEP to renovate and modernize the Noble Army Hospital at Ft. McClellan, Alabama, so the hospital can be used to train doctors, nurses, paramedics and emergency medical technicians to recognize and treat patients with chemical exposures and other public health emergencies. Expansion of the bioterrorism component of Noble Training Center curriculum is a high priority for HHS.

HHS has been working closely with the Office of Justice Program's (OJP) National Domestic Preparedness Consortium and we will continue our excellent relationship with them. OJP and HHS have teamed together to develop a healthcare assessment tool and have also delivered a combined MMRS/first responder training program.

CDC has participated with DOD, most notably to provide distance-based learning for bioterrorism and disease awareness to the clinical community. CDC is now moving to expand such training with organizations, such as the Infectious Disease Society of America (IDSA), and Schools of Public Health, such as the Johns Hopkins Center for Civilian Biodefense. The recent FEMA-CDC initiative to expand the scope of FEMA's Integrated Emergency Management Course (IEMC) will serve as a vehicle to integrate the emergency management and health community response efforts in a way that has not been possible in the past. It is clear that these communities can best respond together if they are able to train together toward realistic scenarios that leverage the best of both organizations.

CONCLUSION

In conclusion, the Department of Health and Human Services is committed to ensuring the health and medical care of our citizens. We have made substantial progress to date in enhancing the nation's capability to respond to a bioterrorist event. And, Mr. Chairman, the Department is prepared to respond! But there is more we can do—- and must do—- to strengthen the response. Priorities include strengthening our local and state public health surveillance capacity, continuing to enhance the National Pharmaceutical Stockpile, and helping our local hospitals and medical professionals better prepare for responding to a bioterrorist attack. Our mission is to accelerate these efforts.

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

Senator HARKIN. Mr. Secretary, thank you for a very poignant and well-stated statement. It was right to the point.

Two things I would observe before I ask just one question. First, I just want to note for the record and recognize Mr. Scott Lillibridge, who is with you as the Special Assistant for Bioterrorism. You mentioned public health being part of national security. I think that is a concept that we now really have to think about. Public health is a part of our national security, and so I applaud you for thinking about it in those terms.

Second, there is a lot of talk, of course, about increasing airport security and federalizing employees and making them more professional. Again, I am glad that you noted in your comments another part of our uniformed services that gets overlooked a lot in our country, and that is the Public Health Service Commissioned Corps. The Corps is one of our uniformed services, and again, I

think we need to do more to heighten their public appearances out there so that people know who these Commissioned Corps officers are, to elevate their status, and to bring more people into the Public Health Service.

Secretary THOMPSON. Thank you for saying that, Senator. I congratulate you.

Senator HARKIN. I would like to work with you on that.

Secretary THOMPSON. Scott Lillibridge is a captain.

Senator HARKIN. Well, that's good that he is in the uniformed services, and we have got to do more to get information on this out there to people, and we will work with you on that. The only question I have, Mr. Secretary, and I know your time is precious, in the next few weeks we are going to be working, as Senator Byrd said, to allocate this $20 billion that we appropriated earlier. Again, we want to work with you to get the resources you need for CDC, and the rest of your Department. I understand that you have submitted certain requests to OMB; you have submited a budget for this additional funding, and they are reviewing it.

Can you provide this subcommittee with your professional judgement of what those needs are, such as how much is needed for stockpiling activities, the training you mentioned, the local public health departments, the EIS people? We need to have some of that information. If you cannot provide it now, could you help get it to us? In other words, just as we are asking Senators Kennedy and Frist where they think we need to go, we need to ask you, also, where do you think we need to put this?

Secretary THOMPSON. Thank you, Senator Harkin. I have to defer until OMB makes a decision on my request, but my request is very much in line with what Senators Kennedy and Frist have indicated, and we have worked with Senators Kennedy and Frist's staff, and we are relatively close on the numbers, not completely, but I am very impressed by their proposal and where they want to spend the money.

The public health system at the local level is where we need to invest our dollars, and that is the area that I think the Senators have indicated, what you talked about, Senator Specter has talked about, and I applaud you for that, and that is exactly what we need.

Senator HARKIN. Thank you very much.

Secretary THOMPSON. I will get you more information by the end of the week, as soon as OMB makes a decision.

Senator HARKIN. Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman. Secretary Thompson, the day before yesterday I was at Lincoln University in the Philadelphia suburbs, and was asked about protection for the populace, and I was asked about gas masks, and I told them I had no gas mask, and from what you have testified to I take it you have no gas mask either.

Secretary THOMPSON. I do not, Senator.

Senator SPECTER. With respect to any special antibiotics to counter any bioterrorism, I told them that Senators had no special antibiotics. I take it you have none, either.

Secretary THOMPSON. I have none, but we have 400 tons of that in our Push Packs for the American people at large.

Senator SPECTER. So that will be available to Secretary Thompson and Arlen Specter, like any other citizens, with no special preferential treatment for the Cabinet?

Secretary THOMPSON. No preferential for the Cabinet, I am sorry to report, or the Congress.

Senator SPECTER. Well, that is what equal protection means, Mr. Secretary.

Mr. Secretary, you have been quoted as saying that the Government can, quote, handle any contingency right now. Your statement in your oral testimony has been that the Government is prepared to respond, but that there are gaps. Was that an accurate quotation that the Government, quote, can handle any contingency right now, and do you stand by that?

Secretary THOMPSON. We can handle, we think we can handle any contingency dealing with bioterrorism at this point in time, Senator, but we also understand that there needs to be improvements, especially in the local public health system. I mentioned that, and the quote that you mentioned, was on "60 Minutes". I went on to articulate that we need to invest money in the local health system for education, for infrastructure, and I also pointed out that I would like to see some EIS agents that graduate from CDC's educational program after 2 years placed in every State health department.

Senator SPECTER. Mr. Secretary, stay with C–SPAN. They do not edit your comments.

I can understand your caution, and your measured words. How would you respond to Dr. Steven Cantrill, who is going to testify later, probably early this evening the way we are proceeding so far—he is with the Emergency Medicine Department at Denver Health Medical Center—when he said, quote, this problem would only be partially alleviated by the dispatching of Federal resources to a specific locale, and would be further of no help if terrorists opt to involve dozens of metropolitan areas simultaneously?

When you see the coordination of four hijackings, and perhaps others which failed, and you see the level of sophistication and their resources, what are the realities if, as Dr. Cantrill says, dozens of metropolitan areas are attacked simultaneously?

Secretary THOMPSON. How we have got it set up, Senator, is we have the Health Alert Network, and we put that on notice. Every one of the 50 State health departments immediately after bioterrorism attacks, or even after the terrorist attacks on September 11—they were notified, and we monitor State health departments. They are supposed to feed into CDC any mysterious outbreaks of any illnesses whatsoever.

We have also got 81 laboratories on notice that will be able to analyze any blood or any samples, and we would send CDC EIS specialists like Scott Lillibridge into communities if there was any type of an outbreak, if we found anything mysterious whatsoever, and they would get on the ground in that community, in Denver, in Milwaukee, in Pittsburgh, and be able to work with the State and local health departments.

Senator SPECTER. You did not mention Philadelphia.

Secretary THOMPSON. And Philadelphia, I am sorry, and we would then be able to develop a plan, and if necessary move our

Push Package in, move extra personnel in. We have 7,000 DMAT teams ready to be activated and placed into any particular community.

I agree with the doctor that at the local level there needs to be more education, more opportunities for research, and more things—we think we could provide a good share of that through CDC, Senator.

Senator SPECTER. Are the lights on? They should be set for 5 minutes so we can control the time, but I am going to conclude here. Just very briefly let me ask you about the comments of the GAO report, Mr. Secretary, which focused on the lack of laboratory capacity for a large outbreak, and the lack of hospital emergency capacity. How do you respond to those accounts by the GAO?

Secretary THOMPSON. I think we do lack laboratory capability and we do lack hospital space, and we discussed that. I discussed that with the American Hospital Association, I believe last Friday. I also discussed it with the Department of Defense last week. I talked to Secretary Don Rumsfeld and I asked if, in fact, we needed some mobile hospitals from the Department of Defense, could we be able to use them, and he said absolutely. We also asked them the same thing about vaccines, dealing with anthrax, and the Department of Defense said, absolutely.

Senator SPECTER. My final question relates to the issue raised by the GAO regarding the adequacy of coordination with the responsibilities being lodged in many departments, HHS, the Department of Justice, the Department of Energy, the Environmental Protection Agency, FEMA, and others.

Governor Ridge's duties have not been defined with any precision, and in the speech that the President made, he talked about a Cabinet-level position, a Secretary of Homeland Defense, and now there is talk about an agency, and I think we are really in the formative stage as to what is going to be done here.

I am preparing some legislation in collaboration with Senator Lieberman, and it is our view, or it is my view—we have not worked it all out yet—that there ought to be Cabinet rank and there ought to be a way to have some authority when you start dealing with various Secretaries. Washington is famous for turf battles, and absent——

Secretary THOMPSON. I am understanding that, Senator.

Senator SPECTER. I understand that you understand that. I have seen that. I have seen some of the understanding back and forth.

Now, I know you cannot speak for the President, but as a judgment, if Governor Ridge is going to come in and do an effective job, is he not going to need some line of authority beyond having access to the President? To try to arbitrate every single dispute, we know the reality is that simply cannot happen. You have been very experienced in Government. Do you think we need a Cabinet level position? Do you think we need some specific statutory authorization which will enable Governor Ridge to do an effective job?

Secretary THOMPSON. First off, I think Governor Ridge is going to do an outstanding job. He is a wonderful individual, and I think the President chose very wisely. I think the President is looking at this. I have not been privy to those discussions as such, and so I

do not think I should be talking for the White House on this subject, Senator.

Senator SPECTER. Thank you very much, Secretary Thompson.

Senator Byrd, Senator Harkin had to absent himself for a few minutes. We are going to proceed in order of arrival: Senator Byrd, Senator DeWine, Senator Landrieu, Senator Durbin, Senator Murray, Senator Gregg, and Senator Kohl, and I think Senator Gregg ought to be higher here. He came in earlier.

Senator GREGG. That is okay.

Senator SPECTER. Senator Byrd.

Senator BYRD. Thank you, Mr. Chairman.

Mr. Secretary, you indicated that 42 epidemiologists were in the 50 States. I believe you said 42.

Secretary THOMPSON. That is correct.

Senator BYRD. You said we needed one in each State.

Secretary THOMPSON. I said at least one in each State.

Senator BYRD. How many States do not have at least one?

Secretary THOMPSON. I would think there are 13 at the present time.

Senator BYRD. Including West Virginia?

Secretary THOMPSON. I am not sure about that, but I can check and get back to you. I understand West Virginia does not have one.

Senator BYRD. How much money do you need to have 13 additional epidemiologists?

Secretary THOMPSON. We have them, but we would have to give money to the States, or put in a Federal position in the State health departments. I do not exactly know. We think that we should have at least one in each and every State, Senator. I can get you the exact figures and send them to you without any problem whatsoever.

Senator BYRD. Yes, if you would, please. Also, you indicated that your proposal is pretty much like the proposals that are being talked about by Senators Kennedy, Frist, Hagel, and Edwards. How much difference is there in your amounts?

Secretary THOMPSON. There is some difference—I think, Senators Hagel and Edwards, about $1.6 billion, I think Senators Kennedy and Frist about $1.4 billion. I think ours is a little bit under that, and we have made a proposal to OMB. But together, there is very much uniformity in strengthening the local public health systems and protecting food safety and security.

Senator BYRD. How much do you need? If it could be appropriated in the remainder of this calendar year, how much do you need immediately?

Secretary THOMPSON. We think we need somewhere around $800 million.

Senator BYRD. May I ask, if you already have not done it, that you break that down and send it to this committee immediately?

Secretary THOMPSON. I have to wait till OMB makes a decision, but I would be more than happy to give it to you.

Senator BYRD. If we could know what you are asking for.

Secretary THOMPSON. I certainly will, Senator. I will get it to you by the end of the week.

Senator BYRD. Very well. Now, you mentioned local, State, and Federal health officials, and you emphasized the problem that ex-

ists in preparing the local and State officials to adequately deal with a bioterrorism attack.

What is being done to establish clear channels of communication between local, Federal, State, and other officials to enable them to consult with one another in the aftermath of a bioterrorist attack, and what do you think needs to be done at the Federal level to best equip our State and local health departments to effectively prepare for and respond to a chemical or biological terrorist attack?

Secretary THOMPSON. The best thing we could do right now is to connect every State health department and as many of the local health departments as possible with our Health Alert Network. We have a very sophisticated computerized system in Atlanta through CDC. That is where the experts are in infectious diseases, and what we need to do is expand that into the regional and to local health departments. That would be the best way to disseminate information as well as education from CDC through the States down to the local levels.

The second thing is, putting, as you have indicated, these EIS specialists in every State health department—at least one and probably more. Third, we have got to put on more expanded educational courses, especially for emergency doctors and nurses that go into the emergency clinics. Fourth, we have got to discuss how we would get the extra hospital beds if we needed them in a surge capacity kind of situation.

Those are the four things, and it is communication, it is education, it is personnel, and it is space.

Senator BYRD. Now, as to Federal resources to help bring these things together, do you have a figure, and if so, has that request been made to OMB?

Secretary THOMPSON. Those requests have been made to OMB, and those requests have also been made by Senators Kennedy and Frist in their proposal.

Senator BYRD. Would you mind adding that to the information you are going to provide me?

Secretary THOMPSON. Absolutely, Senator.

Senator BYRD. One final question—and is the light red?

Senator SPECTER. I think it is yellow for you, Mr. Chairman.

Senator BYRD. Mr. Secretary, reference has been made to some of your public statements to the media. You have said, or are supposed to have said, in a recent media interview that the U.S. Government is: "prepared to take care of any contingency, any consequence that develops from any kind of bioterrorism attack." That is a pretty broad statement.

Secretary THOMPSON. It is.

Senator BYRD. Do you stand by that today?

Secretary THOMPSON. I do.

Senator BYRD. Well, Mr. Secretary, I want to tell you in the nicest way I know how——

Secretary THOMPSON. I said we could respond, and evidenced by what we did on September 11, I am absolutely assured that we could respond to any contingency and control it.

Senator BYRD. Well, will you still love me if I say to you, I do not believe that?

Secretary THOMPSON. I still love you.

When you are the chairman of the Appropriations Committee, I will love you even more, Senator.

Senator BYRD. That is a broad statement, and Washington is so full of hyperbole and broad statements. We know, or we should know, because we make them, too. They tell me that it is a bad thing to do if we mislead, and I know you do not intend to do that.

Secretary THOMPSON. I do not want to mislead. I want to calm the American people so that people understand that we are prepared.

Senator BYRD. Well, I just do not believe that, and I say that to you very kindly. I think we ought to be very careful. I try to be. Next year is my 50th year in Congress, and I have heard a lot of broad statements made, and some of them were not kept, but I hope that we will both be very careful what we say in this matter. There is nothing more important. I want to help you get the money you need. I want to do what I can.

Secretary THOMPSON. Thank you very much, Senator.

Senator BYRD. Thank you.

Senator HARKIN. Secretary Thompson, I would support what Senator Byrd just said. There is a lot of concern in the land, but I think Americans are not going to be intimidated, or reassured from what you testified to regarding the response on September 11. Those categorical statements will not really help, but the specification as to what is being done in addition I think will be helpful. I think America will be reassured that Senator Byrd spent a couple of hours at this hearing, because he deals with the final markup in the appropriations process.

Secretary THOMPSON. All I can say, Senator, is that we meet on a daily basis with, I think, the best doctors and researchers and scientists in the country—on a daily basis on this subject, and Scott Lillibridge, if you would respond, are we prepared?

Dr. LILLIBRIDGE. Let me say we are ready to respond, that we have many, many things in progress for preparedness, and that those things need to be accelerated. Many of those things have been. There is a complex task before us, and I agree that the public health infrastructure, the hospital community and the other components need to move in lockstep.

Senator SPECTER. I would yield back to the new chairman and call on Senator DeWine first.

Senator HARKIN. If I just might interject, Senator DeWine, if you would defer just a second, Mr. Secretary, I do not know what your time is. I had information that you had to leave. I hope that Senators would respect that, and please let us know if you have something urgent that you have to go to. If you do, we would respect that. Maybe Dr. Lillibridge could stay and answer questions that are not answered by the time you have to leave.

Secretary THOMPSON. Thank you.

OPENING STATEMENT OF SENATOR MIKE DE WINE

Senator DEWINE. Mr. Chairman, I will be very brief.

Mr. Secretary, thank you very much for joining us. I want you to put your old hat back on as Governor and look at it from the point of view of a Governor or local official. It seems to me that we

have an immense challenge, certainly not a challenge we cannot meet, but it is an immense challenge.

My home State is probably not unusual. We have county health departments, we have a State health department, we have local fire departments, some entirely voluntary, some are mixed, some totally paid, Nation-wide tens of thousands of them, and within a State, so many different people that may be the first line of defense, the first people who respond to the problem, or maybe the first people who have to try to detect that we do have a problem. From a Government point of view, from a Governor's point of view, what do you think are the biggest challenges, and how are we meeting those?

The second question related to that is, what has been your consultation with Governors and with mayors and with local officials?

Secretary THOMPSON. I think some States are better prepared than others. As it is in any case, any issue you will find some States excel in certain areas and are far superior to other States. I think what Governors have got to do is, they have got to work with the National Governor's Association, with the Department of Health and Human Services, and with FEMA, and they should be setting up an annual meeting, a summit on bioterrorism preparedness, and I think it should be in consultation with our Department.

In fact, I sent out a letter, Senator DeWine, asking the National Governors Association to call such a summit as soon as possible, in consultation with us. I think that is the best way.

I think also that our local health support network is not as strong as it should be, and I have said that many times, and even though I think we are prepared to respond at the Federal level, I do not believe that all State local health departments are as ready as they need to be, and some of them will not be able to recognize, some of them will probably not have the education or the experience, and that needs to be strengthened. That is why these EIS specialists that I am asking be put in every State health department is so very important.

In regards to what I would suggest from Governors, I would suggest that they come together and form an advisory committee through the National Governor's Association to put together more information, more education opportunities for local health departments.

Senator DEWINE. Thank you, Mr. Secretary. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator DeWine. Senator Durbin.

OPENING STATEMENT OF SENATOR RICHARD J. DURBIN

Senator DURBIN. Thank you, Mr. Chairman. I want to thank the subcommittee for their gracious hospitality. I will be very brief, and speak to one particular issue, and it is one that has been already alluded to in terms of my interest and Senator Harkin's interest. We at this moment in history have a great challenge and a great opportunity. For 40 years, we have been debating bringing together under one agency food safety inspection in America. Everyone is agreed in theory, and we have been unable to do it.

We have, as I mentioned earlier, a dozen agencies, and 35 different laws. We have no standards that we can point to that make any sense from the aspect of food safety or security.

Now we have a convergence of events here. We have the election of a President who campaigned on creating such an agency. We have a national challenge to deal with the safety and security of our food supply, and I think we have a better political environment than at any time in recent memory to finally tackle this.

I would like to ask you, Mr. Secretary, two questions. First, will you join with Senator Harkin and myself and people from the administration to talk about the road map to move us from where we are today to such an agency? How we might achieve that in a timely fashion?

Secretary THOMPSON. Absolutely, without a doubt, I think we need to discuss it. I am not sure that we need a separate Department. I think put under the rubric of FDA we could handle it. But I certainly would love to discuss it, because to me, food safety has got to be uppermost in every one of our minds. We have got to do a better job, and we have not invested the resources.

I have got lots of ideas and I would like to share them with you, Senator Durbin. I know you are passionate about it. And Senator Harkin, I would love to be able to have the opportunity to sit down with the two of you or your staffs or whatever and discuss how we might be able to proceed to get this job done.

Senator DURBIN. I am going to have a hearing next week, and I hope if you cannot attend that someone from your Department can attend.

Secretary THOMPSON. I will try and attend.

Senator DURBIN. Thank you very much.

The second point is fairly obvious. Once we have established to our satisfaction the improvement and modernization of our food safety inspection system, it is clear that there will be countries around the world who export food into the United States who will also want to be part of this conversation so that they can export and we can import with peace of mind.

I am hoping that we can then take whatever our initial thinking is on this and expand it into a much larger dialogue involving the European Union and other friendly, civilized countries around the world that want to help us establish standards of safety and security so that we can say to the American people, our food supply is not only the safest in the world today, it will continue to be, even if we bring in food from overseas. So I hope that we can find a way to bridge our conversation into a much larger context.

Secretary THOMPSON. I would like to make sure that we invite Secretary Veneman, because I know she is also, as Secretary of Agriculture, extremely interested in this subject, and is very knowledgeable.

Senator DURBIN. Thank you. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Durbin. Senator Gregg.

OPENING STATEMENT OF SENATOR JUDD GREGG

Senator GREGG. Thank you, Mr. Chairman. Mr. Secretary, it is a pleasure to discuss this issue with you.

The chairman, in opening this hearing, in fact went into some length about the exercise Top Off, which was an exercise which was energized as a result of the Commerce, State, Justice Subcommittee of the Appropriations Committee and which we discussed, in fact in this room about 4 months ago when all the major Departments involved in terrorism testified, and one of the conclusions which I think came out of that hearing was that we did not have adequate coordination amongst our Departments especially in a variety of areas, but especially in the area of health care, and the doctors who were on the ground in Denver who came and testified felt very strongly that that was the case. I was wondering to what extent your agency has reviewed the Top Off findings in Denver, and what conclusions you have come to as a result of that.

Secretary THOMPSON. We have reviewed Top Off, we have reviewed Dark Winter, and we have taken all of the suggestions and conclusions in developing them, and we looked at the problem. We have tried to come up with a solution—how we would fix it—and that is what Dr. Lillibridge has been doing for the last 5 months. He has been evaluating them, and I think we have been making a lot of progress in that area. But coordination is still a problem.

Senator GREGG. It is a huge problem. I congratulate the President for bringing in Governor Ridge. I think that is going to be a very significant effort in coordinating, but one of the issues that was raised there was the availability of vaccine.

Today, as I understand it, there is no vaccine being manufactured for anthrax, none for pneumonic plague, none for botulism, and the smallpox vaccine is being manufactured both for DOD and for HHS, but the HHS timetable is next year, which I congratulate you on accelerating that, but basically, it means we really do not have any current existing new product in any of these areas, is that correct?

Secretary THOMPSON. That is correct. I would like to point out, though, that NIH is doing a wonderful job of research in coming up with some new vaccines. They are not there yet, but there is a lot more money that has been put into Dr. Tony Faucci's expertise in trying to come up with this.

Senator GREGG. What should we do at FDA, then, I guess is my question, to assist us in accelerating this process?

Secretary THOMPSON. What we do about every morning, Dr. Scott Lillibridge meets with Kathy Zuhn from FDA and several other specialists, and we are looking at ways in which we could expedite and move this along, and I would rather have Dr. Scott Lillibridge answer that question.

Dr. LILLIBRIDGE. Let me just mention this in brief discussion of the activities. It takes a lot of elbow grease with the manufacturer, FDA, scientific experts, and our best team from NIH, CDC, and FDA to get together and push this issue forward. We have in the space of about 2 weeks begun to accelerate smallpox vaccine production activity. We have a timeline, we have a process, and again, as the Secretary mentioned, we had a timeline of 2005, and we are moving it down.

I think you also allude to the systemic problem of getting at vaccines. A couple of things on the horizon—we are working with the Secretary of Defense on finalizing plans and collaborations on a

Government-owned contractor-operated facility for vaccines. We are reaching out to the manufacturers in ways that we have not before. We have also invited foreign manufacturers to come to the United States to present their data about safety and efficacy, to get it expedited and reviewed so we can use it to protect the population.

As for anthrax vaccine, the production facility is being worked with almost on a weekly basis, daily basis with the Food & Drug Administration to help that facility get into full production shortly. And they anticipate in perhaps as soon as 6 weeks they will be able to resume production towards a licensed product.

Senator GREGG. Is this Dynpor?

Dr. LILLIBRIDGE. I would hesitate to mention the manufacturer, but suffice it to say, the manufacturer for anthrax vaccine in this country.

Senator GREGG. Now, if we would put the Defense Department in charge of manufacturing vaccines, which is essentially one of the proposals, is that really the best approach? One of the problems we had that I think it was that we stopped producing pneumonic plague vaccine because we could not get the Defense Department to be the big player.

Dr. LILLIBRIDGE. Sir, that is exactly right. As we looked at this, it looks like it is going to require multiple solutions, some with the Government, some with private industry, some within regulatory issues that we have to work through, and incentives across the industry, both public and private partnership working together and looking at some of the off-shore options as well to get complete coverage on all these issues.

Senator GREGG. My time is about up, but should this be decided by you folks or by the Defense Department or by the Homeland Secretary, the decision as to where these manufacturing capability occurs, and what the time line is, and who is going to drive the process of getting it done?

Secretary THOMPSON. I think it should be done in consultation with all three, plus this subcommittee and your subcommittee.

Senator GREGG. Where does the buck have to stop?

Secretary THOMPSON. I think the buck has to stop on the medical and health conditions. I think that has got to be the determining factor.

Senator GREGG. Okay.

Secretary THOMPSON. Suffice it to say, it should be a medical decision as much as possible.

Senator HARKIN. Senator Kohl.

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. Governor Thompson, good to see you.

Mr. Secretary, I appreciate the tremendous efforts you made at your Department to respond to a biological attack, and I know it is a comfort to many Americans to know that our Government, through your efforts, is prepared, but the question I most often get asked by my constituents back in Wisconsin is, what should I do, not so much what are you doing, but what should I do?

People want to know what they can do today to protect their families from a biological attack. They ask questions like, should they ask the doctors for vaccines, should they secure a room in

their house, should they make efforts to avoid public places, or certain areas of the country, are there questions they should ask their doctor to determine whether or not the doctor is capable of recognizing the symptoms of a biological attack?

Is the Department issuing recommendations or advice, Mr. Secretary? In other words, what can you tell, or what would you say to Americans all across our country today with respect to what they can or should be doing to respond to this threat?

Secretary THOMPSON. I would strongly tell Mr. and Mrs. Siddleson of Milwaukee, as I would Philadelphia, as I would San Francisco, be very vigilant. Be very vigilant about your activities, and anything suspicious, any kind of cold, or anything mysterious dealing with your body. Illness or infections or rashes or coughing, get to a doctor and ask that doctor if he or she knows anything about smallpox, anthrax, botulism and so on.

I would not suggest buy a gas mask. I would not suggest that they go out and buy a lot of cyprofloxin, or doxycycline, or penicillin. I would strongly just urge them to be more alert than they have in the past. If there is anything that their body is telling them, they should check with their doctor as soon as possible, and they should ask their doctor if their doctor knows things about bioterrorism.

Senator KOHL. All right, Governor. As you know, some of the most advanced biological research in the world is occurring every day at federally funded labs and our public universities, including the University of Wisconsin, as you well know. We also know that very important and vital research involves the use of dangerous biological agents. Of course, we must secure these labs and not allow these lethal pathogens to fall into the wrong hands.

The CDC regulation that will go into effect next January will require upgraded security measures at these labs. I read in the paper that you said that you would like to expend funds in order to increase security at Government labs. My question to you is, what are we going to do at university labs?

Secretary THOMPSON. I think we should find ways to increase the security in all of our laboratories. I think it is very important, Senator Kohl. I am very happy you brought that up, and if I might I would just like to ask Scott Lillibridge—I forgot to do this—about getting vaccinated, because I think this is a question that a lot of people—and I think that we have looked at it, and we would strongly suggest that that is not the best way to go. Scott.

Dr. LILLIBRIDGE. Thank you, sir. I have two things I wanted to mention. Although the public health infrastructure is weak and we are investing in the infrastructure to improve surveillance, the laboratory science, and health alerting, our medical community and our public health officers have never been better in history. They have had more information, better education, local people must still trust and seek advice locally. I do not want to dissuade anybody from doing that.

The first issue, of course, in lockstep with, do we need gas masks, is, do we need vaccinations at this time, and the answer is no. We are not taking them in our senior management, nor are we recommending them to the population, and the primary reason is that most of the things we deal with have an incubation period. And

second, in the absence of disease, we would be confronted with large numbers of side effects.

Senator KOHL. But don't you, or don't we vaccinate our soldiers before they get involved in situations in which they may be threatened?

Dr. LILLIBRIDGE. Well, I will not speak to the DOD vaccination policy on soldiers in combat or staged in potential combat areas, but we think the risks for civilians are different.

Senator KOHL. Is it because we do not have enough to vaccinate all Americans today?

Dr. LILLIBRIDGE. No, sir. The primary issue is health and safety, and our confidence that we would use those at the time of crisis to be able to control the epidemic.

Senator KOHL. That is fine, and I will not spend too much time contending that with you, but it does seem not to answer the question of why would we vaccinate our military personnel as they are entering combat, but not suggest that the civilian population needs the same kind of protection. I do not think you have really responded to that in a way that I understand.

Dr. LILLIBRIDGE. Well, let me just add, then, that the policies of the Department of Defense on vaccination have to do with practical situations, expected exposures, and the way they deploy their troops in high-risk areas. Looking at what we know and the way we respond now, we do vaccinate for illnesses that are present in the population. A case in point, childhood immunizations. However, we do not vaccinate nor recommend in a public health standard at this time to vaccinate the public for illnesses that are not moving through the population if we have the capacity to respond accordingly.

The other thing, in specific anthrax in the military, the Department has taken the position that our response—primary response modality—is not vaccine. It is antibiotics for 30 or 60 days, for a length of time to treat and prevent the illness, and that makes it a little different for us on that issue.

As for smallpox, again there is an incubation period, and we can target the vaccine most effectively. If you look back at the smallpox eradication campaigns, it was not area vaccination that controlled the outbreak, it was targeted surveillance and containment that helped us control the outbreak, and we would do likewise if that would recur in this country.

Senator KOHL. I just would like to get an answer from you, Governor, on whether or not there will be some Federal funds available to help university labs meet new security requirements.

Secretary THOMPSON. I cannot answer that, Senator Kohl. I wish I could, but I cannot. A lot depends upon the request we put into OMB. A lot depends upon Senators Kennedy and Frist's proposal. I do not think they put that kind of money in for securing labs on our universities, but I think it is something that States should certainly consider strongly.

Senator KOHL. Thank you. Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Mr. Secretary, for being so generous with your time and your expertise, and thank you for your leadership on this issue. Again, following up on Senator Durbin's comments, we look forward to working with you.

Secretary THOMPSON. I appreciate that. Thank you very much.

Senator HARKIN. We will now turn to panel 3. I would like to call to the witness table Jonathan Tucker, Stephen Cantrill, Jerome Hauer, Patricia Quinlisk, and Rex Archer. I thank this panel for being so patient and for being here this morning. Some of you are coming a great distance.

I will again state that all of your statements will be made a part of the record in their entirety. We would be appreciative if you could summarize them succinctly and hit the high points for us. We would appreciate that so we might get into a generalized discussion with you, the experts in this area, and we will just go down the line in which I called the names, or in which I have them listed here.

First I would recognize Dr. Jonathan Tucker, who directs the Chemical and Biological Weapons Nonproliferation Program at the Monterey Institute of International Studies, and is the editor of Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons. He is also the author of Scourge: The Once and Future Threat of Smallpox.

Dr. Tucker, welcome to the committee.

STATEMENT OF JONATHAN TUCKER, Ph.D., DIRECTOR, CHEMICAL & BIOLOGICAL WEAPONS NONPROLIFERATION PROGRAM, MONTEREY INSTITUTE OF INTERNATIONAL STUDIES

Dr. TUCKER. Thank you, Mr. Chairman. Mr. Chairman, distinguished members of the subcommittee and guests, many thanks for the opportunity to testify before you today on a concern that has gripped the Nation in the wake of the September 11 terrorist attacks on the World Trade Center and the Pentagon, which is the possibility that terrorists might escalate their horrific campaign of death and destruction by resorting to the use of unconventional weapons, including biological pathogens.

Although experts disagree on the ease with which terrorists could acquire and use biological agents, many studies have concluded that the threat of bioterrorism against the United States is growing, and that the Nation is not adequately prepared to handle even a medium-sized biological attack. With a potential health emergency in the making, time is of the essence in reducing our vulnerability to this threat, and I believe there is much we can do in the near term.

It is important to note that bioterrorism and the growing challenge of national emerging infectious diseases are two sides of the same coin. Both phenomenon would manifest themselves in an unusual outbreak of infectious disease, one that would have to be rapidly detected, identified, and contained to minimize the harmful consequences. Because some of the most deadly biological warfare agents such as anthrax and plague respond to antibiotics administered during the early phase of the infection, prompt diagnosis and treatment could save many lives.

In the case of a contagious agent, rapid containment by isolation and vaccination could prevent further spread. Both the emerging infection and bioterrorist threats can be addressed most effectively by strengthening the Nation's public health systems, which unfortunately have been allowed to atrophy over the past several decades.

In the event of a major outbreak of disease, whether the result of a natural emerging infection or a deliberate terrorist attack, city, county, and State health departments would be the Nation's first line of defense, backed up by the medical detectives and virus centers at the CDC, the National Institutes of Health, and other Federal agencies.

The first indication of an unusual disease outbreak, as others have testified today, would be when the initial victims became ill and sought treatment at emergency rooms and doctor's offices. For example, a group of people in an urban neighborhood or an office building who were infected by a covert bioterrorist attack might come down days later with nonspecific, flu-like symptoms.

Today, I believe it is essential to bridge three critical gaps that would seriously impede the Nation's ability to detect and respond rapidly to an unusual outbreak of disease. The first gap in the U.S. infectious disease surveillance system is between primary care providers and public health departments. Today, disease surveillance systems in the United States are patchy in their coverage and lack adequate resources.

In the case of the West Nile virus in New York City, the surveillance system worked. Reporting by an alert physician was key to the early detection of the outbreak. Nevertheless, a bioterrorist attack or serious natural outbreak of disease would permit little margin for error. If health care providers are to be effective sentinels of an epidemic, they must have the necessary training and professional awareness to include the possibility of emerging infections and bioterrorism in the differential diagnosis. In addition, they must have direct communication channels to the public health department, and be able to report cases at any time, day or night.

The second gap in the Nation's infectious disease surveillance system is between the human health and animal health communities. Many emerging infectious diseases and putative bioterrorist agents are zoonotic, which means that they originate in animals but can also affect humans.

Given the considerable overlap of animal and human pathogens, animals can serve as useful sentinels for outbreaks of zoonotic diseases. The West Nile investigation, however, exposed a major gap between the veterinary and public health communities. Although the key to identifying the causative agent lay in merging information from the parallel investigations of the bird and human outbreaks, communication between animal health and public health agencies was poor, and what limited cooperation occurred was the result of informal personal relationships, rather than official coordinating mechanisms.

Finally, the third gap in the Nation's infectious disease surveillance system is between public health specialists and intelligence analysts. The dual threats of emerging infections and bioterrorism pose major conceptual and technical challenges for the U.S. intelligence community, such as distinguishing between an actual outbreak of an emerging disease and the deliberate release of a pathogen by terrorists.

Although the CIA has recruited a few microbiologists and other scientists for its analytical staff, this solution is not optimal, because scientists need to interact freely with colleagues from other

countries if they are to remain current and well-informed. A better approach would be to provide for routine exchanges of people and training between the U.S. public health and intelligence agencies. To date, however, sharp differences in organizational culture such as the need for secrecy versus scientific openness have impeded interagency collaboration in analyzing bioterrorist threats.

I would like to make a number of recommendations now on how these three gaps can be filled. To bridge the first gap between primary health care providers and public health practitioners, I would recommend the following steps. First, the Department of Health and Human Services should expand the national program of awareness training by professional medical societies for primary health care providers, including health care practitioners, emergency room physicians, and nurse practitioners.

Second, the Department should provide grants to State and local public health agencies to establish simple reporting mechanisms and clear communication channels between medical practitioners and city, State, or county public health departments, including 24-hour telephone or e-mail hotlines to respond effectively when doctors call, day or night. State and local health departments will need additional funds to hire more staff members with expertise in infectious disease epidemiology and information technology.

To briefly summarize my other recommendations on the need to bridge the second gap between human and animal health communities, I recommend that the Department of Health and Human Services and Department of Agriculture establish a surveillance network that covers livestock, zoo animals, and wildlife so that unusual patterns of zoonotic disease will be reported promptly to State and local health departments.

And to bridge the third gap between public health specialists and intelligence analysts, I recommend the Department of Health and Human Services establish formal exchanges of people and training between public health agencies such as CDC and Federal intelligence services.

In conclusion, Mr. Chairman, the natural emergence of a deadly and contagious infectious disease such as the Spanish flu of 1918, or the deliberate release of anthrax or some other pathogen as an act of bioterrorism could result in serious loss of life and social disruption. Unless corrected, the three gaps that currently exist among the U.S. medical, public health, animal health, and intelligence communities could seriously delay detection of the resulting disease outbreak and impede the prompt response needed to minimize its medical impact and social consequences. Bridging these three gaps will be essential if the Nation is to be better prepared to deal with the dual threats posed by emerging infections and bioterrorism.

PREPARED STATEMENT

The good news is that, despite the anxieties we all share today over this issue, the U.S. Government can take practical steps to reduce the threat. Improved disease surveillance, combined with other preparedness measures, may make it possible in the not-too-distant future to render biological weapons in the hands of terror-

ists, to borrow a phrase from President Ronald Reagan, impotent and obsolete.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF JONATHAN B. TUCKER

Mr. Chairman, distinguished Members of the Subcommittee, and guests: Many thanks for the opportunity to testify before you today on a concern that has gripped the nation in the wake of the September 11 terrorist attacks on the World Trade Center and the Pentagon: the possibility that terrorists might escalate their horrific campaign of death and destruction by resorting to the use of unconventional weapons, including biological pathogens. Although experts disagree over the ease with which terrorists could acquire and use biological weapons, many studies have concluded that the threat of bioterrorism against the United States is growing, and that the nation is not adequately prepared to handle even a medium-sized biological attack. With a potential health emergency in the making, time is of the essence in reducing our vulnerability to this threat, and I believe there is much we can do in the near-term.

It is important to note that bioterrorism and the growing challenge of natural emerging infectious diseases are two sides of the same coin. Both phenomena would manifest themselves in the form of an unusual outbreak of infectious disease-one that would have to be rapidly detected, identified, and contained to minimize the harmful consequences. Because some of the most deadly biological warfare agents, such as anthrax and plague, respond to antibiotics administered during the early phase of infection, prompt detection and treatment of an outbreak could save many lives. With a contagious agent, rapid containment by isolation and vaccination could prevent further spread.

The threats of emerging infections and bioterrorism can both be addressed most effectively by strengthening the nation's public health systems, which have been allowed to atrophy over the past several decades.[1] Back in the 1950s and 1960s, publicly supported community hospitals and public health laboratories supported an effective early-warning network for detecting and containing epidemics. Since then, however, the shift to privatized medicine and managed care has largely eliminated this system. Shortages of manpower and infrastructure in the nation's public health departments have also impeded effective epidemiological surveillance, leaving the public more vulnerable to serious outbreaks of infectious disease.[2]

My testimony will briefly address the dual threats of bioterrorism and emerging infectious diseases, point out some key gaps and weaknesses in our current public health defenses, and conclude with a number of practical policy recommendations for improving U.S. response capabilities.

THE THREAT OF BIOTERRORISM

Although it is unlikely that a small terrorist group working on its own would have the technical and financial resources to carry out a major bioterrorist attack on the scale of the September 11 event, a state-sponsor might provide the terrorists with the necessary know-how, seed cultures, and specialized dissemination equipment. Alternatively, a wealthy terrorist organization might be able to recruit scientists and engineers formerly employed by a state-level biowarfare program, such as that of Iraq, South Africa, or the former Soviet Union. As the biotechnology industry continues to spread rapidly around the world, fermentation tanks and other equipment used to produce biological warfare agents-much of which has commercial as well as military applications-will become increasingly accessible to terrorists. Moreover, given the current high level of public anxiety over bioterrorism, even a relatively small-scale attack with anthrax or some other biological agent could have a disproportionate psychological impact, eliciting widespread panic and undermining trust in government.

Defense analysts also worry about the possible use of biological agents by hostile states as a means of "asymmetric warfare"-David-and-Goliath strategies in which small countries would seek to circumvent or blunt the conventional military supremacy of the United States and its ability to intervene in regional conflicts. Such strategies might involve the use of disease agents to attack troops or civilians, destroy

[1] This testimony draws extensively on the following publication: Jonathan B. Tucker and Robert P. Kadlec, "Infectious Disease and National Security," Strategic Review, vol. XXIX, no.

[2] (Spring 2001), pp. 12–20. 2 Rick Weiss and Ellen Nakashima, "Biological Attack Concerns Spur Warnings," Washington Post, September 22, 2001, p. A04.

U.S. crops or livestock, or contaminate the nation's food supply. Biological attacks could be carried out on a scale large enough to hamper or deter U.S. intervention abroad, yet without crossing the mass-casualty threshold that could credibly trigger nuclear retaliation. Even in the face of U.S. deterrent threats, a rogue state or terrorist group that believed it could carry out an attack without attribution might be tempted to do so, particularly in the heat of crisis or war.

A bioterrorist attack would probably involve the covert release of a microbial pathogen that would give rise to detectable illness only after an asymptomatic delay, or incubation period, when the microorganism is multiplying in the host to cause disease. For example, Bacillus anthracis, the bacterium that causes anthrax, has an incubation period of roughly six days. Individuals who had been exposed to an invisible aerosol cloud of anthrax spores would probably be unaware at the time that they had been infected. The first evidence of the attack would emerge days later, when the infected individuals, by now widely dispersed, began to develop nonspecific, flu-like symptoms such as fever, fatigue, cough, and chest discomfort. A few days later, severe symptoms would set in, including pneumonia, sweating, anoxia (causing the victim to turn blue), and death, if the disease remained untreated. Anthrax is not-I repeat, not-transmissible from person to person, but because the disease is generally fatal within 24 to 36 hours after the onset of severe symptoms, antibiotic therapy (possibly combined with post-exposure vaccination to enhance the patient's immune response) must begin as soon as possible to have any chance of success. It is therefore essential to identify an outbreak linked to a bioterrorist attack early, while the disease is still treatable.

An even more challenging scenario would involve the deliberate release of a contagious agent, such as plague bacteria or smallpox virus. Plague has an incubation period of one to six days, whereas smallpox has an incubation period of roughly 12 to 14 days. By the time the first cases of smallpox were diagnosed, the initial group of cases would probably have infected close contacts, such as family and friends. In this case, it would be essential to launch an aggressive vaccination campaign to contain the epidemic before the infection spread through the general population in a series of expanding waves.

THE THREAT OF NATURAL EMERGING INFECTIONS

In parallel to the emerging threat of bioterrorism, the United States faces a growing problem of infectious disease from natural sources. During the 1960s and 1970s, powerful antibiotic drugs and vaccines appeared to have banished the major infectious scourges from the industrialized world, leading to a sense of complacency and neglect of programs for disease surveillance and prevention. Over the past two decades, however, several well-known diseases, such as tuberculosis, malaria, and cholera, have re-emerged in more virulent or drug-resistant forms or have spread geographically. At the same time, scientists have identified a host of previously unknown infections, including Legionnaire's disease, AIDS, Lyme disease, Sin Nombre virus, hepatitis C, "mad cow disease," Nipah virus, and new strains of influenza. AIDS was not recognized until the 1980s, yet it now infects some 36 million people worldwide and kills 3 million annually. Since 1980, the U.S. death rate from AIDS and other infectious diseases has increased by about 4.8 percent per year, compared with an annual decrease of 2.3 percent for the 15 years before 1980.[3]

Several factors have contributed to the problem of emerging infections:

—The inappropriate use of antibiotic drugs has fostered the evolution of resistant strains of tuberculosis and other bacterial diseases, even as the development of new generations of antibiotics has lagged.

—Ecosystem disturbances, such as clearing rainforests for economic gain or human settlements, have altered the geographical distribution of disease vectors such as rodents, monkeys, and mosquitoes, increasing their contact with humans.

—Rapid population growth and rural-urban migration have given rise to "megacities" in the developing world with poor public health infrastructure, enabling diseases that once remained isolated in rural areas to spread to large urban populations.

—The collapse of public health systems in Russia and other parts of the former Communist world have fostered the spread of diseases such as AIDS and drug-resistant tuberculosis.

---

[3] National Intelligence Council, *The Global Infectious Disease Threat and Its Implications for the United States*, NIE 99–17D, January 2000 [www.cia.gov/cia/publications/nie/report/nie99–17d.html].

—The rising volume of tourism, trade, and imported agricultural goods associated with economic globalization has created new opportunities for the introduction into the United States of disease vectors and microbial pathogens from other parts of the world.

Because most U.S. cities are within a 36-hour commercial flight of any part of the globe, or less than the incubation period of many infectious diseases, infected individuals may not be visibly ill when they cross a U.S. border. The risk of disease importations is greatest in major hubs of global commerce such as New York City, Los Angeles, and Miami. Indeed, the source of the 1999 outbreak in New York of West Nile encephalitis, a viral disease never before seen in the Western Hemisphere, may have been travelers from the Middle East who were incubating the disease or a stray infected mosquito on an airplane. Having spread widely over the past three years, West Nile virus is now permanently entrenched in the United States.

A future emerging infection introduced into our country could be far more deadly. In the worst-case scenario, a new pathogen would have the attributes of the 1918 strain of influenza virus, or Spanish Flu, which was highly transmissible through the air and uncharacteristically lethal to young, healthy people. This disease caused a global pandemic that claimed more than 20 million lives in less than two years. The speed at which the U.S. public health system could identify and contain such an outbreak would mean the difference between life and death for a large number of Americans.

CURRENT DEFICIENCIES IN INFECTIOUS DISEASE SURVEILLANCE

In the event of a major outbreak of disease-whether the result of a natural emerging infection or a deliberate terrorist attack-city, county, and state health departments would be the nation's first line of defense, backed up by the medical detectives and virus hunters at the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and other federal agencies. The first indication of an unusual disease outbreak would be when the initial victims became ill and sought treatment at emergency rooms and doctors' offices. For example, a group of people living in an urban neighborhood or working in an office building that had been subjected to a covert bioterrorist attack might initially develop nonspecific, flu-like symptoms. Detection and containment of a disease outbreak would entail four basic steps:

1. *Recognition and diagnosis by primary health care practitioners*.—Medical clinicians would identify cases of an unusual infectious disease or an undiagnosed "syndrome" (cluster of symptoms). Clinical laboratories would then attempt to identify the causative agent from patient blood, urine, or other specimens.

2. *Communication of surveillance information to public health authorities*.—Physicians and infectious-disease specialists who had detected an unusual pattern of disease incidence, such as several patients with the same symptoms, would report their observations to local or state public health authorities.

3. *Epidemiological analysis of the raw surveillance data*.—Epidemiologists working for the health department would interpret the disease-surveillance data to determine the source of the outbreak, the mode of transmission, and the extent of exposure. They would then make recommendations for appropriate treatment and public health measures (e.g., vaccination) to contain the outbreak.[4]

4. *Delivery of the appropriate medical treatment and public health measures*.—Patients seriously affected by the disease would be admitted to hospitals for treatment. Those infected with a contagious agent would be isolated and all potential contacts vaccinated (if vaccine is available) to prevent the disease from spreading.

Today, a major epidemic arising either from a natural emerging infection or an act of bioterrorism would pose serious challenges to the U.S. public health system in all four areas identified above. Useful lessons can be drawn from the 1999 epidemic of West Nile encephalitis in New York City, which revealed some serious gaps in the existing system of disease surveillance and response. These gaps must be remedied if the nation is to be better prepared in the future.

The first manifestation of the West Nile epidemic appeared in early July 1999, when common birds such as sparrows, robins, and crows began to die in unusual numbers in northern Queens and the South Bronx. One month later, humans in the same area began to be stricken with encephalitis, or inflammation of the brain, although a possible connection with the bird die-off was not suspected at the time. The human outbreak was detected when a physician at a hospital in Queens admit-

[4] Chemical and Biological Arms Control Institute, *Bioterrorism in the United States: Threat, Preparedness, and Response*, Executive Summary, November 2000, p. 12.

ted several elderly patients with an atypical form of encephalitis that was accompanied by severe muscle weakness. Unable to diagnose this condition, she took the initiative of reporting the unusual cases to the New York City Department of Health. Recognizing the possibility of an infectious disease outbreak, health department officials then called doctors at 70 hospitals around the city and identified 30 similar cases of encephalitis.[5]

In early September 1999, the Centers for Disease Control's laboratory for vector-borne infectious diseases in Fort Collins, Colo., analyzed patient specimens from the New York outbreak and identified the causative agent as St. Louis encephalitis virus. Three weeks later, however, the CDC was forced to admit that its initial diagnosis had been incorrect and that the infectious agent was actually West Nile virus, a disease endemic to East Africa and the Middle East that had never before been reported in the Western Hemisphere. The three-week delay in reaching the correct diagnosis revealed some significant deficiencies in the U.S. public health system:

—CDC scientists investigating the outbreak suffered from "tunnel vision" by screening only for encephalitis viruses commonly found in the United States and neglecting those linked to foreign outbreaks or possibly developed for bioterrorism.

—CDC scientists repeatedly rebuffed a veterinary pathologist at the Bronx Zoo who suspected a possible link between the bird and human outbreaks. Community newspapers in northern Queens had reported bird die-offs as early as late June 1999, or five weeks before the first human cases were detected. If the veterinary investigation had begun earlier and been pursued more aggressively, it is possible that the human epidemic could have been mitigated or even averted.

—Throughout the outbreak investigation, communication among the 18 participating local, state, and federal agencies was complex and difficult, and was achieved primarily through conference calls lasting several hours.

—The various city, state, and federal laboratories involved in the case used different diagnostic techniques, making it difficult to compare results.[6]

This experience indicates the need for better information-sharing at all levels, as well as a common database for disease surveillance and laboratory tracking.

BRIDGING THE GAPS

Today, the U.S. response to a serious epidemic resulting from an emerging infectious disease or an act of bioterrorism would be seriously constrained by poor communication and coordination among the diverse array of federal, state, county, and city agencies responsible for medical care, public health, animal health, law enforcement, and intelligence collection. Efforts to improve interagency coordination face formidable obstacles, including fragmented jurisdiction and differences in organizational mission and culture among the various players.

In particular, it is essential to bridge three critical gaps that would seriously impede the nation's ability to detect and respond rapidly to unusual outbreaks of disease. These disconnects exist between: (1) primary care providers and the public health system, (2) the human and animal health communities, and (3) public health experts and intelligence analysts.

The Gap Between Primary Care Providers and Public Health Departments

Disease surveillance systems in the United States are patchy in their coverage, and most rely on reporting by primary health care providers. In the most common type of surveillance, physicians and nurse-practitioners are required to report certain infectious diseases or "syndromes" (undiagnosed clusters of symptoms) to local health departments. Even when disease or syndromic reporting is mandatory, however, it is often incomplete. Doctors may be too busy to comply, or they may simply not know to whom to report.

In the case of West Nile virus, the system worked: reporting by an alert physician was key to the early detection of the outbreak. Nevertheless, a bioterrorist attack or a serious natural outbreak would permit little margin for error. If health-care providers are to be effective sentinels of an epidemic, they must have the necessary training and professional awareness to include the possibility of emerging infections and bioterrorism in their differential diagnosis. In addition, they must have direct communication channels to the public health department and be able to report cases at any time, day or night.

---

[5] Jennifer Steinhauer and Judith Miller, "In New York Outbreak, Glimpses of Gaps in Biological Defenses," New York Times, October 11, 1999.

[6] Marcelle Layton, M.D., M.P.H., "Outbreak Surveillance and Management at the State and Local Level: Current Realities," presentation at the Second National Symposium on Medical and Public Health Response to Bioterrorism, Washington, D.C., November 28, 2000, transcript.

The Gap Between the Human and Animal Health Communities

Many emerging infectious diseases and putative bioterrorist agents are "zoonotic," meaning that they originate in animals but can also infect humans. Examples of zoonotic diseases that have been developed as biological warfare agents include anthrax, tularemia, brucellosis, plague, and Venezuelan equine encephalitis. In addition, many natural epidemics have begun in wild or domesticated animals and then spread to humans, including the outbreaks of bubonic plague in India, Sin Nombre virus in the U.S. Southwest, Nipah virus in Malaysia, avian influenza in Hong Kong, and West Nile virus in New York City.

Given the considerable overlap of animal and human pathogens, animals can serve as useful "sentinels" for outbreaks of zoonotic diseases. Sheep, for example, are far more sensitive to anthrax infection than humans. Nevertheless, the West Nile investigation exposed a major gap between the veterinary and public health communities. Although the key to identifying the causative agent lay in merging information from the parallel investigations of the bird and human outbreaks, communication between animal health and public health agencies was poor. What limited cooperation occurred was the result of informal personal relationships rather than official coordinating mechanisms.

This disconnect arose from the fact that the expert communities that address the health of people, domesticated animals, and wildlife are separated organizationally, geographically, and jurisdictionally-despite the fact that infectious diseases do not respect these artificial boundaries. State and local veterinary agencies focus on the health of domestic pets, horses, livestock, and other economically important species, but they rarely communicate with agencies involved in safeguarding human health. Low priority and funding are devoted to the health of wildlife, particularly non-endangered species such as crows and rats, which are the responsibility of parks departments and animal control officers. Monitoring the health of zoo animals is another "gray area" with no clear leadership, and only six zoos in the United States employ full-time veterinary pathologists.[7]

The 1999 outbreak of West Nile encephalitis in New York City indicated that outbreaks of zoonotic disease in wildlife and zoo animal populations could provide early warning of an impending human epidemic. In 2001, the CDC agreed to fund a pilot project for monitoring the spread of West Nile virus by testing blood and tissue specimens from zoo animals, as well as dead birds and other wildlife found on zoo property. A centralized database will be established to summarize the results, which will be made available to the public health surveillance system. For the project to be effective, the participating zoo pathologists must build a relationship with local public health officials, and the zoo data must be reliable (using a validated diagnostic methodology), consistent, and reported in a timely fashion. If this pilot program is successful, it could serve as the basis for further interaction between the zoo and public health communities for the surveillance of other zoonotic diseases.[8]

The Gap Between the Public Health Specialists and Intelligence Analysts

The dual threats of emerging infections and bioterrorism pose major conceptual and technical challenges for the U.S. intelligence community, such as distinguishing between a natural outbreak of an emerging disease and the deliberate release of a pathogen by terrorists. In 1984, for example, members of the Oregon-based Rajneeshee cult used salmonella bacteria to contaminate ten restaurant salad bars in a trial run of a scheme to manipulate the outcome of a local election by making large numbers of voters too sick to go to the polls. After 751 people fell ill with food poisoning, public health investigators concluded initially that the outbreak had resulted from natural sources. The true cause did not emerge until a year later, when a cult member confessed to the crime.[9]

During the West Nile investigation, the belated discovery that the causative virus had originated in the Middle East reportedly raised red flags with biological warfare analysts at the Central Intelligence Agency (CIA). The reason was an eerie coincidence. In April 1999, Mikhael Ramadan, a self-declared Iraqi defector who claimed to have worked as a body-double for Saddam Hussein, published a memoir in England titled In the Shadow of Saddam in which he asserted that in 1997, the Iraqi

---

[7] Tracey McNamara, Bronx Zoo, presentation at Workshop on Agro-Terrorism, Cornell University, November 13, 2000.

[8] Tracey S. McNamara and Dominic Travis, Project Co-coordinators, *Surveillance for West Nile Virus in Zoological Institutions: Report of a Workshop*, June 21–22, 2001, Lincoln Park Zoo, Chicago.

[9] W. Seth Carus, "The Rajneeshees (1984)," in Jonathan B. Tucker, ed., *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons* (Cambridge, Mass.: MIT Press, 2000), pp. 115–137.

leader had ordered the development of a highly virulent strain of West Nile virus as a bioterrorist weapon.[10] Additional concern was raised by the fact that during the 1980s, the CDC had shipped an Israeli strain of West Nile virus to a microbiologist in Basra, Iraq, ostensibly for public health research.[11] Nevertheless, further analysis turned up no evidence that the Iraqis had developed West Nile virus as a biological weapon.[12]

The ability of the CIA to assess whether the West Nile outbreak was a deliberate attack was hampered by the agency's lack of technical expertise: few intelligence analysts have a solid grounding in infectious diseases or epidemiology. Trained epidemiologists would have recognized immediately that West Nile virus was a poor candidate as a bioterrorist weapon because it causes neurological injury and death in only about 5 to 10 percent of those infected, mainly children, the elderly, and those with a weakened immune system. Moreover, because the virus is transmitted to humans by mosquitoes, the putative terrorists would have had to import virus-infected insects, release them, and wait for the disease to spread-an unlikely scenario.

Although the CIA has recruited a few microbiologists and other scientists for its analytical staff, this solution is not optimal because scientists need to interact freely with colleagues from other countries if they are to remain current and well informed. A better approach would be to provide for routine exchanges of people and training between U.S. public health and intelligence agencies, but differences in organizational culture have impeded collaboration in analyzing bioterrorist threats. For intelligence specialists, working closely with medical doctors and epidemiologists pose risks to the security and effectiveness of their operations. CDC epidemiologists, for their part, see themselves as members of the international scientific community, publish their research results, and interact with colleagues from politically sensitive countries; few are cleared for classified information or have access to encrypted phone and fax lines. Public health experts also worry that cooperation with defense, law enforcement, or intelligence agencies could taint their public image. Indeed, any link between the CDC and the U.S. intelligence community, however innocent, could undermine the ability of epidemiologists to investigate natural disease outbreaks in foreign countries.

POLICY RECOMMENDATIONS

New policies are needed to bridge the three gaps identified above in order to improve the nation's preparedness for rapidly identifying and containing outbreaks of disease associated either with emerging infections or bioterrorism.

Bridging the Gap Between Primary Care Providers and Public Health Departments

—The Department of Health and Human Services (DHHS) should expand the national program of awareness training for primary health care providers. To ensure timely detection of an unusual outbreak of disease, general practitioners, emergency-room physicians, and nurse-practitioners must be familiar with the signs and symptoms of exotic diseases that they would not normally encounter in their medical practice. Professional medical societies, physician-oriented web sites, and continuing medical education programs should offer training and refresher courses in the diagnosis and treatment of bioterrorist agents. Such courses might eventually be made a prerequisite for medical licensing or board certification.

—DHHS should provide grants to state and local public health agencies to establish simple reporting mechanisms and clear communication channels between medical practitioners and city, state, or county public health departments, including 24-hour telephone or e-mail "hot lines." To respond effectively when doctors call, day or night, state and local health departments will need additional funds to hire more staff members with expertise in infectious diseases, epidemiology, and information technology.

—DHHS should increase the number of clinical laboratories associated with public health departments around the country that are capable of diagnosing exotic diseases, including suspected bioterrorist agents. Standardized testing protocols should be developed so that laboratories can easily exchange and compare diagnostic findings.

---

[10] Richard Preston, "West Nile Mystery," The New Yorker, October 18–25, 1999, pp. 90–108.

[11] Jonathan B. Tucker, "Lessons of Iraq's Biological Warfare Programme," Arms Control/Contemporary Security Policy, vol. 14, no. 3 (December 1993), p. 238.

[12] Vernon Loeb, "CIA Finds No Sign N.Y. Virus Was an Attack," Washington Post, October 12, 1999, p. A2.

—In conjunction with the Department of Defense, DHHS should improve basic and applied research on bioterrorist threat agents by increasing funding for this purpose. Knowledge of the pathophysiology, virulence factors, immunology, and genomic structure of disease agents is vital for the development of improved diagnostic tests, therapeutics, and vaccines. Yet such knowledge is limited for the roughly two dozen classical biological warfare agents, and almost nonexistent for more than 100 microbial pathogens of potential bioterrorist concern.

—DHHS should facilitate prompt and accurate disease reporting by expanding its current efforts to establish an electronic infrastructure for this purpose at the city, county, and state levels. At present, few cities have established electronic systems for the exchange of surveillance data, and roughly half the public health agencies in the United States are not connected to the Internet. Also needed is a national electronic information system for exchanging disease-reporting data between state health departments and the CDC.

—DHHS should attempt to attract more talented individuals into the public health field by offering mid-career fellowships and internships for medical doctors, both at CDC and at public health departments around the country.

—CDC should assist hospitals to incorporate bioterrorist scenarios in their emergency response plans and to carry out frequent dress rehearsals.

Bridging the Gap Between the Human and Animal Health Communities

—If the pilot zoo surveillance project for West Nile virus is successful, DHHS and the U.S. Department of Agriculture (USDA) should expand this program into a veterinary surveillance network in which unusual patterns of zoonotic disease in livestock, zoo animals, or wild animals are reported promptly to state and local public health departments. In some cases, susceptible species living in a city zoo could serve as "sentinels" of a covert bioterrorist attack against the urban population.

—DHHS and USDA should support improved communications infrastructure between veterinary agencies and public health departments, including telephone and e-mail hot lines, so that unusual outbreaks of zoonotic disease in animals can be reported to the appropriate public health authorities.

—DHHS should fund more epidemiological research on the complex relationships between human and animal health. Already, the West Nile outbreak has served as a catalyst for greater interdisciplinary cooperation among veterinarians, physicians, ecologists, and wildlife biologists.

Bridging the Gap Between Public Health Specialists and Intelligence Analysts

—The U.S. intelligence community should recruit more individuals with advanced training in microbiology, infectious disease, and epidemiology to work as intelligence analysts focusing on biowarfare and bioterrorist threats. In particular, the Defense Intelligence Agency's Armed Forces Medical Intelligence Center (AFMIC), the one intelligence organization specializing in infectious diseases, should be expanded by hiring more technically trained staff. Individuals with experience in the biotechnology industry are also needed to detect the subtle indicators of clandestine biological weapons production, particularly at dual-use facilities such as vaccine plants.

—DHHS should establish formal exchanges of people and training between public health agencies such as the CDC and federal intelligence services such as the CIA, the Defense Intelligence Agency (DIA), the National Security Agency (NSA), and the Federal Bureau of Investigation (FBI). To this end, DHHS should create a cadre of specialists in public health and biomedicine who have security clearances and access to secure communications, such as encrypted phone, fax, and videoconferencing facilities. These experts could then provide technical advice to intelligence analysts as needed concerning suspicious disease outbreaks that could be the result of covert biological weapons use.

—CDC should establish a reporting mechanism so that unusual outbreaks of disease in the United States detected by the Epidemic Intelligence Service (EIS) are routinely reported to the FBI and other law-enforcement agencies.

In conclusion, the natural emergence of a deadly and contagious infectious disease such as the Spanish Flu of 1918, or the deliberate release of anthrax or some other pathogen as an act of bioterrorism, could result in a serious loss of life and social disruption. Unless corrected, the communication gaps that currently exist among the U.S. medical, public health, animal health, and intelligence communities could seriously delay detection of the resulting disease outbreak and impede the prompt response needed to minimize its medical impact and social consequences.

Bridging these gaps will be essential if the nation is to be better prepared to deal with the dual threats posed by emerging infections and bioterrorism. The good news

is that despite the anxieties we all share today about this issue, the U.S. government can take practical steps to reduce the threat. Improved infectious disease surveillance, combined with other preparedness measures and continued research, may make it possible in the not-too-distant future to render biological weapons in the hands of terrorists—to borrow a phrase from President Ronald Reagan—"impotent and obsolete."

Senator HARKIN. Thank you. Now we will go to Dr. Stephen Cantrill, associate director, Department of Emergency Medicine, Denver Health Medical Center. Dr. Cantrill served as the Regional Medical Coordinator for Denver's participation in Operation Top Off, which simulated a bioterrorist incident, which I mentioned in my opening statement a while ago. He has also been involved in weapons of mass destruction training for the Denver area.

Dr. Cantrill, welcome.

STATEMENT OF STEPHEN CANTRILL, M.D., ASSOCIATE DIRECTOR, DEPARTMENT OF EMERGENCY MEDICINE, DENVER HEALTH MEDICAL CENTER

Dr. CANTRILL. Mr. Chairman, and members of the subcommittee, thank you. I consider it a privilege to have been asked to testify before this subcommittee today on our experience with Operation Top Off and on some local perspectives and concerns about our country's efforts to improve our domestic preparedness to deal with the possibility of a bioterrorism event.

Even before our participation in Top Off, a major issue of concern in our preparedness was achieving adequate involvement in training on the part of the general medical and public health communities. This oversight has been partially remedied by recent CDC grants to State public health departments, but lack of awareness training and preparedness in the general medical community continues to be a major issue.

This also represents a major paradigm switch for the public health sector, as they have not been trained in medical aspects of disaster management and medical incident command, which are two areas of major importance in adequately dealing with a biological terrorism attack. We must somehow stimulate interest and seek incentives for the individuals in these communities so they will avail themselves of WMD training.

We must also stimulate and encourage training and integration between hospitals and State and local departments of public health, especially in the areas of information systems, communication systems, and coordinated test readiness. This task will be made especially difficult by the decades-old contraction of the public health infrastructure in this country, which must be reversed. It will also be complicated by the recent adoption of the Federal HIPAA regulations governing excessive confidentiality of patient information that could potentially be used to detect the early stages of bioterrorist attack, and most domestic WMD preparedness hospitals and other health care institutions have been the forgotten components.

Most hospitals are financially strapped due to low levels of reimbursement for care. At this time there are few public policy incentives to encourage or enable health care institutions to invest in WMD planning or training. With a large number of dollars going

to other sectors, we must not forget our hospitals and public health institutions to assist them in their preparedness.

An additional concern is the illusion shared by many that our health care system could adequately deal with a significant WMD incident. In this area, I must respectfully disagree with Secretary Thompson, as you heard me quoted earlier. Due to multiple pressures, including fiscal, regulatory, and inadequate available staff, our hospitals today have no surge capacity. They could not adjust to a sudden increase in patient load without degenerating into chaos.

This has been clear to those of us in health care, and it is well-demonstrated by Operation Top Off. This problem would only be partially alleviated by the dispatching of our Federal resources to a specific locale, and could be of no help if terrorists opt to involve dozens of metropolitan areas simultaneously. This problem is further complicated by regulations such as the Centers for Medicare and Medicaid Services, the old HCFA, EMTALA regulations.

Our national capability to limit the spread of a WMD infectious agent is also inadequate in many areas. For example, with an estimated 42 percent of our population susceptible to smallpox, and with the potential case fatality rate of 20 percent or greater, our national lack of adequate smallpox vaccine and smallpox immunoglobulin would severely limit our ability to contain the spread of this dreaded disease where it is used as part of a terrorist attack. Such an attack would make our 1918 influenza pandemic truly look like a walk in the park. The ongoing problems with the manufacture and availability of anthrax vaccine are also troubling.

Another concern is the potential lack of coordination between federally funded efforts such as the Metropolitan Medical Response System, the MMRS, and systems that are already in place. Every effort must be made to have these new initiatives interdigitate with plans and systems that already serve these metropolitan areas. When possible, it would be better to augment current systems rather than constructing competing systems.

The Federal Government should also increase its research efforts in some other potential aspects of dealing with a WMD incident. For example, what are the best techniques to use for the emergency vaccination of thousands of people in a metropolitan area? How do we expeditiously distribute prophylactic antibiotics to a million people in 48 hours? These and other operational issues must be researched and the results disseminated and incorporated into the planning for all major metropolitan areas.

All said, I do not want to appear negative or ungrateful. I applaud the Federal Government's effort at initiating and encouraging local training and planning for a potential bioterrorism or other WMD event. I do feel we have made significant strides in the area of WMD awareness and preparedness. We now have an opportunity to fine-tune and improve our efforts for domestic preparedness.

In closing, I would like to thank you, Mr. Chairman, and the subcommittee for this opportunity to discuss some of the issues that are of concern to the medical and public health communities in our preparations to combat domestic terrorism at the local level.

PREPARED STATEMENT

Mr. Chairman, this concludes my testimony. My written testimony does include other comments concerning the national disaster medical system, and the National Pharmaceutical Stockpile. I am happy to address any questions you or the subcommittee members may have.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. STEPHEN V. CANTRILL

Mr. Chairman and members of the Subcommittee, I am Dr. Stephen Cantrill, Associate Director of Emergency Medicine at Denver Health Medical Center in Denver, Colorado. I have been involved in local preparation and training for weapons of mass destruction for the last four years and was a participant in the planning and execution of Operation TopOff in May, 2000. I consider it a privilege to have been asked to testify before the Subcommittee today on our experience with Operation TopOff and some local perspectives and concerns about our country's efforts to improve our domestic preparedness to deal with the possibility of a bioterrorism event, even though I do so with a heavy heart, due to the recent terrorist events that have shocked our country.

As you may know, Operation TopOff was a Congressionally mandated, no-notice, multi-site disaster exercise to evaluate our country's ability to deal with multiple simultaneous disasters from weapons of mass destruction. We in Denver had the good fortune to be selected to participate in this exercise as the site for a simulated bioterrorism attack with pneumonic plague. This exercise involved initial exposure of more than 2500 patients with thousands of fatalities and tens of thousands of ill patients. Even before our participation in this exercise, a major issue of concern in our preparedness was achieving adequate involvement and training on the part of the general medical and public health communities. Many efforts to date have focused on training and material support for police, fire and emergency medical services. This includes the training efforts under the Nunn-Lugar-Domenici Act that were directed towards "first responders" with no attempt to engage the general medical community nor the state and local public health sectors. This oversight has been partially remedied by recent CDC grants to the state public health departments, but lack of awareness, training and preparedness in the general medical community continues to be a major issue. The message must be clearly conveyed that our health care system is of central importance in our fight against weapons of mass destruction. Medicine and public health must be called to the table and included and supported in the planning and training for dealing with weapons of mass destruction. This will be a major paradigm switch, especially for the public health sector, as they have not been trained in the medical aspects of disaster management and medical incident command, two areas of major importance in adequately dealing with a biological terrorism attack. Current efforts in these areas have been largely done pro-bono by a small number of dedicated individuals with little interest or enthusiasm on the part of the general medical or public health communities. We must somehow stimulate interest and seek incentives for the individuals in these communities so they will avail themselves of WMD training. We must also stimulate and encourage training and integration between hospitals and state and local departments of public health, especially in the areas of information systems, communication systems and coordinated tests of readiness. This task will be made especially difficult by the decades old contraction of the public health infrastructure in this country, which must be reversed. It will also be complicated by the recent adoption of the federal HIPPA regulations governing excessive confidentiality of patient information that could potentially be used to detect the early stages of a bioterrorist attack.

In most domestic WMD preparedness, hospitals and other health care institutions have been the forgotten components. For example, hospitals are not currently allowed to receive any Department of Justice or CDC grant monies to deal with their WMD needs including drugs and equipment that would be specifically used for a WMD event. Most hospitals are financially strapped due to low levels of reimbursement for care. They cannot pass on these WMD preparedness costs to normal patients. At this time, there are few public policies or incentives to encourage or enable health care institutions to invest in WMD planning or training. The federal government must engage and support the medical and public health leadership in

building the critical elements of WMD preparedness. With the large number of dollars going to other sectors, we must not forget about our hospitals and public health institutions to assist them in their preparedness.

An additional concern is the illusion shared by many that our health care system could adequately deal with a significant WMD incident. In this area I must respectfully disagree with Secretary Thompson. Due to multiple pressures, including fiscal, regulatory, and inadequate available staff, our hospitals today have no "surge capacity". They could not adjust to a sudden increase in patient load without degenerating into chaos. This has been clear to those of us in health care and was well demonstrated by Operation TopOff. Unfortunately, this problem is not well appreciated in many governmental circles and by the lay public. This problem would only be partially alleviated by the dispatching our federal resources to a specific locale and could be of no help if terrorists opt to involve dozens of metropolitan areas simultaneously. This problem is further complicated by regulations such as the Centers for Medicare and Medicaid Services (the old HCFA) EMTALA regulations that require a medical screening examination for all who present to an emergency department but do not allow for suspension or alteration of these requirements under the duress of a patient load that could balloon to ten to twenty times normal.

Dealing with a massive increase in hospital admissions in a metropolitan area during a WMD attack could theoretically be alleviated through the activation of the National Disaster Medical System, with transfer of patients to distant participating hospitals. It is not clear to us in the trenches, however, that this system, which was designed more for dealing with natural disasters, could adequately ameliorate the problems seen with a WMD incident. Would remote hospitals, whose participation is voluntary, be willing to accept contagious patients suffering from plague? The capacity and design of this system should be reassessed in light of these issues.

Several areas in which WMD preparedness work has begun could benefit from some additional attention. The National Pharmaceutical Stockpile maintained by the CDC is a major step forward in our ability to deal with a WMD attack. However, the packaging of the drug items in the stockpile remains largely oriented towards fiscally advantageous stock rotation, not efficient distribution once the stockpile arrives at the locale of the terrorist attack. Also, significant thought should be given to increasing stocks of several of the drugs at a local level: a 12 to 24 wait would render most of the utility of the treatments for a chemical attack unhelpful as most of the severely afflicted patients would be dead. Also, more effort must be made to incorporate state-of-the-art treatments that are widely used in Europe (such as hydroxocobalamin for the treatment of cyanide poisoning) into our medical armentarium in the United States.

Our national capability to limit the spread of a WMD infectious agent is also inadequate in many areas. For example, with an estimated 42 percent of our population susceptible to smallpox and with a potential case-fatality rate of 30 percent or greater, our national lack of adequate smallpox vaccine and smallpox immune globulin would severely limit our ability to contain the spread of this dreaded disease were it used as part of a terrorist attack. Such an attack would make our 1918 influenza pandemic, with a case-fatality rate of 2 percent and more than 670,000 deaths, truly look like a walk in the park. The ongoing problems with the manufacture and availability of anthrax vaccine are also troubling.

Another concern is the potential lack of coordination between federally funded efforts, such at the Metropolitan Medical Response Systems (MMRS) and systems that are already in place. Every effort must be made to have these new initiatives interdigitate with plans and systems that already serve these metropolitan areas. Unfortunately, often the federal funding stream has been haphazard, uncoordinated and operated in a counter-productive fashion, thwarting successful integration. We must be careful not to create new systems that not only conflict with current in-place systems, but also may not have sufficient ongoing maintenance funding to successfully survive if they are not integrated into current plans and organizational structures. When possible, it would be better to augment current systems, rather than constructing competing systems.

This process, by its very nature, will take time. It is not something that we can throw a lot of money at and expect instant success, but rather will require a long-term, ongoing commitment. It would be most helpful, if it could be achieved, for all regional funding to have a single point of contact. There should also be an increased emphasis on involving regional emergency managers in this integration process. Our goal should not be to develop a separate system to deal with nuclear- chemical-biological events, but rather to have this preparedness be part of the existing systems that we have in place to deal with all other disasters. Hopefully, FEMA's announced role as an integrative force in this area will address some of these deficiencies.

The federal government should also increase its research efforts in some of the practical aspects of dealing with a WMD incident. For example, what are the best techniques to use for the emergent vaccination of thousands of people in a metropolitan area? How do we expeditiously distribute prophylactic antibiotics to a million people in 48 hours? In Denver, during Operation TopOff, we exercised a demonstration distribution center for the dispensing of prophylactic antibiotics to the general population. With 60 workers, we could dispense to only 3360 patients in a 24 hour period. Extrapolating this to the need to deliver prophylaxis to a population of one million patients within a 48 hour period, we would need 1400 distribution centers utilizing 84,000 workers. Clearly not doable. These and other operational issues must be researched and the results disseminated and incorporated into the planning for all major metropolitan areas.

All said, I do not want to appear negative or ungrateful. I applaud the federal government's efforts in initiating and encouraging local training and planning for a potential bioterrorism or other WMD event. I do feel we have made significant strides in the area of WMD awareness and preparedness. Exercises such as Operation TopOff have proven invaluable to stimulate interest and planning for the unthinkable. We now have an opportunity to fine tune and improve our efforts for domestic preparedness.

In closing, I would like to thank you, Mr. Chairman, and the Subcommittee, for this opportunity to discuss some of the issues that are of concern to the medical and public health communities in our preparations to combat domestic terrorism at the local level. Mr. Chairman, this concludes my testimony. I am happy to address any questions that you or the Subcommittee members might have.

Senator HARKIN. Thank you, Dr. Cantrill. Next, we will go to Mr. Jerome Hauer. Mr. Hauer is director of the Crisis and Consequences Management Group at Kroll Associates. Previously he was director of New York City's Office of Emergency Management, where he was responsible for drafting the city's emergency response plans to national and manmade disasters, including biological terrorism.

Mr. Hauer, welcome.

STATEMENT OF JEROME M. HAUER, MANAGING DIRECTOR, CRISIS AND CONSEQUENCES MANAGEMENT, KROLL ASSOCIATES

Mr. HAUER. Thank you, Mr. Chairman. I appreciate the invitation to be here today, and I, too, would like to commend you for your leadership in holding these hearings. As you mentioned, I am former Director of the Mayor's Office of Emergency Management, and I also served as an advisor to Secretary Thompson on national security issues. I would like to spend the next few minutes addressing the issues State and local governments confront as they plan for managing the consequences of biological terrorism.

Let me begin by stating the obvious. A biological incident is significantly different from that of a chemical incident. A chemical incident is a lights and sirens response by fire departments, police departments, and emergency medical services.

A biological incident, however, evolves over days, and may not be evident until victims begin to die. It will be recognized by primary care providers and changes in health care utilization, and not your first responders. Preparing for a biological incident at the local level, therefore, does not entail protective suits and decontamination units, but,rather, training, surveillance, and developing plans to support the needs of the community following the incident.

A window of opportunity exists following the release of a biological agent. If a State and local government is prepared, they can reduce morbidity and mortality, and if they are unprepared at the time of detection of an incident, people will die unnecessarily. The

key is ensuring that the window of opportunity is as large as possible.

Let me take a few moments to talk about three areas, training, surveillance, and logistical support. I will start with training. Most primary care practitioners have never seen a case of anthrax or smallpox. The symptoms would likely be missed, or thought to be those of more common illnesses like cold or flu. For a patient with anthrax, this delay could mean the difference between receiving care that could save their life, or being sent home with a misdiagnosis and then returning in 48 hours and being untreatable.

Training is essential for these care providers in two realms. The first is in recognizing these diseases and symptoms of other threat agents, and the second is in knowing what to do when there is a suspicion that something out of the ordinary has occurred.

Few physicians or nurses know who to call in their local health department when they have a concern about an unusual cluster of disease. Most contact with the local county health department is a three-part disease or reporting form for a limited number of reportable diseases. It is important we develop strong links between the medical community and the public health community, which brings me to my next point.

The public health infrastructure in this country has been allowed to deteriorate over the past 2 decades. The key to recognizing that something out of the ordinary has occurred is by having a sensitive surveillance system in place that monitors the health of the community and sets off alarms when something out of the ordinary is occurring.

In New York, we developed a system called the DHI, or daily health indicators, that tracks a number of activities. Any spike in any one of these indicators requires investigation by the department of health. Things such as EMS runs for respiratory or abdominal symptoms, admissions to the hospitals through the emergency rooms, sale of antidiarrheal and cold and flu medication over the counter, and influenza-like illness in nursing homes, are monitored and an algorithm is in place that causes an alarm when a spike in any one of the indicators occurs.

The data is also linked to a geographic information system so that patterns can be relayed on a map, and geographic distributions of the patients can be discerned. This system is simple in its design, and can be used in any city or county or State in the United States. Once it is determined that an incident has occurred, cities must be prepared to manage massive numbers of patients and have plans in place to distribute antibiotics or vaccinate people in a very short period of time.

The logistical support necessary for this will have to come from State and Federal resources. No city in this country can handle the demands that will be placed on them during one of these events. Let me give you a quick example as I conclude my remarks.

In New York, we modeled two scenarios, one in which we went door-to-door to give out antibiotics, and the other in which we set up POD's, or points of distribution so that people could come in to pick up antibiotics. To go door-to-door in Manhattan alone I would need over 40,000 people to give out antibiotics in a 36-hour period.

To set up POD's, I would need about the same amount of people, but I could give antibiotics out to the entire city.

In either case, these resources are simply not available in New York. I have not yet discussed the large number of medical personnel that would be required to treat those who have succumbed to the disease. We have developed plans to set up alternate care facilities to take the load off hospitals and casualty collection points to treat or isolate the overflow of patients.

In summary, I believe that we must continue to build our stockpiles of vaccines and antibiotics at the national level, as it is impractical for cities and States to do this. HHS is moving forward on this aggressively. Congress, however, must make a commitment to reinvigorate the public health system of this Nation, beginning with the development of sophisticated surveillance systems in all State and local health departments to detect a terrorist attack. Cities and counties should feed their data into State health departments and State health departments should feed their data into CDC's so cross-jurisdictional patterns can be detected.

Mr. Chairman, it is important we as a Nation focus on these threats. We have underestimated the level of sophistication that our enemies have. We know that the capability to manufacture these weapons exists in countries that are not our friends.

Mr. Chairman, that concludes my remarks, and I would be happy to answer any questions you have.

Senator HARKIN. Thank you very much, Mr. Hauer, for your leadership in this area.

Now we turn to Dr. Patricia Quinlisk, medical director and State epidemiologist for the Iowa Department of Health. She is the former President of the Council of State and Territorial Epidemiologists, and is one of its primary consultants on bioterrorism preparedness. She is also a member of the Gilmore Commission which is assessing the capabilities for responding to terrorist incidents involving weapons of mass destruction. Dr. Quinlisk, welcome.

STATEMENT OF PATRICIA QUINLISK, M.D., M.P.H., MEDICAL DIRECTOR AND STATE EPIDEMIOLOGIST, IOWA DEPARTMENT OF HEALTH

Dr. QUINLISK. Thank you very much. I am honored to appear today before the subcommittee dealing with this very important issue, and I am particularly honored to testify before you, Mr. Chairman, one of Iowa's Senators and an important long-time advocate of public health, for which we deeply appreciate your leadership.

Since the horrible attacks of September 11, we have seen from news and media reports that some members of the public are becoming so frightened by the possibility of a terrorist attack involving biological/chemical agents that they are purchasing antibiotics and gas masks in a mistaken belief that these measures will protect them from harm. However, since many of these agents are colorless, odorless, could be released covertly and, most importantly, especially with biological agents, would have an incubation period before symptoms occur, an individual would have to be taking these antibiotics or wearing their gas masks continuously for protection.

Therefore, the best defense against grievous harm that would result from one of these chemical or biological attacks is a robust public health system at the local, State, and Federal level. This system would be able to detect rapidly that an attack had occurred, investigate the nature of that attack, diagnose the agent involved rapidly, immediately institute responses that would get the right treatment to those who are ill and the right prevention measures to those who are exposed, and implement other protection strategies for everyone else.

But right now, the Nation's public health system is not robust. It is fragmented, ill-equipped, and seriously understaffed. There are not trained epidemiologists, those people who detect, investigate, and stop epidemics. There are not trained laboratorians or other critical personnel.

Over the past 3 years, CDC has had a bioterrorism preparedness cooperative grant program for State and local health departments. This is an important beginning, but it is only that, a beginning. Last year, Congress enacted the Public Health Threats and Emergencies Act to focus on building our Nation's public health infrastructure.

This has resulted in a consensus process, now accelerated, about needed core capacity and an appropriate assessment tool, but to date there has been no funding for States to conduct these assessments, which must be done in order to determine how to be fully prepared and where we have weaknesses. While I lack the resources of a documented assessment, I have been asked to provide this subcommittee with a description of what Iowa would need to be prepared for a terrorist attack. I am confident that a formal review would confirm much of what I am going to tell you, and I am also confident that Iowa's needs are typical of all the States.

Iowa's public health system needs strengthening in five major areas: Workforce, particularly in epidemiology, laboratories, communications, information systems, and planning. With regard to workforce, the Iowa Department of Public Health estimates it would need at a minimum 25 additional people at the State level alone to address the present needs.

Currently, we only have one person whose job it is to enhance surveillance for possible terrorist agents, to coordinate education with health care professionals in over 100 hospitals on identification and reporting, to organize an emergency alert system, and everything else that is needed. A similar number of people would be needed at the local level. We estimate that this would cost approximately $8 million.

I would like to emphasize that finding and attracting trained infectious disease epidemiologists to fill these types of positions will be difficult, particularly in this environment of intense competition with other States. Iowa tried to hire a bioterrorism coordinator. It took us over a year and three rounds of position announcements and interviews to find someone. I urge that the subcommittee give immediate attention to the problems of the public health workforce training, particularly epidemiology.

Iowa's public health laboratory needs are ongoing for support for equipment, materials, staff, and training, and needs to add chemical terrorism capacity. This alone will cost another $1 million.

An additional $500,000 to $1 million would be needed to build a comprehensive, rapid, and secure communications system. I will give you just two other examples of our basic communication needs. Right now in Iowa, only about 10 of the 99 counties have anyone on call 24 hours day, 7 days a week.

The State public health laboratory system currently reports diseases to me, the State epidemiologist, on paper through the U.S. mail system. The National Electronic Disease Surveillance system is a priority both for CDC and epidemiologists. It is designed to technically integrate as many as 100 separate data systems currently used in our Nation's public health system. It will allow the rapid identification of disease trends which may signify biological or chemical attacks much clearer and more quickly across States and regions.

CDC estimates this program should be funded at a minimum of $50 million. Iowa has received only planning and assessment funding, and will need $1 million to implement and integrate a disease information collection and analysis system. I cannot stress enough the critical nature of planning, including regular testing with exercises for preparedness for biological and chemical attacks. Iowa, as well as 39 other States, receive no funding to address this formal need. I would guess $200,000 per year would be needed for this activity.

In summary, looking only to Iowa's public health system's needs to prepare and respond to a biological or chemical attack, the total comes to approximately $11.5 million. This estimated amount is much closer to Iowa's real minimum needs than to the funding that we have already received under the current preparedness programs. This level of funding also needs to be made available over a period of several years, because it will take time to build the system, particularly in light of a workforce that is not prepared. After this, significant funding must continue to keep the system maintained. This is consistent with the $1.4 billion mentioned earlier.

PREPARED STATEMENT

One final point. By building a robust public health system, we will be building a multiuse system for diseases and situations that are occurring every day, such as emerging diseases like West Nile virus, which was now discovered in Iowa 2 weeks ago, the predicted pandemic flu, as well as every-day food poisoning outbreaks. Thus, when and if a terrorist event occurs, the system will be well-tested and familiar to those involved in ensuring an effective and efficient functioning system in a crisis.

Thank you again for the opportunity to provide testimony on this important matter.

[The statement follows:]

PREPARED STATEMENT OF DR. PATRICIA QUINLISK

Mr. Chairman, Members of the Subcommittee, I am Patricia Quinlisk, MD, MPH, Medical Director and State Epidemiologist for the Iowa Department of Public Health. I am here today not only representing the Iowa Department of Public Health, but also the Council of State and Territorial Epidemiologists (CSTE) as a former Council President and as one of its primary consultants on bioterrorism preparedness. In addition, my written statement includes comments provided by the

Association of Public Health Laboratories (APHL) on the need for enhanced laboratory capacity at the state and local level.

I am very honored to appear before the Subcommittee today, and particularly you, Mr. Chairman, as one of Iowa's Senators and an important, long-time advocate for public health. The Iowa Department of Public Health deeply appreciates your leadership.

I am also very honored to provide testimony on one of the most critical issues facing our nation: terrorism preparedness. The comments I will provide are from the perspective of a state health department and our specific and immediate, as well as long-term needs, to be prepared for a serious terrorist event involving biological or chemical agents.

BIOLOGICAL AND CHEMICAL TERRORISM: STRATEGIC PLAN FOR PREPAREDNESS AND RESPONSE.

Over a year ago, the national *Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response* was developed with input from experts from across the public health spectrum. This strategic plan is based on the following five focus areas, each of which is a primary function of public health:

—Preparedness and prevention;
—Detection and surveillance;
—Diagnosis and characterization of biological and chemical agents;
—Response; and
—Communication.

Working in coordination, federal, state and local public health agencies will also rely on other groups in the health and medical community to fully address each area to ensure preparedness. Examples are:

—Medical research centers,
—Health-care providers and their networks,
—Professional societies,
—Medical examiners,
—Emergency response units and responder organizations,
—Safety and medical equipment manufacturers,
—U.S. Office of Emergency Preparedness and other Department of Health and Human Services agencies.

In the state of Iowa, the Iowa Department of Public Health has been given statewide responsibility in four areas: traditional public health functions, medical services, mass casualty, and radiologic preparedness. I believe that most state public health agencies have similar preparedness responsibility in addition to their more traditional functions. Thus, in the above list, Iowa's Department of Public Health not only needs to coordinate with the listed groups that are state based, but also has primary responsibility to ensure their preparedness.

The national plan identifies nine critical steps in preparing for Chemical and Biologic attacks. I am going to name each step, and describe in each case where Iowa, a typical state, stands.

STEPS IN PREPARING FOR BIOLOGICAL AND CHEMICAL ATTACKS

—*Enhance epidemiologic capacity to detect and respond to biological and chemical attacks*.—Right now, Iowa depends entirely upon physicians and other health care providers to recognize and respond to illness in a possible victim of a biological or chemical attack. Yet after the events of two weeks ago, I received many phone calls from medical professionals asking what they should be looking for, and how to report suspicious illnesses. I would guess that the majority of Iowa health care providers do not know what to look for, how to send laboratory specimens for diagnosis of these rare diseases and whom to notify if they do suspect something. And yet this is the base of our present surveillance system. We need help in providing these professionals with education and training, diagnostic tools, and communication systems for rapid reporting.

—*Supply diagnostic reagents to state and local public health agencies*.—Right now in Iowa, if a large attack using anthrax occurred, there is only one laboratory that has the reagents, i.e. laboratory supplies, to rapidly and correctly diagnosis this disease. And the supply of these critical laboratory reagents would be depleted within hours.

—*Establish communication programs to ensure delivery of accurate information*.—Right now in Iowa, I, as the state epidemiologist, have no easy means to alert the health care system, or our public health department, other than personally calling someone. I am able to fax or send e-mail messages, but if an incident occurs after working hours, I would have to call. Only about 10 of the 99 local

health departments in Iowa have someone on call 24 hours-a-day, 7 days-a-week. Two years ago, when a petting zoo bear was diagnosed with rabies on a Saturday, there were several health departments with victims living in their counties that I could not contact until the next Monday morning when their offices opened. Also, the systems I do have available are not secure, thus I would not be able to send or receive confidential information without jeopardizing the privacy of that information. Our state public health laboratory, located in Iowa City, sends confidential patient information via the U.S. postal service, on paper, to insure safety.

—*Enhance chemical and bioterrorism-related education and training for health-care professionals, as well as traditional first responders*.—Right now in Iowa, public health only has one person with the responsibility to address training for over 100 hospitals, all health care providers, and emergency medical personnel regarding biological and chemical terrorism and medical/public health coordination. This is obviously inadequate. Everyday, we receive requests to give seminars, lectures, and provide information on these diseases and the appropriate response to terrorist events. We are lucky in Iowa to have a statewide fiber optics network, which we used two days ago to broadcast a "lunch time briefing on terrorism" to almost 200 sites, and thousands of health care providers. But since only the basic information can be addressed in an hour, this can only be the beginning of our educational efforts.

—*Prepare educational materials that will inform and reassure the public during and after a biological or chemical attack*.—Since terror, rather than illness and death, is the primary goal of terrorist, one of the best tools we have against this is timely, accurate and believable information. Iowa has only just begun to work with the media on this issue, yet this may be one of the most important actions we take during an attack.

—*Stockpile appropriate vaccines, drugs and antidotes*.—It is estimated that it will take approximately six to twelve hours for some of the federal stockpiles of critical medical supplies to reach Iowa, we believe it is necessary to survey Iowa's hospitals and pharmacies to understand the resources that would already be here prior to an attack. Yet this takes time and personnel, which we do not currently have.

—*Establish molecular surveillance for microbial strains, including unusual or drug- resistant strains*.—The use of DNA fingerprinting of bacteria is critical since those destined to become ill may disperse across the US after exposure. Thus laboratories must be able to link infections they identify with those occurring in other states to understand the scope of the attack. However, right now this is only occurring with about six bacteria, most of which would not be used in a biologic attack.

—*Support the development of diagnostic tests*.—Since some chemicals, such as toxins that a terrorist might use, do not persist in the human body, we need to develop tests for surrogates to enable us to quickly recognize what chemical was being used so that we can protect others by providing antidotes.

—*Encourage research on antiviral drugs, vaccines and bioassays for chemical injuries*.—Right now there is no effective treatment for smallpox. Research is needed to develop treatment, as well as preventive vaccines, for some of these diseases.

As the Iowa examples above illustrate, in order to implement many of these critical preparedness steps, capacity at the state and local level must be built. Consensus about what constitutes core public health capacity to prepare and respond to bioterrorism, and how to assess that state by state, is now occurring within the public health community.

DEVELOPING NATIONAL CONSENSUS ON CORE CAPACITY TO PREPARE AND RESPOND TO BIOTERRORISM

Dr. Jeffrey Koplan, Director of the Centers for Disease Control and Prevention (CDC), gave an address over the Public Health Training Network Broadcast to state and local public health officials a week after the September 11th attacks. His topic was the importance of strengthening the nation's public health infrastructure to protect the public's health. He stressed seven priority areas for capacity building at the state and local level that have been developed through a consensus process. These are, briefly:

(1) *Public health workforce*.—a well-trained, well-staffed, fully prepared public health workforce is the most fundamental need in Iowa and in all states;

(2) *Laboratory capacity*.—to produce timely and accurate results for diagnosis and investigation

(3) *Epidemiology and Surveillance*.—to rapidly detect health threats;

(4) *Information systems*.—that are accessible, rapid, permitting effective analysis and interpretation of health data and provide public access to health information;

(5) *Communication*.—that is rapid, secure, two-way flow of information that includes the ability to provide timely, accurate information to the public and advice to policy-makers in public health emergencies;

(6) *Policy and evaluation*.—routine evaluation of how effective we are at rapidly detecting health threats and making improvements; and

(7) *Preparedness and response*.—developing response plans and then regularly testing them to maintain a high-level of preparedness.

The enactment of the Public Health Threats and Emergencies Act (PHTEA) last year has provided an authorized process for accomplishing these seven priorities. This process has now been accelerated, and is concentrating first on bioterrorism preparedness. CDC is about to publish a document identifying the core capacities needed by state and local health departments for terrorism preparedness and response. It reflects the input of epidemiologists, laboratories, state and local health officers, and many others in the public health practitioner community.

The next step is for CDC to provide grants to states to assess themselves against these core capacities. Assessment tools have been developed for this purpose and CSTE has provided its capacity assessment tools for epidemiologic surveillance and response to CDC's Public Health Practice Program Office (PHPPO) for use in the assessment phase (see attached document). However, at this time, there are no federal resources for conducting this assessment of bioterrorism capacity even though it is clear that every state should undertake this task.

The final step authorized under PHTEA is for CDC to provide grants to state and local health departments to fill any gaps they have identified in their assessment process. Again, while there has been three years of bioterrorism preparedness funding flowing to state and local health departments via CDC—and this has been a critical beginning for most states—it has been far too little to begin to fill the gaps that are going to be identified more systematically in the capacity assessment phase—if and when that phase is funded.

SOME SPECIFICS ON WHAT CONSTITUTES CORE EPIDEMIOLOGIC CAPACITY IN STATE HEALTH DEPARTMENTS

To make the core capacity assessment process concrete let me give you a specific example. The first goal listed for CDC's document Bioterrorism Preparedness and Response Core Capacity Project 2001, now in final draft, is: Surveillance and Epidemiologic Investigation: The public health system monitors community health status to detect the presence of critical bioterrorism agents and characterize the public health emergency. Under this goal, the first objective is: Ensure early detection of an outbreak through prompt and systematic collection and interpretation of timely patient-based and healthcare utilization data. Under this objective are a number of indicators in three groups. I will provide and discuss a few of these:

—*Legal authority to collect personal information*.—Iowa is in the administrative process of making diseases and syndromes that may be the result of a deliberate act using biologic or chemical agents notifiable. This allows us the authority to collect appropriate medical information, however, it does not ensure the timely identification and reporting of these diseases and syndromes.

—*Disseminate notifiable disease information and reporting requirements on a periodic basis*.—As mentioned earlier, Iowa has no means to immediately alert all its health departments in 99 counties, over 100 hospitals, its public health laboratory, and other key entities such as community health centers and large physician group practices on either a routine basis, or in the event of a possible terrorist attack, especially during non-office hours. At the very least, every local health department in Iowa should have coverage 24/7. All of them need pagers, and secure communications systems to send confidential information to the state health department. Also, a system for secure, rapid communications with Iowa's health care systems, including laboratories is critical, yet even the state's public health laboratory reports its findings on paper via the U.S. Mail service.

—*Establish systematic data collection protocols that monitor community health indicators (e.g., aberrations in utilization trends or syndrome-based presentations)*.—Iowa has no systematic surveillance for syndromes, instead we are relying on the traditional passive surveillance system and two sentinel surveillance systems. We have no capacity to monitor aberrations in, for instance, emergency room utilization trends based on syndromic presentations. This is now being done in New York City requiring 70 individuals with some epidemiologic training who are conducting syndromic sweeps of all major emergency

rooms in the city. This is funded under CDC's bioterrorism grants for special epidemiologic projects. It requires intensive efforts to educate health care professionals, set up systems to do surveillance and report the findings, and personnel to assess the incoming data for indications of a possible terrorist event. Iowa, like most states, does not even come close to having this capacity.

—*Ensure healthcare providers understand the medical effects and public health consequences of diseases caused by bioterrorism agents*.—As mentioned earlier, two days ago, the Iowa Department of Public Health presented health care professionals with a briefing on terrorism. We asked the hospitals to pull out their emergency plans, most of which address disasters such as airline crashes, and review them for ability to respond to a biological or chemical attack. Items that need to be assessed include isolation beds for infectious disease and decontamination facilities for chemical injuries. This is just one hour for healthcare providers when they need on-going, regular communication and assessment assistance from either their state or local health department, regular, on-going education of their physicians about biologic and chemical terrorist agents and their lab personnel about what and how to handle specimens. What is needed, immediately in Iowa, is ten additional masters level, or equivalently experienced bachelor's level, public health personnel to liaison, continually, with Iowa's hospitals and other health care providers: community health centers, health clinics, major physician group practices, etc. This will insure timely response to requests for training and information, a knowledgeable cadre of providers, good reporting of syndromes and diseases, and coordination of the communications systems. In addition, each large local health department in Iowa needs at least one person to coordinate the health and medical aspects of terrorism response with the law enforcement agencies, fire and HAZMAT departments, and emergency management in their county.

—*Train public health, infection control, and clinical staff to collect and rapidly analyze and interpret surveillance data*.—As already noted, at the state health department level, Iowa needs 10 additional, trained individuals to connect to the medical care system to educate, monitor, assess, and collect data in an ongoing fashion. Iowa also needs three additional epidemiologists at the state level to conduct training of staff at local health departments, conduct on-going, active surveillance, including analysis of disease clusters, and to coordinate communications and investigations.

IOWA'S OTHER PRESSING TERRORISM PREPAREDNESS NEEDS

In addition to the above examples of Iowa's current capacity gaps when compared with core bioterrorism capacity goals, Iowa has great needs in several other areas. Iowa is a major agricultural state, but it currently has only one public health veterinarian assigned to the state health department. Iowa needs at least one additional public health veterinarian to set up and conduct active surveillance on animals to monitor for West Nile Virus, and economically devastating diseases such as Bovine Spongiform Encephalapathy (or mad cow disease) and Foot and Mouth Disease. The latter would be a very effective bioweapon in a state like Iowa or in any state with a large agricultural base. Also, surveillance for animal diseases can serve as the "canary in the mine" and give us advance notice for diseases that can affect human health.

Iowa's medical examiner's office, which has been given the responsibility for mass casualty response, urgently needs one nurse administrator full-time to: 1) organize medical examiner teams for response to a mass casualty event; 2) survey available resource such as refrigerator trucks, x-ray equipment, autopsy supplies; 3) conduct and coordinate surveillance for unusual deaths; and 4) prepare for coordination of information and possible notification of victims families.

Also, Iowa needs one doctoral level person who can educate medical professionals, coordinate communications, and provide consultation to the medical care system with regard to chemical weapons. This will free up the one person currently assigned to chemical weapons to conduct full time surveillance for chemical related injuries. Right now, Iowa is relying on our poison control center for information about chemical injuries and possible attacks. This is haphazard at best.

Iowa is currently trying to develop a critical response capacity with Medical Assistance Disaster Teams. These teams, critical in rural states that have no major metropolitan centers like Iowa, will be recruited from the medical care system. They will be able to move in a moment's notice anywhere within Iowa's borders, or surrounding states, in the case of a terrorist attack involving mass trauma, or illness, to assist the local medical care system since it will take at least 24–36 hours before federal teams can get to Iowa. The Iowa Department of Public Health has absolutely

no additional resources to coordinate and train these teams, or to pay for their deployment if needed.

Another pressing need in Iowa, and many other states as I have learned from my colleagues around the country, is more a problem of perception than funding. Public health has to be seen by all as a major player, and having expertise, thus needing to have control over some issues, especially in bioterrorist events. We need to be at the table, not an after thought. Last Saturday, a town hall meeting was put together in Iowa, to address "Terrorism: Risk and Response." Five U.S. Congressmen, police, fire, a city manager, the CIA, former FBI, etc were invited. Not one single public health or even a practicing health care professional was invited. We continue to be forgotten.

Finally, last week, Iowa has created an Office of Medical and Public Health Disaster Preparedness. The director will coordinate all of the various public health and medical elements in the state health department that might respond to a natural or deliberate disaster. This is a function every state needs to address. We have hired a director, but have taken her from the Emergency Medical System (EMS) unit, which the health department also administers. EMS will have to fill this vacated position in the current climate of terrorism preparedness. The new director will eventually need to hire additional staff to manage all of the required duties. Each county in Iowa with 500,000 or more population also needs a full-time bioterrorism coordinator in the local health department.

CDC GRANTS TO IOWA FOR BIOTERRORISM PREPAREDNESS

Iowa has received a total of $953,181 over three years under CDC's Public Health Preparedness and Response for Bioterrorism Cooperative Agreement Awards program. Of this amount, $545,430 has been used to help Iowa's public health lab meet the specifications of a Bio Level 3 laboratory. But more funding is needed to keep the lab sustained—adequately equipped, with appropriate reagents for example, and trained staff. In addition, the lab needs to add an entire chemical terrorism capability. Finally, funding is needed to make it part of the National Laboratory System with enhanced communication and collaboration with Iowa's independent and hospital based clinical labs, and secure electronic connection to the state health department's epidemiology office, at a minimum.

Iowa received no epidemiologic and surveillance funding in the first year of CDC's grant program and only $96,000 in Year 2. This money has been used to hire an epidemiology nurse for my office, the state epidemiology office, but we need three more epi-trained individuals. It took three rounds of position announcements and interviews to find and hire this person; hiring additional trained individuals is clearly going to be very difficult and we are competing intensely now with many other states. The Year 2 epi-surveillance funding has also been used to pay for the one-hour broadcasted terrorism seminar for the medical system described earlier, and to provide support for the newly hired terrorism coordinator. Iowa has just received $170,000 for epidemiology and surveillance for the current fiscal year—Year 3. While we are still working on specific plans, we will be attempting to hire more epi-trained individuals.

Iowa also just received its first Health Alert Network grant for $143,000. This money will be used to facilitate training and education of our state's public health workforce and to begin to address a system for emergency alerts. It will clearly not be enough to establish the communication network for local health departments and medical systems that is needed across the state that I have described earlier.

And, as I mentioned before, Iowa has received no planning money—the logical first step in bioterrorism preparedness.

These funding levels are not unusual. A colleague in Texas, who helped CDC design its bioterrorism planning grant, also has not received any planning funding. He was so concerned about preparing his state that he dropped all his other public health duties to work with his staff to plan for a biological or chemical attack. This is typical of dedicated individuals in state health departments where there is a chronic shortage of trained staff. This shortage has also been well documented in federal reports on health workforce needs.

I also know that my Texas colleague has been seeking, at a minimum, 33 additional trained staff for the state health department alone to conduct surveillance and provide response. Only about six of Texas' major cities have an identified epidemiologist on staff in their health department. This slows down the ability to detect disease and puts additional burden on the state to cover. And these deficiencies do not include concerns the department may have about the needs of its public health laboratory, or the continuing need for overall planning, and testing that plan

in regular training exercises. Texas' needs, therefore, mirror Iowa's only on a larger scale.

The past three years of federal funding has been critical to begin to build the nation's public health terrorism preparedness and response. But it is simply not enough when states like Iowa and Texas cannot get planning money, and can only get a fraction of what they need for epidemiologic surveillance and response, laboratory capacity, and secure, electronic communications. This also does not address other related issues such as information systems that are accessible, and allow for rapid analysis and interpretation of health data as Dr. Koplan noted. The National Electronic Disease Surveillance System, or NEDSS, is an important CDC effort in collaboration with states, to allow the technical integration of a myriad separate data bases that currently obfuscate important disease trends, or service utilization, and so slow down our ability to detect outbreaks of disease and quickly respond. NEDSS is a CDC and a CSTE priority and it needs to be fully funded at $50 million.

COMMENTS FROM THE ASSOCIATION OF PUBLIC HEALTH LABORATORIES

Iowa needs to enhance its public health laboratory system. This is also true for all of our states' public health laboratories. The public health laboratory is a critical component of the national and state surveillance for bioterrorism. In order to be prepared for bioterrorism public health laboratories need safe facilities, trained personnel, modern equipment, rapid assays, and communications tools. Courier services are also needed to move specimens to the public health laboratory. To prepare for chemical terrorism our states need containment laboratories, trained personnel and equipment to perform rapid screening for toxic chemicals.

To prepare Iowa, and our nation's public health laboratories, we recommend enhancement of the following three programs: The Laboratory Response Network, the National Laboratory System and the development of a Chemical Terrorism Preparedness program.

The Laboratory Response Network (LRN) is critical to the success of the United States response to terrorism. The national Laboratory Response Network (LRN) is composed of county, city, state, and federal public health laboratories, and was established to help public health laboratories across the nation prepare for and respond to acts of terrorism. This network of laboratories can accept specimens and samples from hospitals, clinics, the Federal Bureau of Investigation (FBI) and other law enforcement groups, emergency medical services, the military, and other agencies. With adequate resources, this multi-level network will be able to function effectively even if airplane travel is simultaneously grounded. During the recent events in New York City and Washington, D.C., if there had been simultaneous attacks with physical and bioterrorism agents, patient samples could have easily been transported over the ground to adjacent states.

Definitive identification of agents of biologic terrorism in both an overt or covert attack will depend on laboratories having technical capabilities, equipment and trained personnel. Laboratories must be able to identify a broad range of potential agents including organisms that could be used to compromise the food supply, water or air. Conventional identification methods are now in place and more rapid methods are being evaluated prior to implementation in public health laboratories. There is no reliable alternative to the testing by the network laboratories. The hand held devices that are widely touted by industry often provide false positive results and false negative results and cannot be relied upon to provide accurate testing at this time. Therefore, the LRN should not only be sustained it must be augmented. In order to prepare the LRN member labs at the local, state, and federal level an additional $50 million is needed.

The National Laboratory System (NLS) is an essential component of a laboratory preparedness plan for biological and chemical terrorism. The National Laboratory System (NLS) is a demonstration program funded by the Centers for Disease Control and Prevention (CDC) in response to the growing threat to public health posed by bioterrorism, food-borne diseases, and emerging infectious diseases. A major goal of the NLS is to facilitate communication between public health laboratories and the medical community and hospital/independent laboratories. Accurate and timely laboratory detection is critically important to identify, track, and limit public health threats like biologic and chemical terrorism. Today, most diagnostic testing for infectious agents occurs in 170,000 private hospital or commercial laboratories nationwide. These facilities will very likely be the primary sites for detecting an act of bioterrorism or the introduction of an unusual infectious agent into a community. Improvements are needed in the integration of public health laboratories and private clinical laboratories. These two types of laboratories have independent yet com-

plementary roles to safeguard public health. To reach this goal, the CDC, in conjunction with the Association of Public Health Laboratories, has been piloting the National Laboratory System within the states of Minnesota, Michigan, Nebraska and Washington. The National Laboratory System focuses on building enhanced collaboration, communication and coordination between Public Health Laboratories and private clinical laboratories to develop a network of alert and responsive laboratories. The National Laboratory System must be expanded to all states to maximize our nation's preparedness to detect and provide public health interventions for infectious disease outbreaks. Through improvements in communication, collaboration, and coordination, the NLS initiative is successfully providing links to the public and private sectors necessary for an effective response to terrorism, emerging infectious disease, antimicrobial resistance, and food borne diseases. Mr. Chairman, Iowa needs to be part of a National Laboratory System. An additional $50 million is needed to fully implement the NLS in all 50 states.

For Chemical Terrorism Preparedness, expanding the number of laboratories able to handle chemical agents and agents present in environmental samples is essential. The likelihood that chemical agents will be used for terrorist purposes is high. Unlike biological agents, chemical agents can produce immediate effects; are cheap, easy to use, stable, and can be precisely delivered; and can be easily, efficiently, and rapidly dispersed. Terrorists can use thousands of commercially available chemicals. These chemicals can be purchased throughout the world. These include herbicides, blood agents, choking agents, blistering agents, and nerve agents. Currently only five state public health laboratories (New York, Virginia, New Mexico, California and Michigan) have received funding and training from the CDC, and are beginning to serve as "surge capacity" laboratories for CDC chemical terrorism analyses of clinical specimens. At present there are no efforts to coordinate laboratories testing environmental samples for evidence of terrorist attacks. Additional public health laboratories, strategically located throughout the country, must be prepared for the threat of chemical terrorism. At a minimum, a total of $25 million additional dollars is needed to enhance and expand public health laboratories testing clinical specimens for chemical terrorism. Additional dollars would also be needed to fully implement a program of testing for environmental samples.

SUMMARY AND RECOMMENDATIONS

(1) *Capacity Assessment Needs*.—In order to provide you with a well-documented cost estimate of Iowa's needs with regard to capacity for terrorism Iowa would need to conduct an adequately funded assessment. A consensus process for this is well underway, but has received no funding to date. I understand that CDC believes each state will need $1 million to conduct an assessment of capacities under three categories authorized by PHTEA: bioterrorism, antimicrobial resistance, and major naturally occurring infectious diseases. I do not know if CDC would estimate it will cost less to limit this to bioterrorism, including chemical and radiological agents. I would guess that it will cost Iowa a minimum of $750,000 to conduct a thorough biological and chemical terrorism preparedness and response assessment.

(2) *Workforce Needs*.—Again, I am reluctant to make specific funding recommendations until and when an adequately funded assessment is concluded. However, the Department of Public Health estimates it will need, at a minimum, 25 additional people—at the state level alone—to address the needs of the epidemiologic surveillance system as described in this statement. This is estimated to cost $2 million in salaries, taxes, and benefits. But each additional person will also need office space, a computer, educational materials, and various support staff including data analysis and computer technicians. This will cost an estimated additional $2 million. We also estimate that this amount will be needed at the local health department level, for a total of $8 million for an investment in the right kind of trained workforce for Iowa. I would like to stress that finding and attracting trained, infectious disease epidemiologists to fill these positions will be difficult, if not impossible, particularly in an environment of intense competition with other states. Great attention needs to be given immediately to public health workforce training, particularly epidemiology.

(3) *Laboratory Needs*.—I cannot speak specifically for Iowa's public health laboratory, and it would obviously be included in a capacity assessment process, but it is clear that it will need on-going support for equipment and materials, staff and training, and will need to add chemical terrorism capacity. As the APHL comments make clear, Iowa's lab should also be part of a National Laboratory System that will improve its connection to the numerous clinical labs and tie it electronically to the state epidemiology office, at a minimum. I would assume that this level of need is approximately $1 million.

(4) *Communication Needs*.—The $143,000 grant to begin to establish a Heath Alert Network in Iowa is an important beginning. The communication goal must be comprehensive, rapid, and timely. This means it needs to be electronic, two-way, and secure and include all major medical system sites, state and all local health departments, the public health lab, the state's clinical labs, and the CDC. This needs to be supplemented with a system that allows immediate ability to contact at least one person in each county health department on a 24 hour, seven day-a-week, availability. Again, I am hesitant to estimate the cost of a comprehensive communications system for Iowa. Some of this cost is built into the estimated cost for workforce needs, and laboratory needs. But I would guess an additional $500,000—$1 million would be needed for the whole system.

I would like to mention here the importance of CDC's Epi-X program. The mission of Epi-X is to provide rapid, secure communication about outbreaks and other acute or emerging health events among public health officials. It is a secure Web-based system with participants from CDC, state health departments, and the military. Epi-X also provides emergency notification by: telephone, including office, home, and cell; fax; pager; e-mail. During the September 11th attacks, Epi-X provided secure communications for state epidemiologists to post information on surveillance and response activities for 500 public health officials around the country, including the U.S. military. As Iowa's state epidemiologist, I have found Epi-X to be extremely effective. CSTE urges the Subcommittee to provide $10 million in annual funding for Epi-X.

(5) *Information Systems Needs*.—Every state has now received at least $85,000 in funding for assessment and planning under the National Electronic Disease Surveillance (NEDSS) program. Several states are progressing to the next stage, the inclusion of element development, at an average cost of $300,000 and even finished, prototype testing at an average cost of $1 million. The NEDSS program is designed to technically integrate as many as 100 separate data systems currently used by the nation's public health system so that data analysis can be done rapidly, across data sets, across regions including multi-states, and so that mandated reporters, such as physicians, will find reporting diseases significantly simplified. This is a priority program for CDC and CSTE; it will make trends that may signify a biological or chemical attack much clearer more quickly. It will also, eventually, permit analysis of many other disease trends including environmental exposures and chronic disease. CDC estimates the NEDSS program should be funded at a minimum of $50 million. Iowa has only received planning and assessment funding and would need an estimated $1 million to fully implement an integrated data collection and analysis system.

(6) *Planning Needs*.—I cannot stress enough the critical nature of planning, including real and regular testing of the plan, to be prepared for a biological or chemical attack. Iowa, as well as 39 other states, has received no funding to address this foremost need in the nation's effort to combat terrorism. Again, this is an unprepared, and undocumented estimate of what Iowa needs in this area, but I would guess $200,000 per year, should be committed to this activity.

(7) *Bioterrorism Response Needs*.—This would need careful review under a well-funded assessment process, but I would anticipate that if Iowa can put in place the workforce, laboratory, communications and information systems identified here as needed for bioterorism—and chemical terrorism—this is the system, with regard to public health, that would also respond in the event of an attack. The workforce would need to be immediately expanded in an emergency to conduct an outbreak investigation in the case of infectious disease, or evaluation of victims exposed to toxins in the case of a chemical attack. But we could draw upon epidemiological staff in other areas to accomplish this. CDC's Epidemic Intelligence Service teams would likely supplement these efforts. Iowa would additionally draw upon the Medical Assistance Disaster Teams we hope to create to fill the gap that would necessarily occur before federal D-MAT and D-MORT teams could arrive. None of these estimated expenditures address the deficiencies of our medical system, which will need to develop surge capacity for infectious disease patients and victims of chemical attack including decontamination facilities. It also does not include the expense involved in conducting a survey, which Iowa feels it must do now, of its hospitals and pharmacies to determine the resources our state has on hand immediately in case of attack. Again, obtaining and distributing national stockpile pharmaceuticals will take at least 24 hours.

Total Estimated Needs for Iowa to Prepare and Respond to a Biological or Chemical Attack.—Looking only at Iowa's public health system needs, items 1–6 above, the total comes to $11,450,000. This does not include the specific response needs noted in item 7. It does include preparedness for a chemical, as well as a biological attack. It also includes some items that may be one-time expenditures, or periodic

expenditures. But this estimated amount is much closer to Iowa's real minimum needs than the funding we, or any state, has received under the current CDC bioterrorism preparedness program. This level of funding also needs to be made available over a period of several years, as it will take time to build the system, particularly the right workforce. After that, significant funding must continue to keep the system maintained.

Estimated National Need.—CSTE is aware of a proposal by Senator Kennedy, Chairman of the Senate Health, Education, Labor and Pensions (HELP) Committee to provide $625 million to improve the ability of state and local health agencies to monitor, contain, and respond effectively to the effects of a bioterrorist attack. CSTE believes this is much closer to the real needs of the nation in confronting an enemy that could strike with terror using biological or chemical weapons.

I would like to make one final point about the extended value of strengthening public health while preparing for a bioterrorist attack. By continuing to build toward a robust comprehensive public health system, we will be building a multi-use system that will be used for diseases and situations that are occurring everyday. For example, responding to emerging diseases like West Nile Virus, which was discovered in Iowa two weeks ago, the predicted pandemic flu and the more mundane food poisoning outbreaks. Thus, when and if a terrorist event occurs, the system will be familiar to those involved which will help ensure efficient and effective functioning in a crisis.

Thank you again for this opportunity to provide testimony on this important matter before the Subcommittee. I am pleased to answer any questions you may have.

Senator HARKIN. Thank you very much, Dr. Quinlisk, for your statement.

Now we turn to our final panelist, Dr. Archer, who is here on behalf of the National Association of County and City Health Officials. Dr. Archer is the director of Kansas City Health Department, and is chairman of the Bioterrorism and Emergency Response Task Force of the National Association of County Health Officials. He has been involved in bioterrorism and emergency preparedness planning in Kansas City, and has helped to develop guidance and performance standards on bioterrorism preparedness for local public health systems.

Welcome, Dr. Archer.

STATEMENT OF REX ARCHER, M.D., M.P.H., DIRECTOR, KANSAS CITY HEALTH DEPARTMENT

Dr. ARCHER. Thank you. On behalf of those almost 3,000 local health departments, we really want to thank you for your leadership on this issue. Are we prepared for bioterrorism? One of the advantages of being last is, I do not have to repeat everything in my written comments, so I am going to jump right into this. As said earlier, we are not unprepared, but we are certainly underprepared, and I think everybody testified that it is at the local level that we are most vulnerable. We have been working very strongly on partnerships with CDC, with a lot of different partners on this, but it does not get you where you need to go if you do not have all the resources.

One of the advantages here is that every dollar we spend at the local level for preparedness really can improve our overall public health threats response. As mentioned, I have been working with a number of partners on a core set of capacities that are needed at the State and local level. That work is what our needs at the local level is based on.

It might surprise you that in almost every city, in fact almost every community that I am aware of in the United States, we have more deaths from infectious diseases, natural causes, than we have from motor vehicle crashes, burns, drowning, falls, and homicides

combined. So again, everything that we need we should be already doing, and we should be recognized as public safety agencies, but in the last 2 decades this system has really been crumbling.

We have a 50-percent increase in deaths from infectious disease over the last couple of decades. We have been doing a lot of innovative activity at the local level, attempting to take all of these silos of grants and create generalists so that we have surge capacity to be able to handle an outbreak, but our field staffs still have to handle over 800 cases in a year in regards to being able to do all of the contact tracing and to make sure that that disease is not spreading to others.

We believe that that needs to be cut in half in regards to those caseloads. We do 24-hour-7 days a week coverage, but we don't pay the people anything for it. It is just an added responsibility that they have to carry the pager.

I want to go down the kind of staffing we need. Obviously, we need a full-time bioterrorism coordinator. We are almost a one-half million population. In the metropolitan area we are 1.8 million. We have 9 or 10 hospitals—one may be closing—but we believe we need a liaison staff person from our health department at these hospitals that would be working with them on infectious diseases, on reportability, and on training.

All the kinds of issues that have been talked about, such as coordination, that have been trouble at times at the Federal level, have been issues at the local level. Any dollars that come into the local community, we need to be aware of them. We need to coordinate that activity, and if we are doing training of physicians, nurses, and other providers, public health needs to coordinate and be at that training table, because then the providers will report to you if they see a face and they know who you are when they are being trained.

This is not one-time training, either. We all know that this has to be ongoing. We need a full-time training coordinator because of that.

In addition, as I mentioned, we need to double our epidemiological field staff; that is another 12 individuals. We believe we need at least four data entry people to be able to maintain our Health Alert Network and other systems. Those broadcast-back systems are not any good if the numbers are not correct and are not updated.

In addition, we believe that we need a full-time high-level computer professional, because actually the first responders are actually probably going to be in the pharmacies. If you think about it, people self-medicate first, and as was mentioned earlier, with Milwaukee or other places, it is actually in the pharmacies that you will run out of the anti-diarrhea medication or the cough medicine.

So if you add that up, that is about 30 people. Take that up at a per capita rate across our Nation, and that is probably around 13,000 additional local public health workers that we need in this country. So I could say very conservatively, at least let us get 10,000 up and running right now.

PREPARED STATEMENT

I know you share our sense of urgency, and it is really a shame that we have had to take this catastrophe to pull us together to move forward on this. We must keep our military defense strong, but it is now obviously even more apparent that we have to keep our public health system strong, and unless somebody comes up with a better way to name this, I think what we need to call this is really Operation Bio Shield, and that is improving our infrastructure for public health, for all of these purposes.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. REX ARCHER

Good morning, Mr. Chairman and members of the Subcommittee. I am Rex Archer, MD, MPH. I am Director of the Kansas City Health Department in Missouri. I chair the Bioterrorism and Emergency Preparedness Committee of the National Association of County and City Health Officials (NACCHO). NACCHO is the organization representing the almost 3,000 local public health departments in the country. I have been deeply engaged in bioterrorism and emergency preparedness planning in Kansas City. I have also participated in national work to develop guidance and performance standards in bioterrorism preparedness for local public health systems. I am here today to tell you about some of the lessons we have learned in our work, and how much farther we need to go.

Senator Harkin and Senator Specter, you have been leaders in providing funding for public health preparedness and in recognizing how local health departments serve on the front lines in battling public health crises of all types. Local public health agencies are the first responders on the ground in a bioterrorism incident. We are particularly grateful for your support of the Health Alert Network. CDC used this system, although it is not yet complete, at mid-day on September 11 to advise public health officials to begin heightened disease surveillance.

Are we prepared for bioterrorism? Not nearly enough. Local public health departments have long experience in responding to infectious disease outbreaks and other local emergencies with public health implications. We have made progress and learned important lessons about the challenges of bioterrorism preparedness in the last few years. But we have a very long way to go to achieve the capacities we need to detect and respond to an act of bioterrorism as quickly as possible, to prevent the spread of disease and save as many lives as possible.

Our nation's bioterrorism preparedness activities have been limited, but we are not starting from scratch. We have some experience and some results from funding that Congress has appropriated thus far that I will share with you. In addition, we have a legislative framework in place for expanding our general public health preparedness. The Public Health Threats and Emergencies Act of 2000, which has not yet been funded, establishes a process for systematically defining what our federal, state and local public health systems need to do, for assessing what they already can do, and for filling in the gaps. Every component of the public health system plays a vital role. State and local public health agencies must collaborate closely, sharing information and resources. Properly equipped laboratories and data management and communication systems are essential, as is leadership and support from the Centers for Disease Control and Prevention (CDC).

We urge you to provide ample funding to allow bioterrorism preparedness to move forward swiftly. The Chairman of the authorizing committee, Senator Kennedy, is requesting sums that we are confident will provide an excellent, reasonable start. We fully believe that, when a systematic assessment permits us to quantify more precisely the national needs for staffing and systems, we will find that developing and maintaining the state and local public health preparedness capacities the nation needs will require more than a one-time boost.

LESSONS LEARNED FROM THE HEALTH ALERT NETWORK PROGRAM

The Health Alert Network (HAN) program was established to enable rapid, secure communications among local and state public health agencies and CDC. In addition to helping fund electronic communications systems in 37 states and 3 large cities, HAN has funded three Local Centers for Public Health Preparedness. These are model programs that have explored how local bioterrorism preparedness can be

built, emphasizing cutting-edge uses of information technology. These programs have shown us what can be done with additional resources and we're ready to apply the lessons learned in many more jurisdictions.

The three model programs are in Denver, Colorado, DeKalb County, Georgia (near Atlanta), and Monroe County, New York (Rochester). CDC has spent $4 million total on these three centers, beginning in fiscal year 2000. The Centers used the funds to develop their capacities in three areas: advanced communication and information systems; advanced operational readiness assessment; and comprehensive training. These three public health agencies already had advanced levels of information technology. To build on that, Monroe County developed software to link various local networks together to enable secure communications across multiple agencies involved in bioterrorism detection and response. They are installing desktop computers in hospital emergency departments to enable instant reporting of unusual disease syndromes. In Denver, new handheld devices are being piloted and will be used in data collection for disease surveillance and field investigation of outbreaks. Disease investigators will be able to input data directly from the field into the state reportable disease system. DeKalb County has built the capacity to acquire electronic data from a variety of sources, including 911 systems, county emergency medical services, the medical examiners' office, and local hospitals. This is being used to develop a web-based notifiable disease reporting system that will enable early recognition of unusual events.

The three centers are also using unique approaches to training, so that bioterrorism preparedness training is available and appropriate for all the people who need it. Denver has developed Web-based curricula to address personal protective equipment, epidemiology and disease surveillance, victims' assistance, and hospital logistics and operational readiness. As these modules are used, they will also be evaluated to see how well they work and what more is needed. DeKalb and Monroe counties have devoted some resources to assessing types of preparedness training among private physicians, hospital staff, fire departments, law enforcement, and the medical examiner, as well as public health staff. All three Centers have gained extensive experience developing and conducting tabletop exercises and other preparedness drills in which hospitals and all other first responders have participated.

The lessons are still coming in. What have we learned so far? First, we have learned that the real challenges to improving technology are not really technical. Rather, they are related to training, institutionalizing the use of new technology, and finding the funding to sustain it.

Another important lesson, which many other jurisdictions that have undertaken bioterrorism preparedness planning also have learned, is that partnerships between public health agencies, health care providers, and the traditional first responder communities, such as fire, police and emergency services, can be built and are essential to progress. When many public and private agencies in a city or county have to work together to respond to an emergency, they need to know each other and to have planned together far in advance. Local surveillance and response systems won't work unless we have people to use them and the people who use them know exactly what to do and gets lots of practice in doing it.

Finally, we have demonstrated what we really already knew—that preparing for bioterrorism also prepares us for other public health emergencies. The three Local Centers are stronger public health agencies in many ways, not just in their ability to address bioterrorism. The systems for disease surveillance, for communication, for data management, for interagency planning, for mobilizing the community to respond, are the same for bioterrorism as they are for any other disease outbreaks. They have multiple uses, extending even to improving our abilities to address other public health problems more effectively. Every dollar we spend on bioterrorism preparedness will pay off in countless other ways.

The three model centers are showing us what can be done. It is important to note that they embarked upon building state-of-the-art bioterrorism preparedness with better, more advanced technology and programs than the average local public health department has. Many local public health agencies will need significant resources just to get to the level that the three model centers had before they started their upgrades.

PROVIDING GUIDANCE TO LOCAL AND STATE PUBLIC HEALTH AGENCIES

NACCHO has also been working with CDC and other public health partners on a national level to define just what public health agencies need to prepare for and respond to a bioterrorist act and to provide them solid guidance. We have developed a set of core capacities and some ways to measure whether an agency has achieved them. Defining measurable objectives is an essential part of achieving preparedness.

Setting standards will enable us not only to assess where we stand, but also to assure that funds are spent prudently, and that the outcome ultimately will be an effective system serving the country's needs.

These core capacities include (but are not limited to):

—Routine surveillance and epidemiologic investigation
—Enhanced surveillance during a suspected emergency
—Laboratory work to identify or rule out biological threat agents
—Rapid reporting of laboratory results to the right people and agencies
—Communications networks among the agencies involved in emergency detection and management
—Methods and systems to receive and transmit data needed to make emergency management decisions
—Plans and protocols for communicating to the public
—Integrating the public health emergency response into a community's overall emergency response planning
—Activating and enforcing emergency public health and infection control measures, including mass distribution of medications or vaccination, closure of public places, travel restrictions, and evaluation and handling of the dead.

The next step is to enable states, counties, cities and towns to transform this framework into their own practical action plan for bioterrorism preparedness and response. One of our highest priorities now must be to give states and localities the resources to take this next step and to develop more tools to help them. Evaluating their progress against measurable objectives is critical to assuring accountability.

A CASE STUDY—BIOTERRORISM PREPAREDNESS IN KANSAS CITY

We have never had a bioterrorism incident in Kansas City and I hope we never do. Nonetheless, we lose more lives from infectious diseases in Kansas City than we do from all motor vehicle crashes, burns, drownings, falls, and homicides, combined. The local public health department is just as essential a public safety agency as the police or the fire department. At the moment, though, we have just one duty officer on call for nights and weekends, after regular business hours. We can't afford 24/7 coverage for urgent situations or emergencies.

I am proud of some innovative steps we have taken to maximize the resources we do have. Our funding for disease surveillance systems has been based on programmatic funding, one disease at a time. We have eliminated these "silos" and have developed a fully integrated surveillance staff that handles everything from HIV to measles. Yet we need additional staff to make their workload more manageable and to provide for surge capacity in the event of an epidemic. Each member of our epidemiology field staff handles 800 case reports of reportable disease a year, doing whatever is necessary to locate and interview patients, trace contacts, assure that infectious disease is being contained as much as possible. We need to double our staff to reduce the workload to 400 cases a year and have enough trained people to work 24/7 in a crisis.

Let me tell you what I think my agency needs in terms of human resources to have an effective system for detecting and responding to a bioterrorist event. First, we need a full-time bioterrorism coordinator to work with other city agencies and the health care community. Kansas City has nine hospitals. I would like to place one full-time infectious disease officer in each institution, to work with hospital staff in bioterrorism training and emergency planning, to assist with their ongoing infection control work, particularly antimicrobial resistance, and to be in place as the active liaison with the health department in any public health emergency. We need a full-time trainer in the health department to train both health department employees and the medical care community on bioterrorism surveillance and response. We need a full-time public information officer to develop working communication relationships with the media and the public, so that mechanisms are in place when we must help the public understand and deal with an emergency. We need a full-time high-level computer professional to manage the funds and contracts for building an electronic disease reporting system and four lower-level data entry and processing staff. We need twelve additional epidemiology field staff. Including supervisory and support staff, we need 30 more people. As you can see, we will gain in two ways. These staff will position us to detect and respond more effectively to a bioterrorism incident. In addition, their ongoing responsibilities will improve our overall effectiveness as a public safety agency.

On a per capita basis, Kansas City's need for 30 additional public health personnel to prepare for bioterrorism and for other public health emergencies translates nationally to about 15,000 more people working at the local level. The cost of adding such personnel, who are the backbone of surveillance and emergency re-

sponse systems, does not include the costs of additional training, enhanced laboratories, secure and reliable communication and data management systems—all the components of public health emergency response that the public may take for granted, but that we know are not in place.

Mr. Chairman, I know that you share my sense of urgency and recognition that we have before us a momentous challenge. We wish that it hadn't taken a catastrophe to call public attention to the fact that, just as we must keep our military defenses strong, so must we also keep our public health defenses strong. Thank you for our longstanding encouragement and support.

Senator HARKIN. Dr. Archer, thank you very much. I know Senator Specter is late for another appointment. I am going to turn to him now.

Senator SPECTER. Thank you very much, Mr. Chairman. We are working simultaneously on the Judiciary Committee down the hall. We are working on the antiterrorism bills, but I want to join Senator Harkin in thanking all of you for coming.

You are devoted professionals. You have been standing in the wings, and now you are on center stage, and this is a matter of tremendous urgency, and we thank you for your professionalism and for your testimony, and there is a great deal which has to be done. It is very reassuring to this subcommittee and really to the entire Congress that you professionals are here to help us out and give us direction. I do have to excuse myself at this point in time, so given the 5 minutes for my questioning, I would allocate it to Senator Harkin. Thank you all very much.

Thank you, Tom.

Senator HARKIN. Again, I would just join Senator Specter in appreciating your past service in which you have all been leaders, and I have read your testimonies and your backgrounds, and it is true you are now going to be in the forefront of this effort nationally, and as more than one of you have said in your statements, while we are not totally prepared, we are not starting from scratch. Someone said that, I forget who, and that is true, we are not starting from scratch.

We do have a good infrastructure out there. We do have the network. We have the Public Health Service, we have our epidemiologists, but there are gaps. A couple of you talked about the gaps. I think we are in pretty good shape for addressing naturally occurring types of biological outbreaks. Are we in reasonably good shape? Correct me if I am wrong. I thought we were not in very good shape if it is not naturally occurring, either biological or chemical.

Dr. ARCHER. Many natural outbreaks happen over weeks or a month, whereas this kind of an event, it is hours and days, so it really ramps up your surge capacity. But with West Nile, which was natural, it crippled or it stressed one of the strongest health departments we have in the country, and so our public information side is not adequate to handle these issues.

Senator HARKIN. Dr. Quinlisk.

Dr. QUINLISK. I would just like to add, if you are talking about the small, food-borne outbreaks, something like that, I think we are handling those. But any time you have an outbreak where there is serious illness, with large numbers of people ill, unexpectedly occurring, basically right now in Iowa, the people who are supposed to be handling this cannot do it. We start having to pull peo-

ple from other areas of the health department to assist in calling people, doing interviews, whatever, which then takes them away from the other things, such as vaccinating children.

So I would say small things, maybe yes, we have the capacity, but once you get beyond a small number, no, we really do not have that capacity, and systems that support that capacity, such as laboratory reporting, the coordination with the health care agencies, data analysis, that is woefully inadequate at this point.

Senator HARKIN. Now, Dr. Cantrill, I have talked about, read the whole scenario of Operation Top Off, and obviously that sort of indicates that we are not prepared to meet at least the nonnaturally occurring. Do you want to address yourself to that?

Dr. CANTRILL. I think that is definitely true. Even now, as I mentioned, we have no surge capacity. People will wait in emergency departments for hours, sometimes days for a bed to become available upstairs, which I think is bad medical care. Because of bed availability in most metropolitan areas there are major problems with getting patients beds in institutions in those cities, and so then you add an additional stress on top of that.

Quite honestly, pretty quickly the wheels come off. You are doing the best you can. We certainly would do the best we could do, but I think it would be very, very difficult. I think we would really compromise care in many cases.

Dr. TUCKER. I just wanted to comment on the threat of naturally emerging infections. The scenario that scares a lot of epidemiologists is the possible resurgence of an endemic influenza that is highly virulent, such as what occurred in this country in 1918, 1919. We are overdue for another major epidemic of this type, and our public health system is not prepared even for that contingency.

Senator HARKIN. Now, again, just thinking this whole thing through as I have for sometime now, it seems that you have got a problem first of all in initial recognition among primary care providers out there. You may have heard earlier, I said that a doctor over the weekend in Iowa had said to me, we need training. He wouldn't even know what to look for in these things. He has never had any training in this area. It seems to me that is the first area.

Dr. CANTRILL. Senator, I think that may be a little less of an issue in terms of knowing there is something bad going on, at least from the emergency department point of view. When you in one 8-hour period admit your second normally healthy adult individual who has to be intubated to go to the intensive care unit, the light should click on, and that is where we need to increase awareness amongst medical personnel that something is bad, and we need to train them to go ahead and call their State health department to get them going. I think we will know, especially when people are breaking down your doors to get into the ED because they are so ill, you will know there is something bad going on. You will not know what it is yet.

Senator HARKIN. Well, Operation Top Off indicated there was some lag time.

Dr. CANTRILL. Nominally 12 hours.

Mr. HAUER. There is a lag time, Senator, and the problem we have got is, with most of these types of agents our surveillance systems are not sensitive enough at this point in time to pick up the

early indications of an incident. We have to rely on our primary care providers to recognize that, and the training at the local level for our primary care providers has not been there.

It is evolving now, and HHS has been rolling it out, but as Secretary Thompson said, we need to do more along these lines. The training at the local level is a big issue, and not just the primary care providers in emergency rooms, but nurse practitioners that take care of rural areas, family practitioners, they have to be trained as well.

Dr. QUINLISK. I was going to add that I think that a medical system realizing something might be odd probably does occur, it does occur quickly. One of the biggest problems I see is, since there is no training for them regarding how to then take that information they have and get it to the health department, there is an incredible gap there.

We had whole busloads of ill children brought into the emergency rooms, and not a single person ever even thought to contact the health department. I do not think that ER doc did not realize something was going on, but there was the disconnect between the medical system and the public health system that desperately needs to be addressed.

Dr. ARCHER. That is why I propose we need that liaison function there in the hospital that is part of the health department that keeps that on a day-to-day basis, because one-shot training will not do it. You have to keep that relationship going.

Senator HARKIN. There has to be a system whereby those primary care providers who may not be an M.D., such as a nurse practitioner, could report this quickly through some centralized board, where you would recognize it.

Now, something has to be done immediately, and I do not know that that kind of system is in place.

Mr. HAUER. In point of fact, in most county and State health departments it is a 9-to-5 operation. Some of them do have on-call folks, some do not.

When I worked for then-Governor Bayh in Indiana, and I was out there for 7 years overseeing the public safety agencies, we had an occasion to call the department of health, and we put a system in place. But when the Governor first came into office there was no system, and getting people on the weekends was impossible. We could not find a public health professional on the weekends. There was no on-call system. If they wanted to report, you called in Monday morning to report.

Senator HARKIN. If you are a bioterrorist you would strike Friday night.

Mr. HAUER. Absolutely right.

Senator HARKIN. And you would have the whole weekend.

Mr. HAUER. By Monday morning, particularly with anthrax, the event would be so far along, that window of opportunity would be so narrow that we would at that point not be treating people, because once you get through the first phase of anthrax, they are not treatable.

Senator HARKIN. Dr. Quinlisk.

Dr. QUINLISK. I wanted to make the point too it is not just getting information from the hospitals to the public health system, but

the public health system has to get information down to the hospital level to alert them to look for specific things, or that things might be happening. We talk about the Health Alert Network, and it is true that CDC alerted everybody on September 11, but the problem is, they came to me at the State health department in Iowa.

Right now I have no easy way of getting information out to the hospitals, or down even to our local public health departments. We sent out an e-mail, but then we had to call everybody in our department to start making phone calls to tell people to go look at their e-mail that they received.

Now, we were lucky that that happened on a week-day. If that had happened on an evening or a weekend, I do not know that we would have had any possibility other than just call everybody we can by telephone to put them on alert that way. That would have been 99 county health departments even if we had been able to get a hold of somebody, and calling over 100 hospitals personally in that kind of system just is not going to meet these needs.

Mr. HAUER. Senator, I think one important point is, part of this is our fault in public health. We have never looked at this as a responsive or proactive type of approach. There has always been the luxury of time. In public health emergencies in the past you did not have to respond in 4, 6, 12 hours.

Most reporting, as I mentioned in my testimony, has been by three-part cards that you mail in to the department of health, and they get it, and sometime over the next 4 or 5 months it gets entered into the computer, because it has been mostly for sexually transmitted diseases or other types of diseases that are required to be reported. That urgency has not been there in the public health arena, and that is something we have to instill, and we are instilling into the public health arena. It has not been there in the past.

Dr. ARCHER. We changed our reporting ordinance so that within 4 hours of the suspicion of any of these conditions you had to report those kinds of things. You would not have a police or fire department close at 5:00 and not be available until the next morning, or over the weekend, and yet we allow that with our public health agencies.

For years we have underfunded our public health positions at the local level. Those individuals, then, if they did not want to do shiftwork in a hospital, might take a lower paid position. Even if we want to go 24–7 and go 12-on, 12-off during an emergency we have people who's lives may not be easily adjusted to even do that, because we have not thought in that way. We have got some major overhauling that needs to be done.

Senator HARKIN. Let me, if I might, turn to another aspect of this which you heard me talk about and others talk about today, and that is the whole issue of food safety. Now, again, it seems to me there are at least a couple of objectives of terrorists. One is to kill people. Now, that is what we are talking about when you are talking about anthrax and botulism and these virulent pathogens. That is meant to kill people and strike terror. But there may be another objective of striking terror into people and disrupting the economic system of our country.

With the food distribution system we have in America today, an animal could be slaughtered in Kansas, and it could be processed and within 24 hours people in Portland, Oregon could be eating some of that, people in Miami, Florida could be having some of that, and people in New York City could be having some of that. It just goes all over the country within a day, and we have seen cases where we have had to track back to find out exactly where the origin of some salmonella, for example, originated.

I mean, consider the scenario that might happen if someone were to place within our food supply chain at a certain point certain pathogens that might not kill you, but could really make you awfully sick, and what would happen to the public confidence in our food supply system if that were detected and we found that it was a manmade cause that was injected at a certain point?

The scenario would be that people would become very terrified of buying food, and where would they go to get the best food, and how could they be reassured, and yet from my vantage point of being both on the Agriculture Committee and on this subcommittee, we really have not done much to address that, and I need your thoughts and your suggestions on how we might, both prevent and rapidly address this to reassure people that we have caught it, that we have stopped it, and that they are assured that the food they buy the next day is going to be safe.

Do I make myself clear on that? How do we do that? Can we set up that system?

Dr. ARCHER. One problem is that we might not even know that if the cases are spread out enough, because now frequently these people are treated symptomatically without laboratory testing or confirmation. It is probably something we need to change, that if the physician feels or sees more than one case, that the companies would pay for even the laboratory testing, because we miss most food-borne illness. We do not even pick it up, so we have got that piece also. If we picked up more, we could handle, I think, more of these types of things.

Most of these pathogens, if you cook it adequately, if you do the food preparation things that people used to get in home economics and may not get any more, then it would help reduce that risk.

Mr. HAUER. Also, finding out this is an intentional type of an event is very difficult in one of these outbreaks. If you remember the 1984 incident in Oregon, with the Rajneesh, over 750 people were impacted.

Senator HARKIN. That was salmonella.

Mr. HAUER. Right, and it was almost 2 years later that we found out that it was not accidental. When the FBI was interrogating one of the members, they found out that it was, in fact, intentional. Accidental outbreaks versus intentional outbreaks can be very difficult to discern in this kind of an environment.

Dr. QUINLISK. That is the public health function. Hopefully these things could be investigated very quickly, and we could find out those kinds of things much more quickly and then do whatever kind of prevention measures necessary to then go back to the public and say, we have taken care of this, and you can go buy your food tomorrow and feel okay.

Dr. CANTRILL. Senator, one of my concerns is, if we start having to report every case of diarrhea to the public health department, that is a very onerous obligation. In medicine today we are just overregulated, and this would be an additional regulation if every time I have a case of diarrhea I have to fill out a form in three parts, so we need to work on smoothing those things out.

And quite honestly, the HIPAA regulations are an issue here too, in terms of patient confidentiality. I think we have not fully investigated those yet, but I think those may compromise some of our abilities to look over from a global vision point of view and see patterns of diseases. We can maybe look at the individual patterns, but we cannot get to the patient because that information is protected, so there are some very complex issues here we have to address.

Mr. HAUER. Senator, I understand Steve's concern about reporting, but I think with the right data-mining systems in place, the right surveillance systems, it can all be automated as we have done in New York City, and you really take the load off the medical care providers and just do it in an automated fashion.

There are some issues with hospitals. They are concerned about sharing data with their local health departments or their local emergency management agencies, and we ran into that. But when they realize that we were going to shield patient ID's, or maintain confidentiality, and that we were not looking at their morbidity and mortality rates, which was a big concern and real sensitive issue, and that we were really just trying to track the health status of the city on a daily basis, we got a fair amount of cooperation.

Dr. TUCKER. Just in terms of threat assessment or probability of bioterrorism, I think food contamination is probably the most likely type of incident, because the technical challenges are quite limited.

The Rajneesh, for example, used a low tech approach. They just took vials of salmonella and poured them on restaurant salad bars in 10 restaurants in the town of The Dalles, Oregon. It did not require a sophisticated dissemination system that many people have talked about.

So if, as you said, terrorists are just wanting to scare people and kill a few and scare a lot more, this would be the easiest approach.

Dr. QUINLISK. I would just add something. The Dalles salmonella and the shigella from the medical center in Texas, were both laboratory organisms. They actually went into a laboratory that actually had the legal authority to have those organisms. So going back to some of the security things that need to be done, we do need to make sure that the people who have the right to have those organisms have them under some kind of a secure method so that somebody else cannot get a hold of them.

Senator HARKIN. There is one last thing I just wanted to cover with you before we adjourn, and we have gone on long enough, but I keep hearing about surge capacity. I think I have a vague idea of what you are talking about. It is about the influx of patients and we do not have the room, or the places, or the emergency rooms to take care of that. How do we address the surge capacity problem that hospitals have?

Mr. HAUER. Quite frankly, I do not think we ought to put these patients in the hospitals. I think initially a lot of them will go to

hospitals, but as Steve has said, hospitals will be overcrowded. We did some modeling in New York, and we believe that you can set up alternate care facilities and depending on the nature of the agent and the type of illness you shunt these people away from the hospital, and then if they are really sick, you put them in the hospital, or if the hospitals are overwhelmed, you set up alternative facilities.

We identified a number of locations throughout New York where we could put 5,000 or 10,000 people, like the Javits Convention Center. The biggest problem you have is needing to have a surge of medical personnel, because I have to assume that a certain percentage of the medical providers are victims themselves, and will want to stay home with their families. So I might lose 10 to 15 percent of the medical care providers that I already need, so I am going to have to rely on State and Federal resources to come in and provide the care.

Finding the facilities should be relatively easy, and if it is a prolonged type of an incident, as you would see with smallpox or anthrax, DOD also has the ability to come in and set up medical facilities as well, but I think this is a role that local government should be providing, and they ought to be identifying these facilities now.

Senator HARKIN. Get them identified now, and locate them now, so that they are ready.

Mr. HAUER. Then you integrate Federal and State resources into the local response, and that ought to be the hallmark of any response. You take Federal assets and integrate them into the State and local response to supplement what is going on at the State and local level.

Dr. ARCHER. We have to look back at our history such as the 1918 flu pandemic. We certainly have more hospital beds now than we did then. Our city charter allows me to in effect commandeer hotels, and set those up as a place to be able to put patients. If this is communicable, we do not have enough negative pressure rooms in our hospitals to have these patients there anyway, and we cannot afford to take our hospitals offline for other treatment purposes.

We have talked about issues of using drive-through banks and fast-food places to hand out medication to be able to keep people from getting in the same air space even, as a way to reduce the spread.

The other issue on surge capacity, though, is being able to do the outbreak investigation. What I mean by that is, we talk about in some cities whether can we get the second SWAT team there in 15 minutes. With this, we need to be able to interview, like, 100 patients at 10 different sites in less than an hour, get them entered into a computer data base, merge that, do an analysis to see whether they all were at this building, this sporting event, where were they exposed, so we can prioritize where we do our prophylaxis so we know what we are dealing with. We do not have that capacity, but we are working on it.

Dr. QUINLISK. I would just like to say, too, one of the things we have learned from some of these terrorist attacks, specifically, the Sarin in the Tokyo subway, is that the number of people who were

actually killed by this and the number of people who were actually injured were very, very low, as compared to the numbers of people who showed up for emergency care because they were concerned, the worried well. That is, I think, a very big issue we need to be addressing, and not just at the hospital systems or the public health systems, but with the media.

They have got to get the correct information out to people and not to panic them, because we have seen instances where the media has, unfortunately, played into people's panic and created more of a hysteria than maybe was necessary. So that is another area that I think we need to have very good relationships with and communications with to make sure that the proper information gets out to the public, because that is who people are going to be relying on to get their medical information at a time of crisis.

Senator HARKIN. That is an excellent point.

Dr. CANTRILL. One issue about the surge capacity, as Senator Kennedy mentioned, hospitals continue to close, and I think that heightens any potential surge capacity problem we might have.

We have had 5 hospitals close in Denver in the last 5 years. We have fewer beds now than we had 15 years ago, and 1½ times the population. This is a major problem. I do not have the answer for it, but I think it really does need to be looked at. We need to keep every bed that we have now.

I think staffing certainly has become an issue as well. Even though we may have alternative sites, we may not have enough staff to deal with some of the very ill patients.

Senator HARKIN. Any final comments or suggestions, advice you might have, before we adjourn?

Dr. CANTRILL. I would like to personally thank you for having these hearings. Having been in this area for several years, I am very encouraged now that there is a resurgence of interest in this area, and I think it is marvelous.

Senator HARKIN. The one thing that I hope comes out of it, and I am sure that will come out of it, is a renewed interest in our Public Health Service, and public health in general. It has been sort of relegated to the back porch for a long time, and I think now we should recognize we are all in this thing together. We need stronger support for all of our public health systems out there in very many ways.

So hopefully this will at least boost that recognition, and get the necessary funds out there to help on the local, State, and Federal level to coordinate this. Public health, as someone said earlier, is a national security issue, it really is, and now I think we are seeing recognition of that.

So again, I thank you, as Senator Specter did, for your public service and for your help in this area. As we move ahead in developing different responses and funding programs, please feel free to give us your input either by phone or by e-mail, or whatever. If you see us doing things you think we should not be doing, or we need to boost something else, please, you are the experts, and we rely on you, so please give us your best input as we move forward.

SUBCOMMITTEE RECESS

Thank you all very much for being here, that concludes our hearing.

[Whereupon, at 1:40 p.m., Wednesday, October 3, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

BIOTERRORISM

TUESDAY, OCTOBER 23, 2001

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 11 a.m., in room S–5, the Capitol, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Reid, Murray, Landrieu, Specter, Hutchison, and Craig.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, and Education Appropriations Committee will come to order. Among the duties we have on this subcommittee is to provide the necessary funding for the protection of the public health here in America. It is an important responsibility, and one that has taken on even greater significance over the last month.

In combatting bioterrorism, we face one of the greatest public health challenges of our lifetime. Meeting that challenge will require considerable resolve, know-how, and resources. Read that as money.

This subcommittee is prepared to do its part and I hope that the Department of Health & Human Services understands that it is this subcommittee of the Appropriations Committee on the Senate side that will decide how much and how that money is going to be spent. I have a feeling that some people at the Department of Health and Human Services do not understand that, and they had better understand it, and they had better start working with us so that we can get the right information and that we are able to decide on an appropriate basis not only how much, but where that money is to go.

Several weeks ago we heard from Secretary Thompson and other experts about the extent of the threat of bioterrorism. I think we all came away understanding that we need to view our public health system as a front line of our national defense. Just as we need an army of well-trained and well-equipped soldiers to defend us overseas, we need a well-trained and well-equipped public health force to defend against bioterrorism. While we have made some improvements, today I state emphatically we are in no way as well-prepared to fight bioterrorism here at home as we are to defeat enemies overseas. To use military terms, our troop force is inadequate and ill-trained, our radar and communications systems

are outdated, we are short on ammunition, and our weapons systems need updating.

Well, we want to change that. Over the last several weeks, Senator Specter and I have consulted with experts, our colleagues, and the administration to try to develop a comprehensive antibioterrorism plan to include in the emergency supplemental appropriations bill. We have put forward a $2.3 billion proposal that both Senator Specter and I have worked on.

Now, the administration says that they think $1.5 billion is enough. We think that is insufficient, and we need them to get back to the pencils and sharpen them a little bit.

Now, in terms of medicine supplies and equipment, we believe we need $643.6 million to acquire medicine, supplies, and equipment for the National Pharmaceutical Stockpile. This would enable us to treat an additional 10 million Americans exposed to anthrax and other bacterial infections, and others exposed to possible chemical weapons. We believe we need $509 million to acquire and stockpile enough doses of the smallpox vaccine, and we will hear about that this morning, to inoculate every American should that ever become necessary.

We feel we need at least $700 million to beef up our State and local public health capabilities and hospital surge capacity. This would include training of doctors, nurses, and other health professionals, expanding the Health Alert Network, improving their capacity for early detection and surveillance, and increasing the capacity and security of public health laboratories.

We believe we need $140 million to expand the capacity of CDC, including their labs, and assigning every State trained disease investigators to be on duty 24 hours a day, 7 days a week.

We need $10 million to establish a comprehensive data base and tracking system for all biohazardous pathogens. We have this for nuclear material. We should have it for biological agents. I know this is difficult, and there may be some problems involved, but I think we have to tackle it.

We feel we need $250 million to double our commitment to the inspection of imported foods. Only about 1 percent of those foods are currently being inspected. The administration only asks for $75 million. We believe we need $250 million.

So today's hearing will enable us to get input on this plan. We will try to get answers on a number of questions, like how quickly we can acquire this stockpile of vaccines we need, what steps are most urgent to take, what resources are required, what is the most effective course of treatment for those exposed to anthrax and other biological pathogens, and what about electronic pasteurization, and I will speak more about this with Dr. Koplan and others.

Can electronic pasteurization, which is approved by the FDA for food safety processes, be used to make our mail safe and, if so, how rapidly can we get it involved in some of our mail processing centers?

What can be done better, and I am glad the FBI is here today, to coordinate public health and law enforcement resources? From what I have seen, there has been some disconnect there and I think we need to reassure ourselves that there is a good working relationship between law enforcement and our epidemiologists.

We have a very distinguished panel of witnesses. I look forward to hearing from each of them. I want to just conclude with this. This is not the time to panic. We do not need to push any panic buttons. That is what the bioterrorists want. But it is the time for us to meet the requirements necessary to protect the American people and to make sure we do it in the most expeditious, efficacious manner possible.

There is a lot of misinformation out there. Misinformation can lead to panic and unbased fears, but I believe we need better coordination, we need better information, and I will be asking the FBI about that. Where do you cross the line? They are doing investigations, and a lot of it they need to keep secret, I understand that. But the public needs information. Our public health agencies need information on which to make decisions to protect the American public. That is what we are talking about, not a panic, but we need to determine a course of action and we need to start on it now.

Now, with that, I would recognize my distinguished colleague, Senator Specter.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you, Mr. Chairman, and thank you and the staff for convening this very important hearing under very difficult circumstances. Those who may be watching this on C–SPAN do not know that we are in the tombs of the Capitol, not in our customary hearing room in the Dirksen Senate Office Building, because that building is closed. The Hart Senate Office Building and the Russell Senate Office Building are also closed. But we have pushed hard to convene this hearing today because of the importance of this subject.

The terror of September 11 has resulted in a war on the terrorists now being waged in Afghanistan, but the public concerns and the focal point of attention of America today is on bioterrorism, and that is the subject we are going to address. We have very distinguished witnesses. We have the Director of the Center for Disease Control, a key official from the FBI on counterterrorism, representatives of the scientific and commercial community to deal with this subject, and we do so because of the need for the inquiry to determine just precisely what appropriations need to be made.

The Congress responded immediately on the Friday after the attack by appropriating $40 billion. A portion of that funding is going to be directed to bioterrorism, and we are a rich and powerful and ingenious country, and we can meet the challenge, but we have to do so in a way which is totally realistic.

This subcommittee heard from Secretary of Health and Human Services Thompson a couple of weeks ago and had assurances which Senator Byrd, who is the chairman of the full committee, categorized in very blunt terms, waving his arms for the evening news and saying, I do not believe you. We need to be realistic as to what our problems are and where we are going and assure the American people that the Congress is functioning and that we do have a plan and that we are prepared to do what is necessary.

This subcommittee, and Senator Harkin and I have worked hand in glove as partners for more than a decade. He is now the chair-

man. We had a little reorganizational event in May, but it has not made any difference. When I was the chairman for 6½ years and Senator Harkin was ranking and we were reversed we formed a seamless operation. He and I learned a long time ago if you want to get something done in Washington you have to cross party lines, and we have been attentive to this issue, and that was before September 11.

I made a visit to the Centers for Disease Control a year-and-a-half ago to respond to what I heard were the deplorable conditions there, but they were not as deplorable as I had heard. They were worse, and more than a year ago this subcommittee took the lead in putting up $175 million to improve the infrastructure for the Centers for Disease Control. Before September 11 we put up some $250 million in fiscal year 2002 to continue those improvements at the Centers for Disease Control. The warnings were clear as to what was happening, but the reality is that no one knew the intensity of the problem or could focus on it until the wake-up call came on September 11, and now we are mobilized. Senator Harkin outlined our determination to put up the funds which are necessary.

I found that, being back in the State that there was a real need for Senators and Members of the House of Representatives to communicate with their constituents. There has been a feeling for a long time that if Government was not irrelevant, it was close to irrelevant. You get the Government out of the way and private enterprise will take care of things. Suddenly, Government has become relevant, and shortly before this hearing was convened, the leaders were talking about finishing up our business, which I think we have to do by Thanksgiving, and making the decisions and putting politics aside and returning to our States to take care of very important business and talking to our constituents.

We really should finish our business by September 30, and Thanksgiving it seems to me is the outside date, so Senator Harkin, I thank you for pushing ahead today, and the staff. Late yesterday afternoon we did not think we would have a hearing. We were shut out of the Russell Building, but we are here today and we are prepared to go to work to solve this problem.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator Specter.

Our first panel will be Dr. Jeffrey Koplan, Director of the Centers for Diseases Control. Dr. Koplan has had a very distinguished career. He was a member of the CDC team that helped eradicate smallpox. He has served as Assistant Surgeon General and has been involved in public health for most of his adult life. He has his B.A. from Yale, his M.D. from Mount Sinai School of Medicine, and a master's in public health from Harvard. Also on the first panel is Mr. James Caruso, Deputy Assistant Director of the Counterterrorism Division at the FBI. Before being appointed to his current post, Mr. Caruso served as Special Agent in Charge of the National Security Division in Washington, and also served on the investigation staff of the U.S. House of Representatives Committee on Appropriations.

Before I turn to you, Dr. Koplan, you know I have the greatest respect for you personally and professionally. I have the highest respect for the FBI and for the Centers for Disease Control and Pre-

vention, with whom I have worked closely for the past 15 years. I must tell you I have some deep concerns, and I might as well get it off my chest right now, about the actions of the CDC recently involving the events surrounding the deaths of the two postal workers here in Washington. This is where I hope to get some information from both of you about what is happening in terms of coordination.

Now, I am not one that believes the headlines all the time, but it says here in The Washington Post: " Workers Question Response; CDC Says Policy Evolving. Officials at the U.S. Center for Disease Control acknowledged yesterday that recommendations for postal workers are still evolving." It says in the paper this morning: "We are dealing with something that up until 2 or 3 weeks ago we had not dealt with before, said CDC spokesman Tom Skinner."

Well, that is what CDC is for. Of course there are things we have not been up against before, but we would hope that CDC would have had some kind of a plan that they could have used to trace back, to use the epidemiologists to ensure that we would trace everything back and make sure that everything was covered.

Here is another quote from the story: "What we do is still sort of a work in progress. We are making decisions based on the best scientific information we have at the time.

"Based on that record, and on the absence of evidence of contamination inside the Brentwood building, CDC officials advised the U.S. Postal Service the workers there did not need to take antibiotics. They reversed that advice on Sunday, when the first Brentwood employee was diagnosed with the inhaled form of anthrax."

Well, first of all, we get the letter that comes into Senator Daschle's office. Hundreds and hundreds of people here in the Capitol were tested. We knew at that time, or shortly thereafter, that a couple of officials in Trenton, New Jersey had come down with the skin form of anthrax. Trenton, New Jersey to here, someone here gets it, at least they tested positive, and we know that the powder substance was anthrax. We have officials in Trenton, New Jersey at the postal facility that come down with the skin form of anthrax. In between, it goes through Brentwood, and yet the people at Brentwood are told do not worry about it. At least, that is my reading, and I am very concerned, Dr. Koplan, about what CDC is doing, and how they are operating to make sure that those who have any possible connection with this in any of these facilities are alerted, that they are tested, and that they are treated in a timely fashion.

Now, I do not know, maybe I am wrong, but it just seems to me something broke down here, or is broken down. I do not know whether it is the FBI in terms of trying to find out who is doing this, and trying to trace it back, and needing some secrecy. I do not know if that is a part of the problem. If it is, we have got to get over it, because obviously, people are getting sick and people are dying, and we cannot afford to continue to have this happen.

So whatever happened at Brentwood we just cannot afford to let happen anywhere else. We count on CDC. You are our line of defense at CDC to set out the procedures, the processes, the steps we take to make sure that our people are protected, and quite frankly, as you can tell by my tone of voice, I am a little upset about this,

because I felt all along that CDC really was on top of this. Maybe they still are, and maybe you can reassure us this morning that they are.

Dr. KOPLAN. I hope to.

Senator HARKIN. I appreciate that. Thank you very much, Dr. Koplan, and I would turn it over to you for an opening statement.

STATEMENT OF JEFFREY P. KOPLAN, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. KOPLAN. Thank you, Mr. Chairman, and Senator Specter, I will address in detail the issues you have raised and try to reassure you and every one here and the public that the expectations they have of us have been met and are being met and will be met in this outbreak, and provide you with an explanation and some understanding of the issues you have just described.

Thank you for the invitation to update you on CDC's public health response to the threat of bioterrorism. All of our vigilance, preparedness, and understanding shifted after September 11, but prior to that, this committee under both of your leaderships has recognized the importance of bioterrorism, and has provided us support for many key programs in this regard, but the public health system of the United States is severely challenged at the moment.

At CDC we have reorganized ourselves. We have reassigned staff, deployed over 200 people to the field investigations at several sites, we have laboratory epidemiologists and other public health professionals working 24 hours a day. At State and local levels similar efforts are being undertaken, but the system is stressed through years of neglect and underinvestment. Labs are inundated with specimens. Epidemiologic investigative staff, where present, are being run ragged. Communications capabilities are strained, and cash-strapped States and localities face extraordinary unbudgeted costs for overtime, reagents for tests, extra equipment, et cetera.

Despite this stress, one can see how public health works in a crisis, and the unseen system which has been taken for granted and now expected to perform has performed admirably, from the initial disaster in New York and the response to the New York City Health Department to a wide variety of health problems there, in trying to anticipate other health problems. We have worked with them from September 11 afternoon on, and still have many dozen staff there working on everything from bioterrorism issues to environmental health issues, in Florida and in New York and Washington, D.C. similarly.

If you like, I could now expand on the situation in Washington that you have just targeted and explain a little bit, but if you will permit me, let me back up a little bit to some of the other investigations, because these are stepwise pieces of information that we acquired.

Yes, we are amongst the most knowledgeable places in the world in epidemiologic investigation and in the problems of anthrax as well, but sometimes the information we have on day 14, which would have been very valuable on day 10, cannot be used on day 10 when you do not get it until day 14, and while we do try to an-

ticipate things like this, there is a stepwise process of building information that derives both an epidemic investigation and permits us to take the appropriate steps to control it. Let me back up a little bit and talk about some of these pieces.

In the initial investigation in Florida—you have heard a lot about what state the U.S. public health system is in. Here is a case where an astute clinician could have easily passed over an ill patient and said, I just do not know what this is, and we will ascribe it to a pneumonia or a meningitis of unknown cause, but instead this individual sent specimens, took collected specimens, sent them to a lab specifically to test for anthrax, which he had never seen before, had not been present in the State of Florida for years, but because of this increased sensitivity, because of educational courses provided for infectious disease specialists on potential bioterrorist agents his antennae were up. He got an initial positive.

It was then sent to the Florida State lab. Through support that you all have provided to us, that Florida State lab had had recent training on the diagnosis of anthrax at CDC and had the reagents to do it, and they did that testing and got an initial positive.

At that point, they needed confirmation from another backup facility and called us. They called us on a Wednesday night, late, described the situation to us, described the results, wanted to send a specimen, got it on a plane that night, we received it on Thursday morning in Atlanta, and had confirmed the diagnosis by noon.

Prior to that, not even waiting for that diagnosis, we, in consultation with the Florida State Health Department, had put together an investigative team, had them on a plane and on their way, prior to the confirmation being received, and that investigation went into play.

Yes, we know something about anthrax, but I would have you keep in mind that in the course of our 50-plus years of history there have been 200 cases of anthrax in this country as a whole, all of them associated with people who deal with hides, animals, wool-sorting, et cetera, so we have a body of experienced based on that, and like everyone else in the world, most of the rest of our experience is on reading things, studying things, doing things in the laboratory, but we are all thankful we have not had to have the experience with a bioterrorist event, per se, before.

In the case in Florida and then in our subsequent information in New York, we began to piece together what placed people at risk in these circumstances and in Florida, as you know, there have been only two cases, and very unfortunately one of the gentlemen died from inhalation anthrax, another person is still hospitalized and stable with it, but it was related to either opening mail or being in a closed space where mail was opened, and again from past knowledge, from reading about others' experiences with anthrax, one has to base one's approach from the information available and towards what we learn on a day-to-day basis from the lab and, as you say, epidemiologic investigations.

So as we pursued things in Florida, we looked for all different kinds of spread and other modes of transmission, and we backed up through the system. We go upstream from where the cases are, and continue to look, is there exposure, are there cases—we reach

a wider community. Are there cases that we are missing of this that would give us more information?

In this instance, there continued to be the linkage between an opened letter, and it's a physical property, a physical substance that this anthrax is present in a powdered form and needs to get out in order to expose people.

Following that, we had experience working closely with our New York City Health Department colleagues on cases in New York, again, where we and our colleagues at FBI are open as to how is this being spread? You cannot assume the same cause each time, but here was again a place where the letters were received, where an incriminating letter this time was found, and that is the difference between New York and Florida. Each one of these is a little different.

In Florida, we did not have a letter in our hand. We knew the people worked with mail, and suspected that is what had happened, and they remembered having mail that was suspect that had come through, but we did not have that letter in our hand that we could look at and test to see what the powder was, to see how it might have been transmitted, to see what its properties were.

In New York, there was such a letter, which in turn confirmed this association with mail from Florida, and in turn, in New York, the association with the letter and opening it involved a second form of anthrax, a less severe form called cutaneous anthrax on the skin, and there was no evidence of inhalation disease there.

We are puzzled. Why was there inhalation disease in Florida attached to the letter there, but there was no explanation. There was no one present when the individual involved had opened it. He opened it in a way that caused the dust to come out. Was there more dust in that letter—and we do not have the letter, so we cannot tell whether it was ragged or whether it was leaking, or whether it had other properties attached to it.

So that we end up at this point with two cases of inhalation anthrax associated with opened mail, and all of our cases in New York associated with either a given open letter, or places where mail gets opened, desk tops, people whose job it is to open the mail, not just to handle the mail but to open the mail.

So one of our questions throughout this has been, how far back up the mail chain do you go? It can go to every household in the country eventually, at an extreme, or it can go to every post office in the country, or what we try to do is go backwards from the cases that we found and see, is there evidence of anthrax present in these places, is there evidence of illness in these other places, to go backstream to it.

Here in Washington, we have been involved with a number of other partners. In both Florida and New York and in New Jersey our primary linkage is with State and local health officials and with the FBI who do the criminal investigations out of this. In Washington, there have been a number of folks involved in this, where it started at the Hart Office Building, and again, let me reassure you and say, absolutely that we used the same standards, we used the same approach, and we tried to be as diligent, as quick, and as thorough no matter where or to whom these cases appear, or where the threat is.

We work in public health. There is no favoritism. In fact, it is quite the reverse. We are most interested in folks who are less famous, less well-off, and less visible, throughout the field of public health, so our approach has been to take a systematic, rational approach to dealing with this, because it is natural in epidemics, and we have experience in thousands of epidemics, for people to want to rush to make a decision early, and it may be the wrong one and can cause more harm and illness than not.

Let me also add the antibiotics in this are not without harm themselves. We have no desire to withhold antibiotics, nor does anyone in the health field, from people who need it. Our key goal is to identify who needs it, and let us make sure they get it, and not have people take it unnecessarily, because there is a risk.

We have already had some significant and serious adverse reactions from people taking these, including some of our own staff taking these antibiotics, so we want people on them who need them, and we do not want people to take them unnecessarily, so there is a balance in there. Where we have to err, we want to err on the side of more people taking antibiotics to better cover them for this serious disease.

In the case of the Hart Building, the investigation again, just as you indicated, Senator Harkin, we tried to target it by epidemiologic grounds. In other words, just not distribute samples and distribute environmental swabs all over the place, but target where there is a problem. Again there is a letter, and it is a letter on someone's desk, and we are able to go find a potential source of exposure in this instance. The letter was opened, and again the people right around it were the ones at greatest risk, and our experience in New York, when we did both environmental specimens from people and from surfaces, the spread was pretty much confined If we opened a letter here, it would be in this space around here, with very little going beyond it, so that was our approach in the Hart Building as well.

Many people came who wanted both swabs and who wanted antibiotics, and our policy wherever we have been is not to discourage anyone who wants it from getting it, and so many staff came who we did not feel were likely to be exposed, but ours is not to say you cannot have it or you should not get it. Instead we say, and we have said it in every instance, including the Postal Service, take it, take it for *x* number of days. It comes to in some cases 10 days, in some cases 14, in some cases fewer, and we will come back to you then and determine what your risk is. You may have to take it for 60. We may be able to say to you, your risk is really negligible, you do not have to keep taking it.

And I think that is what we have seen at the Hart Office Building, where the environmental isolation was targeted, not just in the suites immediately around Senator Daschle's office, but on the fifth and sixth floor, and a mailroom in Dirksen, so we used the environmental specimens to correlate our previous observations, and that makes a rational approach in this, where lots of people do not have to be on the antibiotics unnecessarily, with potential risk to them, yet the people who need it are taking it.

In the issue with the mail sorting facility, as we had had no cases of inhalation anthrax in a mail-sorting facility, and there was

no reason to think, based on everything we had seen so far, that this was a possibility, because open mail had been the relationship between these cases and mail was not being opened in these facilities, as soon as the first inhalation case became known, we immediately, working with—and we are part of the larger team in this.

There is the D.C. Health Department, there is the Postal Service itself, and let me just say to you that my very first conversation with the Postmaster General, as soon as this started his word to us was, he will do whatever is necessary to protect the health of his workers. That is number 1, and that no modification has to take place for any other of their responsibilities. Nothing supersedes the health of his workers, and he has had that attitude at every discussion we have had together.

On inspecting that place, we could not be sure what letters had gone through there.

Senator HARKIN. What place, Brentwood?

Dr. KOPLAN. I am sorry, the Brentwood facility. On getting there, what was troublesome was that obviously mail is not opened there, so that the hypothesis we were working on all along, that you had to have an open letter to spread this, which—and I hope you will agree with me is somewhat reasonable. Most things that are in letters are in that letter, and our past experience in other places was that only when it was opened did the person get inhalation anthrax, and even in some cases where it was opened, it was still cutaneous, and we had not seen inhalation anthrax in places where the mail was not opened, so this was the first case, with that very first case, which was new information, and very different from what we had been seeing.

We immediately—in consultation with the Postal Service, the station was closed by them. Specimens were taken from all over. All of the staff was offered antibiotics, and that was supplied. We had the material here in town, and got it to them to take. Everyone was told to take it. The people in the immediate area around the facility where the first case occurred were urged and told that they were going to need to take it for 60 days, even then. Everyone else was told, here is 10 days, and we will determine further needs then.

Senator HARKIN. Do you remember what day that was, Doctor?

Dr. KOPLAN. I am afraid all of these days are flowing together. It was, I believe, Sunday or Monday morning.

Senator HARKIN. Like, yesterday?

Dr. KOPLAN. Exactly.

Senator HARKIN. After the two people had already expired?

Dr. KOPLAN. The two people that expired were not—yes, that may have happened after the two people had expired, but those two people who expired had not been identified earlier either to us or had come through the system. You can only act on the information you have got in hand.

We were not passively collecting information. One of the things we do in Florida and New York and Washington, DC is we had active surveillance going on in hospitals throughout Metro DC, including Virginia and Maryland, looking for other ill people who might even possibly have inhalation anthrax, and these two did not turn up. I think in one of them—and these are terrible cir-

cumstances for the individuals and their families, and again let me assure you, we are health professionals. Our job is for people not to get ill or to die, so these are tragedies for us as well, and not something that we take lightly in the least, but you have got to know about the cases as well in order to take action on them, and one of these individuals had been seen, had relatively mild symptoms, and was not associated with the outbreak in any way, or the Brentwood mail facility, and progressed very rapidly, extremely rapidly, and died before the medical staff could do much at that point.

So that yes, these two cases came in, but already action had been taken. The action, the decision to both close the facility and to get people on treatment did not await these two cases. My understanding from discussion with colleagues up here was that that decision was made immediately after that first case. It did not await these two deaths.

Senator HARKIN. Do you mean the decision was made to put everyone on antibiotics?

Dr. KOPLAN. Put everyone on antibiotics and begin to take specimens, close the facility to take environmental specimens to see how far the anthrax had spread.

Let me reiterate. Knowing what we know today, would we have done things differently 3 days ago, or 4 days ago, yes. Let me add that that is true in every epidemic I have ever investigated. We always learn things, because we are out looking for things a day after or 2 days after that could have helped us 2 or 3 days before, but the absence of this investigative approach, the absence of doing this at all can mean a much more serious and longstanding epidemic.

We do not want any cases, and we do not want any deaths, but we do not always get the information necessary to permit us to operate that way.

Senator HARKIN. I hate to interrupt you, but you had the Trenton facility, and you had the postal workers there that had cutaneous anthrax. Now, was that because of open mail, that they opened something in that facility, or what?

Dr. KOPLAN. There seemingly was a heavier level of contamination related to the Trenton area.

Senator HARKIN. But you do not know if it was open mail or unopened mail?

Dr. KOPLAN. We do not know, nor do we know whether it was packages or what it was. We only know that the postmark on a couple of these letters did come through Trenton, and we had a letter from NBC in New York that had a Trenton postmark on it, and then I believe Senator Daschle's had a Trenton postmark.

Senator HARKIN. So when did you first test the Brentwood facility?

Dr. KOPLAN. I believe Friday night was the first time we got into the Brentwood facility. I do not have a chronology in front of me to go over this with you, but we could certainly provide that.

Senator HARKIN. Would you provide a chronological order of that, because I want to know how soon it was after the workers in Trenton were diagnosed, how soon after that did you start to test or

start to at least inform the employees at the Brentwood facility. I would ask for that chronology.

Dr. KOPLAN. Sure.

Senator HARKIN. But the point is, we do not know whether the contamination at Trenton was from open mail or not. We just simply do not know that.

Dr. KOPLAN. I think that is being investigated now. There are several cases there. They perform different tasks, and we are checking as to what they might have been exposed to and what they did and what they saw. I think the supposition that it has to be open mail is clearly not a sole supposition now.

Clearly, that puts people more at risk, but what is very disturbing about this to all of us is that apparently closed envelopes can potentially transmit as well. We do not know whether that is out of open flaps in the envelopes, whether it potentially can pass through the envelope, we do not know. Lots of this would be easier if we had answers to all of these things. Some of them we learn as we go along, and some we may not know for sometime, but we have investigated thousands of outbreaks over 50 years, and have a pretty good track record. I have investigated dozens myself.

PREPARED STATEMENT

The difference is, this one is—as you are all well aware, is not a naturally occurring event, and we have experience with how things pattern themselves in a naturally occurring event, but here we have an ongoing malevolent force working against us and possibly a force with some level of sophistication, so I can assure you we are working hard, we are working fast, and absolutely working equitably in every single place. We do this—whether we can get the answers as fast as we would all like to have them, probably that will not be the case, because we would like to have those answers yesterday, but I do not think you would find a better place, or an institution, or a people to be doing this than the ones you have doing this, whether it is in New York, Florida, New Jersey, or Washington, D.C.

[The statement follows:]

PREPARED STATEMENT OF DR. JEFFREY P. KOPLAN

Good morning, Mr. Chairman and Members of the Subcommittee. I am Dr. Jeffrey P. Koplan, Director, Centers for Disease Control and Prevention (CDC). Thank you for the invitation to update you on CDC's public health response to the threat of bioterrorism. I will update you on CDC's response to recent anthrax exposures, and I will discuss the status of implementing the overall goals of our bioterrorism preparedness program.

As has been highlighted recently, increased vigilance and preparedness for unexplained illnesses and injuries are an essential part of the public health effort to protect the American people against bioterrorism. Prior to the September 11 attack on the United States, CDC was making substantial progress toward defining, developing, and implementing a nationwide public health response network to increase the capacity of public health officials at all levels—federal, state, and local—to prepare for and respond to deliberate attacks on the health of our citizens. The events of September 11 were a defining moment for all of us, and since then we have dramatically increased our levels of preparedness and are implementing plans to increase it even further.

RECENT ANTHRAX EXPOSURES

As you are aware, many facilities in communities around the country have received anthrax threat letters. Most were received as empty envelopes; some have contained powdery substances. Moreover, in a few cases, actual anthrax exposures have occurred. On Wednesday, October 3, the Florida Department of Health notified CDC of a positive anthrax laboratory test result in a Florida resident who had recently visited North Carolina. Samples were sent overnight to CDC for confirmatory testing, and CDC dispatched two investigative teams—to Florida and North Carolina—the next day. By Sunday, October 7, test results confirmed that a second person—a coworker of the first individual—had been exposed to anthrax and that traces of the bacteria had been found in the workplace. A decision was made to close the building, and additional CDC staff were sent to help manage notification, health evaluations of other coworkers, and provision of prophylactic antibiotics after the National Pharmaceutical Stockpile was deployed.

As CDC was continuing to receive clinical specimens and environmental samples from Florida, we became aware of a possible case of cutaneous anthrax in New York City. This person, an NBC employee in Rockefeller Plaza, had received an envelope containing powder on September 25. The diagnosis was confirmed by immunohistochemistry on a skin biopsy specimen in CDC's laboratory in the early morning of October 12, and the New York City Health Department and CDC immediately implemented appropriate public health actions, including restricting activity on two floors of 30 Rockefeller Plaza and evaluating workers for the need for prophylactic therapy. CDC sent additional investigative personnel to New York, joining the more than 30 epidemiologists and other CDC stall assisting with worker injury and enhanced syndrome surveillance following the September 11 terrorist attack. Laboratory studies on the powder from the September 25 letter were negative for the organism causing anthrax. Subsequent investigation identified a second letter that arrived on September 18, which was found to be contaminated with *Bacillus anthracis*, the organism that causes anthrax.

Last week, on October 15, CDC was notified of a possible anthrax exposure on Capitol Hill. A letter, which has now been confirmed to have contained *B. anthracis*, was opened by a Senate staff member. This person took appropriate action, notifying emergency personnel, and Capitol, local, and federal emergency workers immediately implemented public health measures. Certain areas of the office building were closed, and employees were screened by history for exposure and started on antibiotic prophylaxis after a nasal swab was obtained for epidemiologic purposes. CDC sent two teams of epidemiologists to assist local, state, and federal authorities in the investigation.

The best defense against such biologic threats continues to be accurate information regarding how to recognize a potential threat and knowledge of appropriate actions. In the *Morbidity and Mortality Weekly Report (MMWR)* and in multiple health advisories distributed via the Health Alert Network, CDC has issued several updates on the investigations as well as interim guidelines for state health departments with recommended procedures for handling such incidents. These guidelines include advice to the public and state and local health officials dealing with suspicious incidents, as well as guidance to clinical laboratory personnel in recognizing *Bacillus anthracis* in a clinical specimen. The guidelines also outline post-exposure prophylaxis recommendations. In persons exposed to *Bacillus anthracis*, disease can be prevented with antibiotic treatment. Early antibiotic treatment of all forms of anthrax is essential. *Bacillus anthracis* usually is susceptible to penicillin, doxycycline, and fluoroquinolones; but for bioterrorism planning, ciprofloxacin or doxycycline is recommended as the antibiotic for initial use for prophylaxis. Copies of the October 19, 2001, *MMWR*, which addresses these issues, have been provided to the Subcommittee.

In collaboration with state and local health and law enforcement officials, CDC and the FBI are continuing to conduct investigations related to anthrax exposures. During this heightened surveillance, cases of illness that may reasonably resemble symptoms of anthrax will be thoroughly reviewed until anthrax can be ruled out. The public health and medical communities continue to be on a heightened level of disease monitoring to ensure that any potential exposure is recognized and that appropriate medical evaluations are given. This is an example of the disease monitoring system in action, and that system is working.

As of noon October 22, 2 cases of inhalational anthrax have been identified in Florida, 2 cases of inhalational anthrax have been identified in Washington, DC, 5 cases of cutaneous anthrax have been identified in New York City, and 3 cases of cutaneous anthrax have been identified in New Jersey.

PUBLIC HEALTH LEADERSHIP

The Department of Health and Human Services' (DHHS) anti-bioterrorism efforts are focused on improving the nation's public health surveillance network to quickly detect and identify the biological agent that has been released; strengthening the capacities for medical response, especially at the local level; expanding the stockpile of pharmaceuticals for use if needed; expanding research on disease agents that might be released, rapid methods for identifying biological agents, and improved treatments and vaccines; and preventing bioterrorism by regulation of the shipment of hazardous biological agents or toxins.

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

In 1998, CDC issued *Preventing Emerging Infectious Diseases: A Strategy for the 21st Century*, which describes CDC's plan for combating today's emerging diseases and preventing those of tomorrow. It focuses on four goals, each of which has direct relevance to preparedness for bioterrorism: Disease surveillance and outbreak response; applied research to identify risk factors for disease and to develop diagnostic tests, drugs, vaccines, and surveillance tools; infrastructure and training; and disease prevention and control. This plan was developed with input from state and local health departments, disease experts, and partner organizations such as the American Society for Microbiology, the Association of Public Health Laboratories, the Council of State and Territorial Epidemiologists, and the Infectious Disease Society of America. It emphasizes the need to be prepared for the unexpected—whether it is a naturally occurring influenza pandemic or the deliberate release of smallpox by a terrorist. It is within the context of these overall goals that CDC has begun to address preparing our nation's public health infrastructure to respond to acts of biological terrorism. Copies of this CDC plan have been provided previously to the Subcommittee. In addition, CDC presented in March a report to the Senate entitled *Public Health's Infrastructure: A Status Report.* Recommendations in this report complement the strategies outlined for emerging infectious diseases and preparedness and response to bioterrorism. These recommendations include training of the public health workforce, strengthening of data and communications systems, and improving the public health systems at the state and local level.

CDC'S STRATEGIC PLAN FOR BIOTERRORISM

CDC outlined necessary steps for strengthening public health and healthcare capacity to protect the nation against bioterrorist threats in its April 21, 2001, *MMWR* release of *Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response—Recommendations of the CDC Strategic Planning Workgroup.* This report reinforces the work CDC has been contributing to this effort since 1998 and lays a framework from which to enhance public health infrastructure. In keeping with the message of this report, five key focus areas have been identified which provide the foundation for local, state, and federal planning efforts: Preparedness and Prevention, Detection and Surveillance, Diagnosis and Characterization of Biological and Chemical Agents, Response, and Communication. These areas capture the goals of CDC's Bioterrorism Preparedness and Response Program for general bioterrorism preparedness.

Preparedness and Prevention

CDC has been working to ensure that all levels of the public health community—federal, state, and local—are prepared to work in coordination with the medical and emergency response communities to address the public health consequences of biological and chemical terrorism.

CDC is creating diagnostic and epidemiological guidelines for state and local health departments and will help states conduct drills and exercises to assess local readiness for bioterrorism. In addition, CDC, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Department of Defense (DOD), and other agencies are supporting and encouraging research to address scientific issues related to bioterrorism. In some cases, new vaccines, antitoxins, or innovative drug treatments need to be developed, manufactured, and/or stocked. Moreover, we need to learn more about the pathogenesis and epidemiology of the infectious diseases which do not affect the U.S. population currently. We have only limited knowledge about how artificial methods of dispersion may affect the infection rate, range of illness, and public health impact of these biological agents.

Detection and Surveillance

As was evidenced in Florida, New York, and Washington, DC, the initial detection of a biological terrorist attack occurs at the local level. Therefore, it is essential to educate and train members of the medical community—both public and private—who may be the first to examine and treat the victims. It is also necessary to upgrade the surveillance systems of state and local health departments, as well as within healthcare facilities such as hospitals, which will be relied upon to spot unusual patterns of disease occurrence and to identify any additional cases of illness. CDC is providing terrorism-related training to epidemiologists and laboratorians, infection control personnel, emergency responders, emergency department personnel and other front-line health-care providers, and health and safety personnel. CDC is providing educational materials regarding potential bioterrorism agents to the medical and public health communities on its website for Public Health Emergency Preparedness and Response at *www.bt.cdc.gov*. CDC is working with partners such as the Johns Hopkins Center for Civilian Biodefense Studies (*www.hopkins-biodefense.org*) and the Infectious Diseases Society of America to develop training and educational materials for incorporation into medical and public health graduate and postgraduate curricula. With public health partners, CDC is spearheading the development of the National Electronic Disease Surveillance System, which will facilitate automated, timely electronic capture of data from the healthcare system.

Diagnosis and Characterization of Biological and Chemical Agents

To ensure that prevention and treatment measures can be implemented quickly in the event of a biological or chemical terrorist attack, rapid diagnosis is critical. CDC has developed guidelines and quality assurance standards for the safe and secure collection, storage, transport, and processing of biologic and environmental samples. In collaboration with other federal and nonfederal partners, CDC is cosponsoring a series of training exercises for state public health laboratory personnel on requirements for the safe use, containment, and transport of dangerous biological agents and toxins. CDC, also in cooperation with the Association of Public Health Laboratories (APHL) and the National Laboratory Training Network (NLTN) have sponsored a "hands-on" laboratory course for public health microbiologists. In conjunction with the course, CDC produced two videos that were distributed to the participants as well as to members of the NLTN. The participants in this course are now using these videos and the other materials developed by CDC to train other laboratorians in their states. CDC is also enhancing its efforts to foster the safe design and operation of Biosafety Level 3 laboratories, which are required for handling many highly dangerous pathogens. Furthermore, CDC is developing a Rapid Toxic Screen to detect people's exposure to 150 chemical agents using blood or urine samples.

Response

A decisive and timely response to a biological terrorist event involves a fully documented and well rehearsed plan of detection, epidemiologic investigation, and medical treatment for affected persons, and the initiation of disease prevention measures to minimize illness, injury and death. CDC is addressing this by (1) assisting state and local health agencies in developing their plans for investigating and responding to unusual events and unexplained illnesses, and (2) bolstering CDC's capacities within the overall federal bioterrorism response effort. CDC is formalizing current draft plans for the notification and mobilization of personnel and laboratory resources in response to a bioterrorism emergency, as well as overall strategies for vaccination, and development and implementation of other potential outbreak control strategies such as quarantine measures. In addition, CDC is developing national standards to ensure that respirators used by first responders and by other health care providers responding to terrorist acts provide adequate protection against weapons of terrorism.

Communication Systems

Rapid and secure communications are crucial to ensure a prompt and coordinated response to an intentional release of a biological agent. Thus, strengthening communication among clinicians, emergency rooms, infection control practitioners, hospitals, pharmaceutical companies, and public health personnel is of paramount importance. To this end, CDC is making a significant investment in building the nation's public health communications infrastructure through the Health Alert Network (HAN). HAN is a nationwide program to establish the communications, information, distance-learning, and organizational infrastructure for a new level of defense against health threats, including bioterrorism. Currently, 13 states are connected to all of their local health jurisdictions; 37 states have begun connecting to

local providers as well; and CDC is also directly connecting to groups, such as the American Medical Association, to cast a broad net of coverage. CDC has also established the Epidemic Information Exchange (Epi-X), a secure, Web-based communications system that provides information sharing capabilities to state and local health officials. CDC also provides timely satellite broadcast and web-broadcast training through the Public Health Training Network. For example, just last week, CDC experts shared information on anthrax with physicians, hospitals, and other healthcare providers across the country.

Ongoing communication of accurate and up-to-date information helps calm public fears and limit collateral effects of the attack. CDC communicates with the public directly through its website on emergency preparedness and through a public inquiry telephone and e-mail system, which, since the recent attacks, has responded to hundreds of questions daily. In addition, CDC communicates to the public by releasing daily updates to the news media, answering inquiries from the press and providing medical experts for interviews.

THE NATIONAL PHARMACEUTICAL STOCKPILE

Another integral component of public health preparedness at CDC has been the development of a National Pharmaceutical Stockpile (NPS), which is mobilized in response to an episode caused by a biological or chemical agent. The role of the CDC's NPS program is to maintain a national repository of life-saving pharmaceuticals and medical material that can be delivered to the site or sites of a biological or chemical terrorism event in order to reduce morbidity and mortality in a civilian population. The NPS is a backup and means of support to state and local first responders, healthcare providers, and public health officials. The NPS program consists of a two-tier response: (1) 12-hour push packages, which are pre-assembled arrays of pharmaceuticals and medical supplies that can be delivered to the scene of a terrorism event within 12 hours of the federal decision to deploy the assets and that will make possible the treatment or prophylaxis of disease caused by a variety of threat agents; and (2) a Vendor-Managed Inventory (VMI) that can be tailored to a specific threat agent. Components of the VMI will arrive at the scene 24 to 36 hours after activation. The NPS was mobilized for the first time on September 11, when a 12-hour push pack was deployed to New York City, delivering 50 tons of medical supplies to the site of the disaster in 7 hours. In addition, substantial quantities of VMI were delivered to New York City within 24 hours. Components of the VMI were deployed to Palm Beach, Florida, this month to provide adequate supplies of ciprofloxacin to provide prophylaxis to individuals who were potentially exposed to anthrax. CDC has developed this program in collaboration with federal and private sector partners and with input from the states.

CORE CAPACITIES FOR STATE AND LOCAL HEALTH BIOTERRORISM PREPAREDNESS AND RESPONSE

CDC has been working with partners at all levels to develop core capacities needed to respond to pubic health threats and emergencies. CDC is also developing specific guidelines to assist public health agencies in their efforts to build comprehensive bioterrorism preparedness and response programs. This collaborative effort engages federal, state, and local partners in determining what is needed for state and local public health agencies to improve their preparedness and response to bioterrorism. This process enables health departments to more effectively target specific improvements to protect the public's health in the event of a biological or chemical terrorist event and will provide the framework for future program efforts. The core capacities effort is for dual purpose. While these capacities focus on bioterrorism events, they are also relevant to naturally occurring infectious disease outbreaks and natural disasters.

CHALLENGES

CDC has been addressing issues of detection, epidemiologic investigation, diagnostics, and enhanced infrastructure and communications as part of its overall bioterrorism preparedness strategies. Based on federal, state, and local response in the weeks following the events of September 11, and on recent training experiences, such as the National TOPOFF event and the *Dark Winter* exercise, CDC has learned valuable lessons and identified gaps that exist in bioterrorism preparedness and response at federal, state, and local levels. CDC will continue to work with partners to address challenges such as improving coordination among other federal agencies during a response and understanding the necessary relationship needed between conducting a criminal investigation versus an epidemiologic case investigation. These issues, as well as overall preparedness planning at federal, state, and

local levels, require additional action to ensure that the nation is fully prepared to respond to acts of biological and chemical terrorism.

Disease experts at CDC are developing strategies to prevent the spread of disease during and after bioterrorist attacks. Specific components include (1) creating protocols for immunizing at-risk populations; (2) isolating large numbers of exposed individuals; (3) reducing occupational exposures; (4) assessing methods of safeguarding food and water from deliberate contamination; and (5) exploring ways to improve linkages between animal and human disease surveillance networks since threat agents that affect both humans and animals may first be detected in animals.

CONCLUSION

In conclusion, CDC is committed to working with other federal agencies and partners as well as state and local public health departments to ensure the health and medical care of our citizens. We have made substantial progress to date in enhancing the nation's capability to prepare for and respond to a bioterrorist event. The best public health strategy to protect the health of civilians against biological terrorism is the development, organization, and enhancement of public health prevention systems and tools. Priorities include strengthened public health laboratory capacity, increased surveillance and outbreak investigation capacity, and health communications, education, and training at the federal, state, and local levels. Not only will this approach ensure that we are prepared for deliberate bioterrorist threats, but it will also ensure that we will be able to recognize and control naturally occurring new or re-emerging infectious diseases. A strong and flexible public health infrastructure is the best defense against any disease outbreak.

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

Senator HARKIN. Is there anything else? I am going to turn to Mr. Caruso, now, from the FBI, and to brief us on, along the same line of questioning here, what you see as the situation right now regarding the anthrax investigation, and I will have questions for you about this investigation.

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

Mr. CARUSO. Thank you, Mr. Chairman, Senator Specter, members of the committee. I will briefly address the FBI's coordination with State and local law enforcement agencies, the first responders and the scientific and medical communities. Each FBI field office, in addition to having squads responsible for investigating suspected acts of domestic and international terrorism, has weapons of mass destruction (WMD) coordinators. These individuals are trained to address incidents involving chemical, biological or radiological attacks or incidents that the Federal Government, State, and local agencies need to be prepared to deal with, as we have been dealing with over the past weeks, and this committee is discussing.

DUTIES OF WEAPON'S OF MASS DESTRUCTION COORDINATOR'S

The WMD coordinator's duties include establishing and maintaining liaison with State and local first responder communities, such as the police, fire, hazmat materials units, and establishing a local FBI WMD incident contingency plan, which is our own FBI response to a suspected or actual WMD incident.

The coordinator participates in planning and execution of State and local WMD exercises and participates in established counterterrorism working groups. Additionally, many FBI field offices have established Joint Terrorism Task Forces, JTTF's. Presently, there are 35 JTTF's Nation-wide, with 24 of those task forces participating in 6 Regional Terrorism Task Forces (RTTF's). As a

result, all 50 States are represented, receive and contribute to the flow of information at law enforcement centers of intelligence.

JTTF's are staffed by FBI, State and local law enforcement, as well as with other personel from Federal agencies. The FBI utilizes the JTTF's, the RTTF's, and the National Law Enforcement Telecommunications System, known as NLETS, to provide hazardous materials assistance and guidance to first responders.

Beginning in 1998, the FBI, the Centers for Disease Control (CDC), and the Association of Public Health Laboratories (APHL), partnered together to assure a united and coordinated response to suspected and actual biological incidents. Known as the Laboratory Response Network (LRN), this group was composed of over 80 State public health, private, and military laboratories. The CDC and the APHL set out the scientific protocols for the testing of specimens. The FBI sets out the chain of evidence, or evidentiary protocols to be used in gathering and testing specimens.

A question posed to the FBI is, what have we done to coordinate efforts with State and local representatives on crime scenes? In the anthrax venues such as those in Miami, New York, New Jersey, and Washington, DC, the local FBI field offices work closely with State and local government officials, public health agencies, and law enforcement and first responder units, to expeditiously identify and isolate any potential crime scene. The FBI is coordinating sampling, and testing operations with the CDC and the Department of Health and Human Services (HHS) to ensure public safety. We are also closely aligned with the U.S. Postal Service and the Office of the Chief Postal Inspector at the local and headquarters levels.

The FBI deployed members of its Hazardous Materials Response Unit out of Quantico, Virginia to assist State, local, and Federal personnel in the sampling of locations and facilities believed to be contaminated with anthrax. Currently, there is a CDC official and U.S. Postal Service officer assigned to the domestic terrorism section at FBI Headquarters to ensure direct connectivity and information-sharing.

Finally, Mr. Chairman, the FBI's mission is to investigate and to prevent future acts of terrorism, whether committed by a single individual or a terrorist cabal.

Thank you.

BIOTERRORIST INCIDENTS AND INFORMATION

Senator HARKIN. Thank you, Mr. Caruso. I just have one more question, and then I will turn to Senator Specter and the other Senators who are here. This is the question I started out with.

In the bioterrorist incidents, it is necessary we tell people what is going on. People have to have information. Our public health officials, not only at CDC but those at the State and local levels, have to have information. Do you think there is a conflict with the FBI's need to control that information due to the fact that it is an ongoing criminal investigation? I am getting a sense there may be some conflict here, and I do not know who is ruling the roost.

Is it Dr. Koplan and the people at CDC on whom we rely to do the epidemiology of this, to track it down, to let us know where it is coming from, how to control it and contain it? Or are you ruling the roost in trying to go after the people who are doing it, and try-

ing to do a criminal investigation? How well is that being coordinated? Who is running this show?

Mr. CARUSO. Mr. Chairman, the mission of the FBI is to investigate and prevent act of terrorism, thereby saving lives. We turn to the CDC for guidance in doing that. If there is information that is law enforcement-sensitive, or information that may tip into the classified world, we find a way to make sure that information gets to the proper authorities so that we can save American lives. There is no question in our mind what our mission is with reference to that, and we try to live up to that every day.

Senator HARKIN. I have no doubt about that.

Dr. KOPLAN. Can I expand on that a bit? We are not two agencies that normally work together on a day-to-day basis. We have had some contact on West Nile, and some laboratory work, as has just been indicated. In this particular instance, from the get-go both of us were involved in the Florida investigation, and it became clear we were mutually dependent on each other for a wide range of activities, and it worked extraordinarily well. That does not mean that every day there was not a question on who does what and how do we do it, but we got it resolved well.

We had a team leader, they had an investigative team leader. We assigned someone from our epidemiology staff to sit in their emergency operations office, and they did the same with us. We assigned a senior CDC person who knows this area well to come to FBI Headquarters in Washington and sit there and we have made great efforts to ensure an enmeshed cooperative venture in this, and I think it has worked well.

So in terms of, they lead the criminal investigation, we lead the epidemiologic investigation, and when we get in the way of each other, we try to sort it out.

Senator HARKIN. Well, that is sort of the concern that I have, and others have, too, and it is a balancing act. I assure you we want to get these people, there is no doubt about it. But we also want to protect people, too, so we need as much information about what is going on so we can protect people. I can assure you there is a great deal of concern here, when we think about that Brentwood facility. The fact that we were here and had exposure, and so did Trenton, and it was not until somebody got sick there that we finally decided to start testing people there and giving antibiotics, that is something that bothers us.

Mr. CARUSO. Mr. Chairman, from early on in this investigation, under the leadership of Attorney General Ashcroft and Director Mueller, the FBI has provided information to the State and local representatives. One of the ways we do that most effectively is through the National Law Enforcement Telecommunications Center, NLETS, and that is a communications system that electronically connects us to about 18,000 law enforcement agencies across the country.

Under General Ashcroft and Director Mueller's leadership, we have been providing information even of a general threat nature to the law enforcement community to make sure that they are properly postured, and that we get information out.

Sometimes we have been criticized for giving information out that was not terribly specific in particular areas. It is more impor-

tant to have the law enforcement and the American people be informed. That is the springboard from which we in the FBI are coming with reference to providing information as soon as we can get it.

Senator HARKIN. Thank you very much.

Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman.

Mr. Chairman, since we are in this makeshift room we do not have the lights on, and I am going to take 5 minutes, which is our custom, and I would appreciate it if the clerk would hand me a note when I have 1 minute left so I will know when my time is up. We have a very long list of panelists beyond Dr. Koplan and Mr. Caruso, and we have caucus luncheons where we have to figure out the schedule as to how we are going to complete our business, so we are going to be under very tight time constraints, so I am prepared to observe time limits meticulously.

RESONSIBILITY FOR ANTHRAX DISTRIBUTION

Mr. Caruso, it is very important that we be sure about what we say as to who is spreading the anthrax. We speculate or wonder if there is a connection between the September 11 attack by Osama bin Laden and Al Qaeda and the anthrax, and until we know, we should not jump to any conclusions.

There has also been speculation about what is happening with Saddam Hussein and Iraq. As we know, we have not been able to inspect Iraq for many years now, and we know that Saddam Hussein has been actively engaged in bioterrorism. Is there anything in the FBI investigation which suggests any connection to either Osama bin Laden or Al Qaeda or Iraq's Saddam Hussein?

Mr. CARUSO. Senator, we do not have information at this point that would make evidentiary links to Osama bin Laden or Al Qaeda.

POSSIBLE RANGE OF BIOTERRORIST THREATS

Senator SPECTER. When you say evidentiary links, I do not think we need admissible evidence in court, but that is something which is very much on our minds, so while not to jump to any conclusions at all that is something that we ought to focus on, and the subcommittee would like a follow-up from you, if you could give it to us, as to what your line of inquiry is and we will treat it on a confidential basis.

Now, Dr. Koplan, looking at the broader picture on bioterrorism, you hear a lot of talk about smallpox. You hear talk about anthrax. There are concerns about water, and there are concerns about chemicals, as the Japanese subway incident several years ago. As a matter of public information, what is the range of possibility with respect to bioterrorist attacks?

Dr. KOPLAN. Unfortunately, it is very broad. There is a wide range of agents, both biological and chemical, that can be used.

Senator SPECTER. Would you furnish to this subcommittee a list as to those substances?

Dr. KOPLAN. Sure.

Senator SPECTER. Would you also furnish to this subcommittee a list as to what ought to be done about it? We have certain re-

sponses to anthrax. We would like to have an update as to what is happening with respect to smallpox. We would like to have a specification as to what other threats are out there, and what ought to be done by the Government to act if we find that they strike, and we also need to know what the cost factor is.

Senator Byrd and Senator Stevens, Senator Harkin and I wrote to the President several weeks ago after Secretary Thompson testified asking what figure we need, and we are prepared to spend whatever it takes, but we need to have the specifications and the range of problems, and what the answers are and what the costs are.

You see a lot of information about crop-dusting. What kind of a risk is posed to Americans across the land by materials which could be spread with crop-dusters?

Dr. KOPLAN. Again, it is difficult to determine. There is a variety of factors in that, many of which involve the criminal FBI side of this.

Senator SPECTER. I only have 60 seconds left, Dr. Koplan.

Dr. KOPLAN. So I should not use up a lot of it. Quickly, there are some elements that could be sprayed in that form, but it s not quite as simple as people would think in terms of clumping and particle size and all of that. It is an issue.

Senator SPECTER. A last question. I have 25 seconds left, and I want to be within the time limits. If somebody in America has a problem, or a question, what should they do? Whom should they call? Do you have a number, or a hotline?

Dr. KOPLAN. I think the best source of information for everybody in the country is their local county or city health department, No. 1, their State health department, No. 2. They have been given a wide range.

Senator SPECTER. Dr. Koplan, could I suggest we establish a national hotline so that we have one number where people could call?

Dr. KOPLAN. We have a hotline for State and local health departments but it would be virtually impossible to answer all of the calls on a national basis.

Senator SPECTER. I am glad it is only virtually impossible.

Thank you, Mr. Chairman.

Senator HARKIN. In order of appearance, let us now turn to Senator Murray.

TESTING OF POSTAL FACILITIES AND WORKERS

Senator MURRAY. Thank you very much, Mr. Chairman, especially for holding this hearing today.

Dr. Koplan, I know many of us are very concerned that the postal workers at the Brentwood facility were not tested in now what appears, looking back, a timely manner, and given the treatment that many people here on the Hill were given almost immediately, and I think that is very disconcerting to many of us here.

It seems to me, if I remember correctly, that we knew on Wednesday that there was anthrax on a mail machine in the Dirksen Building. At what point did we go backwards from there and start checking where did this mail come from? Obviously, it is on a postal machine in Dirksen, and where was it before, and why was

there a gap between that and the Brentwood facility and beginning to take a look at whether there was exposure there?

Dr. KOPLAN. Thank you, Senator Murray. Before you came in I offered to get a chronology of this for Senator Harkin. The presence of environmental isolates in places does not necessarily correlate with people getting ill from the disease, and as I indicated, there had still been no evidence of inhalation anthrax in a place where people had not opened mail, and that is the change in what we learned in this instance.

On the Wednesday you are referring to, I do not think we had received, or anyone had received results of any isolations from the Brentwood facility. There was an association with a sorting machine in—and I am not sure where the environmental specimen was from in Dirksen—the mail room, but I believe the investigation had continued at that point, looking again downstream. There is a P Street station that was looked at, and then Brentwood after that.

Senator MURRAY. So that was ongoing?

Dr. KOPLAN. I believe it was.

Senator MURRAY. Well, obviously we have learned a lot in a week in terms of unopened mail, opened mail, where exposure can be and all of that, and I am curious, are we now putting together a protocol so that the next time a letter appears some place we will know immediately how to backtrack it?

Dr. KOPLAN. Well, we have been trying to put together protocols at each day in this, and have had to change them each day based upon new information as it comes in, and absolutely we have been working for several days with the Postal Service and others to try to come up with what is a rational and the best approach to take to make workers safe in the postal facilities.

It has to change based upon new information, but we are discussing on a daily basis with the postal authorities and their unions and everyone else involved what are the best steps we can take. Some of this I will tell you is somewhat arbitrary, and we are not sure on all of these things, but we are going to try to step as far over towards workers' safety as we possibly can to get this thing done.

Some of the questions are, what type of protective barriers—there has been a focus on protective barriers of gloves and masks, et cetera, and which are the best of those to use. It is more complicated than just saying gloves and masks. For some of the equipment I understand postal workers use there can be a danger in getting a hand caught, or something caught.

PROPER PROCEDURES TO HANDLE OPENING OF MAIL

Senator MURRAY. And I think that goes to my second concern. Everybody hears something different. Are we doing research quickly, I mean, really quickly to let postal workers or people in offices who open mail know what is the proper procedure? We hear from one group to wear gloves, we hear from another do not wear gloves.

Dr. KOPLAN. We are not waiting for research for this. We are trying to bring folks who have the most to offer, and it is mixed skill sets, occupational experts and occupational health and safety.

Senator MURRAY. How soon will we know what those rules are?

Dr. KOPLAN. We are meeting later today to talk about it, but I would rather have rules that make sense and work, rather than just get rules out in the next couple of hours. We will be working as quickly as we possibly can to get valid and appropriate rules out, in the meantime trying not to put anyone at further risk.

Senator MURRAY. I think that is really important, that people just have the facts so that they know how to deal with this. Most people just want to know, how do I protect myself?

GETTING INFORMATION TO HEALTH CARE PROFESSIONALS

My time is almost up. I have a few other questions. It seems to me there was so much information in the press and everywhere we went about anthrax. How could it possibly be that someone showed up at a health care professional's office and was turned away and sent home who may have been exposed to anthrax and subsequently died? How do you get information out there? Where was the hole?

Dr. KOPLAN. Well, we have had a number of people who have recognized it, or whose antenna went up and reported it both in the cutaneous cases in New York and in the case in Florida and some other instances. In this particular instance, when doctors or health professionals see people it is not always obvious what that is, and unfortunately in the early stages of inhalation anthrax it can look like any one of a number of things that people see hundreds of cases of every day, and again, it is easy for me sitting here thinking that I might have thought, well, maybe it is anthrax, I probably would not if someone comes in with a cough and a cold and a headache.

The difference now is, I think the level of suspicion is up all over. Nevertheless, it is hard for me to find fault with an individual in that circumstance, and one of the issues in this particular unfortunate patient was the rapid deterioration that occurred after what was seemingly symptoms like you see for a large number of other illnesses.

A key issue here, and an important issue for the public and the health education message is, it is the combination of those symptoms and where this person worked, and that is the key linkage.

Senator MURRAY. That was my last question. Is that going to be part of the protocol for doctors to understand?

Dr. KOPLAN. Yes, and now one of the things is we have association with handling mail, and not just opening mail, that that has got to be raised, and it is one of the things that all health professionals now have to say to people is, you have got a cold, you have got a cough, you have got a fever, now what kind of job do you do and where do you do it, and do you handle mail. It is again something we would not have asked 2 weeks ago that we need to ask now.

Senator MURRAY. Thank you very much.

Senator HARKIN. Thank you, Senator Murray.

Senator Landrieu.

Senator LANDRIEU. Let me just begin by following up briefly, and thank you, Mr. Chairman, for holding this hearing, and our Ranking Member, for the timeliness of this hearing.

But to follow up with what Senator Murray said, it does seem difficult to fathom, though, how here in the District, that anybody showing up at a hospital who was a postal worker with flu-like symptoms could have been sent home. I just think we need to explore that in a little bit more detail, because it is important, as the chairman said, to learn our lessons quickly, because of course these families have suffered tremendous loss, and there are thousands and thousands of postal workers and families and children of the postal workers and mothers and fathers of postal workers throughout the Nation that are obviously very, very concerned. So it is very important, Mr. Chairman, that we learn that lesson quickly and apply it.

Second, I think to keep this in perspective, because I think it is important for all of us, the Members of Congress and the public generally to do that, I found a quote that Samuel Adams gave in a speech in 1771, and I thought, Mr. Chairman, I would share that. He says: "the necessity of the times more than ever calls for our utmost circumspection, deliberation, fortitude, and perseverance. Let us remember that if we suffer tamely a lawless attack upon our liberty, we encourage it, and involve others in our doom."

Now, of course, this was prior to the Revolution, but throughout the history of our Nation we have had very serious attacks, and this is one that we are in.

Another point I want to make, and we continue to refer in this hearing to this outbreak, this anthrax outbreak, I would suggest that we use a little tougher language to understand what we are in, because this is an attack. We do not know the perpetrators. We do not know the exact linkages, but we do know enough of the substance to realize that someone most certainly intended this act to cause death and destruction and disruption, and to a certain degree they obviously have been successful, and so this is not just our usual public health situation. This is a purposeful, merciless attack in this way, and it may not be, unfortunately, the last time that we see it.

PROUD POSTAL WORKERS AND AWARENESS

The next point is that I have shared with my staff, and many of the Senators and House members have expressed this to their staffs, that although we do not show up in a uniform, we wear regular clothes, we are, this staff here, like we wear a uniform. The postal workers out there, I want them to be proud of the uniform that they wear, because everything that we do, whether it is opening mail, delivering mail, preparing for hearings like this, giving speeches, conducting hearings in very difficult circumstances like the chairman has had to put this hearing together, and all of you, it is a way that we stand up to the flag every day, and I hope that we can communicate that.

There is no sense in blaming, but we do need to get about quickly finding some answers, and so for my question, I wanted to ask the FBI, because we went to the web site and looked at the advisory that has been put out for letters that is on the FBI web site, and it is obvious to me just looking at this that we might need to revise the web site somewhat. It talks about letters, for us to be aware of. Be aware of letters, it says, with no return addresses. Be

aware of letters with postage that is more than necessary. Be aware of letters that are postmarked or post-stamped from a foreign source.

Well, these letters, at least the letter to Senator Daschle that we know of, had a return address from a fourth grade class in New Jersey, it was clearly marked, the postage was mailed from a domestic box with a local postmark in New Jersey, so I think that is what Senator Murray and others are referring to. We realize we are all learning, but the faster we learn, and the more clear, specific, reliable information that we can put out there, the better. I would only ask, first, and I know I have got a minute left, can this be revised, and should it be?

My second question is, what is the FBI doing to rely on and connect to the military, which does have a lot of experience dealing with weapons of mass destruction, which this most certainly is?

And my third question to the FBI is, of the 2,300 incidents that you say that have been reported, could you provide to the chairman, because we do not have time to go over this, our time is short, how many of those incidents were shared with local law enforcement, and how many were not? I think that would be important for this committee to know so we can see if the local law enforcement is, in fact, getting the information that they need to be getting.

And finally, you can submit this for the record later, because we do not have time, what is the penalty for hoaxes that the FBI is either suggesting for Congress to consider, or suggesting for local legislators to take up across this country, because Mr. Chairman, the last thing we need is for our resources to be stretched with people who are sort of conducting hoaxes on their own. I think the swiftest penalties need to be given out so that we can nip this in the bud and give the American people the confidence and the comfort they need.

You can answer one or two for the time, and then if you would just submit the rest in writing. Thank you.

[The information follows:]

INFORMATION SHARING WITH LOCAL LAW ENFORCEMENT

The response to suspected Weapons of Mass Destruction (WMD) threats or incidents typically involves both the Federal Bureau of Investigation FBI and local law enforcement entities. In reference to the 2,300 mentioned incidents, the majority (no specific number available) were investigated by both FBI and local law enforcement.

The FBI maintains weekly statistics of all FBI responses to suspected or actual WMD threats or incidents to include anthrax. For the period between September 11, 2001, and November 19, 2001, the FBI responded to approximately 14,000 incidents throughout the United States in which the distribution/release of anthrax was suspected, as well as responding to approximately 750 incidents in which other WMD were suspected of being involved. The FBI response to these incidents was based on information that it received from a variety of sources, to include referrals from local law enforcement and first response entities and telephonic tips from the general public. The FBI takes each and every report seriously and expends the resources necessary to address the threat and provide a measured response.

As noted in Mr. Caruso's statement, the FBI has established several mechanisms that facilitate the sharing of WMD-related information with local law enforcement entities. The working relationships emanating from the existence of Joint Terrorism Task Forces/Regional Terrorism Task Forces (JTTF/RTTF) and the outreach efforts of field office WMD coordinators have resulted in the establishment of mechanisms for the exchange of information with local law enforcement entities. These mechanisms, which can include passing information to local police officer's on a JTTF or

telephonic contacts between a field office WMD coordinator or management official and the appropriate counterparts at local law enforcement entities, serve as the means for timely dissemination of information regarding incidents in which a WMD is suspected of being involved.

FIRST RESPONDERS

Mr. CARUSO. I think your suggestions on the announcement there are very wise, and we will see if we can incorporate those to make them look a bit more like some of the letters you referred to. I think that is a very good observation. Thank you for that.

We are working closely with the Department of Defense in those areas where we can. For example, we use their institute to take a look at some of the anthrax or the material that they determine to be anthrax, and we have a very good, close working relationship with them, as well as with CDC. With reference to the 2,300 incidents, I will get you that information.

Specifically, my expectation is the vast majority, if not all of them, have local law enforcement involvement because local law enforcement or fire departments are really the first entities who are called by an individual who says, "I have a strange and suspicious package before me. What do I do?" It is the first responders, the local law enforcement agencies and five departments that are the first responders. But I can get you some more specific information. My expectation is the vast majority will have local connectivity and response with the FBI.

PENALTIES

The hoaxes penalty issue is something that I will talk with the Department of Justice about. The Attorney General, as you know, and Director Mueller have vigorously gone after and arrested individuals who have played hoaxes to show individuals that their comedic attempt is not appreciated, and we will apply the full extent of the law against what they have done. There have been a number of instances in that regard. Increasing penalties is something to be discussed with the Department of Justice.

Thank you.

[The information follows:]

PENALTY FOR HOAXES

Prior to October 23, 2001, no penalties existed for weapons of mass destruction "hoax devices" in the Federal Criminal Code. However, within sections 175 (biological weapons), 229 (chemical weapons), 831 (nuclear material), and 2332a (weapons of mass destruction), it is illegal to threaten the use of such weapons. The threatened use of a WMD does not constitute a "hoax," but involves the articulated threat that a chemical, biological, nuclear, radiological, or high explosive device is present. A statute is needed which specifically addresses instances in which an individual falsely reports the presence of a WMD or the action does not rise to the level of a threat. The proposed language, H.R. 3209, satisfies this law enforcement need.

Specific to the question regarding current penalties under these statutes:

Section 175.—As of October 24, 2001, Section 175 was amended pursuant to the "Patriot Act" to include a penalty provision, 175 (c), which includes fines and imprisonment of not more than 10 years or both.

Section 229.—As defined under 229A, Criminal penalties include: fines or imprisonment for any term of years, or both; death penalty or life imprisonment where violation of 229 results in the death of another person; and, Civil Penalties may include an amount not to exceed $100,000.

Section 831.—As defined under 831 (b), Criminal penalties include: a fine and imprisonment for any terms of years or life, depending on relevant conduct.

Section 2332a.—As defined under 2332a (b), imprisonment for any term of years or life; and if death results, punishment by death, or any term of years or for life.

Under the proposed H.R. 3209, an individual who violates this statute may be fined or imprisoned for not more than 5 years.

ANTHRAX AND SMALLPOX AS BIOTERRORIST TOOLS

Senator HARKIN. Senator Craig.

Senator CRAIG. Mr. Chairman, thank you. Again, I would echo my colleagues' appreciation for the timeliness as we work with people like our folks at the FBI and the CDC to learn as we go, and hopefully gain very rapidly from these experiences.

In what we have had made available to us as it relates to the use of anthrax as a bioterrorist tool, it appears that while it does and can take life, and we are now experiencing that, it is rather limited in its application. The ability to apply it to a wide range of the population would be more difficult, and we do have the appropriate medical application, and we are on alert, if you will to largely save lives and how to substantially lessen impact on the populace.

I think it was the Soviets, when they were developing bioterrorists, said they had more of a psychological impact on a society than an actual, physical impact, and we are learning that, although it is not in any way to suggest that what has occurred is not important, and we are very concerned about it.

We hear a great deal, though, being talked about in the media, and therefore the public is concerned about smallpox, the discontinuation of the kinds of treatments we have had in the past for our children to be inoculated some number of years ago, wiping it off, or believing we have wiped it off the face of the earth.

Doctor, could you tell the committee, or talk to the committee briefly about—and I know you are going to list these and provide us additional information—the ability to apply smallpox to a broader base of the population? It has a tool of bioterrorism versus that of anthrax. Now, we are talking about 19-plus million inoculations available, or something in that range. We are proposing to spend a great deal more money and possibly attempt to inoculate the whole population in this country and get back into the business of inoculation. I think that all has to shape itself with the use of it as a tool and the ability to apply it as a tool to expose a broad population base in this country.

What are the factors? What are the risks?

Dr. KOPLAN. Thank you, Senator Craig. My first job in public health was working in the smallpox eradication.

Senator CRAIG. Then I have asked the right person.

Dr. KOPLAN. I do not know about that. I had two roles, one when I started in 1972 at CDC it was to discourage the routine, continued use of smallpox vaccination, because we had determined that the risk of the vaccine outweighed the benefits of being vaccinated, because the risks in the U.S. were so low at that time.

The other half of my job was to work on the worldwide smallpox eradication, including doing clinical care of patients with smallpox in Bangladesh. I thought that this was a wonderful experience. At the end of those 2 years I would never have to use this information again, and it shows you how humbling health and public health

events are, that something that I had hoped would remain history is something that is very much now present upon us.

The issues you raise are considerable. The vaccine which we are in the process of funding in, and we will hear from a colleague who is actively involved in the production of this vaccine, we have a contract in for the production of many more millions of doses of this vaccine. Some of the issues are, should it be deployed, should it be held and await its need, how much vaccine is necessary?

The decision of the Department has been, and we are part of that, is that it is valuable to have enough vaccine should we need it for every American in the country. The widespread use of the vaccine, though, would be attendant with a certain number of predictable adverse reactions, including enough for hospitalization, enough for people to have if there is an encephalitis attached to it.

So that is the balance that has to be taken into play, is both the investment in the vaccine, which I think is worthwhile, but whether to deploy it prior to is an issue of, you will certainly have people severely ill, and some deaths from the use of the vaccine alone, and then that has to be matched with the risk of introduction and the threat.

SMALLPOX PREVENTION AND USE AS A THREAT

One of the advantages of smallpox vaccine, there is no treatment for smallpox. There is no antibiotic, no antimicrobial, no antiviral that has been proven effective against smallpox, so the vaccine is the only preventive device, and yet it is a vaccine that can be used in the first few days of exposure, which is quite unusual, and gives us some leeway to get it into people in those first few days of exposure.

Senator CRAIG. You are suggesting, then, if there is a known exposure of a population base and we have a vaccine available, they can be treated and it would lessen the impact of that exposure dramatically?

Dr. KOPLAN. It can prevent the disease, but a key element of that is not just the production of the vaccine, and let me emphasize to all of you, it is the ability of State and local health departments to then distribute that vaccine and get it into people, and the degree to which State and local health departments are pressed now, they would be sorely tried, with current resources, to get those vaccines into people. They do it, but they would sure need some help in getting it done.

Senator CRAIG. Mr. Chairman, I understand I have a little time left. I did ask another question that was maybe a bit elusive, and that is the ability to use it as a tool of bioterrorism, and therefore the ability to apply it.

Dr. KOPLAN. This is smallpox itself?

Senator CRAIG. Smallpox itself, comparatively to anthrax.

Dr. KOPLAN. I think one, and I hate to even use this phrase, but one aspect of anthrax which is in all of our advantages is, it cannot spread from person to person. It is not contagious. It is horrible when one person gets it, a tragedy when that person dies, but it cannot be spread from that person to another person.

Smallpox is a contagious illness, and can be spread from person to person, making it—we have a vaccine for it, but it is contagious,

so with each of these agents, there are different approaches, different ways of dealing with it, and different downsides to them that makes them more difficult, one than another.

ANTHRAX ANTITOXIN

Senator HARKIN. Senator Hutchison.

Senator HUTCHISON. Thank you, Mr. Chairman. Dr. Koplan, I picked up the Austin American Statesman on October 10, and the headline is: "UT researchers close in on antidote to anthrax toxin." It appears that there is a consortium of the University of Texas, Texas Tech, and the University of South Florida that has been testing an anthrax antibody on mice, and that the antibody has been demonstrated to kill the anthrax bacteria.

The next step for them is to inject the mice with live anthrax, rather than just the anthrax toxin, and test it there, but they say they are some weeks away from this antidote. I wondered if you are aware of this. My original intention had been to see if we could get the money from the emergency appropriations bill we have already passed to let them proceed with their experiments on an expedited basis, particularly considering the ongoing threat of anthrax attacks. So I just wanted to ask you if you were aware of this research, and whether or not you think there is something that we might be able to do to facilitate these experiments?

Dr. KOPLAN. Thank you. That certainly sounds promising. I was aware of antitoxin work going on. I did not know the particulars of this experimentation. There is a real time gap between mouse experiments and work there, and then getting it into humans, which even in trying to increase the amount of research, it still takes time to sort out the experimentation. I would be glad to have folks look into it and see whether we can make direct linkages. Certainly FDA would have an interest in this, and NIH as well, and we would be glad to get the information.

Senator HUTCHISON. That is exactly what I want. I want to do all the right things, but I am sure that if the NIH and the FDA and you are working on something, perhaps we could speed it up if this is going to continue to be the urgent problem that we see it, at least isolated in this area. I would like to just try to do everything we can to get it on the right track and shorten the timetable if, in fact, it would help save some of these lives that have already been hurt by this anthrax.

ANTIBIOTICS FOR USE AGAINST ANTHRAX

Thank you, Mr. Chairman, for giving us this opportunity.

Senator HARKIN. Thank you, Senator Hutchison. Just one last thing. In every instance of anthrax exposure during the past 2 weeks, Cipro has been prescribed, but my understanding is the FDA is officially approving the use of two additional generic antibiotics for the treatment of anthrax, doxycycline and penicillin. My question is, why are we giving people Cipro when other drugs are available? Secondly, can people who are now on Cipro switch to a cheaper drug?

Dr. KOPLAN. Expense has not been our primary consideration to get started. As you indicated, there are several antibiotics that can be used in this, and in the antibiotic sensitivities we have gotten

from the organisms we have isolated from these different outbreaks there are a number of antibiotics that seem susceptible to it.

I believe today we are coming out—we have gotten a group of experienced clinicians, people who care for people and take care of people and engage in treatment for infectious diseases to spell out alternative antibiotic guidelines, but Cipro remains a primary drug of choice for people who are sick with the disease. Other antibiotics may also be used in that regard for people who are taking it in a preventive way, such as folks exposed, or in the city Cipro might be a reasonable start and then shift after a period of time to doxycycline. All of these things have some side effects to them, and so probably the thing is to explain to people what the options are for them and both make a suggestion to them, but let them choose which they think would be best for them as well.

An example is doxycycline, you cannot go out in the sun with it. It causes a skin rash if you are in the sun. That might not be an issue for most of us who spend all of our time indoors, but certainly in Florida it was not something we wanted the people exposed to, so it is a balancing act, but you are absolutely right, doxycycline, there has been this rush for Cipro, but doxycycline works terribly well, and we would recommend it.

Senator HARKIN. And penicillin?

Dr. KOPLAN. Penicillin, our folks are looking at in a little more detail in the lab as to whether in the isolates we are seeing whether that is going to be recommended. I think at the moment I would stick with doxycycline or Cipro for these cases we are seeing now.

Senator HARKIN. Dr. Koplan, Mr. Caruso, thank you very much. I think you have given us some good reassurances. I think what you have just spelled out indicates that CDC is on track, and I am hopeful that we will continue to get the kind of information we need and support for our public health agencies. Thank you so much.

Our next panel will include Mr. Robert Kramer, president and chief operating officer of the BioPort Corporation, who is accompanied by Robert Myers, who is a doctor of veterinary medicine and is executive vice president of Bioport; Mary Kuhn, vice president of Bayer Corporation, makers of Cipro; Thomas Monath, vice president of research and medical affairs for Acambis, the makers of smallpox vaccine; Hilary Koprowski from Thomas Jefferson University; Mary Gilchrist, director of the University of Iowa Hygienic Lab; and Barbara Hunt, district health officer for the Washoe County health department in Nevada.

Again, I would ask if you have any lengthy types of documents, if you would submit those for the record. Barring any objections, all of your statements will be made a part of the record in their entirety. I would hope that you could, in less than 5 minutes, sum up for us your views and your opinions of what has happened during the recent events, and any advice and suggestions you have for us as we pursue this. With that, I would open first with Mr. Bob Kramer of the BioPort Corporation.

STATEMENT OF BOB KRAMER, PRESIDENT AND CHIEF OPERATING OFFICER, BIOPORT CORPORATION, ACCOMPANIED BY DR. ROBERT MYERS, EXECUTIVE VICE PRESIDENT

Mr. KRAMER. Thank you, Mr. Chairman. I want to thank you for your invitation to discuss the anthrax vaccine and the current status of the vaccine production, and the process we have been working through with the FDA. In addition, I will use this opportunity to set the record straight on BioPort and our FDA licensed anthrax vaccine.

Before I begin, I would like to introduce Dr. Robert Myers, our executive vice president of BioPort, who will assist me in answering your questions.

The history of the anthrax vaccine begins in Michigan, with its Department of Public Health. During the 1920's, Michigan was one of several States with its own vaccine research facility. Michigan developed a number of critical vaccines to protect public health, including one of the first combined pediatric vaccines in the country. In response to Department of Defense requests, the Michigan facility took over development of the anthrax vaccine in 1965, when no one else was interested, and in 1970 a U.S. license was granted for the Michigan anthrax vaccine, the only FDA licensed anthrax vaccine in the Nation.

From 1970 to 1989, the Michigan facility shipped 68,000 doses of the anthrax vaccine. Then in 1990 Iraq invaded Kuwait, and the Persian Gulf conflict began. The Michigan plant stepped up again to meet the needs of the U.S. military at the request of the Department of Defense. During the past 10 years, the FDA has continued to increase its compliance standards for biologics manufacturers. These higher standards more fully assure that vaccines and other biologic products will continue to be safe, pure, and effective. We fully support these higher standards.

By 1996, in the midst of having amassed a sizeable stockpile of anthrax vaccine, the State of Michigan facility faced a serious regulatory challenge. Consequently, in 1997 the State moved forward with its decision to sell the assets of the facility. Meanwhile, to address these concerns, Michigan State government officials, in tandem with the Department of Defense, decided to suspend production of the anthrax vaccine in January of 1998 to begin a long-planned, much-needed renovation of the facilities.

BioPort Corporation, the only U.S. company participating in the final round of bids, acquired the facility from the State of Michigan on September 4, 1998, and became responsible for the renovation. We completed the renovation process, resumed production in 1999, and submitted our biologics license application supplement to the FDA. The FDA subsequently conducted a preapproval inspection, and identified more work in order to get the facility approved.

BioPort immediately prepared a detailed plan. The FDA has concurred with that plan, and we have since met regularly with them, briefing them on our execution. We submitted our amended biologics license application supplement to the FDA on Friday, October 12 of this year, and are confident that this submission, the culmination of 20 months of work, satisfies all FDA requirements and will allow the agency to complete its comprehensive review and ap-

proval process. We stand ready to respond to any additional questions raised by the FDA during this review period.

The events of September 11 and the subsequent intentional exposure to anthrax have undoubtedly changed the landscape of public health and protection from terrorist attacks for years to come. As well, recent national events have altered the profile of the BioPort Corporation, a privately held vaccine manufacturer that employs 220 people.

The media coverage of anthrax exposures, and the subsequent public health response, was initially characterized as an Olympics of misinformation. As it relates to BioPort Corporation and its vaccine, this is certainly the case. I would like to correct some of these myths that have been out there.

Senator HARKIN. I am going to ask you to collapse them. I think they are very good, but you cannot read them all. We do not have the time. Just give us the myth and a brief fact.

Senator KRAMER. The first myth was the anthrax vaccine is not safe and may not be effective. The truth is, there are over 18 studies by independent professionals who consistently demonstrate and show the vaccine is safe, and as well the FDA has consistently testified to the same.

The second myth is that we have failed to produce any anthrax vaccine since acquiring the facility from the State of Michigan. Contrary to this, BioPort has maintained and significantly added to a significant stockpile of the anthrax vaccine and can make it available, with the concurrence of the Department of Defense who owns the anthrax vaccine stockpile, to the CDC, who would make the medical determination when it is necessary, and the FDA must release the product.

The third myth was that BioPort has been mismanaged since acquiring the facilities from the State of Michigan. The fact is that we have hired and been successful in bringing in a number of experienced managers from the industry and technical experts, and we have the right people doing the right things to get this job done, and we will get the approval of the renovated facility.

The funding from the Department of Defense in the last 3 years has been substantial, and BioPort is grateful for the Department of Defense's continued support, but these expenditures need to be placed in the overall perspective of the industrial cost of vaccine development and manufacture. It is comforting to hear from Senator Specter that you are prepared to spend whatever is necessary to make sure these important products are made available.

Senator HARKIN. How much would it cost?

Mr. KRAMER. I guess I would have to ask, cost to do what?

Senator HARKIN. To vaccine Americans with this vaccine.

Mr. KRAMER. For all public citizens?

Senator HARKIN. Yes.

PREPARED STATEMENT

Mr. KRAMER. If you are talking about 300 million people, our contract right now with the Department of Defense has us selling the vaccine to them for just under $11 a dose. That will likely increase as we work with the Department of Defense in the current contract, but that is probably a good ballpark.

Senator HARKIN. Over $3 billion. Thank you very much, Mr. Kramer.

[The statement follows:]

PREPARED STATEMENT OF BOB KRAMER

Good afternoon Chairman Harkin and esteemed members of the committee. I'm Bob Kramer, President and Chief Operating Officer of BioPort Corporation. I want to thank the members of the committee for the invitation to discuss the history of the anthrax vaccine, the current status of vaccine production, and the approval process we have been working through with the FDA. In addition, I will use this opportunity to set the record straight on BioPort and our FDA-licensed anthrax vaccine. Before I begin, I would like to introduce Dr. Robert Myers, Executive Vice President of BioPort, who is with me today to assist in answering your questions.

VACCINE HISTORY

The history of the anthrax vaccine begins in Michigan, with its Department of Public Health. During the 1920s, Michigan was one of several states with its own vaccine research facility. Michigan developed a number of critical vaccines to protect public health, including one of the first combined pediatric vaccines in the country.

Anthrax was a disease feared by a limited population, particularly by textile workers who handled imported wool and hides, and farmers and ranchers who worked with livestock.

The Department of Defense conducted the initial work on an anthrax vaccine. The department's results were outlined in a patent that highlighted the concept of the vaccine and its manufacture. Merck produced some initial lots of a further developed vaccine in the 1950s for the original field tests. The company declined continued work on the vaccine.

In response to a Department of Defense solicitation, the Michigan facility took over development of the anthrax vaccine in 1965, and, in 1970, a U.S. license was granted for the Michigan anthrax vaccine—the only FDA-licensed anthrax vaccine in the nation.

From 1970 through 1989, the Michigan facility shipped 68,000 doses of the anthrax vaccine. Then, in 1990, Iraq invaded Kuwait, and the Gulf War began. Since Saddam Hussein had developed anthrax weapons, the Michigan plant stepped up production to meet the needs of the U.S. military at the request of the Department of Defense. Approximately 400,000 additional doses were shipped to protect our service members during the Gulf War.

During the past ten years, the FDA has continued to increase its compliance standards for biologics manufacturers. The agency now requires manufacturers of biologics to meet the highest global standards for process validation and Good Manufacturing Practices. These higher standards more fully assure that vaccines and other biologic products will continue to be safe, pure and effective. We fully support these higher standards. Another dynamic has occurred in the past 10 years—a declining interest in vaccine production, due principally to the aforementioned rising compliance standards and the diminishing profitability of vaccines. This is particularly true for bio-defense vaccines, where the non-government market is uncertain.

Beginning in 1996, the State of Michigan's facility faced serious regulatory challenges. In 1997, the State made the decision to sell the assets of the vaccine facility, and allow private business to assume the renovation and subsequent production of vaccine.

Meanwhile, in January of 1998, Michigan state government officials—in tandem with the Department of Defense—made the decision to suspend production of the anthrax vaccine in order to begin a long-planned and much-needed renovation of the facility. BioPort Corporation, the only U.S. company participating in the final round of bids, acquired the facility from the state of Michigan on September 4, 1998. One of the early decisions we made was to suspend all production of other biological products so we could concentrate on the anthrax vaccine.

And so the renovation of the facility became BioPort's responsibility. We completed the renovation process and resumed production in May 1999. BioPort submitted its Biologics License Amendment supplement to the FDA in August 1999. The FDA subsequently conducted a pre-approval inspection in November 1999, and imposed additional requirements before approval of the renovated facility would be granted. The additional requirements were directly related to the higher standards imposed by the FDA on vaccine manufacturers.

BioPort immediately prepared a detailed plan for meeting the additional requirements and presented it to the FDA in January 2000. The FDA concurred with the

plan and implementation by BioPort began. Since then, we have met regularly with FDA representatives, providing updates on our progress. We submitted our amended BLA supplement to the FDA on Friday, October 12, 2001 and are confident that this submission—the culmination of 20 months of work—satisfies all FDA requirements and will allow the agency to complete its comprehensive review and approval process. We stand ready to respond to any additional questions raised by the FDA during this review period.

MYTHS VS. FACTS

The events of September 11, and the subsequent intentional exposures to anthrax have undoubtedly changed the landscape of public health and protection from terrorists attacks for years to come. As well, recent national events have altered the profile of BioPort Corporation—a privately held vaccine manufacturer that employs 220 people.

The media coverage of anthrax exposures and the subsequent public health response was recently characterized as an Olympics of misinformation. As it relates to BioPort Corporation and its vaccine, this is most certainly the case. I will first point out the myths and then lend clarification.

Myth.—The anthrax vaccine is not safe.

Fact.—The safety of this vaccine is well documented. It is one of the most studied vaccines. To date, 18 human studies and the CDC's independent expert Advisory Committee on Immunization Practices have assessed the safety of the anthrax vaccine. Some of these studies stretch back many decades. They also include very close scrutiny of more than two million doses of anthrax vaccine given to over 500,000 recipients over the past three years. The side effects of this vaccine are similar to those of other vaccines routinely administered to both adults and children.

An independent, civilian vaccine expert safety panel, the Anthrax Vaccine Expert Committee (AVEC), has reviewed all reported reaction rate data and found no evidence of a causal link between the vaccine and serious, long-term medical conditions. As of October 2, 2001 the AVEC has reviewed 1,623 adverse event reports obtained through the FDA's Vaccine Adverse Event Reporting System. From these reports, there were 57 that involved hospitalization. The AVEC found that only 10 of these were likely caused by the anthrax vaccine. All 10 involved allergic, inflammation reactions at the injection site and the patients have since recovered.

The FDA has concurred with this assessment. On October 3, 2000, Mark Elengold, Deputy Director of the Center for Biologics Evaluation and Research, in testimony to the House Government Reform Committee, commented about the 1,561 adverse event reports that had at the time been submitted. He said: "None of these events, except for the injection site reactions, can be attributed to the vaccine with a high level of confidence, nor can contribution of the vaccine to the event be entirely ruled out. With the exception of injection site reactions, all of the adverse events noted above occur in the absence of immunization." He further went on to say, "FDA continues to view the anthrax vaccine as safe and effective for individuals at high risk of exposure to anthrax, when used in accordance with the approved labeling."

Earlier that year, on April 13, 2000, before the Senate Armed Services Committee, Dr. Kathryn Zoon, the Director of the Center for Biologics Evaluation and Research, said in her concluding remarks: "We believe the anthrax vaccine is a safe and effective vaccine for the prevention of anthrax disease—an often-fatal disease—when used according to FDA approved label."

In conclusion, on the topic of safety, extensive studies of those vaccinated as well as independent review of reported adverse events, lead to the certain conclusion that anthrax vaccine is safe. The FDA, in its testimonies before congressional committees, has also stated it has found the vaccine to be safe.

Myth.—BioPort's anthrax vaccine is not effective.

Fact.—The effectiveness of the anthrax vaccine was documented in three ways:

—Clinical trials showing protection of human subjects exposed to the infectious agent;

—Demonstration of a measurable immune response following immunization;

—Demonstration of protection of immunized animals when challenged with the infectious agent.

I will now describe these in further detail.

Clinical Trials.—A single-blinded well-controlled trial was conducted in the 1950s by Dr. Phillip S. Brachman and co-workers in the employees of four U. S. textile mills. Those workers were processing imported goat hair known to be occasionally contaminated with anthrax spores. A similar but less potent predecessor to the current vaccine was used in this trial. A total of 26 cases of cutaneous and inhalational

anthrax occurred during the course of the trial. The efficacy of the vaccine in preventing anthrax was found to be 92.5 percent. In one of these mills, five cases of inhalational anthrax (four of them fatal) occurred among the unvaccinated workers. No cases of inhalational anthrax occurred in mill workers who had received the anthrax vaccine. With the occurrence of these inhalational anthrax cases, the study was stopped in the mill so that all employees could be offered immunization since it would have been unethical to continue the study. The number of cases of inhalation anthrax was, thus, too small to demonstrate a statistically significant decrease in the vaccinated group. Following universal immunization of employees in this mill, the occurrence rate of anthrax fell precipitously. The FDA has subsequently indicated at Congressional hearings that based on the data from this clinical trial, when supplemented by additional case control studies in humans, and studies in vaccinated animals protected from exposure to inhalational anthrax, there is strong evidence that the vaccine protects humans against inhalational anthrax.

In the 1980s, an Advisory Review Panel was established to review information on biologic products licensed prior to July, 1972. In 1985 this panel recommended continuation of the anthrax vaccine based on substantial evidence of safety and efficacy. This review included a CDC-sponsored vaccine safety study, in which approximately 16,000 doses of vaccine were administered according to the current six-dose schedule to approximately 7,000 study participants from 1967 to 1971. The panel also reviewed surveillance efficacy data collected by the CDC between 1962 and 1974. During this period, 27 cases of anthrax were identified in employees working in or near goat hair mills. Twenty four of these employees were unvaccinated and the remaining three had received only one or two doses of the anthrax vaccine. These two studies, in addition to the efficacy data from the Brachman study, served as the basis for the panel's recommendation. No anthrax cases have been reported in fully vaccinated persons. Since the availability of the current vaccine, the occurrence of anthrax in "at risk" industrial settings, including laboratory workers, has been nearly eliminated.

Demonstration of immune response.—Human immune response studies were recently performed by Dr. Phillip Pittman and co-workers, using an assay which measured the development of antibodies specific for *B. anthracis* Protective Antigen (PA) known to be important to protection. In 28 volunteers immunized according to the current schedule of subcutaneous injections, (0, 2, and 4 weeks), significant immune responses (i.e. seroconversion) were detected in almost all of the recipients after two doses of vaccine, and in all persons after three doses. Other volunteers received vaccine at 0 and 4 weeks only, one group by the subcutaneous route (n=23) and one by the intra-muscular route (n=22). Except for one individual in the intramuscular group, all volunteers tested were found to have seroconverted after the second (4-week) dose. The size of this study was not considered large enough to support a change in the dosing schedule or the route of administration.

Demonstration of protection.—Because it would be unethical to challenge immunized persons with B. anthracis, such studies must be performed in animals. Nonhuman primates, which develop inhalational anthrax much like that seen in humans, have been used extensively. A total of 65 non-human primates, immunized with only one or two doses of anthrax vaccine, have been given inhalation challenges containing hundreds of times the number of anthrax spores known to be lethal in unvaccinated animals. Of these, 62 animals (95 percent) survived the challenges. When eight of the non-human primates received a high-dose inhalation challenge two years after they received two doses of the vaccine, seven survived, indicating long-term immunity.

Similar anthrax inhalation challenges were performed in rabbits, which also develop inhalational anthrax similar to that seen in non-human primates and in humans. Of 117 rabbits challenged following two doses of vaccine, 114 (97 percent) survived.

Dr. Arthur Friedlander and co-workers performed a post-exposure study in nonhuman primates, some of which had also received a 30-day course of antibiotics. The group of animals that received both vaccine and antibiotics following inhalation exposure remained free of disease throughout, and long after, the 30-day period of antibiotic treatment. Furthermore, this was the only group of animals that survived a second inhalation exposure -indicating that they had developed immunity against the anthrax.

The above series of studies of the anthrax vaccine illustrate several ways to overcome the inherent difficulty in demonstrating the efficacy of vaccines to be used for defense against bio-terrorism and bio-warfare agents. Since natural exposure to many of these agents does not exist, and because human challenge studies would be considered unethical, straightforward efficacy studies cannot be performed. Instead, a careful assessment of the immune responses following vaccination in hu-

mans, as well as evaluations of protection against infectious challenges in relevant animal models, must be made.

The currently licensed schedule of subcutaneous injections given over 18 months, will soon be evaluated in a large CDC-sponsored study. Along with evaluations of the safety of the vaccine, the impact of reductions in the number of doses administered, as well as the route of administration (subcutaneous v. intra-muscular), on the immune response to B. anthracis will be determined. These immune responses will be compared to those seen in a parallel study involving non-human primates, which will later be subjected to inhalational challenges with anthrax. Through these studies, a deeper understanding of the immune correlates of protection will be achieved, and the most appropriate dosing schedules determined.

The Advisory Committee on Immunization Practices (ACIP) has recently recommended that in a confirmed post-exposure setting, where anthrax vaccine is available, antibiotic prophylaxis should continue for 4 weeks and until three doses of vaccine have been administered. The consensus that three doses are expected to provide significant protection is justified in the context of the most current medical information available. This includes the known human immune response data and, the above-mentioned, long-term protection seen in non-human primates following only one or two doses.

Our present understanding of the immune system, coupled with the findings of these animal and human studies lead to a reasonable expectation that the anthrax vaccine should be protective after two or three doses. The challenge is to conclusively demonstrate this when direct efficacy studies in humans cannot be undertaken. This challenge applies not only to the current anthrax vaccine, but also to any anthrax vaccine now under development.

Myth.—BioPort has failed to produce anthrax vaccine since acquiring the facility from the State of Michigan.

Fact.—Contrary to news reports, BioPort has maintained and significantly added to a stockpile of anthrax vaccine since acquiring the facilities in Lansing, Michigan, three years ago. Although we cannot discuss the specific numbers contained in that stockpile, there is now a considerable amount of anthrax vaccine that could be made immediately available in an emergency, if fully supported by the FDA. It requires coordination, decisionmaking and action across three Federal agencies:

—The Department of Defense, which owns the vaccine;

—The Department of Health and Human Services, which based on the advise of the medical experts in the CDC, would recommend its use; and

—The FDA, which would authorize the release of the vaccine.

Further, we stand ready to manufacture the licensed anthrax vaccine to full capacity in our renovated facilities. We have met regularly with representatives from each of these agencies to discuss this considerable stockpile and to offer our full assistance and support in the event that vaccine is needed on an emergency basis.

Myth.—BioPort has been mismanaged since acquiring the facilities from the State of Michigan.

Fact.—There is now and there has for some time been a capable management team in place. We have been successful in hiring industry-experienced managers and technical experts. The company culture has been transformed from that of a state bureaucracy to a results-oriented business. For the last two years, we have been meeting regularly with the FDA to update our progress. The relationship with FDA is constructive and the agency has expeditiously reviewed the various segments of our submission. We are also working closely with our partner, the Department of Defense. In short, we have the right people, in the right places, doing the right things to get this job done.

On the financial side, when BioPort took over the vaccine manufacturing facilities from the State of Michigan we were well aware that we were taking over an unprofitable venture with an aging physical plant that had never been operated in a commercial environment. The State had no effective financial accounting system in place for tracking costs. To meet the heightened FDA biological product regulatory standards, a company in this business must have substantial quality control systems, which takes considerable time and expense to put in place. Unfortunately, the State's management practices did not include calculation of these costs. There was no direct relationship between Michigan's total costs of producing the anthrax vaccine and the prices paid by the Department of Defense. It became clear to us that the prices paid to Michigan by the government for the vaccine were significantly below the costs for producing the vaccine under modern regulatory standards. Audits which were conducted by the Department of Defense, supported an adjustment to the contract price of the vaccine.

Furthermore, in the last two years, there have been five major financial audits by the Defense Contract Audit Agency (DCAA). BioPort has submitted over 50 fi-

nancial reports during this time. Our compliance with contract accounting standards has been consistently confirmed by these audits.

In addition to these accounting audits there was a widely reported criminal investigation conducted by the Defense Investigative Services (DIS). What has not been reported is the fact that we were completely cleared of any wrongdoing. A recent DIS letter confirms that fact.

The funding from the DOD in the last three years has been substantial and BioPort is grateful for the department's continued support. But these expenditures need to be placed in the overall perspective of the industrial costs of vaccine development and manufacture. DOD's investment in BioPort over the past three years is the most cost-effective investment that any agency in the federal government is committing to insure the availability of the needed defense or civilian vaccines. DOD's own report on the costs for vaccine research, development and manufacturing estimates that it will require an average of $400 million over a 5- to 10-year period for each FDA-licensed vaccine. Another vaccine company, Aviron has reported that they will have expended between $400 to $500 million over many years in developing and manufacturing their intranasal flu vaccine. They are still awaiting their FDA license. The government has indicated that it will take several billion dollars and many years for other defense vaccines to be developed and manufactured. An October 2000 independent report by the Institute for Defense Analysis (IDA) concluded that the fastest route to a continued supply of licensed anthrax vaccine is through BioPort. Now a year since that report, its findings are still valid.

FUTURE CONSIDERATIONS

Allow me to make a few final points. As you, our nation's policymakers, look to the future for a viable long-term vaccine program, several issues must be resolved. Important among these are:

The oversight and management of the development and manufacture of defense vaccines must be streamlined, becoming less bureaucratic. The creation of a cabinet level position and the appointment of Governor Ridge to that position are encouraging early steps.

The dollars committed to protection against biological threats need to better match the nation's goals. Facing the potential of a cost of $400 million per vaccine developed, the financial commitments now being pledged by Congress will better enable the goals to be met.

There must be adequate incentives to assure the engagement of the private sector to meet these goals. We are aware that several bills are being drafted to specifically address this point and firmly believe that incentives will be adequately considered.

In addition to these incentives, some form of protection from tort is needed for defense vaccines' use in the civilian sector as it is for several products supplied to the DOD.

Just as important, misinformation must be corrected vigorously as soon as it surfaces. As has been clearly demonstrated for anthrax vaccine, left unanswered, misinformation erodes confidence and progress in defense vaccine development and manufacture. It must be countered whenever it occurs.

Once again, thank you for this opportunity. I am eager to respond to your questions.

Senator HARKIN. Next is Mary Kuhn, head of operations for Bayer Corporation.

STATEMENT OF MARY KUHN, VICE PRESIDENT OF OPERATIONS, BAYER CORPORATION

Ms. KUHN. Thank you, Senator Harkin, Senator Specter, and other distinguished members of this Senate appropriations subcommittee. My name is Mary Kuhn, and I am head of operations for the Bayer Corporation Pharmaceutical Division in Westhaven, Connecticut. The core objective of Bayer Pharmaceutical is to significantly improve health worldwide. Since the events of September 11 and the days that have followed, we stand even more committed to that purpose. We at Bayer Corporation would like to assure Congress that we will meet the Nation's demands for Cipro, our antibiotic, which has FDA approval for post-inhalation anthrax.

The issue that looms large with this subcommittee and, of course, with the American public is, can Bayer fulfill our Nation's Cipro requirements? The answer to that question is yes. Please allow me to elaborate.

Bayer is currently producing Cipro at an incredibly rapid and unprecedented rate, over 2 million tablets each and every day. We continue to work closely with the Centers for Disease Control and the Department of Health and Human Services to make available this key weapon in the fight against anthrax. Bayer's U.S. facilities shipped more than 50 million tablets of Cipro in the month beginning September 16 through October 16. In response to the increased demand, Bayer has tripled its production of Cipro.

Prior to the terrorist attacks, typical production of Cipro was about 20 million tablets per month. We have now committed to supplying 200 million tablets over the next 3 months. That is more than 15 million tablets a week. In addition, because of Bayer's global resources, we will be able to supply additional Cipro tablets.

In order to manufacture this quantity, Bayer is now running its Connecticut Cipro production facilities on an expanded production schedule. We are also reopening an additional manufacturing plant to augment active ingredient stock. We are sending shipments of Cipro out every day of the week, including Saturdays and Sundays. We believe that with current inventories, plus the amount we are now supplying, in conjunction with other FDA-approved drugs such as doxycycline, there will be enough Cipro in Government pharmacies and other facilities to treat over 12 million Americans for anthrax, the objective recently set by the Department of Health and Human Services.

In addition, Bayer does support the Food & Drug Administration's approval of doxycycline for the treatment of all forms of anthrax, including inhalation anthrax. These drugs are widely available from a variety of generic manufacturers. We are confident that there should be no concerns about an adequate supply of safe and effective treatments for anthrax. We feel it is important for this subcommittee to realize that Bayer has fulfilled every order from the United States Government within the requested delivery schedule.

We continue to work daily with the Government to define and fulfill future orders. To our knowledge, everyone who has needed Cipro in response to an anthrax event has been able to get Cipro. Soldiers going overseas carry Cipro. The people in New York, Florida, New Jersey and Washington who have been exposed to anthrax have had Cipro prescribed and have been able to procure it.

The CDC, which is in charge of stockpiling the drug, has ordered millions of tablets. These orders have been filled completely, and the agency has them in their inventory. We are working closely with the Nation's drug distribution system to get Cipro to those locales and to those people who are most immediately in need of it.

Our confidence in the adequacy of antibiotic supplies to treat anthrax is further enhanced by the efforts of Secretary Thompson, Surgeon General Satcher, and countless other Government and non-Government authorities. These leaders are advising the public of the harm that could be caused by taking antibiotics just in case,

and to warn people against hoarding drugs through advertising and other initiatives, such as this one in today's paper. Bayer is adding its voice to ensure that these critical messages are understood and followed.

To address any concerns that we will not be able to meet this commitment, we would like to point out that this is not the first time that we have had to respond quickly in a national emergency. During the Persian Gulf War, we were called upon by the Department of Defense to supply 45 million Cipro tablets for air and ground troops. Bayer met these urgent production and delivery targets.

The support of Secretary Thompson, Surgeon General Satcher and others in their educational efforts regarding appropriate use, personal stockpiling, and the wide availability of generic treatment alternatives will help to manage the demand for Cipro in pharmacies throughout the country.

Bayer fully recognizes that it has a compelling responsibility to assist the Nation in addressing bioterrorist threats. We are proud to have a role in this effort to confront this national emergency and protect the health of the American public. We have fulfilled that role in the past, and we continue to do that today.

PREPARED STATEMENT

There is no doubt that comprehensive coordination between relevant branches of Government and the pharmaceutical industry is absolutely critical to addressing bioterrorist threats. We urge this subcommittee to do all in its powers to assure this coordination and cooperation continues. We will face this latest challenge together, and we will succeed.

[The statement follows:]

PREPARED STATEMENT OF MARY KUN

Chairman Harkin, Senator Specter and other distinguished members of this Senate Appropriations subcommittee, my name is Mary Kuhn, and I am the Head of Operations for the Bayer Corporation Pharmaceutical Division in West Haven, Connecticut.

The core objective of Bayer Pharmaceutical is to significantly improve health worldwide. Since the events of September 11 and the days that have followed, we stand even more committed to that purpose. We at Bayer Corporation would like to assure Congress that we will meet the nation's demands for Cipro®, our antibiotic which has FDA approval for post-inhalation anthrax.

The issue that looms large with this subcommittee and of course with the American public is: Can Bayer fulfill our nation's CIPRO requirements?

The answer is yes.

Please allow me to elaborate:

Bayer is currently producing Cipro at an incredibly rapid and unprecedented rate . . . over 2 million tablets each and every day. We continue to work closely with the Centers for Disease Control and the Department of Health and Human Services to make available this key weapon in the fight against anthrax.

—Bayer US facilities shipped more than 50 million tablets of Cipro in the month beginning September 16 to October 16.
—In response to the increased demand, Bayer has tripled its production of Cipro.
—Prior to the bioterrorism attacks, typical production of Cipro was 20 million tablets per month. We have now committed to supplying 200 million tablets over the next three months—that's more than 15 million tablets a week.
—In addition, because of Bayer's global resources we will be able supply additional CIPRO tablets

In order to manufacture this quantity Bayer is now running its Connecticut Cipro production facilities on an expanded production schedule. We are also reopening an

additional manufacturing plant to augment active ingredient stock. We are sending shipments of Cipro out every day of the week, including Saturdays and Sundays.

We believe that with current inventories plus the amount we are now supplying, in conjunction with other FDA approved drugs such as doxycycline, there will be enough Cipro in government, pharmacy and other facilities to treat over 12 million Americans for anthrax, the objective recently set by the Department of Health and Human Services.

In addition, Bayer supports the Food and Drug Administration's approval of doxycycline for the treatment of all forms of anthrax, including inhalation anthrax. These drugs are widely available from a variety of generic manufacturers. We are confident that there should be no concerns about an adequate supply of safe and effective treatments for anthrax.

We feel it is important for this subcommittee to realize that Bayer has fulfilled every order from the United States government within the requested delivery schedule. We continue to work daily with the government to define and fulfill future orders. To our knowledge, everyone who has needed Cipro in response to an anthrax event, has been able to get Cipro. Soldiers going overseas carry Cipro. The people in New York, Florida, New Jersey and Washington who have been exposed to anthrax have had Cipro prescribed and have been able to procure it. The CDC, which is in charge of stockpiling the drug, has ordered millions of tablets. The orders have been filled completely and the agency has them in their inventory. We are working closely with the nation's drug distribution system to get Cipro to those locales, and to those people who are most immediately in need of it.

Our confidence in the adequacy of antibiotic supplies to treat anthrax is further enhanced by the efforts of Secretary Thompson, Surgeon General Satcher and countless other government and non-government health authorities. These leaders are advising the public of the harm that could be caused by taking antibiotics "just in case," and to warn people against hoarding drugs. Through advertising and other initiatives, such as this one in today's newspaper, Bayer is adding its voice to ensure that these critical messages are understood and followed.

To address any concerns that we will not be able to meet this commitment, we would like to point out that this is not the first time we have responded quickly in a national emergency. During the Persian Gulf War we were called upon by the Department of Defense to supply 45 million Cipro tablets for air and ground troops. Bayer met these urgent production and delivery targets.

The support of Secretary Thompson, Surgeon General Satcher and others in their educational efforts regarding appropriate use, personal stockpiling, and the wide availability of generic treatment alternatives will help to manage the demand for Cipro in pharmacies throughout the country.

Bayer fully recognizes that it has a compelling responsibility to assist the nation in addressing bioterrorist threats. We are proud to have a role in the effort to confront this national emergency and protect the health of the American public. We have fulfilled that role in the past and we continue to do that today. There is no doubt that comprehensive coordination between relevant branches of government and the pharmaceutical industry is absolutely critical to addressing bioterrorist threats. We urge this subcommittee to do all in its powers to assure that this coordination and cooperation continues.

We will face this latest challenge together and we will succeed.

Senator HARKIN. Thank you, Ms. Kuhn. Now I would just like to recognize Senator Reid for the purpose of an introduction of our next witness.

Senator REID. Senator Harkin, Senator Specter, I apologize for being late, but I have literally been on the floor since we last spoke. Typically, let me just say that this hearing is very important, like all those you have done on stem cells, diabetes, and I could go on and on.

Senator SPECTER. Go ahead, Senator Reid.

Senator REID. I appreciate this hearing, but I want to take just a minute to introduce Barbara Lee Hunt, who is the Washoe County Health District Health Officer. Washoe County is, we know, the second most populous county in the State of Nevada. She has certainly been in the trenches.

As you know, Reno was deemed to have an anthrax problem 2 weeks ago, or 3 weeks ago, and as a result of the work that was done in Reno, by Barbara Hunt, and all the screening she supervised, she is qualified and very important to speak to what we are trying to determine here in this committee, and it is a pleasure to introduce Barbara Hunt to this committee.

Senator HARKIN. Thank you very much, Senator Reid. Ms. Hunt, welcome to the committee. Please proceed.

STATEMENT OF BARBARA HUNT, R.N., M.P.A., DISTRICT HEALTH OFFICER, WASHOE COUNTY HEALTH DEPARTMENT, RENO, NEVADA

Ms. HUNT. Good morning, Mr. Chairman, Senator Specter, and members of this subcommittee. I am Barbara Lee Hunt, District Health Officer for Washoe County. I was asked to present a little bit of our experience in Reno a couple of weeks ago, and I will try to do that as briefly as possible.

I think a key point is that when it became public that a suspicious letter that was delivered to Microsoft in Reno had tested presumptively positive for the bacillus anthracis, both health departments, Clark Health Department in Las Vegas and our department in Reno, and our Reno 911 dispatch centers were inundated with calls from concerned citizens, hospitals, law enforcement, and physicians' offices, to the point that the State Emergency Operations Center had to be activated to help take calls.

The District Health Department in Reno appropriately took the lead in the public health investigation and the overall response. We identified, interviewed, and collected specimens for testing from six people who had contact with the letter. We did personal and environmental risk assessment, and made appropriate recommendations. We coordinated with the hospitals, law enforcement, and emergency medical responders, and we were the local information source.

What went well was the State Emergency Operations Center. It took calls for the entire State for 3 days. The Health Alert Network worked well in sending us updates on anthrax and related issues on a regular basis.

We managed to prevent further strain on public health and safety systems by educating the public with frequent, consistent, and coordinated communications through the media and by other means. We provided intensive on-site education for hundreds of employees in the Sierra Pacific Power Building where Microsoft is located.

We were in constant communication with Microsoft and the Sierra Pacific Power management, forging relationships that resulted in support for our recommendations. Despite some pressure from offices and the advice of medical consultants that conflicted with our recommendations, they even participated in all of our press conferences.

What did not go quite so well is that the initial publicity placed us in a reactive position for a few hours, which contributed to delays in communication and coordination with health and public safety agencies and delayed the establishment of telephone hotlines. This contributed to an initial overloading of the ambulance and 911 dispatch systems. Hospital emergency rooms were flooded

with the worried well. It took quite a while to get definitive laboratory results.

What we learned was that we can handle small, contained events. A larger event, especially a covert attack with a disease agent that is transmissible person-to-person would overwhelm not only the public health system but our hospitals and public safety systems, and emergency medical responders as well.

What we have identified as needs to improve our response capabilities include increased public health laboratory staff, equipment, and training for more rapid assessment of biological threat agents. A great deal of public concern could have been avoided if we had been able to obtain definitive laboratory results sooner. In Nevada, we also need another location for our public health laboratory. There is one location in the entire State. That is in Reno. Las Vegas needs a public health laboratory.

As we know across the country, not only public health practitioners but physicians, hospitals, and emergency responders all need training in bioterrorism and how to respond to it. We found a situation where a local official advised Sierra Pacific Power not to bring their employees together for an educational meeting about anthrax because they thought it would be risky.

Additional epidemiology staff for the State and local health departments is extremely important. We must increase our capacity to conduct public health investigations and surveillance, and particularly to heighten surveillance during high profile events that are so common in Las Vegas and Nevada, and that bring so many tourists from all over the world, not to mention all over the country. We need a bioterrorism coordinator to coordinate training and preparation not only in-house, but coordinate training and preparation with the community, the hospitals, public safety, and emergency responders.

We found that something very important to have was a public information officer to coordinate communication with the public. The health department needs such a public information officer. If Washoe County had not generously loaned us their entire public education staff we would have had much greater public concern and a greater strain on health and public safety resources.

Our key objective was to avoid the kind of panic that had people flooding the 911 system and the hospital emergency rooms. We need good data systems at Washoe County District Health Department. We need a full-time physician. We do not have a physician on staff. We have a medical consultant who has other full-time employment.

Hospital capacity is an issue, particularly in Las Vegas. An ordinary flu season can overwhelm the hospitals.

PREPARED STATEMENT

I would like to thank you very much for your support of public health, and to urge that full funding be allocated for the public health threats and emergencies. Thank you.

[The statement follows:]

PREPARED STATEMENT OF BARBARA LEE HUNT

Good morning, Mr. Chairman and members of the Subcommittee, I am Barbara Lee Hunt, District Health Officer for the Washoe County District Health Department, serving Reno, Sparks and Washoe County, Nevada.

BACKGROUND

The only other local health district in Nevada is Clark County Health District, serving Las Vegas. Five hundred miles separate Reno and Las Vegas. The State Health Division serves the remaining 15 rural counties.

We host many high profile events that draw thousands of tourists from all over the world, creating attractive terrorist targets. Depending on the agent used, a bioterrorist attack in Reno or Las Vegas could have national and international impacts.

WHAT HAPPENED

When it became public that a suspicious letter delivered to Microsoft in Reno had tested presumptively positive for Bacillus anthracis, both health districts and Reno's 911 dispatch center were inundated with calls from concerned citizens, physicians' offices, law enforcement, and hospital emergency rooms. The State Emergency Operations Center even had to be activated to assist with calls.

The District Health Department appropriately took the lead in the public health investigation and overall response. We identified, interviewed and collected specimens for testing from 6 people who'd had contact with the letter. We did personal and environmental risk assessment and made appropriate recommendations. We coordinated with hospitals, law enforcement and emergency medical responders. We were the local information source.

WHAT WENT WELL

The State Emergency Operations Center worked well, taking calls for 3 days. The Health Alert Network worked well.

We prevented further strain on the public health and safety systems by educating the public with frequent, consistent and coordinated communication through the media. We provided intensive, onsite education for hundreds of employees in the Sierra Pacific Power building, where Microsoft is located.

We were in constant communication with Microsoft and Sierra Pacific Power management, forging relationships that resulted in support for our recommendations, despite pressure from their corporate offices and advice from their medical and environmental consultants that conflicted with our advice. They even participated in all our press conferences.

WHAT DID NOT GO WELL

Initial publicity placed us in a reactive position for several hours, contributing to delays in communication and coordination with health and public safety agencies and delaying establishment of hotlines. This contributed to initial overloading of the ambulance and 911 dispatch systems. Hospital emergency rooms were flooded with "worried well". Definitive laboratory results took a week.

WHAT WE LEARNED

We learned that we can handle small, contained events. A larger event, especially a covert attack with a disease transmissible from person to person, would overwhelm our public health and safety systems, hospitals and emergency medical responders.

What we need to improve our response capabilities are:

—Increased public health laboratory staff, equipment and training for more rapid assessment of biological threat agents. A great deal of public concern could have been avoided if we had been able to obtain a definitive result sooner.

—Training—few of our staff have had any level of bioterrorism training, and we're not alone. A physician advised Sierra Pacific Power not to bring their employees together for a meeting, advising that it would be risky to have them in the same room.

—Additional epidemiology staff for the state and both local health departments. We must increase our capacity to conduct public health surveillance and epidemiological investigations and heighten surveillance during high profile events.

—A bioterrorism coordinator for each local health district and the state, to coordinate training and preparation in house and with our hospitals, public safety and emergency medical responders.

—A health department public information officer to coordinate communication with the public. Without the loan of public information staff from Washoe County, we would have had increased public concern and greater strain on health and public safety resources.

—A physician—we do not have a physician on staff. We have a medical consultant who has other fulltime employment.

—Hospital capacity to handle a sudden surge of patients.

In addition, our disaster planning must include biological scenarios and realistic simulation exercises.

All of these resources would serve us in day to day public health work and in emergencies, such as emerging infectious diseases, communicable disease outbreaks, toxic spills, and natural disasters.

The Kennedy-Frist bill proposes appropriate initial funding for state and local public health preparedness and response to bioterrorism. I ask that you support it.

Thank you.

Senator HARKIN. Thank you for being here. That is why I think we have more money in our bill for this.

I would recognize Senator Specter for purposes of an introduction.

Senator SPECTER. Thank you, Mr. Chairman. Just a word or two about our next witness, Dr. Hilary Koprowski, one of the world's greatest scientists since he received his M.D. degree from the University of Warsaw in Poland in 1939, and that puts you on the record for 62 years of active work, Dr. Koprowski.

Among his many accomplishments involve his contribution to the development of the first live polio vaccine. I would not want to use his full 5 minutes by describing all of his honors or positions which he holds.

STATEMENT OF HILARY KOPROWSKI, M.D., PRESIDENT, BIOTECHNOLOGY FOUNDATION, INC., PHILADELPHIA, PA, PROFESSOR, DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY, DIRECTOR, CENTER OF NEUROVIROLOGY AND BIOTECHNOLOGY FOUNDATION LABORATORIES AT THOMAS JEFFERSON UNIVERSITY

Dr. KOPROWSKI. Thank you, Senator Specter. Mr. Chairman, I am Director of the Biotechnology Foundation of Thomas Jefferson University, Pennsylvania, and head of the Microbiology Institute. As Senator Specter said, I have developed the first oral polio vaccine that led to the first mass trial with oral polio vaccine, and this bridged the way to eradicate polio from the world in 2004.

For the past 10 years, I have led a team of scientists to study plants as vectors for the production of vaccines and other biomedicals, and our studies of the virus B vaccine was found to create protection of hepatitis, the vaccine which we grew in spinach and fed to human volunteers.

We have successfully in the laboratory created the experimental vaccine in tobacco plants against AIDS. We have both the knowledge and techniques to produce any vaccine, whether it be bacteria or whether it be viral, like smallpox or any other thing, in plants using two techniques. We transform plants whose foreign agents produce vaccines either in seeds, leaves, or fruit. Such plants can be provided indefinitely as a source of vaccine production.

Another approach is we use plant viruses to fuel these foreign agents. Plants were infected with these compounds, and they were isolated in plant virus and the foreign agent to produce vaccine.

As far as the anthrax vaccine project, for several years we have proposed this anthrax project which we thought might be of interest to the military. The project is aimed at developing safe, cost-effective vaccine which could be used for mass oral vaccinations. Our immediate goal of this project is to stabilize the protective antigen of anthrax, the fusion of the plant protein, and then transformations of lettuce and radishes.

Laboratory animals will be fed with raw plants which have been transformed and then tested for resistance at Fort Dietrick. In addition, the transformed plant material will be processed to produce tablets containing the antigen and the vaccines in trials. Clinical trials in man can follow immediately the experimental procedure, which we are dealing with plants, not with animal tissue. This we can process in a safe way, and you have no cross-contaminants which can be produced in animal tissue.

Now, within a year of founding the project, we could start properly having clinical trials. Now, the advantages of this, no cross-contamination, it does not require sophisticated and expensive facilities. Four pounds of specific protein can be recovered from an acre of plants. It can be grown in different geographical and climactic conditions, and it can be used as a vehicle for oral delivery of vaccine.

PREPARED STATEMENT

So this is what I would like to say in our proposal today, that we have done something already with anthrax, and this is, we took three or four domains of the protective antigen and fuse it with a plant virus and then infect it with a plant virus in tobacco plants, and if funds would be available we can check whether it produces immunity. This is just to tell you that there is feasibility in this project and it can be applied to almost every biomedical in the world.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF HILARY KOPROWSKI

My name is Hilary Koprowski. I am presently the Director of the Biotechnology Foundation located at Thomas Jefferson University, Head of the Center of Neurovirology and Professor of Microbiology and Immunology also at Thomas Jefferson University in Philadelphia, Pennsylvania.

To tell you a little bit about myself, I developed the first oral polio vaccine and conducted the first mass trial immunization by oral route with polio vaccine. This bridged the way for a plan to eradicate polio from the world in 2004.

For the past 10 years I led a team of scientists to study plants as vehicles for the production of vaccines and other biomedicals. In our studies, Hepatitis B vaccine, grown in lettuce was administered to human volunteers by feeding and was found to produce antibodies against Hepatitis virus. Rabies vaccine, which we grew in spinach and fed to human volunteers led to immune reactivity to rabies. We have successfully created an experimental vaccine in tobacco plants against AIDS.

We have both the knowledge and the techniques to produce any vaccine in plants using two techniques to achieve our goals:

(1) We transformed plants with foreign agents to produce vaccines either in seeds, leaves or fruit. Such plants can propagate indefinitely as a source of vaccine production.

(2) In the other approach, we used plant viruses to fuse with foreign agents. Plants were infected with these compounds and we isolated the plant virus and the foreign agent to produce the vaccine.

ANTHRAX VACCINE PROJECT

For several years we have proposed this Anthrax project, which we thought might be of interest to the military. The project is aimed to develop a new, safe, cost-effective vaccine which could be used for mass oral vaccination against anthrax. Our immediate goal of this project is to stabilize the Anthrax Protective Antigen (Pa) through fusion with the stable plant protein called ubiquitin and to use this recombinant for transformation of lettuce and radishes. Laboratory animals will be fed raw plants which have been transformed by Pa and then tested for resistance to infection at Fort Dietrich. In addition, the transformed plant material will be processed to produce tablets containing the Pa antigen and these, in turn, will be tested for immunogenic potential. Clinical trials in man will follow the successful outcome of laboratory investigation within a year after funding for the project is made available. The great advantages of plant-derived vaccines are as follows:

—*Safety*.—No cross contamination

—*Inexpensive*.—Does not require sophisticated and expensive facilities; Up to 4 pounds of specific protein can be recovered from an acre of plants.

—*Distribution*.—Can be grown in different geographical and climactic conditions; can be produced locally.

—*Delivery*.—Can be used as a vehicle for oral delivery of vaccines.

—*Continuous production*.—Once transgenic lettuce and radishes become available they can be propagated ad infinitum as a source of anthrax vaccine.

PROGRESS UP TO DATE

In preliminary experiments, we succeeded in the expression (in tobacco plants) of three fragments of anthrax protective antigen (Domains 1, 4 and part of 4) fused with a plant virus in tobacco plants. Virus particles obtained from plant extracts were purified and are ready to be checked for their immunogenicity in animals when funds become available. We are ready to proceed! We are just waiting for funding and the "go ahead."

Senator HARKIN. That is fascinating. We will follow up on that one. Thank you, Dr. Koprowski.

Now let us move to Thomas Monath, vice president for research and medical affairs for Acambis, makers of smallpox vaccine.

STATEMENT OF THOMAS P. MONATH, M.D., VICE PRESIDENT FOR RESEARCH AND MEDICAL AFFAIRS, ACAMBIA, INC.

Dr. MONATH. Mr. Chairman, members of the subcommittee, thank you for the opportunity to speak today about smallpox vaccine and the threat of bioterrorism.

As mentioned, I represent a company called Acambis, a publicly traded company headquartered in the United Kingdom. Our vaccine program is performed solely in the United States, by our division in Massachusetts. I also spent 20 years of my life with the CDC, and I have a perspective on the use of vaccines from a public perspective as well.

As you know, smallpox vaccination has been performed for over 200 years. The market, however, for this vaccine collapsed after eradication of the disease in the late 1970's. The last vaccine made in the United States by Wyeth was in 1982. This was a crude vaccine, made in the way that it had been for 2 centuries, collecting serum from the skin of cows and processing that into a vaccine. That is not a modern way to make a vaccine, so it is really not feasible to go back to that method of preparing a new product.

Now, the last administration became concerned about bioterrorism and the threat of smallpox, and that led to a contract awarded to our company about a year ago, September 2000, to produce about a 40 million-dose stockpile of new, modern smallpox vaccine, using cell culture techniques. Our goal was to prepare a vaccine that matched as closely as possible the biological character-

istics of the original vaccine, since it was unlikely we could actually demonstrate efficacy, since the disease had disappeared.

We were successful in the first few months of this program. Our scientists created a new vaccine with those properties, and the remaining time since the award has been devoted to making the vaccine in a way that the Food and Drug Administration would find acceptable for a new human product, and we are almost there. We plan to begin clinical trials of the new vaccine in January of next year.

Now, the original contract I mentioned was for 40 million doses, and the world has obviously changed. We got a change order to our contract recently to increase it to about 54 million doses, and to accelerate the program. As was mentioned here already, the Government and HHS has determined that they should afford the American people one dose per person, roughly 300 million doses of vaccine, and we are currently responding to a request for information from HHS to greatly increase and accelerate the amount of vaccine that our company could provide.

We teamed up with Baxter Health Care, a big U.S. pharmaceutical company, in order to achieve this. Baxter owns a significant equity share in our company. We have a strong collaboration with them on many fronts. It is our belief we could manufacture the amount of vaccine that the Government has requested in about the first 9 months of 2002. We are looking at the cost of doing this. We are not sure that the estimate that has been mentioned today of $509 million is going to cover such an effort. We will know more in the next day or so.

I want to also make the committee aware that in addition to the vaccine, we have to think about distributing the vaccine. The art of how you perform vaccinations is a lost art, and people need training in order to do this.

There are two other matters which I feel important to bring to the subcommittee's attention. The first is that what we are doing is unheard of in the history of vaccine development. The normal cycle of development of a new vaccine is roughly 10 years, and it is a very difficult proposition to get through all of the regulatory hurdles and clinical trials and so on, so we are planning to do something in record time.

A highly proactive collaboration with the Food and Drug Administration is absolutely critical to make things happen. This is not going to be business as usual, but we have to make sure that no short-cuts are taken, because the product must be of highest quality, since one can certainly imagine the situation in which a lot of vaccine might be given when faced with a threat, only to find out later that that was just a threat and nothing was actually happening. So we need a safe vaccine that meets all of FDA regulations regarding product quality.

Second, I would like to make the point that vaccine manufacturers, including us, require indemnification against tort claims resulting from vaccine-associated adverse events. Dr. Koplan mentioned if the entire U.S. population were immunized with a new vaccine, more than 40 percent or so having never been vaccinated before, that we could expect 2,000–3,000 adverse events, potentially

lethal events, so particularly where the threat is uncertain the safety of a vaccine is imperative.

PREPARED STATEMENT

It is quite extraordinary, but we got this contract from CDC based on our providing private insurance against claims against us and the Government associated with any adverse events. In the setting of providing 300 million doses of vaccine, there is no private insurers willing to pick up that kind of risk. It must be done by the Government, and at the present time, although it has been talked about and there are efforts underway, we are unable to make a proposal to the Government for a lot of new vaccine absent assurances regarding the indemnification piece.

I thank you for allowing me to speak today.

[The statement follows:]

PREPARED STATEMENT OF THOMAS P. MONATH

Senator Harkin, Senator Spector, members of the Committee, thank you for the opportunity to speak about smallpox vaccine and the threat of bioterrorism. I represent a bio-pharmaceutical company, Acambis, which has a contract with the CDC to develop, manufacture, store and distribute a new smallpox vaccine. Acambis is a publicly traded company headquartered in the United Kingdom but, our vaccine program is performed by the United States branch of the Company, located in, Massachusetts. I wish to inform the Committee that I have a financial interest in matters pertaining to smallpox vaccine, and my statements should be viewed accordingly.

Smallpox is a truly horrific disease known from ancient times. Over 200 years ago, a British surgeon, Edward Jenner, developed use of cowpox (a virus related to smallpox) for vaccination. Vaccine was made by scarifying the skin of calves, and serum and pus containing vaccine virus was harvested from the skin. This crude way of making vaccine continued up to 1982. Vaccine manufacture ceased because smallpox disappeared after an intensive eradication program in the 1970s. The possibility that smallpox would be re-introduced as a bio-weapon was not a sufficient priority for governments, including the US, to maintain a manufacturing capability. Worldwide supplies of old, calf-skin vaccine have dwindled to about 60 million doses, of which 15 million reside in the United States.

Rising concern about bioterrorism during the Clinton administration, led—in 1999—to an effort to protect the American people against the threat of epidemic disease. The first step, taken in July 1999 was to identify an appropriate bio-pharmaceutical company willing and able to perform the task. A formal RFP was issued in February 2000, and the CDC contract was awarded in September 2000, at which time our Company initiated work.

The vaccine is a live attenuated virus, which is introduced into the most superficial layer of the skin using a needle using the so-called "multiple puncture" technique, unlike other vaccines which are inoculated under the skin using a syringe. It is worth noting that the method of delivering vaccinia requires skill and experience lost by virtually all medical personnel in the US. Wide-scale use of smallpox vaccine will require concurrent training of medical personnel in the art of vaccination.

After introduction of the virus into the skin, the vaccinia virus produces a limited local infection, which typically results in formation of a single pock within 3–7 days. There are two features of this process that are worth noting. First, the formation of a visible pock rapid evidence of immunity that is obvious and reassuring to both patient and physician. This is unique, since all other vaccines stimulate immunity silently and require a blood test to determine if a "take" has occurred. The second unique feature of the vaccine is that it can be applied up to 3–4 days after exposure to smallpox virus and still .provide protection. Since smallpox virus is transmitted only by patients who have overt signs of rash, and since contacts can be effectively protected by vaccination up to several days after exposure to such patients, there is a very real opportunity to interrupt the spread of the disease. The problem we face is supply and distribution of sufficient vaccine to deal with a wide range of possible scenarios should a bioterrorist attack occur.

Our original contract with CDC was to produce 40 million doses of vaccine using modern methods in cell culture rather than in calf skin.

Our program at Acambis has been devoted to the creation of a new vaccine that matches the safety and effectiveness of the original vaccine. This was accomplished by our scientists in the first few months of the program. The remaining time since the contract award has been devoted to the manufacturing of vaccine that meets the stringent requirements of the Food and Drug Administration. Vaccine manufacturing is being scaled up in our facility, to reach very high levels of production next year.

Acambis, together with our partner Baxter HealthCare, is also responding to a request from the Government for a large number of vaccine doses beyond the scope of the current contract. It is the Government's intent to make sufficient vaccine over the next 12 months, i.e., approximately 300 million doses, to provide for universal coverage of the American people in case of an emergency or a decision to reinstitute routine immunization.

I would like to take this opportunity to make two comments about this accelerated program. First, the Committee should note that what is being tasked is highly unusual, indeed unheard of in the history of vaccine development. The cycle of development from the initial stages through FDA licensure of a new vaccine typically takes 10 years, despite the best efforts on the part of industry to minimize timelines. A highly proactive collaboration between industry and the FDA will be required to achieve the Government's objective. However it is critical that shortcuts do not compromise product quality or demonstration of safety and effectiveness in clinical trials, since is easy to imagine a situation where large numbers of individuals are exposed unnecessarily to the vaccine, which may have a significant risk of serious adverse events.

Second, the Committee should take note of the fact that vaccine manufacturers will require indemnity against tort claims resulting from vaccine-related adverse events. Our current contract at Acambis was awarded based in part on our company having provided private insurance against such claims for the use of up to 40 million doses of FDA-licensed vaccine. The new plan to develop a much larger stockpile of vaccine, which could be used as investigational product in advance of FDA licensure, is certainly beyond the scope of any possibility of coverage by private insurers. If this plan is to succeed, the Government must solve the problem of indemnification. Thank you once again for the opportunity to address the committee.

Senator HARKIN. Did you state $509 million?

Dr. MONATH. I think that was the figure you mentioned.

Senator HARKIN. What did you say?

Dr. MONATH. We are looking at the cost of providing 300 million doses of vaccine. We are not quite there. I think in the next day we have to provide those figures to the Government. I am not sure the $509 million is going to be enough.

Senator SPECTER. But you read it in the newspaper?

Dr. MONATH. I read it in the newspaper.

Senator HARKIN. That is what we have been asking for, and if it is not enough, we had better know about it.

Senator SPECTER. It is interesting you would read it in the newspaper.

Senator HARKIN. Now we turn to Dr. Mary Gilchrist. Dr. Gilchrist is director of the University of Iowa Hygienic Lab, and president of the Association of Public Health Laboratories. I visited the Hygienic Lab at the University just a couple of weeks ago, and was very impressed with your ability to rapidly respond, so welcome, and please proceed.

STATEMENT OF MARY J.R. GILCHRIST, Ph.D., DIRECTOR, UNIVERSITY OF IOWA HYGIENIC LABORATORY

Dr. GILCHRIST. Thank you, Mr. Chairman, distinguished members of the subcommittee. I am honored to be here today to discuss the critical role the public health laboratories play in bioterrorism response, including the most recent anthrax attacks. I am going to

address three important components that do require attention, the bioterrorism response network, linkages between public health and clinical laboratories, and the chemical terrorism response network.

The public health laboratory community spent the last 3 years preparing for a potential bioterrorism event. The Laboratory Response Network, anchored by the CDC, was formed. The public health laboratories in the cities and States were designated to shoulder much of the testing. Methods for identification of bacteria, toxins, and viruses were written, and technologists are being trained and tested with unknown specimens.

Much remains to be done, but the basic structure is effective, as demonstrated by the case in Florida. Now is the time to strengthen the system and fully equip the public health laboratories. At present, many of the 81 labs in the network are inundated with suspicious packages, powders, and other challenging specimens. They require great effort to work up safely, as each is unique. The testing cannot be sustained indefinitely without burnout, given the long hours that the technologists are enduring. The testing must be sustained, however. When testing is readily available, it helps to control fear so that it does not progress to panic.

Last year, a total of only $8.3 million was provided to fund the network. This money helped to build a foundation that should now be enhanced. The APHL is disappointed in the President's recently announced emergency budget for the LRN. We must move beyond the startup phase, and this will require a substantial increase in funding that far exceeds the administration's request.

To adequately fund the LRN, a total of $125 million should be distributed to the States. Funding is necessary for new instruments that will perform rapid tests, for staffing, chemical supplies, communications, information management, facilities, courier systems, biosafety and security.

Let me provide an example that we experienced regarding security. In Iowa, following the unconfirmed report that the Ames strain may have been used in Florida, our security issues became acute. Misleading and inaccurate wording in the press suggesting an Iowa laboratory connection brought the National Guard to our door, and this was pictured on the front page of the New York Times, which spawned interest by other media.

Although the controlled strain at our lab is a vaccine and not a virulent strain, it was deemed necessary to increase security against any anthrax agents that may be isolated in the future. These security advancements were not inexpensive, particularly in a building that was built in 1917 to serve as a tuberculosis sanitarium. Public health laboratories throughout the Nation are critical infrastructure, and these assets must be secure.

The National Laboratory System is a concept that will more closely tie the public health laboratories to the 170,000 hospital and other clinical laboratories, which do most of the testing for infectious agents. Without good linkages between hospital, reference, and public health laboratories, the rapid emergence of threat agents may be missed. The complexities of antibiotic resistance and bioterrorism demand that this system be fully funded and instituted. To fully fund the LNS, $75 million is necessary.

The chemical terrorism laboratory system also requires greater funding. Currently, only five laboratories in the Nation have this capacity, and none of these five are located in the Plains States. Through the events of the past few weeks, we have learned that our laboratories will be called on to detect both microorganisms and chemicals in order to evaluate the threats to our society. However, most, like those in Iowa, do not have the biomonitoring instruments that cost several hundred thousand dollars each. To fully implement this program, a minimum of $100 million is necessary.

The events of the last few weeks have fully demonstrated that response capabilities must be distributed to the States, and not solely available through the Federal system for three major reasons. First, the Nation's public health laboratories can provide important redundancy so that if one or more is incapacitated the rest can take up the slack and provide surge capacity.

Second, they provide geographic dispersal so that ground transportation can be employed should air transport again be compromised.

Third and most importantly, they provide local control so that the most urgent specimens can be prioritized instead of ending up in a queue of nameless specimens at a regional laboratory.

PREPARED STATEMENT

We must sustain and augment this critical infrastructure. This can only be accomplished with your help.

Thank you for the opportunity to testify today. I would be pleased to answer any questions you might have.

[The statement follows:]

PREPARED STATEMENT OF MARY J.R. GILCHRIST

Mr. Chairman and distinguished members of the subcommittee, my name is Dr. Mary Gilchrist. I am the Director of the University Hygienic Laboratory (UHL), Iowa's public health and environmental laboratory. I am also the president of the Association of Public Health Laboratories (APHL), representing state and local public health laboratories across this nation. We are pleased that the Council of State and Territorial Epidemiologists (CSTE) support this testimony, and the written statement reflects comments provided by our epidemiology partners. Both epidemiology and the laboratory must have equivalent strength so that they may function effectively.

I am honored to be here today to discuss the critical role that public health laboratories play in bioterrorism response, and specifically the most recent anthrax threats and attacks.

The public health laboratory is a critical component of national and state surveillance for bioterrorism. In order to be prepared for bioterrorism, public health laboratories need safe and secure facilities, trained personnel, modern equipment, rapid assays, and communications tools. Courier services are also needed to move specimens to the public health laboratory. To prepare for chemical terrorism our states need containment laboratories, trained personnel and equipment to perform rapid screening for toxic chemicals.

In Iowa, following the unconfirmed and false announcement that an Ames or Iowa strain may have been used in Florida, our security issues became acute. News that the Iowa National Guard was guarding laboratories in Iowa City was carried on the front page of the New York Times and this revelation spawned inquiries from the networks. Much misinformation was circulated regarding the Ames strain, an isolate of *Bacillus anthracis* that was identified at the National Veterinary Services Laboratories (NVSL) in Ames some twenty years ago and widely circulated to other facilities for research purposes. Indeed, although the *Bacillus anthracis* control strain at UHL is a vaccine strain and not the Ames strain, it was deemed necessary

to increase security against any anthrax agents that may be isolated in the future. These security advancements are not inexpensive particularly in a building that originally served as a tuberculosis sanitarium.

To prepare our nation's public health laboratories for the biological and chemical terrorism threats our nation faces we urge enhancement of the following three programs: The Laboratory Response Network, the National Laboratory System and the further development of a Chemical Terrorism Preparedness and response program. The approximate cost for the three components would be $300,000,000. Details for each of the three components follow.

The Laboratory Response Network (LRN) is critical to the success of the United States response to terrorism. In order to prepare the LRN member labs at the local, state, and federal level, and to ensure adequate and appropriate expansion, an additional $125 million is needed, at a minimum.

The Laboratory Response Network is composed of county, city, state, and federal public health laboratories, and was established to help public health laboratories across the nation prepare for and respond to acts of terrorism. It is a joint program of the CDC and the Association of Public Health Laboratories and was begun about three years ago. This network of laboratories can accept specimens and samples from hospitals, clinics, the Federal Bureau of Investigation (FBI) and other law enforcement groups, emergency medical services, the military, and other agencies. With adequate resources this multi-level network will be able to function effectively even if airplane travel is grounded. During the September 11 attacks in New York City and Washington, if there had been simultaneous attacks with physical and bioterrorism agents patient samples could have easily been transported over the ground to adjacent states.

The public health laboratory community spent the last three years preparing for a potential bioterrorism event. The public health laboratories in the cities and states were designated to shoulder the bulk of the testing for dangerous biologic agents such as Anthrax, Botulism, Plague, Tularemia and Brucellosis. In fact, the first (index) case of anthrax in Florida was diagnosed because astute private healthcare personnel (a clinician and a laboratorian) saw suspicious "gram-positive" rods and immediately forwarded the sample to the state public health laboratory, which conducted more sophisticated and more definitive tests, and then went on to alert the CDC.

Methods for identification of the designated threat strains of bacteria, toxins and viruses were written and laboratory technologists were trained and tested with unknown specimens. The basic structure is effective but we must fully fund the infrastructure in our laboratories to sustain the efforts that are currently underway.

At present, the laboratories in the network are inundated with many suspicious packages, powders and other very challenging specimens. They arrive in complex and challenging packaging and require great effort to work up as each is unique. This testing is demanding and cannot be sustained indefinitely without burnout, given the risks and long hours that our technologists are enduring.

Definitive identification of agents of biologic terrorism in both an overt or covert attack is dependent on laboratories having technical capabilities, equipment and trained personnel. Laboratories must be able to identify a broad range of potential agents including organisms that could be used to compromise the food supply, water or air. Conventional identification methods are now in place and more rapid methods are being evaluated prior to implementation in public health laboratories. There is no reliable alternative to the testing by the network laboratories.

The hand held devices that are widely touted by industry often provide false positive results and false negative results and cannot be relied upon to provide accurate testing at this time. If there are accurate devices, it is not easy to distinguish them from the problematic ones because reliable evaluations have not been published in an adequate fashion. In fact a recent CDC Health Alert states the following: "Handheld assays (sometimes referred to as "Smart Tickets") are sold commercially for the rapid detection of Bacillus anthracis. These assays are intended only for the screening of environmental samples. First responder and law enforcement communities are using these as instant screening devices and should forward any positive samples to authorities for more sensitive and specialized confirmatory testing. The results of these assays should not be used to make decisions about patient management or prophylaxis. The utility and validity of these assays are unknown. At this time, CDC does not have enough scientific data to recommend the use of these assays."

Importantly, the testing taking place in the public health laboratories controls panic and fear. The ready availability of the testing of these packages, powders and environmental specimens is also providing the CDC respite from a volume of testing

that could never be performed in their laboratories even if the problems with transport, chain of custody and jurisdiction could easily be solved.

Last year, CDC distributed $8.3 million to the state public health laboratories to prepare for bioterrorism. The dollars provided by the CDC were helpful for a network in formation. It has helped to build a foundation that can be enhanced. It is now essential that we fully fund the network.

Therefore, we call for substantial increases for the programs at the CDC that are needed for biological terrorism preparedness and response. Furthermore, we must ensure that the money designated for the CDC flows to our nation's public health laboratories. The state, county, and city public health laboratories are on the frontlines in our nation's response to this crisis. Without a needed influx of dollars our state's public health laboratories will not have the capacity and capability needed to respond to an emergency situation. Funding is necessary for the following: new instruments that will perform rapid tests; staffing; chemicals and supplies; communications; information management; facilities; courier systems; and biosafety and security. Once again, we call for $125 million for the LRN.

The National Laboratory System (NLS) is an essential component of a laboratory preparedness plan for biological and chemical terrorism. Currently, the National Laboratory System (NLS) is a demonstration program funded by the CDC in response to the growing threat to public health posed by bioterrorism, food-borne diseases, and emerging infectious diseases. At a minimum, $75 million is needed to begin to fully implement the NLS in all 50 states.

We are all aware that the health of citizens of the United States is at risk due to potential and real bioterrorist events or exposure to other infectious diseases including organisms that develop antimicrobial resistance. A recent GAO report (Emerging Infectious Diseases, February 1999), and a Lewin Group Report (Public Health Laboratories and Health System Change, October 1997) both address the need for development of a cohesive laboratory system. Consequently, it is important to develop a system that will allow rapid and accurate information to flow between public and private laboratories and to define the roles of each in containing the diseases. Detection of a causative agent and its unique properties is essential for effective public health intervention.

All clinical laboratories are the front-line' of detection of events, whether those events be biologic or chemical. Patients show up at doctor's offices and emergency rooms, not at public health laboratories or public health programs. So public health is dependent on clinical laboratories to be aware of public health concerns and to route appropriate specimens/isolates to public health laboratories.

A major goal of the NLS is to facilitate communication and coordination between public health laboratories and the medical community and hospital/independent laboratories. Accurate and timely laboratory detection is critically important to identify, track, and limit public health threats like biologic and chemical terrorism. Today, most diagnostic testing for infectious agents occurs in 170,000 private hospital or commercial laboratories nationwide. These facilities will very likely be the primary sites for detecting an act of bioterrorism or the introduction of an unusual infectious agent into a community.

Improvements are needed in the integration of public health laboratories and private clinical and hospital laboratories. These two types of laboratories have independent yet complementary roles to safeguard public health. To reach this goal, the CDC, in conjunction with the Association of Public Health Laboratories, has been piloting the National Laboratory System within the states of Minnesota, Michigan, Nebraska and Washington.

The National Laboratory System must be expanded to all states to maximize our nation's preparedness to detect and provide public health interventions for infectious disease outbreaks. Through improvements in communication, collaboration, and coordination, the NLS initiative is successfully providing links to the public and private sectors necessary for an effective response to terrorism, emerging infectious disease, antimicrobial resistance, and foodborne diseases. All states must be part of a National Laboratory System. We urge you to provide $75 million to build the NLS.

For Chemical Terrorism Preparedness and Response, expanding the number of laboratories able to handle chemical agents and agents present in environmental samples is essential. Minimally, $100 million is needed to enhance and expand public health laboratories testing human specimens for chemical terrorism agents as well as to implement a program of testing for environmental samples. Currently there is no program in place to test environmental samples and this is a major gap in testing.

The likelihood that chemical agents will be used for terrorist purposes is high. Unlike biological agents, chemical agents can produce immediate effects; are cheap, easy to use, stable, and can be precisely delivered; and can be easily, efficiently, and

rapidly dispersed. Terrorists can use thousands of commercially available chemicals. These chemicals can be purchased throughout the world. These include herbicides, blood agents, choking agents, blistering agents, and nerve agents.

Last year CDC provided $3.1 million to five state public health laboratories (New York, Virginia, New Mexico, California and Michigan). In addition to funding, these laboratories have received training from the CDC, and are beginning to serve as "surge capacity" laboratories for CDC chemical terrorism analyses of clinical specimens. At present there are no efforts to provide coordinated laboratory testing of environmental samples for evidence of terrorist attacks. Once again, we need a minimum of $100 million to begin to fully implement these programs.

APHL supports the following testimony regarding building state epidemiology capacity. These portions of my testimony have been provided to us by the Council of State and Territorial Epidemiologists.

The Council of State and Territorial Epidemiologists (CSTE) supports the white paper, Providing a Framework for Public Health Action and Bioterrorism Preparedness: Recommendations for Federal Funding of Public Health Activities, prepared by the Center for Infectious Disease Research and Policy at the University of Minnesota, and the Workgroup on Bioterrorism Preparedness. While this document is still a work in progress with regard to supporting points, the overall funding recommendations, and general funding categories, are endorsed by CSTE.

With the Framework as a context, CSTE has specific recommendations within two funding categories. Under item #1, Improving State and Local Preparedness, item (b), Staffing, Training, Epidemiology and Surveillance, a total of $400 million is recommended. Within this total, CSTE recommends the following: $60 million (per year) to expand the Emerging Infections Program (EIP). The current funding level is $18 million. State and local health departments must improve their ability to recognize and respond to bioterrorism events by integrating bioterrorism preparedness activities into existing communicable disease prevention and control programs. CDC's Emerging Infections Programs (EIPs), now operational in nine states, have been highly successful in enhancing the kind of long-term epidemiologic capacity needed at the state level and county level. The EIPs are built around specific "cutting edge" surveillance projects that are collaborative efforts between state and county health departments and the CDC. The infrastructure created by these projects provides a level of surveillance infrastructure that is uniquely suited to challenges posed by bioterorrism. The EIPs also have the flexibility to enhance their capacity to detect a bioterrorism event. This amount of funding would permit expansion to 16–20 states and several additional large cities.

$65 million (per year) to expand the Epidemiology and Laboratory Capacity for Infectious Diseases program (ELC). The current funding level is $50 million. The ELC for Infectious Diseases program is less structured than the EIP Network and builds more basic epidemiologic and surveillance capacity in states and eligible local health departments. Some states have used the ELC to build capacity and have gone on to become part of the EIP Network. dsELC for Infectious Diseases was established in 1995 in response to CDC's national strategy to address emerging infections. Resources are used to hire and train staff, develop diagnostic and subtyping methods, implement electronic disease reporting systems, and strengthen collaboration between laboratory scientists and epidemiologists. As of April, 2001, all states and six Metropolitan health departments, and Puerto Rico have received funds through ELC. More than 200 epidemiologists, laboratory scientists, and technicians have been hired with ELC funding and many states now have modern molecular diagnostic and communications tools. The recommended funding level would double existing core capacity funding, which averages $250,000 per site, and add a bioterrorism component.

Again, within the Framework document, under Item (c) under Improving State and Local Preparedness is Information and Communications Systems and totals $200 million. Within this total for this purpose, CSTE recommends the following: $50 million (per year) to fully implement the National Electronic Disease Surveillance System (NEDSS). The current funding level is $27 million. NEDSS is a system designed by CDC to integrate a myriad separate databases for public health surveillance so that reporting can be simplified and outbreaks (including bioterrorism attacks) can be rapidly detected and characterized across the different systems and, very importantly, across an entire state and multi-state region. The system also provides new, upgraded features such as automatic laboratory electronic reporting and Geographic Information Systems, or mapping to show where cases are occurring. While, this year, 57 states and jurisdictions received some NEDSS funding, 21 states who applied for funds to move their systems ahead were not funded due to insufficient resources. Only two states have fully implemented systems. With additional funding, CDC could provide intermediate NEDSS capacity to all 50 states; it

could add resources to state grants to permit re-examination of their Information Technology security issues which are not adequate; and it could broaden the software licenses beyond just intrastate laboratories to include intrastate providers, reporters, and non-laboratory facilities.

$10 million (per year) to fully implement Epi-X. There is no current appropriation for Epi-X. The Epidemic Information Exchange is software created to provide rapid, secure communication about outbreaks and other acute or emerging health events among public health officials. Epi-X is a secure web-based system with participants from CDC, state and local health departments, and the military. Epi-X also provides emergency notification by telephone and/or pager for defined groups of public health officials. The funding level requested would support state and local health department efforts in all 50 states and large city health departments to integrate Epi-X capabilities into their existing and future disease surveillance and outbreak communications plans.

In closing, I want to thank the members of the Committee for the opportunity to testify during this time of great need.

Senator HARKIN. Thank you very much, Dr. Gilchrist. Thank you all for being here.

I will try to ask just a couple of questions. To BioPort, the anthrax vaccine right now is not available to civilians. Should it be made available to civilians?

Mr. KRAMER. As you correctly point out, the stockpile of vaccine we have is owned by the Department of Defense.

Senator HARKIN. How many doses do they have?

Mr. KRAMER. I have been asked not to comment about the number of doses that is in the stockpile, but I have been assured that the HHS and the DOD are coordinating to make sure that that vaccine will be made available on an emergency basis with the approval of the FDA.

Senator HARKIN. You are saying the number of vaccines we have available for anthrax is a classified matter?

Mr. KRAMER. I have been asked not to comment on the number of doses that are in the stockpile.

Senator HARKIN. I am just wondering, in open testimony, why it is classified. Does anybody know? Well, I will try to find out why it is classified. Why should it be? Do you know why it is classified?

Senator SPECTER. No.

Senator HARKIN. I do not know, either. Well, I do not know what the level of classification is.

The other thing on the anthrax vaccine, do I understand correctly that if someone is exposed, and they have tested positive, this vaccine be helpful to them?

Mr. KRAMER. I will let Dr. Myers answer that question.

Dr. MYERS. Animal studies have shown that when both vaccine and antibiotic are given concurrently after exposure, that protection is 100 percent. In those same animal studies, if only antibiotics were given for a 30-day period, some 17 percent of the animals, regardless of the antibiotic, 9 out of 29 animals would later develop anthrax after the antibiotic were taken away.

It suggests also that perhaps the course of antibiotic therapy can be reduced, therefore expanding the amount of antibiotic that is available for exposures as well as preventing disease on reexposure, so we think it has a place, and we think it is certainly up to the Centers for Disease Control and Health and Human Services to determine what that place is.

Senator SPECTER. Does that mean that it works?

Dr. MYERS. Yes, it does.

Senator HARKIN. That is what it sounds like, although this is based on animal studies.

Dr. MYERS. That is correct.

Senator HARKIN. If you gave this vaccine to someone who is exposed, what is the risk to that person?

Dr. MYERS. Let me be clear that vaccine alone after exposure is not protective. It requires vaccine plus antibiotic, but it may prevent some cases of anthrax that would occur after antibiotic treatment is completed.

Senator HARKIN. How about if someone has inhalation anthrax, would there still be time for the vaccine to work after that?

Dr. MYERS. The Advisory Committee on Immunization Practices recommends that anthrax vaccine be made available, and that post exposure treatment be both vaccine and antibiotic for 30 days, until three doses of vaccine have been given.

Senator HARKIN. Just from a layman's standpoint, it seems to me if someone has the symptoms of inhalation anthrax, in which I think the mortality rate is quite high—I do not know what it is, but it is quite high—then what would be the harm in giving that person the regimen that you suggest, which is antibiotics plus anthrax vaccination?

Dr. MYERS. Certainly what we have seen thus far, and what we would expect from animal studies, is that once symptoms have occurred, the prognosis is poor, and with very aggressive, supportive therapy, as we have seen, a death might still occur, even if vaccine and antibiotics were given after the symptoms begin. So it is probably not going to be real useful at all, after symptoms of inhalational anthrax occur.

Senator HARKIN. If you tested positive at some point for exposure for anthrax, that is when it is useful?

Dr. MYERS. That is correct, before disease begins, and that is the recommendation of the Advisory Community on Immunization Practices.

Senator HARKIN. Thank you very much.

Ms. Kuhn, what is the price of Cipro right now?

Ms. KUHN. We have an average wholesale price, and there are other Government prices, but in my job as operations, I am not really involved in the pricing structure.

Senator HARKIN. So you cannot tell me how much Cipro is?

Ms. KUHN. There are varying prices, depending upon where the purchase is, but if you would like to discuss the pricing further I can take the questions and get back to you.

Senator HARKIN. Senator Specter just said here Bayer supplies Cipro to the U.S. Government at a price of $1.83 per tablet. I guess my question is, could you provide for the record what was the cost to the Government per tablet 12 months ago?

Ms. KUHN. I do not have that information with me. I can get back to you with that.

Senator HARKIN. I think it is incumbent on us to take a look at what the pricing structure of this is, since it is going to be something that is going to be, I think, widely used in the United States. We should take a look at that.

Ms. KUHN. Thank you for that question, and we would welcome that opportunity.

Senator HARKIN. My time is up. Senator Specter.

Senator SPECTER. Thank you very much, Mr. Chairman.

I am very encouraged by what I hear today. When I listen to the comments from BioPort and Bayer and Acambis and Dr. Koprowski, I think the terrorists are overmatched. I think that we have the ingenuity and the capability of meeting this crisis.

When we talk about how much things cost—we always do that around here—but the real question is, what can be produced? What is our capacity for solving the problems? It is very reassuring to hear how good it is, so that it is a matter of pursuing these various courses.

Ms. Kuhn, you talk about what Bayer does and what Cipro does. I think that it is important to inform the public that Bayer officials are meeting today with Governor Ridge and also Secretary of Health and Human Services Thompson to make a determination as to what the needs are of the Departments to actively protect Americans. Are the costs being negotiated and discussed in those meetings, to your knowledge?

Ms. KUHN. I do not have the agenda for that meeting so I do not know if it is being discussed, but we certainly would welcome the opportunity to have those discussions, because we would also like to finalize these contracts.

Senator SPECTER. Well, I am sure those people are not sitting down without getting down to brass tacks, but we would appreciate it if you could provide the subcommittee with the specifics on that letter, and I know in the morning press releases that the issue between Bayer and Canada has been solved. There had been an issue as to your patents and the takeover of the patents, and that has been worked out with Canada, recognizing your patents.

Ms. KUHN. That is correct, Senator Specter. We have reached a deal with the health ministry in Canada for 1 million tablets. Those 1 million tablets are in their inventory, and in addition we will take over inventory management of the generic product and use that as necessary.

Senator SPECTER. The issue of patents, or respecting patents is a very important one, so that there is motivation in our society for ingenuity and for development and an appropriate compensation, but not an inappropriate compensation, and it is important that pharmaceutical companies, when dealing with a problem of this sort, deal with the Government, as Bayer is, with the Homeland Security Director, Governor Ridge, and the Secretary of Health and Human Services, Secretary Thompson, to arrive at what is a fair price, and we want to be kept informed about that.

We want to encourage people to develop products, and you have a constitutional requirement in America that you cannot expropriate property. You cannot take property without due process of law, but the other side of it is that there be fairness, and we want to pursue that, Ms. Kuhn, and we would appreciate it if you would report back to us on that.

Ms. KUHN. I will do that, Senator Specter.

Senator SPECTER. Dr. Koprowski, the comments you have made are really fascinating, especially when the praise does not come from your home State Senator, but it comes from Senator Harkin,

who does not lavish praise without real cause, and so I think that is quite a tribute to you.

Dr. Koprowski, how fast could this vaccine for anthrax be developed by your procedures, if you could give us an estimate?

Dr. KOPROWSKI. Senator Specter, it depends upon funds. The larger the funds, the quicker we can get space and organize it. I have said in my report that it would be not less, but perhaps not more than a year. However, if we had more funds we could accelerate the process, because it really involves growing plants and putting the vaccine in plants.

Senator SPECTER. So if you were funded appropriately, adequately, you could do it in less than a year?

Dr. KOPROWSKI. Yes, we could do it in less than a year if properly funded.

Senator SPECTER. Well, we are going to ask the Federal officials to take a look at your program to see its potential, and with your record for solving problems that is something we really want to take a close look at.

Dr. Monath, when you talk about doses for 54 million people, are you talking about doses for all Americans?

Dr. MONATH. It has been a changing set of requirements. Our original contract was for 40 million. That came out of some considerations of the minimum number of doses needed to interrupt an event using some dynamic modeling. I think everyone has kind of woken up in the anthrax crisis.

Senator SPECTER. Could you provide us with what it would cost for 300 million Americans, tell us what that would cost and how long it would take you to produce it?

Now, are the risks reduced with the vaccine that you are working on? Dr. Koplan testified earlier that the risks outweigh the benefits, and I heard actually my son tell me yesterday that there was one chance out of 4,000 on a smallpox vaccine that there would be very, very serious medical problems. Do you know if that is accurate?

Dr. MONATH. Well, you are referring to the original vaccine, the only material that is in the stockpile that exists today, the 15 million doses at CDC.

Senator SPECTER. The question is, is there a significant risk?

Dr. MONATH. It is about 5 to 10 per million of very severe adverse events.

Senator SPECTER. How about the vaccine which you are preparing?

Dr. MONATH. Well, it has not been made, but our goal is to match the characteristics of the old vaccine.

Senator SPECTER. In that event, the risk would be present?

Dr. MONATH. The risks are going to be significant, so we really need to determine, or have a clear policy regarding, the use of smallpox vaccine.

Senator SPECTER. Well, I compliment you on all you are doing and the public health experts. This is a massive problem, and I like what I hear. There is productivity and there is capacity and there is ingenuity, and there are plans, and it might take us a little time to get on track, but the Congress is just a facilitator. You people are the real answers to the problems.

With all the money that we would put up, it would not be anything unless we had the productivity and the ingenuity to solve the problem, and I think the terrorists are overmatched, and we are going to prove it.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

Dr. Monath, on smallpox vaccine, once you have it, and you have it in a vial, does it degenerate over time? How long will it last? How long will it still have efficacy?

Dr. MONATH. You have to remember the material was made by Wyeth in 1982 which still constitutes our stockpiles. It is a very stable virus. We are estimating a shelf life of 5 years or more, but it will be determined by actual testing, real time stability testing.

Senator HARKIN. What you develop will have a shorter shelf life than what we did previously?

Dr. MONATH. Well, the FDA will give us a shelf life, and what is happening now with the old stockpile is that it is tested every year.

Senator HARKIN. We have 15 million doses right now in the United States, 15 million, and we are relying upon that, I think. If there ever was an outbreak of smallpox, as I understand it, that they would begin to vaccinate ever larger concentric circles and that type of thing. How certain are we that these 15 million vials of viruses are good, or efficacious, or that they will work? How certain are we of that?

Dr. MONATH. We are quite certain. There is a simple test that can be performed on the materials.

Senator HARKIN. That is 20 years old.

Dr. MONATH. Well, people have gotten these pox viruses out of materials that have been sitting around on a shelf for decades, and they are still viable. They are very stable viruses. They are the only class of viruses that have that characteristic, so the vaccine is remarkably stable. It has to be retested to establish its stability from time to time, and we expect that the new vaccine will have a long shelf life. We will have to replace it on a regular schedule. Our contract calls for a 20-year program.

Senator HARKIN. How would someone ever be able to get a hold of a smallpox virus that could infect people?

Senator SPECTER. You do not have to answer that question, Dr. Monath. We do not want to give people any information about that.

Dr. MONATH. Well, I have lived in a world of BW for much of my career. It could happen.

Senator HARKIN. I just wonder what our real fears are. Are there real fears out there that people could manufacture or get a hold of smallpox vaccine? I think we have a right to know. Is this something serious, or is it not?

Dr. MONATH. I consider it to be serious. We knew in 1989, with the first Russian defector of a high level, that the Russians had weaponized smallpox and what has happened to that program is quite uncertain. Much has been said about the possibility that other countries, rogue states, have acquired materials from that program, or maybe acquired it from other means, so I think there is a credible threat.

I think it is less easy to perpetrate than anthrax for a variety of reasons, but it cannot be dismissed, and it has a bigger problem associated with it because it can spread, as was mentioned, so it is a potential epidemic disease.

So whether or not the bad guys have it, I do not know. I do not think anybody knows, but I think there is a real possible risk, and we have to be prepared for it.

Senator HARKIN. I understand. Regarding the 300 million doses, I figured it would cost up to a little over $3 billion as an estimate.

Dr. MONATH. I hesitate, Mr. Harkin, to give you a number.

Senator HARKIN. You gave me $11 a dose.

Dr. MONATH. That was the anthrax vaccine. I do not think it is going to be quite that much.

Senator HARKIN. Well, I would like to get a handle on that, and how fast we could ramp up.

Dr. MONATH. We are providing information to the Government Thursday.

Senator HARKIN. Could you provide us with that kind of information?

Dr. MONATH. The information actually is being provided to the Department on Thursday in response to a request for information issued last week.

Senator HARKIN. One last question I have, and I wanted to ask Dr. Koplan about it, but maybe I will ask some of you. Maybe, Dr. Gilchrist, you are the proper person to respond to this.

There is a front-page article in the paper this morning, well, maybe not the front page. It was on page 11. It says, irradiation is the answer to anthrax. The process used on food can be adapted to rid the mail of pathogens. They talk about electron beams. I am very familiar with that, having started funding a long time ago in the House for the first food irradiator at Iowa State University almost 20 years ago. They first used cobalt, and then they moved into electronic beam pasteurization, or irradiation.

There is a facility now right outside of Sioux City, which I saw a year or so ago. It is now being operated by this company mentioned here in the paper, the Titan Corporation, and a subsidiary called Sure-Beam Incorporated. They have a big electronic pasteurization facility there for meat in Sioux City, Iowa, so all of the hamburger and meat that goes through this electronic pasteurization kills all the pathogens.

They asked whether the beam could kill anthrax, and they replied yes, anthrax bacteria and the spores. Evidently it could do it right within envelopes, within packages and things like that. Could you enlighten us, any of you, on this, and is this a viable thing to look at as a way of protecting our people?

Dr. GILCHRIST. To me it seems very probable that it would work here. You are usually trying to get at the nucleic acids, the spore's resistance, because it protects other parts of the cell. So the fact that you would have to irradiate the envelope and get to the spores, there would be some physical needs you would have to pay attention to. Obviously the need up front is to make sure that the envelope from where it was mailed to where it was irradiated was not a risk to anyone, so those are the things that I see.

I think it should work, absent the concern for the pre-attention to the irradiation. We are now concerned about where were they mailing things, for example, and where do they get sorted. It has to be handled somehow before it gets irradiated, so those would be the only concerns that I would have right now.

Senator SPECTER. Mr. Chairman, I have one more question, if I may.

Mr. Kramer or Dr. Myers, there had been reports in the media about people in the military who were given the anthrax immunization objecting to it, getting sick from it. Are those myths?

Mr. KRAMER. I think if you look at the safety studies that have been provided in the written testimony, you will see that the anthrax vaccine has a side-effect profile that is very similar to any other vaccine. At the site of injection you get redness. There is some swelling.

Senator SPECTER. So there are some side effects?

Mr. KRAMER. There are some local side effects, but not unlike any other vaccine such as diphtheria or tetanus which we give our children.

Senator SPECTER. Some of the military personnel, according to the reports, refused to take it. Do you know if that is a myth, or true?

Mr. KRAMER. Well, you are correct in that some of the military people have refused to take the vaccine, but there is no evidence that I am aware of to support their allegations that what they are claiming was caused by the vaccine.

Senator SPECTER. Thank you very much.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter. Thank you all for being here. I think one thing is quite clear that came out of this, and that is, we are going to do more to help our local public health agencies in the bill that we are coming up with, aside from looking at how much we need to put in for smallpox.

SUBCOMMITTEE RECESS

Thank you all very much for being here, that concludes our hearing.

[Whereupon, at 1:30 p.m., Tuesday, October 23, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

BIOTERRORISM

FRIDAY, NOVEMBER 2, 2001

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:05 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Byrd, Specter, and Stevens.

SMALLPOX

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health, Human Services, Education, and Related Agencies of the Senate Appropriations Committee will come to order. The subcommittee today will have its third hearing on the subject of our Nation's preparedness for bioterrorism.

This morning's hearing will focus on the threat posed by smallpox. In the past couple of weeks we have seen the havoc that can be created by just a few grams of anthrax spores. Several Congressional office buildings were shut down, mail has been disrupted over much of the east coast, and four people have died. So I find it less than comforting when I am told that the greatest risk is not from anthrax, but from smallpox.

An exercise this past June called Dark Winter started with 24 simulated cases of smallpox in Oklahoma, Pennsylvania, and Georgia. The exercise ended after 2 weeks with 1,000 people dead, 15,000 people infected, and the Nation's stockpile of 15 million vaccine doses entirely gone. Had it continued, they expected the number of cases would have grown by a factor of 10 every 2 weeks. Fortunately, this was just an exercise. Nearly one-third of people who contracted the most common type of smallpox died and there is no known cure. Unlike anthrax, smallpox is contagious and a small attack could spin out of control.

There seems little doubt that our efforts to date have not adequately prepared us for this threat. We do not have enough vaccines to respond to an attack. Our public health system has been allowed to decay and needs more help to detect an outbreak quickly, to treat a large number of infectious patients, and to vaccinate large parts of the country.

Under the leadership of Senator Byrd, the proposal that we have put together includes funding for the production of enough small-

pox vaccine for every American, should that ever be necessary. It also includes funds to beef up our public health capacity at the local level so that we will be better able to identify and track and contain a smallpox outbreak should we ever be confronted with it. We expect and hope to include our package in the emergency supplemental appropriations bill to be taken up shortly.

This morning I hope we will learn more about what we can do to better protect against the threat of smallpox. I hope several questions will be answered today: How likely is the threat of a smallpox attack? What is the current state of the stockpile? How many of the doses that we have are still effective? How can we get these doses out rapidly? How quickly can 100 million doses be made to protect all Americans? What else do we need to do to protect ourselves, and how prepared are we at the local level to vaccinate on a mass scale?

So again, as I said, this subcommittee, under the leadership of Senator Byrd and with Senator Specter, has developed a comprehensive $2.3 billion plan to better protect Americans from the threat of smallpox and other bioterrorism threats.

We have a distinguished panel this morning who will help to enlighten us on these questions. I look forward to the testimony and to their answers to the subcommittee's questions.

Before we start, I will recognize first my ranking member Senator Specter and then our distinguished chairman of our full committee, Senator Byrd.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Well, thank you very much, Mr. Chairman. I commend you for convening this hearing on a Friday morning. I think it is appropriate to note that this subcommittee has been very attentive to health care issues. Senator Harkin was chairman of the committee in 1991, 1992, 1993, and 1994. I took over in 1995, 1996, 1997, 1998, and 2000, until the middle part of this year.

But what Senator Harkin and I like to emphasize, and I think it is worth noting because people are so concerned about the need for bipartisanship and to end the bickering on Capitol Hill, is that it does not make any difference which of us is chairman. I slightly prefer it when I am chairman, but the public interest is promoted either way.

We got a very unique compliment this morning, which I do not think is confidential, I will share with you. Senator Byrd called us "the health care twins." I said to Senator Byrd, who is the senior Member of Congress, having been elected in 1952 to the House and 1958 to the Senate, about to celebrate 50 years on Capitol Hill, that was quite a high compliment.

Senator Harkin and I have been very attentive to the National Institutes of Health and to health funding at every level. We have taken a look at this issue of bioterrorism and before the recent concerns we had put in the budget $338 million, last year over $290 million, the year before $255 million. But the fact is that until there was such a focus of attention there was not the ability to put the kind of funds in which are really necessary to deal with the threat that we have now.

We had the Secretary of Health and Human Services in a few weeks ago and we were a little concerned about being candid with the American people and that there ought not to be an overrepresentation, as the statement had been made that we were prepared for any contingency. I made a comment that I thought it was counterproductive to do that. If we lay it on the line, people will understand. They want to know what we are doing now.

When Senator Byrd's turn came he said, in an interesting, maybe flamboyant, gesture: I do not believe you. That is the value of separation of powers. We can speak perhaps a little more candidly and a little more bluntly because we are separate and we are independent. But before that day was up a letter drafted by Senator Byrd, the chairman of the full committee, was sent out with Senator Stevens, ranking on the full committee, and Senator Harkin and myself to the President, asking him what he needed and we were prepared to give him what he needed, Congress was prepared to do that.

As Senator Harkin has noted, we have a package in excess of $2 billion and it may go beyond that, because the real issue is what are the resources of our country, our capability for the vaccines and the health preparedness measures. We have a very wealthy, productive, ingenious country and we can meet this threat.

I might tell you on the personal level it is disconcerting to be 100 yards from the Hart Building and not to be able to get into my office. Senator Daschle had the anthrax envelope. I am right above him. We could not get in the office, and I was tested, fortunately negative, and took Cipro. It is no fun—an adverse reaction. I missed a day of squash.

But I did not think it was possible to get Congress more fighting mad than the September 11 attack, but this anthrax business has done that, and we are prepared to move. I am glad to see the experts here to give us the information as to what ought to be done and how it ought to be done, and we will provide the funding from the Appropriations Committee.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

Now I turn to our distinguished chairman of our entire Appropriations Committee, Senator Byrd.

OPENING STATEMENT OF SENATOR ROBERT C. BYRD

Senator BYRD. Thank you, Mr. Chairman. Thank you for conducting these hearings. This is where the action is, and these are indeed the health care twins. They are both very courteous, very responsive to our health needs, and they are men of action. I have found that in the case of each of them when each has been chairman. So I compliment them and thank them.

I thank you for convening this important hearing on smallpox. I thank the chairman for giving me this moment to address the subcommittee and the witnesses.

Smallpox, whose world eradication in 1980 was hailed as one of public health's greatest triumphs, has turned from a success story to a bioweapons specter. Banquo's ghost at the head of the table is there. Now public health officials in the wake of the September 11 terror attacks are scrambling on several fronts to guard against

a nightmare scenario involving the intentional release of the smallpox virus on a vulnerable population with waning immunity or none at all against the disease.

Smallpox epidemics have changed the course of history, killing as many as half their victims and crippling entire civilizations. In the Twentieth Century, smallpox has killed millions, scores of millions, even hundreds of millions of people, far more than all of the century's wars combined. Smallpox causes unspeakable misery. It cannot be cured with current drugs and spreads easily from person to person.

Thus, in the event of a bioterrorist smallpox attack, our country needs to be prepared to avert widespread fever and immediate system disruptions on a national scale. The only hope of containing an outbreak is when it is still in the foothill stages, when the number of infections is low and targeted vaccination can be used to choke off the virus. Catching an outbreak early keeps it from erupting.

Unfortunately, the public health community seems ill-prepared for an influx of patients and the ensuing chaos. Remember Milton's "Paradise Lost." He used the word "chaos"—chaos.

Since the first case of anthrax was diagnosed in Florida a month ago, almost every assumption about anthrax has been challenged, if not disproved outright. Scientific and medical wisdom has been revised daily, it seems. As our Nation prepares for potential smallpox attacks, it is imperative that we learn from the experience that we have gained in dealing with the anthrax problem.

You know, there were ten plagues of Egypt, and I will see if I can name them in order: blood, frogs, lice, flies; and then there is murrain, I believe it is murrain of cattle, horses, camels, m-u-r-r-a-i-n. That is the one I want to settle upon, so I will not complete the seven. There are actually 10 plagues.

But that is the one, murrain. So I have looked up that word "murrain." It was spoken of in the book of Exodus, having to do with the efforts of Moses to get pharaoh to release the people, release his people. So I have looked it up in the dictionary. The dictionary tells me that it is a disease of cattle, like anthrax; murrain, like anthrax.

So among the seven plagues, the nine plagues of Egypt—some will say there are 10—there is murrain of cattle, a disease like anthrax. That is going back a long way.

It is my hope that we can translate our discussions today into a tangible plan of action to deal with the threat of bioterrorism that for too long we have been reluctant to recognize. Shoring up our public health infrastructure is certainly one of the solutions and we have been tardy in coming to a realization of the importance of our doing something about these potential catastrophes.

As I have been saying for some time, we need to make more investments in the wellbeing of our citizens on our own soil. As part of a $20 billion economic stimulus package, as the chairman has said, I have recently proposed $3.1 billion for bioterrorism prevention and response efforts to strengthen our public health infrastructure and restore confidence in our homeland security.

Congress must act now to ensure the security of this Nation and the American people. You are taking a great first step here. Here is where the action is. You impressed me greatly the other day, Mr.

Chairman, when you spoke of the need to spend $2 billion or $2.5 billion on clean water, on safe water, when you pointed out that there are $22 billion requests backlogged for clean and safe water. Now you are dealing with the problem another day in another way and having this hearing.

I certainly thank you, and I thank Senator Specter.

Senator HARKIN. Mr. Chairman, thank you so much. It is always a learning experience to listen to you and a learning experience to be on your committee.

I personally, and I think on behalf of all the American people, want to thank you for your strong leadership in this area. You were the first one, when we started talking about putting all of this money in to fight terrorism, to say, wait a minute, we have to think about bioterrorism and think about putting that money aside for that and focusing on it.

You have led the way on that and we are proud to follow in your wake.

Senator BYRD. You are my chairman. Just command me; I am your lieutenant.

Senator HARKIN. I think it is the other way around. But thank you so much, Mr. Chairman.

We have a good panel here. I will introduce each of them and then we will start with Dr. Fauci and work on down. First we have Dr. Fauci, who first joined the National Institute of Health in 1968. Since then he has had a distinguished career at the National Institute of Allergy and Infectious Diseases. He became Director of that Institute in 1984. Dr. Fauci has made many important contributions to research regarding immune-mediated diseases, especially with regard to the AIDS virus.

Next will be Dr. James LeDuc. Dr. LeDuc is the Acting Director of the Division of Virus and Rickettsial Diseases of the Centers for Disease Control and Prevention. Prior to joining the CDC, Dr. LeDuc served for more than 20 years as an officer in the U.S. Army, where he directed studies on the epidemiology of virus diseases.

Dr. Michael Friedman was appointed this week to coordinate the pharmaceutical industry's initiative to combat bioterrorism. He is currently a Senior Vice President at Pharmacia Corporation. Prior to joining the pharmaceutical industry, Dr. Friedman served in the Public Health Service for 20 years and held the rank of Rear Admiral and Assistant Surgeon General.

Dr. Anita Barry is the Director of Communicable Disease Control at the Boston Public Health Commission. She is a member of the Council of State and Territorial Epidemiologists and the American Society for Microbiology, and serves on the Advisory Board for the Greater Boston Biodefense Collaborative.

We thank you very much for taking time from your busy schedules to be here to enlighten us.

We are now graced also by our ranking member of the full Appropriations Committee, the former chairman, Senator Stevens. I am delighted to yield to Senator Stevens for any opening remarks or comments that Senator Stevens might have.

OPENING STATEMENT OF SENATOR TED STEVENS

Senator STEVENS. I have extreme interest in this subject and am pleased to join you. Thank you.

Senator HARKIN. Thank you very much.

We are graced by both the chairman and the ranking member of the entire Appropriations Committee, so you can see how important this is to our Senate.

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

Senator HARKIN. With that, Dr. Fauci, welcome. All your statements will be made a part of the record in their entirety, and we would like if you could sort of sum up in maybe 5, 7 minutes each, I would sure appreciate it. Dr. Fauci.

Dr. FAUCI. Thank you, Mr. Chairman, Senator Byrd, Senator Stevens. We appreciate your calling this hearing and giving us, my colleagues and I, the opportunity to address the threat of smallpox bioterrorism and how we may as a group defend against the bioterrorist potential of this pathogen. I represent the National Institutes of Health, which is a component of a multifaceted effort including government and nongovernment, our colleagues, others represented here at this table.

Smallpox is just one of many bioterrorist threats, as you have just mentioned, Mr. Chairman, but perhaps it is the most frightening. Even though the disease was eliminated from the world with the last case documented in 1977, stocks of smallpox vaccine are known to exist in secure facilities, one in the United States and one in Russia. But there are other possibilities that stores may exist outside of those locations, so the threat of the use of smallpox as a bioterrorist weapon are real.

Smallpox is caused by Variola major. It is a virus that is easily transmitted from person to person through aerosolized droplets from saliva and other body fluids. It is unlike anthrax in that it can be transmitted from person to person and not just a danger by a direct contact. The symptoms typically appear about 12 days after exposure, with a characteristic clinical syndrome. At least 30 percent of people infected die and many survivors are disfigured.

In some respects, the situation that we are in today is what we call a victim of our own success, because smallpox was eradicated with a very good vaccine in what is probably the most successful and unprecedented story of a public health victory in the eradication of smallpox.

The Dryvax vaccine, or the classic vaccine that for decades has been used in the ultimate elimination of smallpox, was last produced about 20 years ago. It is very effective in prevention and also likely in post-exposure prophylaxis. This vaccine has not been given routinely in the United States since 1972, except for, for example, workers, laboratory workers who work with related viruses. The military discontinued it several years ago.

In other words, the population, as you alluded to just a little bit ago, who were vaccinated years ago certainly have waning immu-

nity, namely decreasing immuniaty. The exact extent of that residual immunity is really unclear.

In that regard, we have about 15 million doses of the classic original Dryvax vaccine available and owned by the Federal Government. This is not enough for a large-scale epidemic. In this regard, a three-pronged or three-phased approach has been implemented to increase the availability of vaccine.

The first is one that I am sure you have heard of, is the dilutional study, namely to take the 15 million doses, take an aliquot of that and determine, if you dilute it one to five or one to ten, do you get comparable safety as well as what we call a take rate, namely a characteristic skin lesion accompanied by an immunological response. If we are successful, and we have reason to believe that we very well might be since a preliminary study showed that a one to a hundred dilution really did not give a good response, one to ten gave approximately 70 percent take. We want to do better than that.

In the end of October, literally now, October the 26th, we initiated a second dilutional study involving over 650 people. In that we are comparing a one to five with a one to ten dilution. If for example a one to five dilution is successful, then we will have amplified our 15 million doses to approximately 75 million doses. We consider that a short-term, not solution, but a short-term amelioration of the shortage response.

This must come in parallel with what we call an intermediate and a long-range solution. The intermediate solution is to produce a second generation smallpox using not the typical calf lymph approach, but using a cell culture-based approach that will be revved up and accelerated using not only the company that was originally contracted, namely Acambis, but also other large corporations that are being discussed now, which will be large pharmaceutical corporations that would hopefully get us to the desired 300 million doses by the end of the year 2002 and perhaps before that.

There is a third generation of smallpox vaccines that are in the research phase, namely one that we look to several years from now, anywhere from 2 or more years, one that is using a type of virus that might give less potential toxicities such that pregnant women and people with weakened immune systems might be able to be vaccinated. That is more than a year or so away. We consider that the long-range solution.

Finally, in therapeutics, currently only supportive therapy is used for individuals who are infected for smallpox. However, screening efforts have identified the possibility of using anti-virals not only to combat as a second line defense against the potential toxicities of vaccination, but also in an experimental fashion to use in the treatment. One, for example, is a drug called Cidofovir that is made by the company Gilead, that was originally made as a drug to combat cytomegalovirus in HIV-infected individuals.

We now have an investigational new drug application to look at this drug in the vaccination program and we are working towards getting an IND to perhaps use it in treatment if necessary. In addition, we are working with the United States Army and USAMRIID to screen a number of compounds that might have potential use as a treatment of smallpox.

PREPARED STATEMENT

In conclusion, the NIH is committed to focusing its basic and clinical research efforts to approach and hopefully overcome this bioterrorism threat. We are committed to working together with our sister agencies in the Federal Government as well as with industry and the local and State public health groups in a comprehensive effort to keep the citizens of our Nation safe from the threat of a smallpox bioterrorism attack.

Thank you, Mr. Chairman. I would be happy to answer questions later.

[The statement follows:]

PREPARED STATEMENT OF DR. ANTHONY S. FAUCI

Mr. Chairman and Members of the Committee, thank you for inviting me here today to discuss the threat of smallpox as a weapon of bioterrorism and the current efforts by the National Institutes of Health (NIH) to accelerate basic and clinical research related to the prevention and treatment of smallpox.

Recent events, notably the attacks on the World Trade Center and Pentagon and numerous incidents involving the intentional spread of anthrax spores, have highlighted our Nation's vulnerability to attack by bioterrorists. In addition to anthrax, other potential agents of bioterrorism include smallpox virus, the bacteria that cause plague and tularemia, botulinum toxin, filoviruses (e.g. Ebola virus) and arenaviruses (e.g. Lassa virus), and other selected pathogens.

As concern grows about the use of biological agents in acts of terrorism or war, federal health agencies are evaluating and accelerating measures to protect the public from the health consequences of such an attack. The National Institute of Allergy and Infectious Diseases (NIAID), a component of the NIH, supports research on the diagnosis, prevention and treatment of infections caused by a wide variety of pathogens, including those with potential for use as biological weapons.

Our ability to detect and counter bioterrorism depends to a large degree on the state of biomedical science. Basic and applied research supported by NIH complements the efforts of other agencies by developing the essential tools—diagnostic tests, therapies and vaccines—needed by physicians, nurses, epidemiologists and other public health workers to prevent and control a disease outbreak.

SMALLPOX: THE DISEASE

Smallpox, caused by a virus known as *Variola major,* is considered one of the most dangerous potential biological weapons because it is easily transmitted from person to person, and because few people carry full immunity to the virus. Although a worldwide immunization program eradicated smallpox disease in 1977, small quantities of smallpox virus still exist in two secure facilities in the United States and Russia. However, it is possible that unrecognized stores of smallpox virus exist elsewhere in the world.

The symptoms of smallpox infection appear approximately 12 days (range: 7 to 17 days) following exposure. Initial symptoms include high fever, fatigue, and head and back aches. A characteristic rash, most prominent on the face, arms, and legs, follows in 2–3 days. The rash starts with flat red lesions (a "maculopapular" rash); the lesions evolve at the same rate. Lesions become pus-filled and begin to crust early in the second week. Scabs develop and then separate and fall off after about 3–4 weeks. Individuals are generally infectious to others from the time period immediately prior to the eruption of the maculopapular rash until the time of the shedding of scabs. The mortality of smallpox infection is approximately 30 percent; those patients who recover frequently have disfiguring scars. Smallpox spreads directly from person to person, primarily by aerosolized saliva droplets expelled from an infected person. Contaminated clothing or bed linens also can spread the virus.

Smallpox vaccine has proven to be highly effective in preventing infection. In unvaccinated people exposed to smallpox, the vaccine can lessen the severity of, or even prevent, illness if given within 4 days after exposure. Vaccine against smallpox does not contain the smallpox virus, but rather a laboratory strain of a related virus called vaccinia.

Vaccinations to prevent smallpox have not been required in the United States since 1972. People vaccinated prior to 1972 very likely have diminished immunity to smallpox; people born in the United States after 1972 are not routinely vac-

cinated. Currently, smallpox vaccination is recommended and available only for individuals who are at risk of imminent exposure, such as laboratory personnel who work with orthopox viruses related to smallpox virus, including vaccinia. No new smallpox vaccine has been manufactured in almost 20 years.

SMALLPOX RESEARCH: VACCINES

The NIAID strategy for smallpox vaccine research is a three-part program that addresses immediate, intermediate, and long-term needs. In the near-term, a bioterrorist attack involving smallpox would require the utilization of stores of the existing smallpox vaccine. Approximately 15 million doses of the FDA-approved "Dryvax" vaccine have been stored since production stopped in 1983. This clearly would not be enough to respond to a national smallpox epidemic. As a response, NIAID last year initiated a study to determine the feasibility of expanding the use of the existing stores of the Dryvax vaccine by dilution. In this study, investigators examined the skin and immune system responses of normal unimmunized adult volunteers who were given a 1:10 dilution (10 percent) or a 1:100 dilution (1 percent) of off-the-shelf Dryvax vaccine They compared responses to those from other volunteers who had received the full-strength vaccine. The results showed that the full-strength vaccine had maintained its potency, and that 70 percent of people who received a single dose of the 10-percent vaccine developed a sore followed by a scab at the injection site and antibodies in their blood, indicating protection. Even though the 10-percent vaccine was capable of stimulating an immune response in most people in the study, it is unlikely that it would protect enough people in a large population to sufficiently stop the spread of smallpox. Based on these findings, a new study was designed to determine if a diluted vaccine combined with an alternative vaccination schedule could protect a greater number of people than did the standard dose and regimen.

This study, which will enroll up to 684 people, is evaluating three different doses of Dryvax. Researchers will study the ability of the various vaccine formulations to stimulate a scab, or "take," at the vaccination site and to produce antibodies in the blood. If participants have not developed a scab in seven to nine days after vaccination, they will be revaccinated with the same vaccine they received the first time. By that strategy, researchers hope to learn which vaccine dose given in a single injection elicits the best response among the largest number of people and whether "boosters" can fortify the immune response in those who did not react to the first vaccination. This study is being conducted at several NIH Vaccine and Treatment Evaluation Units around the United States, including Saint Louis University, Baylor College of Medicine, the University of Maryland, and the University of Rochester. Recruitment of study participants began on Oct. 26, 2001.

NIAID-intermediate-term plans include development of a new smallpox vaccine: a safe, sterile product grown in cell cultures using modern technology. This vaccine will be rapidly tested in human clinical trials; 250 million doses will be produced and delivered to the federal government by the end of 2002. In the long-term, basic research promises to provide a third generation of smallpox vaccines that could be used in all segments of the population, including pregnant women and people with weakened immune systems. As the research evolves, NIAID continues to be actively involved in the development and testing of new vaccines, including the initiation of clinical trials to determine vaccine safety and efficacy, particularly in special populations.

THERAPEUTICS RESEARCH

NIH therapeutics research focuses on the development of new antimicrobials and antitoxins, as well as the screening of existing antimicrobial agents to determine whether they have activity against organisms that might be employed by bioterrorists. For example, in collaboration with DOD, NIH has rigorously screened a large number of antiviral drugs against smallpox and related viruses. One of these agents is an antiviral called cidofovir, which is approved by the Food and Drug Administration (FDA) for treating certain AIDS-related viral infections. Cidofovir has shown potent activity against smallpox and related viruses in test tube studies and in animal models. NIH has taken the lead in developing a protocol that would allow cidofovir to be used in emergency situations for the treatment of smallpox. Concurrently, other anti-smallpox agents are being investigated. NIAID and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) funded initial screening of approximately 500 compounds for potential antiviral activity against smallpox. Compounds were selected for antiviral testing from the following categories: FDA approved drugs effective against other viruses; antiviral compounds in clinical development for other viruses; known experimental antiviral compounds;

and new chemical entities. Several drugs tested in these screening studies, including several cidofovir derivatives, have been shown to be active against both vaccinia and cowpox by *in vitro* evaluation. Promising leads will be further tested with additional *in vitro* studies, animal model testing, or combination therapy studies. In addition, the design of medications active against known drug-resistant variants of microbes and the development of broad-spectrum agents are important NIH research priorities.

Together with our many research partners, NIH has made substantial progress in the research effort that is critical to our Nation's fight against terrorism. Much remains to be accomplished, however, and the challenges posed by bioterrorism will require a protracted and sustained commitment. With a strong research base, talented investigators throughout the country, and the availability of powerful new research tools, we fully expect that our basic and applied research programs will provide the essential elements that will help enhance our defenses against those who attempt to harm us with bioterrorism.

This concludes my testimony. I would be happy to answer any questions which you or members of the Subcommittee may have.

Senator HARKIN. Dr. Fauci, thank you very much for a very straightforward presentation.

Dr. LeDuc.

STATEMENT OF JAMES W. LeDUC, Ph.D., ACTING DIRECTOR, DIVISION OF VIRAL AND RICKETTSIAL DISEASES, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. LEDUC. Good morning, sir, and thank you for the invitation. I will proceed to brief you on our response to smallpox.

It is CDC's responsibility to provide national leadership for the public health and medical communities to detect, diagnose, and respond and prevent illnesses, including those that are a result of intentional release of agents. This task is an integral part of CDC's overall mission, which is to monitor and protect the health of the United States.

It is within this context that CDC is preparing our Nation to respond to biological terrorism. Last year CDC issued a strategy outlining steps in five areas to protect the Nation against these threats. The first priority area is preparedness and prevention. CDC is working to ensure that all Federal, State, and local public health officials are prepared to work with medical and emergency response communities to address the consequences of biological and chemical terrorism.

We are developing performance standards and we are helping States to conduct exercises to assess local readiness for these issues. As Dr. Fauci just said, we are working in collaboration with scientists at NIH, the Department of Defense, and other agencies to actively research issues on smallpox virus, including anti-viral drugs. We are producing additional smallpox vaccine and we are making sure that the vaccine we now have, the 15 million doses that Dr. Fauci mentioned, are safe and ready for immediate use.

The second priority area is disease surveillance. As was seen recently in Florida, the initial detection of a biological terrorist act will most likely occur at the local level. This is the area that we need to focus our attentions. To do this, we must upgrade surveillance systems of State and local health departments and strengthen their linkages with health care providers so that unusual patterns of disease can be promptly recognized and responded to.

In preparing to respond to smallpox, CDC is building dedicated response teams and we will be offering specialized training both to

State and local health officials and clinicians to better prepare them to handle this tragedy.

Third, to ensure that the control strategies and treatment measures can be implemented promptly, we need to focus on rapid diagnostic capabilities.

Fourth, a timely response to a biological terrorism event involves a well-rehearsed plan to detect, to investigate, and treat. We are assisting State and local health agencies to develop these tests. Because hospitals play a critical role in the response to bioterrorism activities, we are working closely with the various health care institutions and associations to better prepare them for potential bioterrorism events.

The fifth priority area deals with communications. Rapid and secure communications are crucial to ensure a prompt and coordinated response. CDC is building the Nation's public health communications infrastructure through an effort called Health Alert Network. We communicate with the public directly through our web site and through a telephone and email system which since the recent attacks has literally responded to hundreds of inquiries every day.

As has been highlighted recently, increased vigilance and preparedness for unexplained illnesses are an essential part of the public health effort to protect the American people against bioterrorism. Prior to September 11, CDC was making substantial progress towards developing and implementing a nationwide public health response network to help public health officials respond to deliberate attacks.

The events of September 11 were a defining moment for all of us. Since then, we have dramatically increased our levels of preparedness and we are continuing to do so.

PREPARED STATEMENT

In conclusion, the best public health strategy to protect the Nation against biological terrorism is strengthening the public health surveillance and prevention systems. Priorities include improved laboratory capacity, increased surveillance and outbreak response capabilities, and better health communications, education, and training. Not only will this approach ensure that we are prepared for a deliberate biological terrorism attack, but it will also improve our national ability to promptly detect and control naturally occurring outbreaks of infectious diseases.

Thank you very much, sir, for your attention. We will be happy to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF DR. JAMES LEDUC

Good morning, Mr. Chairman and Members of the Subcommittee. I am Dr. James LeDuc, Acting Director, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC). Thank you for the invitation to update you on CDC's public health response to the threat of smallpox. I will address specific activities aimed at preparedness for a deliberate release of variola virus, the pathogen responsible for smallpox.

As you are aware, many facilities in communities around the country have received anthrax threat letters. Most were received as empty envelopes; some have contained powdery substances. However, in some cases, actual anthrax exposures have occurred. As of Wednesday, October 31, 10 cases of inhalational anthrax and

10 cases of cutaneous anthrax have been identified in Florida, New Jersey, New York, and Washington, DC. This is the first bioterrorism-related anthrax attack in the United States, and the public health ramifications of this attack continue to evolve. In collaboration with state and local health and law enforcement officials, CDC and the FBI are continuing to conduct investigations related to anthrax exposures. During this heightened surveillance, cases of illness that may reasonably resemble symptoms of anthrax will be thoroughly reviewed. The public health and medical communities continue to be on a heightened level of disease monitoring to ensure that any potential exposure is recognized and that appropriate medical evaluations are given. This is an example of the disease monitoring system in action, and that system is working.

PUBLIC HEALTH LEADERSHIP

The Department of Health and Human Services' (DHHS) anti-bioterrorism efforts are focused on improving the nation's public health surveillance network to quickly detect and identify the biological agent that has been released; strengthening the capacities for medical response, especially at the local level; expanding the stockpile of pharmaceuticals for use when needed; expanding research on disease agents that might be released, rapid methods for identifying biological agents, and improved treatments and vaccines; and regulating the shipment of hazardous biological agents or toxins.

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

In 1998, CDC issued "Preventing Emerging Infectious Diseases: A Strategy for the 21st Century," which describes CDC's plan for combating today's emerging diseases and preventing those of tomorrow. It focuses on four goals, each of which has direct relevance to preparedness for bioterrorism: disease surveillance and outbreak response; applied research to develop diagnostic tests, drugs, vaccines, and surveillance tools; infrastructure and training; and disease prevention and control. This plan was developed with input from state and local health departments, disease experts, and partner organizations such as the American Society for Microbiology, the Association of Public Health Laboratories, the Council of State and Territorial Epidemiologists, and the Infectious Disease Society of America. It emphasizes the need to be prepared for the unexpected—whether it is a naturally occurring influenza pandemic or the deliberate release of smallpox by a terrorist. It is within the context of these overall goals that CDC is preparing our Nation's public health infrastructure to respond to potential future acts of biological terrorism. Copies of this CDC plan have been provided previously to the Subcommittee. In addition, CDC presented in March a report to the Senate entitled "Public Health's Infrastructure: A Status Report." Recommendations in this report complement the strategies outlined for emerging infectious diseases and preparedness and response to bioterrorism. These recommendations include training of the public health workforce, strengthening of data and communications systems, and improving the public health systems at the state and local level.

CDC'S STRATEGIC PLAN FOR BIOTERRORISM

On April 21, 2000, CDC issued a Morbidity and Mortality Weekly Report (MMWR), *Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response—Recommendations of the CDC Strategic Planning Workgroup,* which outlines steps for strengthening public health and healthcare capacity to protect the nation against these threats. This report reinforces the work CDC has been contributing to this effort since 1998 and lays a framework from which to enhance public health infrastructure. In keeping with the message of this report, five key focus areas have been identified which provide the foundation for local, state, and federal planning efforts: Preparedness and Prevention, Detection and Surveillance, Diagnosis and Characterization of Biological and Chemical Agents, Response, and Communication. These areas capture the goals of CDC's Bioterrorism Preparedness and Response Program for general bioterrorism preparedness, as well as the more specific goals targeted towards preparing for the potential intentional reintroduction of smallpox.

Preparedness and prevention

CDC is working to ensure that all levels of the public health community—federal, state, and local—coordinate with the medical and emergency response communities to deal with the public health consequences of biological and chemical terrorism.

CDC is creating diagnostic and epidemiological performance standards for state and local health departments and will help states conduct drills and exercises to assess local readiness for bioterrorism. In addition, CDC, the National Institutes of Health (NIH), the Department of Defense (DOD), and other agencies are supporting and encouraging research to address scientific issues related to bioterrorism. In some cases, new vaccines, antitoxins, or innovative drug treatments need to be developed or stocked. Moreover, we need to learn more about the pathogenesis, epidemiology, and clinical features of the infectious diseases which do not affect the U.S. population currently. We have only limited knowledge about how artificial methods of dispersion may affect the infection rate, virulence, or impact of these biological agents.

In 1999, the Institute of Medicine released its *Assessment of Future Scientific Needs for Live Variola Virus,* which formed the basis for a phased research agenda to address several scientific issues related to smallpox. This research agenda is a collaboration between CDC, NIH, DOD, and international partners, and is being undertaken in the high-containment laboratory at CDC with the concurrence of WHO. The research addresses: 1) the use of modern serologic and molecular diagnostic techniques to improve diagnostic capabilities for smallpox, 2) the evaluation of antiviral compounds for activity against the smallpox virus, and 3) further study of the pathogenesis of smallpox by the development of an animal model that mimics human smallpox infection. To date, genetic material from 45 different strains of smallpox virus has been extracted and is being evaluated to determine the genetic diversity of different strains of the virus. The NIH, with CDC and DOD collaborators, has funded a Poxvirus Bioinformatics Resource Center (www.poxvirus.org) to facilitate the analysis of sequence data to aid the development of rapid and specific diagnostic assays, antiviral medicines and vaccines. A dedicated sequencing and bioinformatics laboratory has been developed at CDC to help further these efforts. This laboratory will also be used to help characterize other potential bioterrorism pathogens. A team of collaborating scientists has screened over 700 compounds for antiviral activity against isolates of variola (smallpox) virus and other related orthopoxviruses and have found several compounds which merit further evaluation in animal models. Over 20 of the most promising compounds will be further tested for antiviral activity in animal model systems. The identification of one currently licensed compound with in vitro and in vivo efficacy against the smallpox virus has led to the development of an Investigational New Drug (IND) application by NIH and CDC to the FDA for use of this drug, cidofovir, in an emergency situation for treating persons who are diagnosed with smallpox. In addition, CDC has included the use of cidofovir in an existing IND to allow the emergency use of this medication in the treatment of adverse reactions to smallpox vaccination. Researchers also have been funded by NIH to design new anti-smallpox medicines and to create human monoclonal antibodies to replace the limited supply of vaccinia immune globulin that is needed to treat vaccine complications that arise during immunization campaigns.

The Advisory Committee for Immunization Practices (ACIP) worked with CDC to develop updated guidelines for the use of smallpox vaccine. These guidelines were published in the MMWR in June 2001 and serve to educate the medical and state and local public health community regarding the recommended routine and emergency uses and medical aspects of the vaccine, as well as the medical aspects of smallpox itself. Several infection control and worker safety issues were also addressed by the ACIP within the updated guidelines.

We are pursuing the development of additional smallpox vaccine with multiple manufacturers in order to rapidly enhance our vaccine resource capabilities to respond to a smallpox outbreak. We are also working to ensure that the stores of vaccine that we have in the United States currently are ready for use, including protocols for emergency release and transportation of the vaccine. We have conducted potency testing to and have confirmed that all currently existing lots are still potent. On October 26, NIH began recruitment for a study to test Dryvax vaccine efficacy undiluted, at 1:5 dilution, and at 1:10 dilution. Depending on the results of this study, CDC will ensure availability of enough diluent to allow for the appropriate dilution of vaccine. One study has already been completed which found that undiluted vaccine was effective 95 percent of the time, 1:10 dilution was effective 70 percent of the time, and 1:100 was effective 20 percent of the time. CDC is in the process of contracting with additional manufacturers to produce a total of 300 million

doses of vaccine by the end of next year. The President recently signed an Executive Order that allows HHS to provide indemnification for the smallpox manufacturers.

Detection and surveillance

Because the initial detection of a biological terrorist attack will most likely occur at the local level, it is essential to educate and train members of the medical community—both public and private—who may be the first to examine and treat the victims. For example, the Florida physician's ability to recognize a suspected case of anthrax and his awareness of his role in reporting it to the local health department was critical to our initial recognition of the current bioterrorist events. It is also necessary to upgrade the surveillance systems of state and local health departments, as well as within healthcare facilities such as hospitals, which will be relied upon to spot unusual patterns of disease occurrence and to identify any additional cases of illness.

CDC is enhancing its national surveillance system for hospital-acquired infections, dialysis surveillance, and healthcare worker safety surveillance into the National Healthcare Safety Network (NHSN). NHSN, is a web-based tool for collecting and communicating important clinical findings with healthcare facilities. Other partnerships with managed care and provider groups have proved invaluable for communicating recommendations during the recent bioterrorism response, and further activities to improve detection of potential bioterrorist attacks through these partners is planned.

CDC will provide terrorism-related training to epidemiologists and laboratorians, emergency responders, emergency department personnel and other front-line healthcare providers, and health and safety personnel. CDC is working to provide educational materials regarding potential bioterrorism agents to the medical and public health communities on its bioterrorism website at www.bt.cdc.gov.

Preparing CDC, state, and other professionals to respond to a smallpox bioterrorist threat or incident will revolve primarily around training three groups:

—*CDC Response Teams*.—CDC will begin conducting a 3-day course this month for personnel comprising teams that will be deployed to respond to an incident. Training will cover technical issues regarding the disease and the vaccine, operational issues such as isolation and quarantine, surveillance, and communications, and an introduction to CDC's response plan. A scenario-based exercise will be included.

—*State Health Representatives*.—CDC is developing a 3–4 day training course for health representatives from U.S. states and territories who would be involved in responding to a smallpox bioterrorist incident. The objective of this training is that each state/territory produce a Smallpox Response Plan that will be compatible with CDC's national plan. Approximately 150 representatives (up to 3 from each state/territory) will be trained.

—*Clinicians*.—On December 13, CDC will conduct a live satellite broadcast titled *Smallpox: What Every Clinician Should Know*. This training session is targeted toward physicians, nurses, and others who may be called on to identify and handle smallpox cases and to deliver smallpox vaccine. It will cover topics such as smallpox epidemiology, diagnosis, laboratory confirmation, vaccination, and management of suspected cases. After the broadcast, the course will be converted to a web-based format and self-instructional videotapes.

Concurrent with the satellite broadcast, a "train the trainer" session will be held for infectious disease experts at academic institutions and staff at national provider organizations. The goal is to enable representatives from these groups to disseminate smallpox response training to their peers throughout the medical community. Followup sessions will be held through April/May 2002.

CDC is also producing a variety of educational materials to be used by clinicians who may be involved in smallpox identification, care, or vaccination. These materials include an interactive CD–ROM that will contain technical information and practice exercises, fact sheets, aids to smallpox diagnosis, and a smallpox Vaccine Information Statement.

Diagnosis and Characterization of Biological and Chemical Agents

To ensure that prevention and treatment measures can be implemented quickly in the event of a biological or chemical terrorist attack, rapid diagnosis is critical. CDC has developed guidelines and quality assurance standards for the safe and secure collection, storage, transport, and processing of biologic and environmental samples. In collaboration with other federal and non-federal partners, CDC is cosponsoring a series of training exercises for state public health laboratory personnel on requirements for the safe use, containment, and transport of dangerous biological agents and toxins. CDC, also in cooperation with the Association of Public Health

Laboratories (APHL) and the National Laboratory Training Network (NLTN) have sponsored a "hands-on" laboratory course for public health microbiologists. In conjunction with the course, CDC produced two videos that were distributed to the participants as well as to members of the NLTN. The participants in this course are now using these videos and the other materials developed by CDC to train other laboratorians in their states. CDC is also enhancing its efforts to foster the safe design and operation of Biosafety Level 3 laboratories, which are required for handling many highly dangerous pathogens. *Furthermore, CDC is developing a Rapid Toxic Screen to detect people's exposure to 150 chemical agents using blood or urine samples.*

Response

A decisive and timely response to a biological terrorist event involves a fully documented and well rehearsed plan of detection, epidemiologic investigation, and medical treatment for affected persons, and the initiation of disease prevention measures to minimize illness, injury and death. CDC is addressing this by (1) assisting state and local health agencies in developing their plans for investigating and responding to unusual events and unexplained illnesses and (2) bolstering CDC's capacities within the overall federal bioterrorism response effort. CDC has formed and trained multiple outbreak response teams that are available for rapid deployment to assist state and local authorities deal with outbreaks due to any potential bioterrorism agent including smallpox. CDC is formalizing current draft plans for the notification and mobilization of personnel and laboratory resources in response to a bioterrorism emergency such as smallpox, as well as overall strategies for vaccination, and development and implementation of other outbreak control measures such as isolation and quarantine measures. In addition, CDC is developing national standards to ensure that respirators used by first responders and by other healthcare providers responding to terrorist acts provide adequate protection against weapons of terrorism.

Hospitals are critical in the response to bioterrorist attacks. CDC is collaborating with various healthcare associations and infection control societies to better prepare for potential bioterrorist events. Various hospital-based syndromic surveillance activities in regions affected by anthrax exposures have provided critical information on possible cases. Through provider-based sentinel networks, CDC has been able to communicate with infectious disease clinicians, infection control professionals, and other key clinical participants in bioterrorism preparedness and response.

Communication Systems

Rapid and secure communications are crucial to ensure a prompt and coordinated response. Thus, strengthening communication among clinicians, emergency rooms, infection control practitioners, hospitals, pharmaceutical companies, and public health personnel is of paramount importance. To this end, CDC is making a significant investment in building the nation's public health communications infrastructure through the Health Alert Network (HAN). HAN is a nationwide program to establish the communications, information, distance-learning, and organizational infrastructure for a new level of defense against health threats, including bioterrorism. Currently, 13 states are connected to all of their local health jurisdictions; 50 states have begun connecting to local providers as well; and CDC is also directly connecting to groups, such as the American Medical Association, to cast a broad net of coverage. CDC has also established the Epidemic Information Exchange (Epi-X), a secure, Web-based communications system that provides information sharing capabilities to state and local health officials. CDC also provides timely satellite broadcast and web-broadcast training through the Public Health Training Network. For example, on October 18, CDC experts shared information on anthrax with physicians, hospitals, and other healthcare providers across the country via a satellite broadcast, *Anthrax: What Every Clinician Should Know.* Part II of this program is scheduled for this week and will present an update on clinical guidelines and procedures for the early recognition, diagnosis, treatment, and reporting of anthrax exposure.

Accurate and up-to-date information helps calm public fears and limit collateral effects of the attack. CDC communicates with the public directly through its website on emergency preparedness and through a public inquiry telephone and email system, which, since the recent attacks, has responded to hundreds of questions daily. In addition, CDC communicates to the public by releasing daily updates to the news media, answering inquiries from the press and providing medical experts for interviews.

THE NATIONAL PHARMACEUTICAL STOCKPILE

Another integral component of public health preparedness at CDC has been the development of a National Pharmaceutical Stockpile (NPS), which is mobilized in response to an episode caused by a biological or chemical agent. The role of the CDC's NPS program is to maintain a national repository of life-saving pharmaceuticals and medical material that can be delivered to the site or sites of a biological or chemical terrorism event in order to reduce morbidity and mortality in a civilian population. The NPS is a backup and means of support to state and local first responders, healthcare providers, and public health officials. The NPS program consists of a two-tier response: (1) 12-hour push packages, which are pre-assembled arrays of pharmaceuticals and medical supplies that can be delivered to the scene of a terrorism event within 12 hours of the federal decision to deploy the assets and that will make possible the treatment or prophylaxis of disease caused by a variety of threat agents; and (2) a Vendor-Managed Inventory (VMI) that can be tailored to a specific threat agent. Components of the VMI will arrive at the scene 24 to 36 hours after activation. The NPS was mobilized for the first time on September 11, when a 12-hour push pack was deployed to New York City, delivering 50 tons of medical supplies to the site of the disaster in 7 hours. In addition, substantial quantities of VMI were delivered to New York City within 24 hours. Components of the VMI were deployed to various locations along the East coast to provide adequate supplies of antibiotics as prophylaxis to individuals who were potentially exposed to anthrax. CDC has developed this program in collaboration with federal and private sector partners and with input from the states.

CHALLENGES

As has been highlighted recently, increased vigilance and preparedness for unexplained illnesses and injuries are an essential part of the public health effort to protect the American people against bioterrorism. Prior to the September 11 attack on the United States, CDC was making substantial progress toward defining, developing, and implementing a nationwide public health response network to increase the capacity of public health officials at all levels—federal, state, and local—to prepare for and respond to deliberate attacks on the health of our citizens. The events of September 11 were a defining moment for all of us, and since then we have dramatically increased our levels of preparedness and are implementing plans to increase it even further.

CDC has been addressing issues of detection, epidemiologic investigation, diagnostics, and enhanced infrastructure and communications as part of its overall bioterrorism preparedness strategies. Based on federal, state, and local response in the weeks following the events of September 11, and on recent training experiences, such as the National TOPOFF event and the Dark Winter exercise—which simulated a terrorist release of smallpox virus, CDC has learned valuable lessons and identified gaps that exist in bioterrorism preparedness and response at federal, state, and local levels. CDC will continue to work with partners to address challenges such as improving coordination among other federal agencies during a response and understanding the necessary relationship needed between conducting a criminal investigation versus an epidemiologic case investigation. These issues, as well as overall preparedness planning at federal, state, and local levels, require additional action to ensure that the nation is fully prepared to respond to acts of biological and chemical terrorism.

Disease experts at CDC are developing strategies to prevent the spread of disease during and after bioterrorist attacks. Specific components include (1) creating protocols for immunizing at-risk populations; (2) isolating large numbers of exposed individuals; (3) reducing occupational exposures; (4) assessing methods of safeguarding food and water from deliberate contamination; and (5) exploring ways to improve linkages between animal and human disease surveillance networks since threat agents that affect both humans and animals may first be detected in animals.

CONCLUSION

In conclusion, CDC is committed to working with other federal agencies and partners as well as state and local public health departments to ensure the health and medical care of our citizens. We have made substantial progress to date in enhancing the nation's capability to prepare for and respond to a bioterrorist event, but there is much more to be done. The best public health strategy to protect the health of civilians against biological terrorism is the development, organization, and enhancement of public health prevention systems and tools. Priorities include strengthened public health laboratory capacity, increased surveillance and outbreak

investigation capacity, and health communications, education, and training at the federal, state, and local levels. Not only will this approach ensure that we are better prepared for deliberate bioterrorist threats, but it will also enable us to recognize and control naturally occurring new or re-emerging infectious diseases. A strong and flexible public health infrastructure is the best defense against any disease outbreak.

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

Senator HARKIN. Dr. LeDuc, thank you very much for your testimony.

Now we turn to Dr. Friedman. Dr. Friedman.

STATEMENT OF MICHAEL FRIEDMAN, M.D., CHIEF MEDICAL OFFICER FOR BIOMEDICAL PREPAREDNESS, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Dr. FRIEDMAN. Thank you, Mr. Chairman, Senator Byrd, Senator Specter, Senator Stevens. On behalf of the men and women who are the member companies in the Pharmaceutical Research and Manufacturers of America, I thank you for this opportunity to describe our deep commitment to the national effort to counter bioterrorism and specifically our response to smallpox.

In my new position I am focusing on ways in which we can coordinate and facilitate the pharmaceutical industry's efforts with government and with others to protect the public health. This is a time of unprecedented public health threats and the pharmaceutical industry is completely committed to the government and to the American people to counter this threat. We are already working in a variety of ways to address these issues.

We are uniquely qualified to do so. Our scientists have the ingenuity, the energy, the knowledge, the capability, and the commitment to meet the threat. We are providing antibiotics. We will be providing vaccines. We are making our company scientists available. We are offering government all the tangible resources that we can to assist. The reason we are doing this is because it's our clear duty as American citizens.

We have made many tangible and important contributions, and that is outlined in my written testimony and in the interest of time I will not go through all of those here. Suffice it to say that within hours of the terrorist attack on September 11 our companies began responding in a variety of tangible ways to try and help, and that continues today.

In addition, we reached out to the President, to the Secretary of Health and Human Services, to Governor Ridge and the Office of Homeland Security, to ask them what can we do to complement government activities and to make a more integral overall defense of the Nation. We formed within our organization our own emergency preparedness task force to direct our efforts at bioterrorism, both from an administrative point of view and a separate committee on a scientific level to try and do that.

We have had the privilege of meeting twice with Secretary Thompson very recently, once with Governor Ridge, to discuss very specifically identifying the priority needs that the government has and how we can help address those things. We are committed to working with organizations represented on this panel and other organizations within the government to fully address these issues.

It has been pointed out to you that the global success of vaccination has caused the smallpox threat to diminish until just very recently. Let me outline, if I may, very quickly what several of our companies are engaged in at this moment. Initially, several of our companies were contacted by the government in late September about the feasibility of manufacturing a new version of smallpox vaccine. Today I am pleased to report that they have made really extraordinary efforts to respond in record time.

Even before the formal request for information was issued, they had brought to bear considerable resources to this project, redirecting other priorities and surveying their existing technical capabilities, recognizing what would be needed. They put in place their efforts to respond. Within a week of receiving the initial request, our companies were here in Washington, presenting to a distinguished panel of experts formed by the government what our capabilities for each of those companies might be in the response to that initial request.

This has been a herculean effort. Normally it takes many years to produce a new vaccine, but the government needs it more quickly. They have said that their expectation is 300 million doses, as Dr. Fauci has mentioned, produced within 1 year. This is an extraordinary effort. We are up to this effort and our individual companies are prepared to do what is necessary.

A new vaccine will be needed. New technology will be employed. It will not be the old vaccine produced in the old way. That represents a number of challenges. But I was astonished to learn that if you just add up the number of years of experience that the four companies within our organization bring to this problem, it is 400 years of combined experience, and that is a tremendous resource that we can offer to the American public.

We recognize that there are a number of specific issues and problems that will need to be dealt with. This contracting process is still ongoing and so I cannot speak to any of the specifics. But our companies are fully committed to this and we are working well with government agencies.

The government is best able to assess and identify the risks of various possible agents. Our responsibility, as vibrant and vigorous research organizations, is to bring about those treatments to address those specific needs. We feel it is a privilege to be able to serve in that capacity.

PREPARED STATEMENT

I understand that there may be a number of questions that you would like to ask. We would be very pleased to try and answer those. Uniquely, the pharmaceutical industry has what it takes to win this bioterrorism war, and we are fully engaged in this.

Thank you, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF DR. MICHAEL FRIEDMAN

Mr. Chairman and Members of the Subcommittee: On behalf of the Member companies of the Pharmaceutical Research and Manufacturers of America (PhRMA), I want to thank you for providing me the opportunity to testify on the pharmaceutical industry's response to bioterrorism, and specifically its response to small pox. My name is Michael Friedman and I am the Chief Medical Officer for Biomedical Pre-

paredness at PhRMA, a new position created to help coordinate the pharmaceutical industry's efforts to protect public health. I am a board certified internist and medical oncologist and am currently a Senior Vice President at Pharmacia Corporation. Prior to joining Pharmacia, I spent four years at the Food and Drug Administration (FDA), including more than a year's service as Acting Commissioner. In addition to my time at the FDA, I also spent 12 years at the National Cancer Institute, and 8 years as a faculty member teaching and conducting research at the University of California, San Francisco Medical School. I also served on active duty for many years in the Public Health Service, holding the rank of Rear Admiral and Assistant Surgeon General, and continue today as a reserve officer.

In this time of unprecedented public health threats, the pharmaceutical industry is united with the American people and with our government. We are committed to doing everything possible to help protect the public health. Our scientists have the innovation, the energy, the cutting-edge knowledge, the capability, and the commitment necessary to meet the bioterrorist threat. From providing antibiotics and vaccines, to making available scientists within our companies, we are offering the government our resources to meet the public health threats of bioterrorism. We are here to continue our partnership with the federal government and with the American people in meeting these challenges. This is our first duty as Americans.

INDUSTRY'S RESPONSE TO EVENTS OF SEPTEMBER 11

Let me briefly summarize the pharmaceutical industry's initial response to the tragic events of September 11, a day that none of us will ever forget. Within hours of the terrorist attacks, our companies responded by supplying:

—Transportation/Delivery Support to Hospitals and Medical Facilities—Refrigerated Trucks
  —Helicopter Support
  —18-wheeler transports for military and medical supplies
  —Fire Trucks
  —Ambulances
—Medicines
  —Pain medication
  —Antibiotics
  —Analgesics
  —Anti-fungals
  —Eye lubricants
  —Saline
  —Infant Formula
  —Anesthesia products
  —Alcohol swabs
  —Bags of dextrose solution and sodium chloride
  —Wound care and personal care products in disaster-care modules delivered by mid-afternoon Tuesday to New York area hospitals
—Medical Equipment
  —Masks
  —Tyvek suits
  —Respirators with cartridges
  —IV's
  —Tubing
  —Work gloves
  —Latex gloves
—Aid for burn victims
  —On the night of September 11th, Novartis made a donation of their artificial human skin, Apligraf Graftskin, for burn victims. Working closely with officials in New York and at the Department of Health and Human Services (HHS) in Washington, they have provided technical medical support and enlisted cars, vans and trucks to ship the skin to medical facilities. Additionally, Novartis sent 20,000 bottles of eye solution for rescue workers.
  —In the immediate hours after the attack, Solvay obtained special Food and Drug Administration (FDA) "compassionate use" approval to provide 2,088 bottles of burn cream that is currently in Phase III trials. Solvay worked through the Centers for Disease Control and Prevention (CDC) in Atlanta to arrange for shipment to New York's Presbyterian Hospital Burn Center by Special FedEx truck and state police escort.
—Blood supplies and blood donations
  —With the help of National Guard and police escorts, Abbott delivered critical medical products throughout the day to all of the hospitals in the affected

areas that placed emergency orders. To address the blood shortage, Abbott transported (by refrigerated truck) a supply of blood from the Chicago area and Wisconsin blood banks to hospitals and medical centers in New Jersey and New York area.

—Clothing

—To fire, police and other rescue workers

—Financial Contributions

—Our companies have donated over $80 million in cash to a variety of relief efforts.

Immediately, our companies reached out to President Bush, Secretary Thompson, Governor Ridge and others in government to ask what we could do. In addition, PhRMA and its member companies quickly formed an industry Board-level Emergency Preparedness Task Force to direct PhRMA's efforts on bioterrorism.

INDUSTRY'S RESPONSE TO ANTHRAX

Just weeks ago, when stories first began breaking about cases of anthrax exposure in Florida, the nation quickly became aware that Cipro, manufactured by a PhRMA Member Company, Bayer, was the initial treatment of choice for anthrax exposure. Let me briefly explain what several of our companies have done to specifically respond to fight anthrax:

—Bayer has donated four million tablets of Cipro to HHS for emergency workers on the frontlines and the postal workers who may have been exposed to anthrax-laden mail. They have also tripled production of Cipro to 15 million tablets a week, ensuring that an ample supply of Cipro is available. They have pledged to the U.S. government that they will produce 200 million tablets in the next 90 days for its stockpile. Last, Bayer will sell Cipro to the government at deeply reduced prices.

—Abbott will supply the antibiotics Biaxin and erythomycin, if approved by the FDA for the treatment of anthrax, free to the government for any victims. Abbott is also sending shipments of its antibiotics to the Department of Defense for U.S. military troops involved in the current effort.

—Bristol-Myers Squibb will make its antibiotic Tequin available free to people infected by or exposed to anthrax if the FDA approves its use against anthrax. It will also consider sharing the Tequin license with the government or other companies in the unlikely event the need should exceed the supply.

—GlaxoSmithKline is working with the government on expeditious review of two antibiotics, Amoxil and Augmentin, to be used in the treatment of anthrax. It will make these medicines available to the government free of charge for individuals exposed to, or diagnosed with, anthrax.

—Johnson & Johnson is seeking FDA approval of an existing antibiotic, Levaquin, for the treatment of anthrax and will make up to 100 million tablets of the medicine available to the government free of charge.

—Pharmacia Corporation will make available to the government free of charge an antibiotic, Cleocin HCl, to treat anthrax infection, pending FDA approval for the treatment of anthrax. Other Pharmacia antibiotics are also in laboratory testing to determine efficacy against anthrax and other biological agents.

—Pfizer has increased production of an antibiotic, Vibramycin, which is indicated for the treatment of the cutaneous and inhalation forms of anthrax. Pfizer is also in discussions with public health authorities regarding the possible utility of the company's other human antibiotics. It has also pledged that it will make no profit on medicines supplied to the government to fight bioterrorism.

—Eli Lilly and Company will provide any of its antibiotics that are found to be effective against anthrax at cost to victims of bioterrorism.

PH RMA'S EMERGENCY PREPAREDNESS TASK FORCE ACTION

On October 19, 2001, PhRMA's Emergency Preparedness Task Force met with Secretary Thompson to offer the industry's assistance in responding to the national bioterrorism threats. By October 26, 2001, a follow-up meeting was held with Secretary Thompson to continue sharing information and offering assistance.

As part of this meeting, we pledged to Secretary Thompson a wide array of support. In addition to the Task Force on Emergency Preparedness composed of industry leaders, we also established a Bioterrorism Group of Scientific Experts composed of leading scientists. Through the Task Force, the Bioterrorism Group of Scientific Experts, and myself, we are offering our assistance to the United States Office of Homeland Security, HHS, CDC and any other government agency that we are asked to serve.

On October 31, 2001, our Emergency Preparedness Task Force met with Governor Ridge to offer the industry's support in responding to bioterrorism threats.

In addition to pledging our leading scientists, several companies have stepped forward with other offers of assistance, including:

—Bristol Myers-Squibb will provide a dedicated antibioterrorism team of 20–25 scientists specialized in anti-bacterial research who will initiate a multiprong attack on the microbial weapons of bioterrorism. This team will purse research under government direction and be fully funded by Bristol Myers-Squibb.

—Merck-Medco will help state and federal authorities distribute antibiotics as needed and will use its technology and expertise to transform stockpiles of medicines into individual prescriptions. In New Jersey, Merck-Medco is "on call" to assist the state in dispensing antibiotics to approximately 1,500 postal workers, if needed.

—Pfizer will put its extensive distribution network and warehouses at the disposal of the government to ship medicines as needed.

—Abbott is testing existing antibiotics to see if they would be effective against bioterrorism organisms and offering the assistance of its experts in infectious diseases.

—Johnson & Johnson will makes its scientific and research capabilities, manufacturing facilities, distribution channels and public information and education capabilities available to the government to deal with the crisis.

—Aventis is offering technical and scientific support to the government in the development of new vaccines and antibiotics manufacturing.

—Pharmacia will provide confidential access to its internal scientific information, animal model systems and chemical libraries to government officials.

—The industry will make many of its manufacturing facilities and delivery systems available to the government, upon request.

INDUSTRY'S RESPONSE TO SMALL POX THREAT

In addition to concerns over anthrax exposure, attention and concern is now being focused on other diseases, such as small pox. As you know, the small pox vaccine was credited with eradicating the disease on a global basis. As a result, public health officials terminated the vaccination program within the U.S. in the 1970's.

Several of our companies were initially contacted by the U.S. government in late September about the feasibility of manufacturing a new version of the small pox vaccine. I am pleased to report that they have each made an extraordinary and unprecedented effort, to respond in record time.

Even before the formal Request for Information (RFI), they brought resources to bear on this project, redirecting priorities and surveying existing technical capabilities that could be put into place to address this prospective public health emergency. Within a week of receiving the RFI, our companies were here in Washington making presentations to our nation's public health authorities as to their individual capabilities to produce the necessary amount of small pox vaccine.

This is no small task as the normal course of vaccine manufacturing scale-up is a process than can take 5–8 years.

Our government has requested enough doses of vaccine for the entire U.S. populace (300 million doses) and to have this vaccine available within one year. Our industry stands ready to meet this request.

Since the vaccine has not been produced in nearly a quarter of a century, the United States only has a relatively small amount of this vaccine on hand. In addition, the manufacturing process by which that vaccine was made is not deemed acceptable by modern day standards. Rather than growing Vaccinia (the virus that the small pox vaccine is based on) in cows, a new process of growing it in cell culture must be scaled-up. Developing the appropriate cell culture system and manufacturing capabilities present challenges. However, our vaccine companies can and will meet this challenge. Collectively they have hundreds of company-years of experience in research, scaling up production, and manufacturing and distributing vaccines against many major public health threats.

It is the pharmaceutical industry that manufactured the original small pox vaccine. They have developed numerous viral vaccines for prophylaxis against diseases such as mumps, measles, rubella, polio, and hepatitis and have extraordinary experience in the type of large scale manufacturing operations that lead me to be optimistic that this challenge can be met.

An initial assessment suggests that with extraordinary efforts and an unprecedented crash program, 300 million doses of Vaccinia could be available by the middle of next year. Of course, many tens of millions of doses could be available considerably earlier.

There is no doubt that developing the capabilities to produce enough quantity in a quick time frame will be a massive, unprecedented undertaking requiring companies to retool their production processes on a scale never previously contemplated. Clearly a number of the critical issues will be addressed when the government issues its formal Request for Proposal (RFP) that we understand will be forthcoming shortly.

It is also vital that there be a concerted effort on the part of the FDA to work with industry as this new vaccine is developed. FDA must provide swift and clear guidance to any of the prospective manufacturers of this new small pox vaccine as to the expected requirements for licensure. This is critical as the new process for producing this vaccine is markedly different than the process used in the past. There are two components to this. First, the new vaccine must be evaluated to ensure that it is as efficacious as the older, animal-sourced vaccine. This will require some comparative clinical trials, which should be conducted on an expedited basis. Second, the manufacturing facility or facilities will have to be inspected for manufacturing compliance. It is our assessment that the FDA has all of the requisite authority to make this a priority.

NEXT STEPS

The U.S. government and the pharmaceutical companies have the same goal—protecting the public health. We will assist the government in any way we can to protect the health of our nation's citizens.

We are offering our assistance to the government to help educate consumers and the medical community. We are in the process of establishing a consumer-friendly web site to educate and inform the public. In a meeting with Governor Ridge earlier this week, our companies also offered the use of their work forces, who meet and visit with doctors on a regular basis, to be a tool the government can use to educate doctors about potential public health threats related to bioterrorism.

We will also continue to do what we do—develop new medicines. Today, there are 19 antibiotics and 42 vaccines currently in development, including vaccines for AIDS, malaria and tuberculosis. Continuing research and development of new medicines, both to conquer natural diseases and to assure that our country's citizens have the best possible defenses against bioterrorism. Our armed forces and public safety workers are the nation's first defense. Our country's unparalleled scientific capabilities—characterized by innovation, nimbleness and extraordinary creativity in fighting disease—stand immediately behind them in protecting the public health.

Our government is in the best position to assess the risk of the use of threat agents. This is a difficult task and I know that the health and defense authorities are hard at work on it. We will make our expertise available to assist in designing the right responses to threats. As needed steps are identified, we will do what is necessary to respond, including making the best treatment options available.

CONCLUSION

As I said in the beginning of my testimony, the pharmaceutical industry is prepared to do whatever it takes to win this war. We stand ready to work with the government to identify and respond to threats. Our companies are eager to make contributions to this effort, and we stand ready to be of service.

America's pharmaceutical companies have always been there for our country at times of national crisis. We provided Penicillin for our soldiers in WWII. We responded to the AIDS epidemic, and since the mid-1990's, when the first protease inhibitor drugs were launched and combination drug therapy was introduced, the U.S. death rate from AIDS has dropped 80 percent. We offered medicines, supplies, and financial assistance within hours of the tragic events of September 11th. And we're here for our country again in this time of crisis.

We're in unchartered waters here. We anticipate that this is going to be a long war. And we'll be here for the American people every step of the way. We have what it takes to win this war on bioterrorism—in terms of the innovation, the research, the cutting-edge knowledge, and we'll do whatever it takes to get the job done.

Thank you.

Senator HARKIN. Thank you, Dr. Friedman.

Now we turn to Dr. Barry. Dr. Barry.

STATEMENT OF M. ANITA BARRY, M.D., M.P.H., DIRECTOR, COMMUNICABLE DISEASE CONTROL, BOSTON PUBLIC HEALTH COMMISSION, AND MEMBER, NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS

Dr. BARRY. Good morning. Chairman Harkin, honorable committee members, thank you for inviting me to speak to you today from the perspective of a major urban health department. My name is Dr. Anita Barry and I am the Director of Communicable Disease Control for the Boston Public Health Commission, in the City of Boston, under the leadership of Mayor Thomas Menino.

I am speaking to you today on behalf of the Boston Public Health Commission and also the National Association of County and City Health Officials, or NACCHO. NACCHO represents the Nation's 3,000 local health agencies and NACCHO members serve every day on the front lines to protect the health of their local communities.

As you consider legislation related to bioterrorism and smallpox, I offer you the realities of what dealing with smallpox on a local level would entail. While we have all learned a great deal in responding to anthrax-related bioterrorism, smallpox would be very different. It is highly infectious and can be spread person to person, making it a global as well as a local public health threat.

Thus far, proposals put forward by the administration have focused primarily on creating more vaccines. With smallpox, all the vaccine in the world is not going to do any good without the capacity to distribute and administer this vaccine locally. One thing is very clear. The current levels of staffing, planning, and preparedness at the local level are not enough, even in cities that have initiated bioterrorism preparedness.

Well before September 11, Boston began to prepare for the possibility of a bioterrorist event. City public health officials and safety personnel have participated in Federal emergency planning efforts and have held tabletop exercises to develop city-specific plans. But the recent cluster of anthrax cases, despite the fact that there have been no anthrax cases in Boston, has illustrated the many challenges that bioterrorism presents. These challenges will be magnified manyfold if the disease in question is smallpox, which can be transmitted from person to person, instead of anthrax, which cannot.

If presented with a smallpox case, what would a local health department do? We would first confirm the diagnosis as quickly as possible. But once that happened, we would be faced with a myriad of issues, such as appropriate care for and isolation of the infected individual, identification of the source of infection to determine if others were at immediate risk, identification of exposed individuals who need smallpox vaccination to prevent disease, provision of clinical guidelines for other health care providers in the area to enable them to provide both the best individual and public health care, and the launching of a massive educational campaign for both the public and the health care community.

The local health department would quickly be contacted by the hospital for advice on infection control. We would be asked to perform epidemiologic analysis to identify those at risk in the community. We would have a flood of calls from health care providers concerned that they have the next smallpox case. Citizens would turn

to their local health department with the expectation that vaccination clinics would be widely available ASAP. And all the while, the media would be contacting us to report to the waiting public.

Can a local public health department meet this challenge? I believe that it can, but this smallpox threat highlights the fact that local health departments desperately need increased Federal support in order to plan for and respond to a major infectious disease event like smallpox.

In the communicable disease control program in Boston, we have currently one infectious disease physician and a few nurses, which is not enough for a city with a population of 600,000 residents and a weekday work force of 1.2 million people. Many times this number of clinical and public health personnel would be needed to deal with smallpox, as well as other infections such as meningitis that also urgently demand our attention.

At the most recent Boston Surveillance Task Force on Bioterrorism meeting held last Monday, hospitals were already asking for infection control guidelines related to smallpox. Questions about the imposition and enforcement of quarantine have already surfaced. From my perspective, voluntary in-home quarantine with appropriate support, such as the delivery of medical information, food, and medication, is our most realistic option. But depending on the number of cases, a quarantine facility may need to be set up and staffed as an option for those unable to stay at home.

The Federal Centers for Disease Control and Prevention plays a key role in providing technical assistance of the highest quality. However, expediting direct access to this expertise for local health departments should be a top priority. Already strained State health departments should not have to act as a liaison in this process.

Last week, Boston Mayor Thomas Menino and city public health and safety officials joined mayors from across the country to discuss local preparedness at the U.S. Conference of Mayors Emergency Safety and Security Summit. The following recommendations include public health steps urged by the U.S. Conference of Mayors. These action steps will go a long way to help local public health departments effectively carry out our jobs to protect public health in the event of smallpox or another bioterrorist event.

First, local health departments should be represented at the table at national emergency planning. The Director of Homeland Security should immediately establish a permanent commission including mayors, local public health officials, and local safety officials. Local officials are on the front lines of homeland security and it is essential to forge direct lines of communication.

Second, the technical capabilities and communications infrastructure of local health departments need to be improved. All local health departments should have access to communications systems to receive accurate and timely information from State and Federal authorities. We strongly support full funding and expansion of the Health Alert Network.

Third, Federal agencies should direct significant——

Senator HARKIN. Dr. Barry, could you please sum up, please.

Dr. BARRY. I am. Direct more funding to local communities. Too often, local health departments are left out of the equation, but we bear the burden of the front line response.

PREPARED STATEMENT

In closing, I would like to thank Senators Harkin, Specter, Byrd, and their colleagues, including Senator Kennedy, for recognizing the importance of funding for bioterrorism preparedness, and I would encourage you, as you go forward, to direct funding to those on the front lines, the local health departments.

[The statement follows:]

PREPARED STATEMENT DR. ANITA BARRY

Chairman Harkin, Honorable Committee Members, thank you for inviting me here to speak to you today from the perspective of a major urban health department. My name is Dr. Anita Barry. I am the Director of Communicable Disease Control for the Boston Public Health Commission, the health department for the City of Boston, under the leadership of Mayor Thomas Menino. I am speaking today on behalf of the Boston Public Health Commission and also the National Association of County and City Health Officials (NACCHO). NACCHO represents the nation's 3,000 local public health agencies. NACCHO members serve every day on the front lines to protect the health of their communities.

As you consider legislation related to bioterrorism and smallpox, I offer you the realities of what dealing with smallpox at the local level would entail. While we have all learned a great deal in responding to anthrax related bioterrorism, smallpox would be very different. It is highly infectious and can be spread person-to-person, making it a global as well as a local health issue. Thus far, the proposals put forth by the Administration have focused primarily on creating more vaccines. With smallpox, all the vaccine in the world isn't going to do any good without the capacity to distribute and administer vaccine locally. And one thing is very clear: the current levels of staffing, planning, and preparedness at the local level are not enough, even in cities that have initiated bioterrorism preparedness.

Well before September 11, Boston began to prepare for the possibility of a bioterrorist event. City public health and safety personnel have participated in federal emergency planning efforts and have held tabletop exercises to develop city specific plans. But the recent cluster of anthrax cases—despite the fact that there have been no anthrax cases in Boston—has illustrated the many challenges that bioterrorism presents. These challenges will be magnified many fold if the disease in question is smallpox—which can be transmitted from person—instead of anthrax—which cannot.

If presented with a smallpox case, what would a local health department do? We would first confirm the diagnosis as quickly as possible. But once that happened, we would be quickly faced with a myriad of issues, such as:

—appropriate care for and isolation of the infected individual;
—identification of the source of infection to determine if others were at immediate risk;
—identification of exposed individuals who need smallpox vaccination to prevent disease;
—provision of clinical guidelines for other health care providers in the area to enable them to provide the best individual and public health care;
—launching of a massive educational campaign both for the public and the health care community.

The local health department would quickly be contacted by the hospital for advice on infection control. We would be asked to perform epidemiologic analysis to identify those at risk in the community. We would have a flood of calls from health care providers concerned that they have "the next smallpox case." Citizens would turn to their local health department with the expectation that vaccination clinics would be widely available ASAP. And all the while, the media would be contacting us to report to the waiting public.

Can a local public health department meet this challenge? I believe it can, but the smallpox threat highlights the fact that local health departments desperately need increased federal support in order to plan for and respond to a major infectious disease event such as smallpox. In the Communicable Disease Control Program at the Boston Public Health Commission, we currently have one Infectious Disease physician and a few nurses—not enough to address a major infectious disease emergency in a city with 600,000 residents and a workday population of 1.2 million. Many times this number of clinical and public health personnel would be needed to deal with smallpox as well as other infections such as meningitis that urgently demand our attention.

At the most recent Boston Surveillance Task Force meeting held last Monday, hospitals were already asking for infection control guidelines related to smallpox. Questions about the imposition and enforcement of quarantine have already surfaced. From my perspective, voluntary-in home quarantine with appropriate support (such as delivery of health information, food, and medication) is the most realistic option. But depending on the number of cases, a quarantine facility may need to be set up and staffed as an option for those unable to stay at home.

The federal Centers for Disease Control and Prevention plays a key role in providing technical assistance of the highest quality. However, expediting direct access to this expertise for local health departments should be a top priority. Already strained state health departments should not have to act as a linkage in this process.

Last week, Boston Mayor Thomas Menino and City public health and safety officials joined mayors from across the country to discuss local preparedness at the U.S. Conference of Mayors Emergency, Safety, and Security Summit. The following recommendations include public health steps urged in the U.S. Conference of Mayors National Action Plan for Safety and Security in America's Cities. These action steps will go a long way to help local health departments effectively carry out our jobs to protect the public health in the event of smallpox or other bioterrorist incident:

1. Local public health departments should be represented at the table in national emergency planning. The Director of Homeland Security should immediately establish a permanent commission including mayors, local public health officials, and local public safety officials. Local officials are on the frontlines of homeland security, and it is essential to forge direct lines of communication among the Office of Homeland Security, federal agencies, and local governments.

2. The technical capabilities and communication infrastructure of local health departments need to be improved. All local health departments should have access to communications systems to receive accurate and timely information from state and federal authorities. We strongly support full funding and expansion of the Health Alert Network.

3. Federal agencies should direct significantly more funding to local communities. National public health organizations recommend that at least $835 million of the emergency bioterrorism funding request go directly to local and state health departments. Local communities must receive a significant portion of that funding. Too often, local health departments are left out of the equation, but we bear the major burden of front line response. For example, in Boston, the health department anticipates spending at least $700,000 by the end of this fiscal year on bioterrorism-related emergency medical service response and the surveillance, communication, and coordination activities of the communicable disease program.

4. Federal funding should be flexible—we need to track and respond to a range of public health concerns, including bioterrorist agents as well as influenza and other emerging problems.

In closing, I again thank Chairman Harkin and the Committee for inviting me to speak on behalf of local health departments and NACCHO. I would be pleased to provide any further information in the future.

Senator HARKIN. Thank you, Dr. Barry. Thank you all.

I will turn to Senator Byrd first for questions and then Senator Stevens. But before I do, Senator Byrd, just listening to these witnesses, I thought of comparing our public health officials and our public health infrastructure in America, to our military overseas. If I were to do so, after listening to these people, I would say that if you put it in military terms, our troops are ill-trained, our radar is out of date, and we are short on ammunition with our public health in America. That just seems to me what I am hearing here.

I turn to you, Senator Byrd, for your comments.

Senator BYRD. In other words, as Oliver Twist said, "Heaven is a long way off." We are coming up pretty short.

Well, I thank you, Mr. Chairman, again. I thank Senator Stevens. I am the 23rd chairman of the Senate Appropriations Committee. Now, remember that. There is the best chairman. I have served with a lot of good chairmen on the Appropriations Committee. Where MacDonald sits, there is the head of the table. There

is MacDonald, Senator Stevens, my colleague. As far as I am personally concerned, he is the best chairman I have ever served with.

Now, this is a fine panel, an extraordinarily fine panel. It seems to me that the emphasis here mostly is on building our State and local health departments so that they will be able to respond, so that they will be able to—their labs, building their labs, enhancing their labs, so that they will be able to recognize a variety of pathogens, be able to recognize these pathogens.

I would wager that there are very, very few doctors in the United States who have ever seen a case of smallpox, very few. Therein lies a great need here, a need to be able to recognize smallpox and other bioterrorism pathogens quickly and then, as has been said here, be able to spread the word and be able to take action, be able to isolate and so on.

So let me ask my questions all at once. I have about three or four questions. I will make it easy for you on the panel to answer these questions. I am from a rural State. I say to Dr. Barry, with all respect to the great urban communities of this country: God made the country and man made the town. Now, I am from a rural State. Thank God for that. A small State, a rural people, and my problems—my questions concentrate perhaps on the rural areas.

We all recognize the need, the desperate need, to strengthen the resources of our State and local health agencies. But I fear that one problem may severely limit that effort, namely the critical shortage of well-trained doctors and nurses in our rural areas. So what can NIH or CDC do to bridge this gap in times of medical emergencies? That is question No. 1.

Question No. 2, particularly to Dr. LeDuc. You spoke of the CDC's high tech communications tools—the Internet, email, and so forth. But so many rural health departments do not have access to these communications resources. What is the CDC going to do, and what does it recommend that we do, as members of this panel to overcome this gap?

As we contemplate the dark winter of our discontent, should some medical or emergency workers be vaccinated immediately?

Finally, will the decision to produce so many doses of the vaccine fuel public demand for a potentially hazardous mass immunization campaign? You have indicated that there is some toxicity side effects. Let me speak of one. What happens to those who have asthma, who already have lung diseases, and shortage of capacity, and so on?

That is my contribution, Mr. Chairman. I hope that Dr. LeDuc would begin because I mentioned him specifically.

Dr. LEDUC. Thank you, sir, for those very thoughtful questions. Let me address the specific question you asked about communications in the rural area. It is our plan to develop the Health Alert Network to the local area, to the county level, in all States, and I think we are well on the way to doing that.

I can get back to you for the record—well, maybe I can get to you right now. We are making progress in getting that to all the local county levels. I do not know exactly what the implementation scale is today, but that clearly is one of our highest priorities, especially now that the need is so apparent.

Senator BYRD. Dr. Fauci.

Dr. FAUCI. The question that I could address, Senator Byrd, of the few that you asked is one that is quite relevant and we do need to address it. It is the question of what we call preemptive vaccination, because a lot of people are asking that. We are now on a crash course, as it were, to get enough vaccine to be able to vaccinate the entire population of the United States if necessary.

The public health approach to the identification of a case or cases of smallpox in West Virginia, for example, if that happened, would be to do the approach that you heard mentioned here: you identify, isolate, quarantine if necessary, contact, trace, and vaccinate people in an area that could have come into contact with smallpox virus. That is the classic public health approach to smallpox and is the way that eradication of smallpox was actually accomplished, particularly in developing nations, the strategy that Dr. Bill Foege and others had developed many years ago.

If you have multifocal involvement, where you have many cases in many different places, then you think in terms of a broader, more massive vaccination. I can tell you here today that when we get, and even before we get, enough vaccine to execute something like a preemptive vaccination, a decision needs to be made in a way that is serious and well thought out. The American public needs to hear about this and it needs to be transparent.

Senator BYRD. But what are some of the toxicities that I have heard about?

Dr. FAUCI. The toxicities are as follows, and then perhaps Dr. LeDuc can amplify on them. The toxicities we know come from experience decades ago with vaccination, and there are a few studies that vary with regard to toxicities. For example, the most recent study that we have from 1968 data indicates that for every million people who are vaccinated there will be anywhere from one to four or five deaths associated with the vaccine.

That is generally due to a fulminant response such as encephalitis associated with the vaccination or generalized vaccinia. They are uncommon, but when they occur they are serious. This is relevant to the point that I mention, that if you decide to preemptively vaccinate you must weigh the risk-benefits. I believe this debate is going to occur and it might even occur right here before this committee when that time comes, about whether to do the classic public health approach of trying to isolate the index cases or to think ahead and preemptively vaccinate.

That is a debate that needs to occur in a transparent way for the American people to understand it.

Senator BYRD. I thank you. I do not want to press this further. I am sure that through the questioning of my colleagues here the answers to some of the other questions about the need for more nurses, more doctors, more emergency health responders who will be able to recognize these various pathogens and laboratories enhanced so that they can recognize the early symptoms of these bioterrorist weapons.

Thank you very much.

Senator HARKIN. Thank you, Mr. Chairman.

Senator Stevens.

Senator STEVENS. Thank you very much, ladies and gentlemen. My role here has predominantly been in defense, as I think you all

know. But my basic interests have been in medical research. I am pleased to say Dr. Fauci spent one evening and tried to help educate me. I thank you for that.

But I am constrained to say that if we look at the recent history, the Soviet Union imploded because of the fear of weapons we did not have. I would hate to see us implode because we finance a whole series of actions against fears that could not or would not materialize.

Now, having said that, I would hope that we keep in mind we are into some things that are not detectable. This is a detectable, readily detectable disease if it comes to our community, is it not? It will be readily detectable?

Senator BYRD. The record will not show the nodding of heads.

Dr. LEDUC. Yes, sir. There are virtually no clinically inapparent infections. All infected people will be overt.

Senator STEVENS. I do not want to underestimate the severity of this disease.

Senator HARKIN. Senator Stevens.

Senator STEVENS. Yes?

Senator HARKIN. Could you just yield on that for a little bit of enlightenment on that?

People today do get chickenpox. Do you believe that there are enough health professionals out there that would recognize the difference between smallpox and chickenpox before it got out of hand?

Dr. LEDUC. We have had experience addressing this very issue quite recently and I can tell you that severe chickenpox is extremely difficult to differentiate from classic smallpox. This would be a diagnostic dilemma.

Senator HARKIN. So then your question to Senator Stevens has to be modified a little bit. You nodded your head and said yes, that this is something that would be readily identifiable. But if it is confused with chickenpox, which is rather benign, and is not treated immediately as smallpox, then it could spread out of control very rapidly.

Dr. LEDUC. Well, in fact we are approaching this problem from two perspectives. There is an effective vaccine for chickenpox and we are encouraging health providers to use this, so that we maintain a very high level of coverage for chickenpox immunization, so that we have reduced the risk of having outbreaks of chickenpox.

Senator STEVENS. To show my age, although my senior colleague is not very far off——

Senator BYRD. Do not worry about it.

Senator STEVENS [continuing]. I recall very well both chickenpox and smallpox in my community when I was a boy, and we all got our vaccinations in school and they were automatic. That is another subject, because I was raised by a Christian Science family. So it was a real interesting life that I had.

But as a practical matter I would like to ask you just a couple of questions and see if you can give us the answer—those of us who are old enough to have lived through the seventies were vaccinated for smallpox and I was vaccinated several times. None of those vaccinations have any effect today, is that correct? They are all expired?

Dr. FAUCI. I do not think we can say that, Senator Stevens. I think we can say that from what we classically know about immunology and response to vaccinations, that the immunity that you and I got when we were children and vaccinated is almost certainly diminished. We say "waning immunity." I doubt, as an immunologist and as an infectious disease person, that that immunity is gone, namely zero.

Senator STEVENS. That is my question, doctor. Can those that were previously vaccinated be given a booster, as opposed to those that have never been?

Dr. FAUCI. Yes.

Senator STEVENS. Can you stretch that supply out by saying, you people that were vaccinated before, you get this vaccine; those that have not, you get another?

Dr. FAUCI. No, because the booster for an already vaccinated person, Senator, is exactly the same as a primary for a person who has never been vaccinated.

Senator STEVENS. Then answer another question on an entirely different subject. If an exposure of a community occurred on Monday, how long would it be before a vaccination would not be effective on the populace? How soon do we have this vaccine available to a community after exposure?

Dr. FAUCI. It is approximately 4 days, between 3 and 4 days. Experience tells you that, if you vaccinate an exposed person, you could either prevent infection or significantly modify the disease that that person has.

Senator STEVENS. My other question would be, how effective is real quarantine of a community that has it?

Dr. LEDUC. I think quarantine would be very effective. Isolating patients is what we do, for example, to control ebola outbreaks, where we have no other tools. This interrupts transmission. If you could isolate patients so that they do not come into contact with susceptible individuals, then you can interrupt transmission. We have lots of tools to do that. We can isolate them within established hospital rooms under isolation conditions. We can vaccinate staff even after, as Dr. Fauci said, even after they have been exposed.

So for example, the patient comes into the emergency room and it is determined that that individual has smallpox; we could immunize the attending physician and all those in contact with that patient within four days and certainly alleviate the symptoms and in many cases protect from infection completely.

Senator STEVENS. About the exposure of our community in the case of anthrax, it has obviously taken highly trained people who can refine that product, deliver it without themselves being infected. I have not seen any reports that people who handle it and deliver it have been infected. This process involves a human being with smallpox. Can it be delivered other than by a human being who is infected?

Dr. LEDUC. I do not really have any information on delivery systems. Perhaps others do.

Senator STEVENS. Well, if you had a petri dish here and it spilled, would I get exposed? Or does it take an infectious person who breathes into the air that I breathe?

Dr. LEDUC. You could certainly get it from the virus itself in the equivalent of a petri dish or from a clinically ill individual, that is true. It could be concentrated. It could be disseminated by air.

Senator STEVENS. But I am looking to the question, how can we protect the community against exposure? We have immigrants coming in, we have people coming with visas. To our knowledge, we have no cases of smallpox in the United States today, so this would be something that would have to be imported, right?

Dr. LEDUC. There are no cases anywhere in the world today. The disease has been eradicated, so the virus that causes the illness only occurs in test tubes in stored stocks.

Senator STEVENS. I do not want to prolong it, either, but I think we have a real problem in trying to assess as we go forward now with this money we have available this year the priorities of where we put the money. Very clearly, one of the basic priorities that I have had is the research to determine what substances might be used as weapons.

Dr. Fauci.

Dr. FAUCI. Senator Stevens, let me address directly the direction I believe you were going in, about what we need to do, be it easily recognizable or not, even if we were absolutely correct and expert in recognizing a case of smallpox in this country. That would immediately trigger the need and justification for having vaccine available, because just one case, even if you recognize it totally accurately, tells you that smallpox has been introduced to our society and we need to be prepared with a vaccine.

Senator STEVENS. How about a timetable on that, doctor? If you have an exposure in West Virginia, how soon thereafter with the community at large, the whole country, have to have vaccine if they desired to have vaccine?

Dr. FAUCI. If you fulfilled the strategy of isolating the case and it is only a West Virginia case, and do what I mentioned before about identification, isolation, contact, tracing and vaccination around the case, you can do that at the local level. If you had multifocal cases, then it becomes very complicated.

There was an experiment done that I, interestingly, as a child was part of. That was in 1947 in New York City. There was a misdiagnosis of a case of smallpox that was felt to be chickenpox. An individual went into a hospital and exposed a number of people. Twelve people were infected, 2 people died. The public health approach to that was exactly what we said. There was isolation, quarantine, and vaccination within a 2-week period of 6.3 million New Yorkers, one of which was me at that time. That is how that potential epidemic was curtailed.

That is exactly what the first-line approach would be. The critical issue is if it is a multifocal outbreak, where it is not just New York City or West Virginia, that is the reason why we are talking about the need to have smallpox vaccination on hand.

Dr. BARRY. Could I just clarify for my perspective as a local health person. Let us say we have a case come in the Massachusetts General Emergency Room and the docs there immediately recognize that this is smallpox and they call us at the local health department. First of all, you have to realize that person has been wandering around the city of Boston now for a number of days and

is infectious. So we on a local level are not only going to have to be advising the hospital on types of isolation, but somehow we are going to have to find the staff to try to interview and find out where this person has been in the city.

So you have 4 days from the time you are exposed to get the vaccine and be protected. But we are not going to know where those people are. We are going to have to find those people and we are going to have to have pretrained staff who are going to know how to deliver that vaccine. That is going to be a very challenging task for a local health department.

Also, I have to comment on the issue of community-wide quarantine. I think that is going to be very difficult to do. I think we are really going to have to look at building support structures for people, allowing them to stay for the most part in their own homes.

Senator STEVENS. Doctor, respectfully, I have to tell you that if someone is going to use this as a weapon, you are going to have a peripatetic agent that will probably visit about 10 or 11 terminals in 1 day or 2. I do not think that, if this is to be used as a weapon, we can say it is going to be contained in Boston or Anchorage or somewhere in West Virginia. A weapon is a weapon.

I go back where Dr. Fauci came. I believe in fully available vaccines, but I do not suspect this is going to be some disease that springs out of someone having visited someplace in the world and coming back with smallpox. This comes to us as a weapon and I think we have to think of it as a weapon, not think of it as a public health problem, respectfully. It will be dealing with a weapon, a weapon delivered to our system which we must react to immediately. That does not mean just one community; it means that the Nation is the community.

Dr. BARRY. Oh, I certainly understand that, Senator. But I am just trying to figure out literally step A to step B what is going to happen to get us into that responding to, as you call it, weapons mode. It is going to take a lot.

Senator STEVENS. It will, yes.

Thank you very much. I appreciate your courtesy to me. I am late for another meeting, but I appreciate what you are doing. Thank you.

Senator HARKIN. Thank you, Senator Stevens.

Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman.

With respect to the issue of our preparedness, the testimony and written statements point out that the vaccine will be available by the end of next year, but what do we do now if something should happen immediately? Dr. Friedman?

Dr. FRIEDMAN. If you will, sir, I think that the current stocks of vaccines are the responsibility of the Centers for Disease Control.

Dr. LEDUC. Yes, sir, let me try to answer that for you. As Dr. Fauci said, we have in place a little over 15 million doses of vaccine. That represents our immediate response capability. We have already explored the possibility of diluting that and, for example, as Senator Stevens said, if we think of this as being a formal military attack, I think one of the first challenges or first requests we are going to have is from the Department of Defense.

Senator SPECTER. Let me ask you if there is a way to dilute it, which has been testified to, to increase it substantially, but what can be done now to deal with the population in this country of 280 million people? This subcommittee is prepared to recommend, and I think the Congress will accept, funding for whatever it takes. So what can be done now to have enough vaccines for our entire population?

Dr. LEDUC. We have already begun that process. As Dr. Friedman said, we have met with the major manufacturers. I can tell you, it is a heartwarming experience to have each and every one of these major firms come and say, we recognize this as a major national crisis, we are here to help.

Senator SPECTER. Dr. LeDuc, we understand that the people are willing to cooperate. The question is how fast can it be done. If money were no object—if it was no object; we will make it subjective. If money was no object, how fast can it be done?

Dr. LEDUC. The fastest that we will have a full 300 million doses for the entire population is roughly by the end of next year. Actually, it will be more towards the middle, third quarter of next year, those vaccines.

Senator SPECTER. By the third quarter of 2001?

Dr. LEDUC. 2002.

Senator SPECTER. 2002.

Dr. LEDUC. Calendar year.

Senator SPECTER. Dr. LeDuc, that is not adequate.

Dr. LEDUC. That is as fast as it can be made. Now, let me explain also that this will be an increasing slope. In fact, we are already producing the vaccine, the new vaccine——

Senator SPECTER. How soon can we have it, if not for 300 million people, for 100 million people?

Dr. LEDUC. We are talking with the major manufacturers. Their lot sizes are roughly 20 million doses. When they get going, they produce these in a matter of a couple of weeks. It takes——

Senator SPECTER. Dr. LeDuc, let me ask you to go back to the drawing boards and you, Dr. Friedman, as to what can be done to expedite it.

Dr. LEDUC. Sir, I think that we have pushed this system absolutely as much as we can. I do not think that we can make it go any faster than we already are.

Senator SPECTER. Well, let me ask you, notwithstanding that, to go back to the drawing boards and let this subcommittee know within a week what can be done with more intensity. We have found a lot of lines that we can do more if cost is no object, a life and death situation.

Dr. FRIEDMAN. Senator Specter, may I just interrupt for one moment, because I wanted to just give some amplifying remarks, if I may, sir. Something unprecedented is being offered by our pharmaceutical companies. What they have said is, irrespective of the contracting process, whoever gets that contract, the other companies are willing to dedicate their scientists and their production facilities in order to meet this need.

Now, there are other legal implications of that that have not been fully explored. But when I say that our companies are pre-

pared to do things that have never been done before, that is what I am talking about.

Senator SPECTER. Dr. Friedman, I understand that. I understand that they understand it is an emergency. But the question is how soon for 100 million people or how soon for 200 million people and how soon for 280 million people. We know they are prepared to move ahead, but how soon if cost is no object.

I want to turn now to the question of vaccination. Under normal circumstances, you do not vaccinate because the risks of vaccination are higher than the risks of contracting smallpox. The Washington Post had last Sunday characterizing "Smallpox may be the scariest thing in the biowarfare arsenal." Specifically when the Post writer Shannon Brownley comes down to the issue of vaccination, the statement is made: "A biological attack with smallpox virus, though perhaps not as unlikely as it was just weeks ago, is still a low probability, high impact event."

The experts are said to be opposed to vaccination because of the adverse consequences. Well, it seems to me that that is a valid conclusion under normal circumstances, when you take the likelihood of bad reaction or even death. But I question that in the context of a bioterrorist attack. Now, that is very, very hard to quantify, but it seems to me as a matter of common sense that vaccination may be preferable. But those odds are totally changed.

What about that, Dr. LeDuc? First of all, what are the risks with vaccination? I had heard one out of 4,000 would result in death. Dr. Fauci says no. What are the risks, Dr. Fauci?

Dr. FAUCI. There is a bracket depending on the study and the bracket goes anywhere from one to six per million deaths. There are a lot of serious complications that do not necessarily result in death, but mortality is anywhere from one if you look at the 1968 study, or an early study, it goes up to six or so per million.

Senator SPECTER. So why not vaccinate if the risks are that proportioned? Dr. Fauci?

Dr. FAUCI. As I said before, Senator Specter, I believe that we should seriously consider that, depending upon what the risks are. Right now the risk is unclear with regard to the unleashing of a smallpox bioterrorism attack.

Senator SPECTER. Dr. Fauci, are the risks ever going to be other than unclear?

Dr. FAUCI. If you have good intelligence or an index case—let me, if you would permit me, Senator, to just very quickly go through some scenarios. If you have very good intelligence and we know there clearly is smallpox available and it will be used as a bioterrorism weapon, that weighs toward what you are alluding to. If there is an index case, even if it is not in the United States, that weighs a little bit more. If we have an index case, that makes it very, very heavy.

So myself as a physician, as an infectious disease person, am not at all against vaccination. But we need to weigh the risk-benefits as they evolve. There is a risk, but it may be that those risks should be acceptable. I would not deny that at all. It is entirely conceivable that we will have to accept those risks and vaccinate people. But at this point in time, given the uncertainty as to whether or not there is even material available to mount a bioter-

rorism attack, we do not have the material yet, so we do not have enough even if we wanted to vaccinate everyone.

As we get it, we need to sharpen the debate about whether or not we should preemptively do it. So I think we are on the same channel. You are not hearing me say that we should not do that.

Senator SPECTER. Well, I do not think that we are ever going to have intelligence to tell us that a bioterrorist attack with smallpox is imminent. If we could not find out that they were about to crash into the World Trade Center and the Pentagon, we are not going to find that out. Our intelligence, we just cannot rely upon our intelligence. So I think the time is upon us now to get the maximum amount of vaccine available, which we have already discussed, and then at a minimum to leave it up to people to make the decision as to whether they want to be vaccinated.

That is not really a governmental decision. Tell the American people what the risks are, have the vaccine available, and let them make the decision.

Dr. FAUCI. That is an entirely reasonable approach.

Senator SPECTER. My judgment would be to have my four granddaughters vaccinated. It is one in a million that they are going to have an adverse reaction. It is our job to get the vaccine available. I do not think that—it is not your province to decide what the risk factor is of bioterrorism. That is the province of the Department of Defense or the Central Intelligence Agency, with perhaps some inputs from the Congress.

But you tell us what the risks are and get us the vaccine and let us leave it up to the American people to make their choice.

Dr. FAUCI. What you say makes very good sense, Senator, and as a matter of fact, my own children, I would take the risk of having them vaccinated if given the choice of having it. So I agree with you. I think that is something that should be discussed in detail because it makes sense.

Senator SPECTER. Now we are on the same wavelength.

Dr. FAUCI. Yes, okay.

Senator SPECTER. Put aside the risk factor. We are not going to figure that out any better than we know it now. Let us get the vaccine available and let us have the fathers and maybe even some of the grandfathers make choices.

One more question to you, Dr. Barry. One infectious disease doctor in Boston. How many in Philadelphia? I know you do not know the answer to that, but what can you do? Or Pittsburgh or Harrisburg or Russell, Kansas. What can you do to make more infectious disease doctors available?

Dr. BARRY. Well, the issue is within the city health department. There is one infectious disease doctor within the city health department to deal with bioterrorism, meningitis, hepatitis, tuberculosis, and what can you do? You can increase funding for local health departments so they can hire people.

Senator SPECTER. Okay, that is the city health department, but how about the medical personnel generally in Boston? There are more infectious disease doctors?

Dr. BARRY. There are many excellent infectious disease doctors in the city of Boston and they have been wonderfully cooperative in working with us in our planning efforts. However, their focus is

not on public health. Their focus is dealing with their patients in the hospital or in their practice.

Senator SPECTER. Have they been organized in the event of an infectious disease bioterrorist attack?

Dr. BARRY. Yes. In fact, in 1999 we got about a $1 million grant over 5 years from the Centers for Disease Control to develop a specialized surveillance system and to develop that system we created a citywide task force that included emergency department and infectious disease personnel from all the hospitals in Boston.

Senator SPECTER. Dr. Barry, would you provide to this committee just what you have done there, how many infectious disease doctors there are, what organization there is to pull them into a coordinated response to an attack? I think that is something that we will inquire of other cities, to see what assistance may be necessary.

Dr. BARRY. Sure, no problem. There are infectious disease societies.

[The information follows:]

EMERGENCY COORDINATION AMONG PHYSICIANS IN BOSTON

Emergency Department and Infectious Disease physicians from 9 Boston hospitals as well as physicians from Boston Emergency Medical Services and the Massachusetts Department of Public Health are members of the Commission's Surveillance Task Force. These doctors receive daily reports on emergency department and acute care site volume, frequent clinical advisories from the Boston Public Health Commission, and participate in regular Task Force meetings to monitor and improve the Special Surveillance System.

The Boston Public Health Commission is also in close communication with the Conference of Boston Teaching Hospitals, which receives the regular clinical advisories and forwards these to member hospitals.

Surveillance Task Force physicians have worked with the Commission to develop a "train the trainer" curriculum and implement a program to teach other physicians, nurses and other health care workers about bioterrorism.

Despite intensive education, healthcare providers have relied on Dr. Barry, and the Boston Public Health Commission for guidance on anthrax and other bioterrorism related issues. For example, physicians consult Dr. Barry regarding whether a patient's symptoms and exposure to a "suspicious substance" require antibiotic treatment. In another case, a doctor called the Commission for guidance regarding appropriate measures for a patient complaining of fever and pox. The Boston Public Health Commission assisted in determining that the patient was suffering only from chicken pox.

Dr. Barry also serves on the Public Health Executive Council of the Massachusetts Medical Society and has contributed to the development of educational materials as part of their education group.

We are continuing to discuss ways to better coordinate communication and response efforts among the hospital and public health and public safety agencies of the City. However in the event of a public health emergency, the Boston Public Health Commission will have the primary responsibility for centrally coordinating communication and response efforts.

Therefore, we need more clinical personnel in Boston Public Health Commission, specifically the Communicable Disease Control program, which has played a unique role in a public health crisis. To increase clinical personnel at a large city health department, what is needed is simply additional funding.

Senator SPECTER. Do you have access to the information which is in the hands of Federal authorities, or do you have a problem? Local police departments are complaining that the FBI will not share information.

Dr. BARRY. We have a lot of information available. I think sometimes it would be a little easier for local health departments to be able to deal directly with the technical expertise available at CDC,

as opposed to having to almost always work through the State health departments.

Senator SPECTER. Would you say in the event of bioterrorist attacks with smallpox we need a massive education program?

Dr. BARRY. Yes.

Senator SPECTER. Should we not start that now?

Dr. BARRY. Yes. In fact, we have, as well as we can with our resources, started. We have fact sheets developed on smallpox. We have started to talk to health care providers as part of an educational series. But again, we have limited staff. We have started this process, but we clearly need more to be able to finish it.

Senator SPECTER. Would you provide the information as to what your educational program is?

Dr. BARRY. Certainly.

Senator SPECTER. That is something the subcommittee would like to look at——

Dr. BARRY. Certainly.

Senator SPECTER [continuing]. To see what funding is appropriate for you and for other similarly situated health departments.

[The information follows:]

BIOTERRORISM EDUCATION IN BOSTON

The Boston Public Health Commission (BPHC) has engaged in several initiatives to educate providers and the general public about bioterrorism. In addition, we have conducted trainings and disseminated information on workplace mail safety procedures for other City agencies and a number of major businesses.

Train the Trainer for Health Care Providers

As mentioned previously, the Surveillance Task Force has developed a bioterrorism lecture. BPHC also operates a "train the trainer" program for lecturers. BPHC provides the lecture in a CD–ROM format and also provides written materials for dissemination at lectures. BPHC updates the lecture regularly. To date the lecture has been delivered at Boston hospitals, university health centers, a major HMO, and at schools of public health and nursing.

Clinical Advisories

The Commission's Communicable Disease Control Program develops regular clinical advisories for health care providers with guidance on the latest national and/or local incidents, symptoms, diagnosis, treatment, and any other recommendations from the U.S. Centers for Disease Control and Prevention. These advisories are sent out to all members of the Surveillance Task Force, community health centers, Conference of Boston Teaching Hospitals, university health centers, hospital-based internal/primary care providers and school based health services as well as posted on the BPHC website.

Training Commission Staff

The Commission has identified key clinical staff from all its programs as well as key non-clinical staff with the capacity to serve as public educators and staff the hotline in the event of a major mobilization. These staff have received in-depth training regarding bioterrorism issues and response plans.

General Public

In addition to regular media appearances by BPHC staff, the Commission web site is regularly updated with the latest news and recommendations, in addition to fact sheets about bioterrorism in many languages. See www.bphc.org for this information. This information can also be accessed through the City of Boston website at: http://www.cityofboston.com/.

A dedicated phoneline has been established with a recording in Spanish and English. Staff is available to answer questions in both languages during usual business hours. A manager on call is available by pager to answer urgent questions after hours.

The Commission also partnered with the state health department to develop a supplement on bioterrorism for a major daily newspaper offering practical informa-

tion for readers, and a monthly health education column in community papers provides similar practical information.

Senator SPECTER. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

Well, this has been a very informative gathering. I thought I would start my line of questioning by responding a little bit to what Senator Stevens had said. I had interrupted him once. I did not want to interrupt him again. But regarding the point that Senator Stevens made about building up and spending all this money against a nonexistent threat, let me put a different face on it.

I remember the farewell speech that another former chairman of this full committee gave when he left the Senate, Senator Mark Hatfield. I was sitting on the floor listening to that, and I remember he was talking about where we ought to be focusing our attention in terms of governmental spending. I think that is sort of the gist of what it was.

He said: No longer is the threat that the Russians are coming, the Russians are coming. He said: The threat is the viruses are coming, the viruses are coming. I will never forget that. Now, he was not talking about it in terms of a bioterrorist threat. That was not even on the horizon. He was talking about it in terms of the naturally occurring viruses that mutate over time, that evolve and threaten us periodically, the new pathogens that arise. Maybe we dealt with one, but over time they mutate, they become stronger, they develop different strains that we have to attack.

Sometimes, as we know, they can become very virulent, HIV for example. We still do not know how to attack the HIV virus, but it has killed millions and millions of people.

So building up against a nonexistent threat. Well, maybe in terms of the bioterrorist threat, it may be so. But if we build up, we protect ourselves against the naturally occurring disease threats that also may come down the pike in the future.

There is an old saying, there is no dark cloud but what has a silver lining. Perhaps out of what is happening to us in this country may come a silver lining. Now we recognize the need to bolster our public health system in this country and around the world.

I just think for too long we have just sort of skimmed by, and now we recognize in this hour of darkness that we have in our country right now the need to respond to the possibility of man-made threats. But out of that comes the possibility that we will also build up our defenses against the non-man-made threats that come down the pike in the future.

So I see it a little bit differently, that it is an existing threat. As long as there are viruses and pathogens in the world, there is that threat. Regarding food safety, we lost about 5,000 people I think in New York in the World Trade Center buildings, but last year there were about 5,000 who people died of food-borne illnesses in the country. Millions more got deathly sick and lived. So we are finding that some of these strains in our food are becoming more virulent than they were in the past, strains of salmonella, botulism, things that we have attacked with antibiotics over time, but they have become more resistant and they have become harder to attack.

So our public health system needs to be beefed up. Regarding communications, Dr. LeDuc, I believe it was in your statement that only 13 States, 13 States, have connections from their central State public health office to all of the local public health offices. Is that right?

Dr. LEDUC. That is correct, sir.

Senator HARKIN. That is abysmal. I found out that there are some States that do not even have 24-hour, 7 day a week response from their hygienic labs. Some States do, some States do not. I do not know how many there is like that.

You talked about the Health Alert Network. Senator Byrd said in his opening statement that there are some of them are not even hooked up to the Internet. They do not even have a fax machine to be able to respond. Right, Dr. Barry?

Dr. BARRY. That is absolutely true. There are some small community health departments that do not have fax machine, Internet access, that is true.

Senator HARKIN. I will bet you they are mostly in our rural areas. That is where they mostly are. There may be some in cities too, but I bet you in rural areas there are even less.

So I make those points again just to say that we are all on the right track, Senator Byrd. You are on the right track in getting this money out there to beef up our public health system in America. Certainly there are different priorities.

Right away, I think the first priority is to ensure that we have adequate vaccines against smallpox. We are on the way to that, and I am going to ask a couple of questions about it. But then we need other kinds of responses for the other type of weapons of mass destruction that might be introduced by a terrorist.

But then beyond that, I think we have to do other things. By the way, Dr. LeDuc, I was a little remiss in not thanking you for the phone call last week. I had a lot of my colleagues asking me all these questions about smallpox and I did not have the answers, so I had to get some answers, and I appreciate that.

Dr. LEDUC. It was my pleasure, sir. Thank you.

Senator HARKIN. I listened to Dr. Barry speak about the lack of coordination and the Health Alert Network. Is there a manual, is there a blueprint, is there something that a local health department could go to and say, we have got something here, open the book, here is what we do? Is there such a blueprint, is there such a manual from CDC?

Dr. LEDUC. Yes, sir, there is. It is just in final review stage. That will be sent out in the next couple of weeks as a draft, with "Draft" on the top, so that we can get more active feedback from the local level. That is, a very comprehensive plan, and is ready to go.

Senator HARKIN. Will that be made available on the CDC website? How will local health departments get this? You have got to get it out there in a hurry.

Dr. LEDUC. Well, we will certainly use the Health Alert Network as part of that distribution process. I can get back with you for the details of how else we will get it out. I do not have that off the top of my head, but I will.

Senator HARKIN. That needs to be gotten out there in a hurry, because as I understand it there really is no blueprint right now.

There is not a cookie-cutter type of an approach that you can go to and say, here is what we do if this happens.

Dr. LEDUC. It is virtually done.

Senator HARKIN. Now, let us get back to smallpox again. It is my understanding that there are some 400 different strains of smallpox. Is that true or is someone telling me a story here? Dr. Fauci or Dr. LeDuc?

Dr. LEDUC. We have over 400 different isolates from individual patients that are in the CDC collection. That collection was accumulated as the global eradication campaign proceeded. They were put into two different repositories, one at CDC and one in Russia. There are about over 400, about 450 isolates.

Senator HARKIN. Will the vaccines that we have on hand, the 15.4 million doses that we have on hand, that was developed through the old methodology, will that protect against all those strains?

Dr. LEDUC. Yes, sir. This vaccine was used in the global eradication campaign and did protect against wild-type smallpox.

Senator HARKIN. That is comforting to know.

Now let me ask the follow-up question. Regarding the vaccines that you are now developing that are not based upon the old methodology, how confident are you that those will also protect against all those strains?

Dr. LEDUC. We are working very closely with the Food and Drug Administration to develop a strategy to show that the vaccine is not inferior, the new vaccine is not inferior to the old one.

Senator HARKIN. Tell us how you will do that and how long will it take?

Dr. LEDUC. It is being done now. In fact, there is a number of pre-clinical tests have already been done, animal experiments, cell culture experiments, these sorts of things, and at every point we have shown that the new vaccine is identical to the old vaccine.

Senator HARKIN. But you do have to go through some clinical trials, do you not?

Dr. LEDUC. The clinical trials that we will look at are primarily focused on safety—well, making sure that it does not make people sick, then making sure that it produces the kind of immune reaction that we know is protective.

Senator HARKIN. Now, you are absolutely certain, 100 percent certain, that the stored vaccines will protect against all of them because it was used in the worldwide eradication?

Dr. LEDUC. Yes, sir, we are.

Senator HARKIN. Give me your level of confidence in the new vaccines and the ones that are developed in the petri dishes?

Dr. LEDUC. I am very, very confident that this will be equally as effective. There is a very small difference in the new vaccine versus the old one. It is only in the method of manufacture. We no longer make it in calves; we make it in cell culture, which is the way we make virtually all of our other viral vaccines.

Senator HARKIN. As confident? Are you as confident as the old ones?

Dr. LEDUC. You said 100 percent. I am 99.9 percent.

Senator HARKIN. That is pretty good.

Dr. Fauci, in your prepared statement you mentioned there is an anti-viral, I cannot even pronounce it, called Cidofovir.

Dr. FAUCI. Cidofovir.

Senator HARKIN. What?

Dr. FAUCI. Cidofovir.

Senator HARKIN. Cidofovir has been found effective against smallpox. Can you tell us more about this, and will it work?

Dr. FAUCI. Yes. As I mentioned in my oral statement also, Senator, cidofovir was originally developed as an anti-viral against cytomegalovirus for the purpose of treating that complication in HIV-infected individuals. In studies that have been performed in an animal model in which animals were challenged with pox viruses with strong resemblances to smallpox, a variety of viruses, it proved to be highly effective in treating in that animal model, primate monkey model.

Based on that, an investigational new drug application has been taken out to determine, as a secondary backup, if cidofovir could be used in our vaccination programs when people get a reaction against the vaccine. The first thing you would do is to give vaccinia immune globulin. We are going to use cidofovir as a backup. We are also pursuing developing or getting an IND for its use in the treatment of smallpox.

The animal model data are very impressive, but, as is always the case with an animal model, there is a leap from the animal model to the humans. So you cannot say, as Dr. LeDuc mentioned with regard to his confidence in the smallpox vaccine, you cannot have that same confidence in an anti-viral since it has not been tested in humans with smallpox.

But if you look at the data that emanated from the animal studies with similar pox viruses, it is quite impressive, the data. That is the reason why investigators are not only pursuing cidofovir itself, but they are doing a large screening on drugs that are of the class of cidofovir to see if you could come up with even a better one.

Senator HARKIN. That is being aggressively pursued?

Dr. FAUCI. Quite aggressively, yes.

Senator HARKIN. Is that under your guidance?

Dr. FAUCI. It is a combination of ourselves and the Department of Defense USAMRIID.

Dr. LEDUC. And the CDC.

Dr. FAUCI. I am sorry, I am sorry. When I say "us," we do everything together. I take it for granted. It is the CDC, NIH, and USAMRIID.

Dr. LEDUC. Let me just add to that, sir, for clarity. We are actually, and have been for the past 2 years, working with live Variola virus, the virus that causes smallpox, at CDC in our maximum containment laboratory. Senator Specter saw the space suit laboratories. We are actually doing the testing of the drugs that Dr. Fauci mentions against the virus itself.

Senator SPECTER. I saw those when I made the trip down there.

Dr. LEDUC. Yes, sir, you did.

Senator SPECTER. Are you improving those conditions? We have got $170 million last year, $250 million this year, long before this was a focus of attention.

Dr. LEDUC. We are indeed. Thank you very much for that. We thank you for that.

Senator SPECTER. All you had to do was ask.

Dr. LEDUC. Thank you.

Senator HARKIN. I just might say to Senator Byrd, both of us have been down there and looked at CDC. We paid a lot of attention to NIH, rightfully so. We doubled their funding in about 5 years, Senator Specter and I.

Senator SPECTER. May I interject at this point, Mr. Chairman, just for a comment or two?

Senator HARKIN. Let me just finish my statement. I was just going to say that we both visited CDC. The CDC is our front-line defense in America against illnesses and public health. They are spread out all over the place. Some of their labs date back to World War II buildings, really, literally. I could not believe it when I saw how out of date they are.

In fact, I learned when I was down there, they made a movie, one of these scary movies.

Dr. LEDUC. "Outbreak," I think, "Outbreak."

Senator HARKIN. "Outbreak." I saw it. It is one of those movies about an outbreak of disease. They wanted to film a movie, they wanted to film at CDC to show the buildings and how they do all of this. I was told that the buildings were so decrepit and old that the movie producers decided to build their own set because the people would not believe it.

Is that true?

Dr. LEDUC. Yes, sir, that is true. But we are getting better and we appreciate your help.

Senator HARKIN. I am just saying that is why we need to rebuild that. Can we use the movie set? No?

Senator SPECTER. I wanted to make a comment about our level of preparedness and it ties in to what happened with the Center for Disease Control. There had never been a request by the Department of Health and Human Services to improve the physical plant there. Senator Harkin and I heard about it from the people in Atlanta and we took the initiative to go down there. I spent a Sunday taking a look at it and had a hard time. I had heard that it was awful, but what I had heard was wrong. It was worse.

On the initiative of this subcommittee, last year we put in $170 million. That is hard to find in our budget, but we did it because of the importance. This year we put $250 million in before September 11 occurred. But to be candid or really blunt, I do not like what I am hearing today. Senator Harkin says we are on the right track and I think we are, but we are a long way from the station, just a long way from the station.

Now, when it came to the National Institutes of Health this subcommittee took the lead 6 years ago to ask a lot of hard questions. We saw what NIH could do on Parkinson's and Alzheimer's and heart disease and cancer, and every year we brought in the 25 directors of NIH—you were always here, Dr. Fauci—and we said, if we give you a billion dollars more next year, what can you do with it? Then we put a billion in 5 years ago.

We had to take it out of the budget that we had because the Budget Committee would not give us more. $2 billion the year after

and $2.3 billion. Every year we brought in the experts and said, what did you do with the extra money last year and if you get more money what will you do with it next year.

But we did not have the foresight to ask you about diseases. Candidly, Dr. LeDuc, I think the Center for Disease Control should have come to this subcommittee and should have said, smallpox is a problem, we have only got 15 million vaccines, maybe we can dilute them one to five.

Now, I asked Dr. Koplan, the head of CDC, on October 23 to give us a list of all the possibilities of bioterrorism and what it would cost. But I think the American people have the standing to be very dissatisfied with what their government has done. The first responsibility of government is security of the people, and we have so hamstrung the CIA when we had people who were informants that were not Boy Scouts that we precluded the CIA from having those informants to deal with intelligence. So we are vastly unprepared on intelligence.

Now you could itemize the dangers of smallpox which we are talking about today, and as we took the initiative on NIH because we understood that, and we talked about bioterrorism, we put a lot of money into it, but not nearly enough. So I think what we really have to do is face up to the failures and find out how fast it can be done.

I think the American people have a right to be very dissatisfied with what we have done for them.

Dr. LEDUC. Sir, I will relay that message.

Senator HARKIN. Dr. Friedman, did you have something you want to add?

Dr. FRIEDMAN. Not directly to Senator Specter's point, but if you will allow me to go back to the point you were making, Mr. Chairman, if you would allow me to make just a brief comment on the military metaphor that you talked about. Senator Specter was talking about it, Senator Byrd as well. There are differences between wars. You make a mistake if you compare one with the other. But if you think that we were not well prepared when World War II started, the country had to do a lot of work and there were a lot of mistakes made in terms of how quickly we came up to speed, it is not inappropriate to make that comparison.

From my point of view, if you think that our industrial might really helped us to win World War II, and I think that most people would say that it did, what I would suggest to you this morning is that for this war the pharmaceutical industry is the most pertinent power for helping us to defend our freedom. We are not going to do it alone, but we are going to provide the weapons for the public health infrastructure that everyone is talking about here today and which absolutely needs to be improved.

We can provide those weapons and we want to be the industrial might that helps win this war.

Senator HARKIN. Dr. Friedman, as a matter of fact I had a question here. Dr. Friedman, what do we need to do to move this forward more rapidly? I made a note here about joint government-industry effort like World War II.

Dr. FRIEDMAN. Yes, sir.

Senator HARKIN. Just like what we did in World War II. The government joined with the auto industry, it joined with the aircraft industry, it joined with all kinds of industries in a joint effort. I think we can use that.

You are right, not every war is the same. But it seems to me that you are right, the pharmaceutical industry in this country is the best in the world. We take a back seat to no one. Our pharmaceutical industry, our research scientists, our ability to develop and bring to market new drugs and new remedies is unparalleled anywhere in the world, anywhere in history, any time in history.

Dr. FRIEDMAN. That is right, sir.

Senator HARKIN. It seems to me this is the group we have got to go to now to ramp up and to provide the kind of protections our people need. I hope that with this committee and with other committees of the Congress that we could have that kind of joint government-industry cooperation. I see no reason why we cannot.

Dr. FRIEDMAN. We appreciate that, sir. Thank you.

Senator HARKIN. Senator Byrd, I know I wanted to recognize you. You said you wanted to say something?

Senator BYRD. Mr. Chairman, I found so interesting your questions and the questions of others on the panel. I feel that I have gained a great deal of knowledge here today and I think that we four, you and Senator Specter and Senator Stevens and I, are in a position here on this Appropriations Committee to do something about this war and I believe we will.

Now, my mother died in the great influenza epidemic in 1918, and people contracted the disease one day and were buried the next or perhaps died the same afternoon. That epidemic killed 20 million people around the world, 12 million in India and probably 750,000 in this country.

My question would be this. I hardly know how to phrase it. In the context of today's circumstances, today's treatments, today's abilities to recognize anthrax, smallpox, and influenza, and all of the various aspects, if an enemy were to seek to somehow spread any one of these three pathogens, how would you rate the one most dangerous, the one most dangerous to us as a Nation, the one perhaps most easily spread by an enemy?

Which would be worse—I will narrow it down—between anthrax and smallpox? If you were the enemy, which would you think could cause the greatest damage to our country—that is No. 1.

No. 2, what is the lifespan of the smallpox virus? If it were released into the air over in McLean where I live and if the wind is blowing this way, how long, how far would that virus be potent? What is its lifespan?

That leads me to think that if an enemy sought to diffuse this smallpox virus in the air somehow, if he were of a nation across the Atlantic, would he need to be cautious lest this wind drive this virus across the sea to his own country?

Dr. LEDUC. I do not have accurate information on the stability of smallpox virus. I know it is a rather stable virus, especially in the crust after a person has been infected. As an airborne particle, I would assume, like many viruses, that it would be degraded over time by UV, sunlight, radiation. I do not think it would be crossing

any oceans. It would be a matter of hours, I suspect, before it is inactivated. But that is strictly my personal guess.

Senator BYRD. All right. As between this and that, as I said earlier, which would you——

Dr. LEDUC. Well, I certainly do not want to place public challenges on which is better.

Senator BYRD. No, not which is better, but——

Dr. LEDUC. Which is worse, exactly. Actually, we know that there will be influenza outbreaks and I think that this is an area in which we need to remain vigilant. Regarding the comparison between smallpox and anthrax, anthrax is no longer a theoretical risk. I think we need to be very prudent in our approach to this, and I think likewise the steps that we are proposing to take in preparing the Nation for smallpox are equally prudent and essential.

Dr. FAUCI. Senator, as a fundamental principle a microbe that could be transmitted from one person to the other is inherently more dangerous than a microbe that cannot, that does not have that characteristic of transmissabiltiy. So smallpox, being able to be easily transmitted, as well as an aberrant form of influenza like we experienced in 1918, is inherently more dangerous than an agent, regardless of how virulent it is, that can only attack the person exposed to the agent.

Senator BYRD. Mr. Chairman, this is the first line of defense.

Senator HARKIN. You are right, this is it, and we will do our utmost to meet our obligations to give you all the tools you need to work with industry and to work with our local public health departments, to try to get them up to speed, trained, equipped, and working closely with the Center for Disease Control.

We have an opportunity now. We have an opportunity to build the kind of public health system in the United States that we should have done 20, 30 years ago. I believe by doing so we will not only protect our people against the man-made threats, but against the naturally occurring threats that may be coming down the pike also. So out of the dark cloud that is what I see as our silver lining. That is what we will do.

Senator SPECTER. I have another question or two, Mr. Chairman.

Dr. Fauci, in 1994 the budget for the National Institute for Infectious Diseases was $1.063 billion and the current is $2.063 billion. With the increases which this subcommittee has proposed, next year it is going to be $2.375 billion. My question to you is, when we have doubled it and now projecting more than doubling it, has your department in NIH on infectious diseases directed a significant amount of that increase to bioterrorism?

Dr. FAUCI. The increase, yes, Senator. The relative increase of bioterrorism resources compared to the relative increase of other infections, it is on a steep——

Senator SPECTER. Could you give us a ballpark figure?

Dr. FAUCI. Yes, I can do that. If you look at—I can just give you some numbers on bioterrorism from our Institute. In year fiscal 2000—excuse me—fiscal 1999, it was $23.8 million. In the year 2000, $32.6 million. Then it jumps up in 2002 to President's budget of $81.5 million.

Senator SPECTER. Well, I suggest to you that $23.8 million and $32 million are a very, very small part of $2 billion.

Dr. FAUCI. I agree with you.

Senator SPECTER. I think you need to do better.

Dr. FAUCI. We will. I agree with you.

Senator BYRD. Would the Senator yield?

Of the $81.5 million in the budget, how much did you ask for? You have standing between you and the budget the Office of the OMB.

Dr. FAUCI. Right.

Senator BYRD. And they generally cut what you request. How much did you request?

Dr. FAUCI. The initial request was about that ballpark, Senator. But a lot of things happened between the original request and where we are standing right now vis a vis the assessment of that.

Senator SPECTER. Senator Byrd, this subcommittee has seen to it that OMB does not stand between NIH and funding.

Senator BYRD. Hallelujia.

Senator SPECTER. Last year the President asked for a billion dollars. Senator Harkin and I took the lead and put in $2.8 billion. We have made a determination on priorities as to how important NIH was.

But I am a little disappointed, Dr. Fauci, that you only used $32 million of that money for bioterrorism.

Let me say this to you, Dr. LeDuc. I already asked Dr. Koplan, the head of the Center of Disease Control on October 23rd for a list of agency problems in bioterrorism and what it would cost. Go back and give us a figure as to what it would take, what would it take on smallpox to have the vaccine for 280 million Americans. Then go down the list and tell us what it would take, and let us make the decision as to whether we are going to fund it or not. That is a decision for Congress. That is Congress' job. Your job is to tell us what it takes.

You listened to the Boston Public Health Service and Dr. Barry who is struggling under circumstances which are disgraceful—one infectious disease doctor. So if there is going to be follow-up here, let it rest with the Congress. You tell us what it takes and I think we will provide the resources.

Dr. LEDUC. Well, I will certainly relay that message.

Senator HARKIN. With that, we thank you all very much, and thank Senator Byrd for gracing us with his presence and for his interest and leadership in this area. We thank you so much. Thank you all for your leadership in your respective areas. We look forward to working with you.

SUBCOMMITTEE RECESS

Thank you all very much for being here, that concludes our hearing.

[Whereupon, at 11:01 a.m., Friday, November 2, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

FUNDING FOR BIOTERRORISM PREPAREDNESS

THURSDAY, NOVEMBER 29, 2001

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN,
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:08 a.m. in room SD–192, Dirksen Senate Office Building, Hon. Tom Harkin [chairman] presiding.

Present: Senators Harkin [presiding], Kohl, Landrieu, Specter, and Stevens.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health, Human Services, and Education will come to order. Today marks the subcommittee's fourth hearing this year on bioterrorism. This morning we will focus on the resources required to improve our public health infrastructure and protect Americans from a possible biological weapons attack.

In recent years this subcommittee made significant new investments in our public health system. We have made progress, but we know it is not enough. Recent events and expert testimony before this subcommittee have made one thing perfectly clear: Our Nation's public health system is not adequately prepared to either prevent or respond to a biological weapons attack. To properly prepare, we must begin to think of our Nation's public health system as the front lines in our battle against terrorism.

Right now we do not have enough vaccines to protect every American. We will be discussing that this morning. But public health officials are without the tools and training they need to detect an outbreak and rapidly respond. Prudence demands action and that is why Senator Specter, Senator Byrd, and I have crafted a $4 billion bioterrorism initiative. We plan to press ahead with this initiative and we should not end this session without acting to protect the American people.

Last week Director of Homeland Security Tom Ridge stated that the administration intends to request substantial new funding for bioterrorism as part of the 2003 budget request. With all due respect to Mr. Ridge and the administration, these funds would come much too late. Safeguarding this Nation against public health threats demands immediate action. If a nation declared war on the United States, we would not wait until next fiscal year to prepare.

We would act and get prepared now, and that is what we have to do in the public health sector.

That is why Senator Specter and I are finalizing legislation that we will introduce later today hopefully, much of it based on this morning's testimony. Our plan would be to boost our Nation's defenses against bioterrorism. Among other things, we would put the bulk of the funding, $1.3 billion, into improving our public health departments, shoring up local lab capacity, and expanding the health alert network. Our proposal would also allocate $200 million for research at NIH on new vaccines.

Earlier this month our subcommittee heard testimony from Dr. Fauci, who is with us this morning, about the promising future of antivirals against smallpox, and so we want to see again how much more we need to invest in that area.

Our plan also provides substantially more money to boost the work of the Centers for Disease Control and Prevention. We need to upgrade their overburdened lab capacity and their disease surveillance systems.

We need to do more this year to make sure that Americans are fully protected against anthrax, smallpox, other types of pathogens that might be used in a bioterrorist attack. We have a distinguished panel of witnesses before us today. I really want to thank them for joining us. I would, before I yield to Senator Specter, again just pay my respects and my accolades to you, Dr. Koplan especially, and for the Centers for Disease Control and Prevention for all of the great work that you have done out there in responding to the anthrax attacks that have been bedeviling us around the country. I know you have got your investigators hot on the trail. I know they are working hard.

I think Americans everywhere ought to understand that these soldiers working for the Centers for Disease Control are putting their lives at risk every day, in much the same way as our soldiers in Afghanistan are putting their lives at risk. These are the people that go out, that have to expose themselves openly to anthrax, as the case may be right now. They are doing the lab work and they are exposing themselves to the possibility that they too might get infected.

So I just wanted to point that out that they have been doing a great job under very trying circumstances. I hope, Dr. Koplan, you will pass on to all of the people that work in the Centers for Disease Control our high esteem and our genuine thanks and appreciation for all of the hard work that they are doing and the risks that they are taking on themselves for tracking down this anthrax scare.

Dr. KOPLAN. Thank you. That means a lot to us.

Senator HARKIN. Senator Specter.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you, Mr. Chairman.

There is no more important subject for America today than the subject matter of this hearing. The American people face the potential of an imminent threat of bioterrorism. We have had in the past several weeks two high alerts from the administration and the imports of those alerts is the potential for a bioterrorist attack. It is

indispensable that we address the subject now before the Congress adjourns for whatever funding is necessary to meet this danger.

An administration report published in last Friday's New York Times talked about including this funding in next year's budget. That appears to mean for the budget beginning October 1st, 2002, and we know the reality of that is later than the end of the fiscal year and into 2003 before the funding could be started. That, simply stated, is too late.

This subcommittee had an earlier hearing where Dr. Koplan testified when we were ousted from this building because of bioterrorism, because of anthrax, and we asked at that time to have a comprehensive list of all the threats and what it would take in dollars and cents to meet them. Then we had a hearing in this room a couple of weeks ago where Dr. Fauci and others testified about what needed to be done with respect to the focus on smallpox. At that time the debate centered on the issue that vaccinations were not really necessary, that there would be time to inoculate after exposure.

My rejoinder was that the government has the responsibility to have the vaccines available and then the citizens can make a decision as to whether they want to undertake the risks, which were identified as one to six out of a million. Dr. Fauci and I had a little discussion about our grandchildren and I said I wanted my grandchildren inoculated. It is not my decision, by the way. It is my son and daughter-in-law's decision. They are the people to determine what their children will have. I think Dr. Fauci came around to my way of thinking and he wanted his grandchildren immunized, vaccinated, too.

The point is that it is government's responsibility to have it available. I made the point that this subcommittee, with Senator Harkin's leadership and my joinder, has provided enormous funding for NIH. We saw the needs there. NIH did not come forward and ask us to double the money, because NIH is controlled by HHS, and HHS is controlled by OMB, and by the time you finish the alphabet soup Congress cannot find out what is going on, unless we use back channels to find out.

But we saw the potential for NIH ourselves and we took a budget of $12 billion and with this year's appropriation it will be $11 billion more. That is a great tribute to America for what NIH has been doing on Parkinson's and Alzheimer's and heart attacks and cancer and a whole litany of ailments.

When we heard that the CDC needed additional capital improvements—and we did not hear it from the Secretary of HHS—Senator Harkin and I made trips down there on our own to take a look at the facilities. Before we had this emergency of September 11th, more than a year ago we added $170 million to their capital program, because this subcommittee is determined to see to it that the medical needs of America are taken care of.

This year we have added $255 million on our way to a billion dollar program. I think this is a lesson for government generally. You professionals need to tell us what you need, and if we do not fund it then it is our responsibility.

So I am glad that we are going to get the figures today and we are talking about ways to include it in the budget to make sure that it does get done.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

We have been joined by our distinguished ranking member of the full committee, Senator Stevens.

Senator STEVENS. Senator Kohl.

Senator HARKIN. Senator Kohl, did you want to make an opening statement?

Senator KOHL. No.

Senator HARKIN. Senator Kohl is deferring, Senator Stevens.

OPENING STATEMENT OF SENATOR TED STEVENS

Senator STEVENS. I intend to stay, Senator, so I would be happy to—thank you very much.

It is nice to see you again, Dr. Fauci and Dr. Koplan. I am pleased to have a chance to be with you today for a little while. I thank the chairman and the ranking member for holding this hearing.

Yesterday at another subcommittee I had an exchange with regard to the safety of our business, our buildings here, and the mail. We were told it is the responsibility of CDC to set the standards for safety and the standards for the ultimate decision that our buildings are safe for our staff and the public. I am going to have some questions about that later if I may, but for now I would say this, that I do think that we have got a real problem here and the problem is that, at least as far as I am concerned, there are still some areas of great misunderstanding about anthrax.

The front page of the Post today talked about how they had to use a paraffin sheet to capture the anthrax because it is so finely refined into such small units. We are having to face our staff to tell them we are going back into that building. I do not know if you know about it. I asked some questions, for instance, whether the plants were still there. Friends of mine told me all the plants should have been destroyed immediately. But in any event, they said that is where the anthrax spores go around the ranch, into dirt and into manure; they do not go to books and tables, they go into the ground.

Apparently there is a difference of opinion here. We have some real problems ahead of us here now. Dr. Fauci, one of the greatest ones is that in the years that we have doubled NIH, and this is the last year, we have decided not to earmark. Yet now that apparently money should be plentiful at NIH, some of the priorities that the people are screaming at us to get onto the list of these research agencies are being ignored.

So I want to tell the subcommittee, as far as I am concerned this is the last year we do not earmark unless we see some action dealing with some of the issues the public is clamoring for details on. Just for instance, I asked the question, do we know anything about the anthrax spores? What do they do? What is their range? How far can they travel without some type of assistance, either by carrier or by wind, etcetera? We do not know, apparently.

I asked questions about the files and the books in our offices and I was told, no, they did not open those. They did not open the files and they did not open the books, because they do not believe the spores would go there. Well, you try to tell that to a bunch of young college graduates. Yesterday I tried. It was not acceptable.

I think we have to have some answers and we have to have them pretty quick. But we have not had that kind of answer. I would assume someone had tried to determine the characteristics of this anthrax that was headed toward the Senate and the House, but particularly the Senate.

So I am going to have some questions about that. I hope that that is all right with the committee, when we get to that time.

But I do welcome you. Again, we have not spent much time together, Dr. Koplan, but I had some interesting education with Dr. Fauci and I hope to get more today.

Thank you very much.

Senator HARKIN. Thank you, Senator Stevens.

We will turn to our first panel: Dr. Jeffrey Koplan, Director of the Centers for Disease Control and Prevention. After him we will then turn without interruption and without questions to Dr. Fauci, who is the Director of the National Institute of Allergy and Infectious Diseases at NIH. So welcome. Your statements will be made a part of the record in their entirety. Dr. Koplan, we will turn to you first.

STATEMENT OF JEFFREY P. KOPLAN, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. KOPLAN. Good morning and thank you, Mr. Chairman, Senator Specter, Senator Kohl, Senator Stevens. I am pleased to appear before you today on behalf of the Centers for Disease Control and Prevention, the CDC, and thank you for the invitation to discuss CDC's public health response to the threat of bioterrorism.

The terrorist events on and since September 11th have been defining moments for all of us and they have greatly sharpened the Nation's focus on public health. But even before the September 11th attack on the United States, CDC with the support of this subcommittee was making substantial progress to define, develop, and implement a nationwide public health response network to increase public health capacity at local, State and Federal level.

Since September 11th we have dramatically increased our efforts, resulting in a heightened level of preparedness which we are committed to increase even further based on lessons learned in recent months.

CDC has used funds provided by the Congress to begin the process of improving the expertise, facilities, and procedures at State and local health departments and then within CDC itself related to bioterrorism. We have established a bioterrorism preparedness and response program to direct and coordinate our efforts. We have over 100 full-time professionals comprising expertise in epidemiology, laboratory science, surveillance. Over the last 3 years we have awarded over $130 million in cooperative agreements to 50 States, a territory, and 4 major metropolitan health departments to support preparedness, planning and readiness, epidemiology and surveillance, laboratory capacity, and improved communications.

Since September 11th, we have sent over 500 CDC staff to the field. For example, at the height of the anthrax response here in the Washington, D.C., area, we had 85 staff present. Currently in Connecticut in the investigation we have over 25 staff present working with the Connecticut State Health Department. These experts include epidemiologists, industrial hygienists involved in environmental sampling, laboratorians, communications specialists, logisticians, management staff.

CDC has also been working with many of the States where there have not been documented anthrax cases because there have been threats and hoaxes and hundreds of thousands of laboratory specimens sent to these States, putting a tremendous burden on every State in the country. In some instances we have augmented their staff with staff of our own to assist them in getting through the work load that they had.

We have launched an effort to improve health laboratories across the country in a network, a laboratory response network, improving our capability of detecting bioterrorist agents quickly and accurately, and we have done that in partnership with a number of other groups and laboratories.

We have tried to improve communications systems which are antiquated and in which, for example, less than half of the health departments in this country have direct, secure Internet linkage in a national communications system for public health.

We have worked to get pharmaceutical materials available to places in need and we have in place large amounts of materials that include antibiotics, antidotes, vaccines, materials for blood loss and trauma, available to any site in the country within 12 hours of a request for deployment. As an example, in New York the materials were provided within 7 hours of the request and being distributed for use.

A critical issue is preparedness of State and local health departments in this effort. They need to have plans in place to deal with terrorism. Those plans need to include distribution of supplies, such as pharmaceuticals, vaccines, antibiotics. Currently CDC funds only nine States and two cities to do such planning.

Security is a major issue, for facilities in particular, and at CDC we pay particular attention and effort to this, but have more to do to increase the quality and status of our security at several sites.

Our challenges for the future. While we have accomplished a great deal in the past 10 weeks, several challenges remain. One, it is critical that we bolster the infrastructure of State and local health departments in the areas such as early detection, laboratory analysis, crisis communications, and epidemiologic capability.

In addition, we need to forge closer working relationships between clinical medicine and public health, between hospitals in our communities, local health departments, law enforcement, other first responders.

Another important opportunity is to strengthen our relationship with other Federal agencies. While institutions such as the National Institutes of Health and the CDC and the FDA work closely together many, many times a day, we need to broaden that to include the law enforcement community. As we have seen in recent events, a close working relationship can be very helpful in dealing

with an event such as bioterrorism, which includes a public health investigation component and a criminal investigation component. To facilitate that, we have assigned a senior staff member from CDC to work at the FBI to improve and assure an optimal interchange between the two agencies.

Finally, we need to redouble our efforts to enhance our own capacity at CDC to respond to future threats. Since October 4th we have tested over 5,500 laboratory specimens. Our labs are working 24 hours a day. Scientists sleep in their office to avoid losing time. We need to expand that scientific capacity in the areas of epidemiology, surveillance, and laboratory, as well as accelerating our plans to improve our physical facilities and enhance security at all our locations.

In conclusion, the strength of our Nation to deal with bioterrorism is only as strong as our weakest links. That means every local health department, every State health department, and the Federal capacity have got to all be optimal and they have to be optimal in a variety of different capacities: laboratory, ability to investigate quickly and accurately, communication—the range of what modern public health is about.

PREPARED STATEMENT

When that playing field is level, when there are no weak spots, then we will be truly capable of dealing with a wide range of threats as they come to us. But a strong and flexible public health infrastructure is our best defense.

[The statement follows:]

PREPARED STATEMENT OF JEFFREY P. KOPLAN, M.D.,

Good morning, Mr. Chairman and Members of the Subcommittee. I am pleased to appear before you on behalf of the Centers for Disease Control and Prevention (CDC). Thank you for the invitation to discuss CDC's public health response to the threat of bioterrorism.

The terrorist events on and since September 11th have been defining moments for all of us-and they have greatly sharpened the Nation's focus on public health. Even before the September 11th attack on the United States, CDC was making substantial progress to define, develop, and implement a nationwide public health response network to increase the capacity of public health officials at all levels-local, State, and Federal-to prepare for and respond to deliberate attacks on the health of our citizens. Since September 11th we have dramatically increased our efforts, resulting in a heightened level of preparedness, which we are committed to increase even further based on lessons learned in recent months.

CDC's top priority is to protect the Nation's health. To do this, CDC focuses on building a solid public health infrastructure—at CDC, as well as at the State and local level to protect the health of all citizens. As recent events have shown so dramatically, we must be constantly vigilant to protect our nation's health and security. The war on terrorism is being fought on many fronts, and we must ensure a strong, robust public health system to be on guard at all times to prevent and respond to multiple and simultaneous terrorist acts. The arsenal of terrorism may include biological, chemical, and radiological agents as well as conventional and non-conventional weapons, as the attack on the World Trade Center so vividly attests.

BIOTERRORISM PREPAREDNESS

CDC has used funds provided by Congress to begin the process of improving the expertise, facilities and procedures of State and local health departments and within CDC itself related to bioterrorism. CDC has established a Bioterrorism Preparedness and Response Program to direct and coordinate our activities. CDC has a dedicated anti-bioterrorism staff of more than 100 full-time professionals comprising expertise in epidemiology, surveillance, and laboratory diagnostics.

Over the last three years, we have awarded more than $130 million in cooperative agreements to 50 States, one territory and four major metropolitan health departments to support,

(1) Preparedness planning and readiness assessment;

(2) Epidemiology and surveillance

(3) Laboratory capacity for biological or chemical agents; and

(4) The Health Alert Network (a nationwide, integrated, electronic communications system).

Since September 11, we have sent almost 500 CDC staff to the field. For Example, at the height of the anthrax response in the Nation's Capital, there were 85 staff in Washington, DC alone. These experts included epidemiologists, industrial hygienists involved in environmental sampling and clean up, laboratorians, communications specialist to assist with media relations, and logistics and management staff. CDC not only investigated cases that proved to be anthrax in four States and the District of Columbia, but also investigated suspicious cases in six other States. These cases proved not to be anthrax, but required CDC assistance to go through the process of ruling them out. CDC experts were needed to augment the staff of State and local health departments, who would have been severely overtaxed without our help. The Administration has requested $20 million through the Emergency Response Fund to create additional specialized Federal teams and place additional Epidemic Intelligence Service (EIS) officers in more States.

CDC has launched an effort to improve health laboratories that likely would be called upon to identify a biological or chemical attack. The Laboratory Response Network (LRN), a partnership among the Association of Public Health Laboratories (APHL), CDC, FBI, State Public Health Laboratories, DOD and the Nation's clinical laboratories, will help ensure that the highest level of containment and expertise in the identification of rare and lethal biological agents is available in an emergency event. The LRN also includes the Rapid Response and Advanced Technology Laboratory at CDC, which has the responsibility of providing rapid and accurate triage and subsequent analysis of biological agents suspected of being terrorist weapons. The Administration has requested $35 million under the Emergency Response Fund to improve State and local health departments' laboratory capacity and improve CDC's internal laboratory capacity.

The CDC is also working to provide coordinated communications in the public health system, between Federal agencies and between public health officials and the public itself. To this end, CDC has the Epidemic Information Exchange (EPI–X). The EPI–X is a secure, Web-based communications network that will strengthen bioterrorism preparedness efforts by facilitating the sharing of preliminary information about disease outbreaks and other health events among officials across jurisdictions and provide experience in the use of a secure communication system.

CDC has invested $90 million in the Health Alert Network (HAN), a nationwide system that will distribute health advisories, prevention guidelines, distance learning, national disease surveillance information, laboratory findings and other information relevant to State and local readiness for handling disease outbreaks. HAN provides high-speed Internet connections for local health officials; rapid communications with first responder agencies and others; transmission of surveillance, laboratory and other sensitive data; and on-line, Internet- and satellite-based distance learning. With the addition of several recent awards, CDC has provided HAN funding and technical assistance to 50 State health agencies, Guam, the District of Columbia, three metropolitan health departments and three exemplar Centers for Public Health Preparedness. The Administration has requested an additional $40 million through the Emergency Response Fund to improve and expand these systems.

CDC also manages the National Pharmaceutical Stockpile (NPS), which provides us with the ability to rapidly respond to a domestic biological or chemical terrorist event with antibiotics, antidotes, vaccines and medical materiel to help save lives and prevent further spread of disease resulting from the terrorist threat agent. The NPS Program provides an initial, broad-based response within 12 hours of the Federal authorization to deploy, followed by a prompt and more targeted response as dictated by the specific nature of the biological or chemical agent that is used. The first emergency deployment of the NPS occurred in response to the tragedy in New York City.

We saw just how critical local planning is—each State and community needs to plan for terrorism. The planning process builds essential relationships among public health, emergency management, and health care providers. And this coordination, especially with law enforcement must be strong—at the Federal, State, and local level—as the anthrax investigations have highlighted. Currently, CDC funds only nine States and two cities to do this planning. Under the Administration's Emer-

gency Response Fund request, an additional $10 million will allow all States and territories to receive funding for planning and preparedness activities.

In light of the recent terrorist attacks, it is important for CDC to improve security in its facilities. CDC received an additional $3 million in the initial Administration release of Emergency Response Funds, and the Administration's Emergency Response Fund request also includes an additional $30 million to secure CDC facilities, particularly where special pathogens may be stored. Also, as mentioned earlier, there is an additional $20 million to improve and upgrade CDC's internal laboratory capacity.

CHALLENGES FOR THE FUTURE

Although we have accomplished a great deal in the past 10 weeks, we have several remaining challenges .

First, it is critical that we bolster infrastructure in State and local health departments. As evidenced by our experiences following the September 11th and anthrax incidents, public health departments are at the frontlines of emergency response. State and local health departments need expanded capacities and resources for key preparedness and response functions such as early detection, laboratory analysis, and crisis communications.

In addition, we must continue to forge relationships between clinical care and public health. It was through the efforts of clinicians that we were able to identify the cases of anthrax. These physicians reported the cases to their local public health authorities and obtained laboratory specimens for analysis at State laboratories and CDC. The closer the relationship between clinical medicine and public health the faster we are able to identify potential bioterrorist threats and other outbreaks, identify the cause of the illness, and provide early treatment to save lives.

Another important opportunity is to strengthen our relationships with other Federal agencies, and State and local agencies outside the field of public health. Since September 11th, we have created stronger partnerships with a wide range of agencies, particularly the law enforcement community. For example, in response to the recent events, CDC assigned an individual to work at the FBI to assure optimal information exchange between the two agencies. As we prepare for any future threats, we need to maintain and enhance our ties with a much larger range of agencies.

Finally, we must redouble our efforts to enhance our own capacity at CDC to respond to future threats. For example CDC has tested over 5400 human and environmental samples since October 4, our labs have worked around the clock, with scientist sleeping in their offices to avoid losing time. We need to expand our scientific capacity in the areas of epidemiology, surveillance, and laboratory, as well as accelerating our plans to improve our physical facilities and enhance security in all CDC locations.

CONCLUSION

In conclusion, CDC is committed to working with other Federal agencies as well as State and local public health partners to ensure the health and medical care of our citizens. We have made substantial progress to date in enhancing the nation's capability to prepare for and respond to public health threats and emergencies, including bioterrorism events. The best public health strategy to protect civilians against any health threat is the development, organization, and enhancement of public health systems and tools. Priorities include a fully staffed, fully trained, and properly protected public health workforce, strengthened public health laboratory capacity, increased surveillance and epidemiological capacity, secure up-to-date information systems, solid health communications capabilities—all supported by flexible policies and preparedness plans that enable the public health system to prepare for and respond to any type of health emergency at the Federal, State, and local level. Not only will this approach ensure that we are prepared for deliberate bioterrorism threats, but it will also ensure that we will be able to recognize and control any threat to the public's health. A strong and flexible public health infrastructure is our best defense. The Administration's Emergency Response Fund request is an important step in this process and we encourage you to support it.

At this time, I would be happy to answer questions from you and Members of the Committee.

Senator HARKIN. Thank you very much, Dr. Koplan.

Dr. Fauci.

STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH

Dr. FAUCI. Mr. Chairman, Senators Specter, Stevens, Kohl: Thank you for calling this hearing and thank you for giving me the opportunity to testify before you. As you have just heard from Dr. Koplan, the effort to address bioterrorism is out of necessity a comprehensive and multi-faceted endeavor involving multiple Federal agencies, several sister agencies within the Department of Health and Human Services, as well as other agencies such as the Departments of Defense and State, local health departments, and, importantly, private industry.

The NIH's role in this important comprehensive approach is a very specific one and that is addressing the biomedical research component of the counter-bioterrorism effort. We do that with basic research—I will talk about that very briefly in a moment—and we aim to develop and apply basic research to the production of diagnostics, therapeutics, and ultimately vaccines.

We have emphasized, together with the CDC, a number of microbes that we call Category A microbes that are, in our estimation, of the highest risk and greatest impact. Among these are anthrax, smallpox, plague, botulism, tularemia and the hemorrhagic fevers. In the interest of time, I am going to focus my very brief discussion on the NIH research efforts addressing smallpox and anthrax.

First with regard to smallpox, as I testified a short time ago before this committee, we have embarked on dilutional studies to look at the already-owned stock that the Federal Government has under the auspices of the CDC, the 15 million doses, to determine if by diluting them one-to-five or one-to-ten we can preserve the potency as well as expand the numbers. This study is proceeding extraordinarily well. We have an encouraging high rate of "takes." A "take" is an indication that the potency still remains, even when the vaccine is diluted. I will be happy to discuss this a little bit later.

You heard yesterday the announcement of the letting of the contract by Secretary Thompson to Acambis and Acambis-Baxter to have 155 additional million doses of a second-generation vaccine to supplement those that we already have contracted for. Together with the dilutional group, this will allow us to have vaccine available if necessary to give to everyone and anyone in the country.

Importantly the NIH research effort also includes third-generation vaccines, namely the molecular biological approach of looking at purified sub-units that would obviate the concern regarding toxicities of using a live virus. This is years away, but it is one of those future things that we need to approach because this would make it safe for all populations.

We also have an antiviral screening and development program. You have heard of the drug Cidofovir. I mentioned this at the last hearing. It is a drug that we originally developed for the purpose of treating cytomegalovirus infection in HIV-infected individuals. It is now shown in the test tube and in animal models to be highly effective against a variety of pox viruses. We are pursuing this in

investigational new drug applications to determine its capability against disseminated vaccinia and ultimately smallpox.

Moving on to anthrax, the NIH's role is to cooperate with our sister agencies, CDC, USAMRIID, and others, together with the FDA to develop a recombinant protective antigen anthrax vaccine that we could use as a second- and third-generation vaccine. Also, there is a considerable amount of basic research done on the anthrax microbe itself to answer some—not all but some—of the questions that Senator Stevens just brought up.

Integral to our research effort again is another area that we have been working on for a considerable period of time that significantly antedated the September the 11th tragedy. That is the sequencing of the full genomes of pathogenic microbes, including smallpox, anthrax, and several others. The reason that this is important is because this approach gives us a very specific target for the development of diagnostics, therapeutics, and vaccines.

Very briefly, there are other agents that I alluded to. We do not have time to go into them right now, but one of them in particular is the group of hemorrhagic fevers, including Ebola. We have a program at the NIH in the Vaccine Research Center of the NIAID that has shown very convincingly in a non-human primate model that a recombinant type of second-third-generation vaccine was able to protect these non-human primates against Ebola. We are moving as rapidly as we can to get that into phase one trials.

Having said all of this, much still needs to be done because there are many unanswered questions and we need to address these as quickly as we possibly can.

In summary, the NIH is focusing our basic and applied research resources on bioterrorism. We have at the intramural research program at NIH, and in our extramural community of very talented investigators whom we support with grants and contracts, the world's experts in the science of countering bioterrorism. Together with our sister agencies such as the Centers for Disease Control and Prevention, we commit ourselves to meeting this most extraordinary and historic challenge to the health of our Nation.

PREPARED STATEMENT

I would be happy to answer any questions, Mr. Chairman. Thank you.

[The statement follows:]

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

Mr. Chairman and Members of the Subcommittee, thank you for inviting me here today to provide an update on the current bioterrorism research activities of the National Institutes of Health (NIH) and our plans for the future. Any program that will effectively counter bioterrorism out of necessity would be a comprehensive program involving multiple government agencies, local and State health departments, and private industry. An important component of such a comprehensive effort is biomedical research. The role of the NIH in the overall government effort against bioterrorism is to conduct and support such research.

The NIH bioterrorism research program is spearheaded by the National Institute of Allergy and Infectious Diseases (NIAID) and encompasses four broad areas: basic research, diagnostics, vaccines and therapeutics. I would like to briefly describe our research in these broad areas as well as summarize several specific NIAID-supported smallpox and anthrax studies.

Research into the basic biology and disease-causing mechanisms of pathogens underpins efforts to develop interventions against agents of bioterrorism. NIH supports

research to better understand the factors that influence a pathogen's virulence and invasiveness, as well as those that determine antibiotic resistance. NIH also supports research on the host/pathogen interactions. Knowledge from basic research findings is crucial to the development of preventative and therapeutic strategies.

One of the most important basic research tools that has evolved in recent years is the ability to rapidly sequence the entire genomes of microbial pathogens, including potential agents of bioterrorism. Some agents, such as smallpox and other orthopoxviruses related to smallpox, have already been sequenced; the sequences of others, such as Bacillus anthracis (the anthrax bacterium) and other bacteria relevant to bioterrorism are in progress and close to completion. The fruits of genomics research, coupled with other biochemical and microbiological information, are expected to facilitate the achievement of critical new goals, including the discovery of new targets for drugs and vaccines. In particular, comparative genomics (comparing the sequences of different strains of particular organisms) will be an important component of future research, helping us to understand what makes a particular organism either harmful or benign.

NIH also supports research leading to the development of new and improved diagnostics. The goal of this research is to establish methods for the rapid, sensitive, and specific identification of natural and bioengineered microbes as well as the determination of the microbe's sensitivity to drug therapy. These scientific advances will allow health care workers to diagnose and treat patients more accurately and quickly.

NIH-supported researchers are developing vaccines that are effective against many infectious agents, including those considered to be bioterrorism threats, with the intention of developing products that are safe and effective in civilian populations of varying ages and health status. Vaccines against pathogens are being developed using both traditional and novel technologies. Some novel technologies include the development of "DNA vaccines", various vector vaccines, and innovative systems for the rapid creation of vaccines against unfamiliar or genetically altered pathogens; these technologies are in various stages of development.

NIH therapeutics research focuses on the development of new antimicrobials and antitoxins, as well as the screening of existing antimicrobial agents to determine whether they have activity against organisms that might be employed by bioterrorists. Knowledge gained from basic and applied research is helping to identify additional targets for medications against agents of bioterrorism. The design of therapeutic drugs active against known drug-resistant variants of microbes, and the development of broad-spectrum agents are also important NIH research priorities.

Together, these efforts create the strong foundation from which the NIH carries out bioterrorism research activities. Two cogent examples of this multifaceted research approach are the specific NIH projects in the areas of smallpox and anthrax. Smallpox is considered one of the most dangerous, potential biological weapons because it is easily transmitted from person-to-person, and very few people carry full immunity to the virus. Historically, the mortality of smallpox infection has been approximately 30 percent; those patients who recover frequently have disfiguring scars.

NIAID research on smallpox focuses primarily on extending existing vaccine stocks to increase the number of available doses, and developing new vaccines and treatments for the entire population, as well as diagnostic tools to detect the disease quickly.

At present, the approximately 15 million doses of the traditionally employed and highly effective "Dryvax" vaccine that have been stored since production stopped in 1983 would not be enough to respond to a national smallpox epidemic. In response to this shortage, NIAID initiated a study last year to determine the feasibility of expanding the use of the existing stores of the Dryvax vaccine by dilution. In this study, investigators examined and compared the skin and immune system responses of normal unimmunized adult volunteers who were given undiluted Dryvax vaccine, a 1:10 dilution (10 percent) of vaccine or a 1:100 dilution (1 percent) of vaccine. The results showed that the full-strength vaccine had maintained its potency, and that 70 percent of people who received a single dose of the 10-percent diluted vaccine developed a sore followed by a scab at the injection site and antibodies in their blood, strongly suggesting protection. The 1:100 dilution had an unacceptably low take rate.

Based on these findings, a larger study is underway to determine the best strategy for optimal use of available vaccine. This study, which will enroll up to 684 people, is evaluating three different doses (undiluted, 1:5, 1:10) of Dryvax. Researchers will study the ability of the various vaccine formulations to stimulate a scab, or "take," at the vaccination site and to produce neutralizing antibodies in the blood. If participants have not developed a scab in seven to nine days after vaccination,

they will be revaccinated with the same vaccine dose they received the first time. By that strategy, researchers hope to learn which vaccine dose given in a single injection elicits the desirable response among the largest number of people and whether "boosters" can increase the take rate on a population basis.

NIAID is also designing clinical protocols for testing of Dryvax in previously immunized adults and in children. At the same time, we are investigating the newer cell culture based smallpox vaccines as well as alternative vaccination strategies with the goal of designing safer and more effective vaccines.

NIAID/NIH also supports long-established contracts that conduct in vitro and in vivo screening of known antiviral compounds to determine if they are effective against viruses that are similar to smallpox (vaccinia virus and cowpox virus). Compounds with promising in vitro activity are further evaluated in animal models of orthopoxvirus infection by both United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and NIAID-supported investigators. To date, NIAID and USAMRIID have screened approximately 500 compounds. The drug cidofovir has been shown in multiple test systems to have activity against all orthopoxviruses tested in vitro and in vivo. NIAID submitted an Investigational New Drug (IND) application for use of this drug as a backup to vaccinia immune globulin (VIG) in our dilutional vaccine studies and possibly for the emergency treatment of smallpox should a bioterrorism attack occur.

One key collaborative activity that will accelerate the development of new treatments and vaccines for smallpox is the recent establishment of the "Orthopoxvirus Genomics and Bioinformatics Resource Center." NIAID, the Defense Advanced Research Projects Agency (DARPA), the Centers for Disease Control and Prevention (CDC), USAMRIID and the American Type Culture Collection have all contributed toward this Center, which will conduct sequence and functional comparisons of genes to provide insights for the selection of targets for the design of antivirals and vaccines.

With regard to anthrax research, NIAID has been collaborating with the Department of Defense (DOD) to support the development of the next generation of anthrax vaccines that may be more appropriate than the current anthrax vaccine for use in the civilian population. At present, we are currently planning Phase 1 safety and immunogenicity trial for the USAMRIID recombinant protective antigen (rPA), one of the leading anthrax vaccine candidates. In addition, NIAID is utilizing its vaccine production and support contractor, Science Applications International Corporation (SAIC) to facilitate and expedite the development of additional rPA vaccines.

NIAID is also exploring rapid diagnosis of anthrax and the utility of available antimicrobial or antitoxin therapies. Together with the Food and Drug Administration (FDA), CDC, and USAMRIID, NIH is working to prioritize and accelerate testing of existing antimicrobials for use against anthrax. Last month, NIAID-supported investigators published two studies in the scientific journal Nature that help to explain how anthrax toxin destroys cells. In the first study, researchers have identified the site on the cell that binds the anthrax toxin and have developed a compound that may disable it. Another group of investigators has characterized the structure of a major component of the anthrax toxin. The information gained through these studies will likely hasten the development of new drugs to treat anthrax.

In addition, the NIAID, through an Inter-Agency Agreement with the Office of Naval Research, has provided funds to help complete work on sequencing the genome of B. anthracis. The information derived from this genome-sequencing project should be of great value in developing rapid diagnostic tests, as well as new vaccines and antibiotics therapies against mutant strains of B. anthracis.

Although the focus of national attention has been on smallpox and anthrax, we must not overlook other organisms of bioterrorism, including agents that cause plague, tularemia, botulism, and viral hemorrhagic fevers. NIH-supported research is yielding insights in these areas. For example, intramural investigators at NIAID's Dale and Betty Bumpers Vaccine Research Center have developed a DNA vaccine that has protected monkeys from infection with Ebola virus; this vaccine could soon enter human trials.

Together with our many research partners, NIH has made substantial progress in the research effort that is critical to our Nation's fight against emerging diseases, including those that are intentionally released as agents of terrorism. In addition to previously mentioned collaborations with other government agencies, NIAID maintains important partnerships with industry that are essential to the development of new technologies and treatments in the arena of infectious diseases.

Much remains to be accomplished, however, and the challenges posed by bioterrorism will require a sustained commitment over the years to come. Within the next

few weeks, NIH will announce new initiatives for funding in fiscal year 2002 to provide the academic and industrial research communities with an opportunity to propose studies targeting new approaches to research on agents of bioterrorism. For example, we will unveil an initiative entitled "Partnerships for Novel Therapeutic, Diagnostic and Vector Control Strategies in Infectious Diseases," which will involve substantive involvement by a private sector partner and focus on areas that are currently not a high priority or that may be too financially risky for industry to pursue alone, but are likely to have a high impact on public health. The submission, review, and funding of these proposals will be expedited in order to facilitate the rapid advance of these important research endeavors. This information is being made available to the public and the research community through our website.

With a strong research base, talented investigators throughout the country, and the availability of powerful new research tools, we fully expect that our basic and applied research programs will provide the essential elements that will greatly enhance our defenses against those who attempt to harm us with bioterrorism.

That concludes my testimony. I would be happy to respond to any questions that you might have.

Senator HARKIN. Thank you, Dr. Fauci.

I wonder if I could start with you, Dr. Fauci. To go back over smallpox, I would like you to, if you could, in just a little more detail outline for us the proposal that Secretary Thompson made late yesterday afternoon. I spoke with him personally myself yesterday. As I understand it, negotiations have been finished, and there will be, what, three companies that will be supplying the smallpox vaccine?

I am not so much interested in all the minute details. What I really want to know is, give us a time line and let us know, how soon will you be able to tell us whether the 15.4 million doses that we have stockpiled now could be used for, let us say, up to maybe seven, eight times that much, depending on the dilution? How soon will we know that?

How soon will we have enough vaccines available for every person in America? How soon we will have that built up under the agreement that was made yesterday?

Dr. FAUCI. First of all, it is not three companies, Mr. Chairman. The companies involved are the company Acambis that we had already contracted with initially to make 40, but then changed to over 50 million doses of the second-generation vaccine. They have combined with a large company called Baxter. So to avoid confusion, there is the Acambis contract that had already been let, and then there is the Acambis-Baxter contract which was announced by Secretary Thompson yesterday.

So let me run through your questions briefly and tell you how we are going to get to the total number of doses that you refer to. The dilutional study that started at the end of October, in which we are looking at that 15 million doses to see if we could stretch them out, we are doing a one-to-five and a one-to-ten dilution. We have vaccinated essentially everyone with just a few to go in the original 684. The take rate is extraordinarily high.

Senator HARKIN. That is undiluted?

Dr. FAUCI. That is, no, on all of them.

Senator HARKIN. All of them.

Dr. FAUCI. We cannot tell you exactly and I do not want to make any announcement of results because you have to scientifically examine them, put them to peer review, look at the antibody titers that we do not have yet. We are just looking at take rate, and our experiments over the years tell us that take rates coincide very

well with the production of the antibodies that you would like to induce.

So it is not final yet, but things are looking quite good. We will have those results in their final form by the end of January, the very beginning of February. Let us assume that the dilution one-to-five does in fact give you a high rate of induction of immunity. That then would provide us with about 75-plus million doses. So that is one component of the totality of doses.

We have a contract with the CDC and Acambis, that has been going on for a considerable period of time, with the original target to get 40 million doses by the beginning of the year 2004. That has been markedly upscaled to now deliver 54 million doses by the end of the year 2002. That is another 54 million. So it is 75 and 54 million.

Then you have what you heard about yesterday, the 155 million doses in which Acambis and Baxter together are going to give us that second generation smallpox vaccine. They are now going to be having pilot lots probably by the beginning of the year, later winter or so. Then there will be an accrual, that each month that goes by there will be that many more tens of millions of doses, so that by the time we get to late fall, perhaps early winter of 2002, we will have the totality of doses that you referred to, which would be about 280 million some odd doses.

Senator HARKIN. Do you know—I do not know if you are the right person to ask this question, but is the idea then that these vaccines would be distributed around the United States at various locations? Is that the idea?

Dr. FAUCI. The idea is to have them in reserve. I will defer to Dr. Koplan, since the CDC plays such a major role, not only in the advice about how and when and where to vaccinate, but also in the distribution. So if I could pass that over to Dr. Koplan, he could answer that.

Dr. KOPLAN. Thanks.

We have already begun discussions on the appropriate deployment of amounts of vaccine as they become available. What will happen is in the coming months we will have broad public discussions with academicians and scientists from both within the government and outside the government, from academia, elected officials, Congress, and discuss the pros and cons of the various alternative ways of dealing with having a vaccine for which currently there is no naturally occurring infection, but for which there might be a threat of its use as a bioterrorism agent, and the level of that threat is quite unknown at this time.

The issues that will be involved in that discussion are complex and they involve: one, the issue of should there be a mandatory vaccination, should everyone have it? If that were true, does it then get repeated every year for new people who have not been vaccinated?

This is a vaccine which has a low rate of side reactions to it, but a real and a predictable rate of side reactions to it. Some of them are not just significant reactions. Some of them are severely damaging and some of them result in death. So if you use this vaccine in a million people, you can expect a half dozen or more to be se-

verely enough injured from the vaccine to be hospitalized and some number of those to die from it.

So in a widespread use of the vaccine, there will be hospitalizations, there will be people with permanent damage, and there will be deaths. So that has to get balanced with what one considers the threat of an introduction of smallpox. This will take place over the coming months as the amount of vaccine is increased in the country.

We have a mechanism for determining immunization policy in this country using the ACIP, the Advisory Committee on Immunization Practices, which has served us well over decades now and has resulted in the lowest rates of disease from immunizable illnesses that has ever been seen in the world. So they would I think play a major role as well in this.

Senator HARKIN. Thank you, Dr. Koplan. I want to come back and ask you about that later. I see my time is up right now, but I want to ask about Cidofovir and the stockpile, if we are going to stockpile that drug, later on.

Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman.

Dr. Koplan, on October 23rd at our bioterrorism hearing I asked you to furnish a list of all the threats and the costs involved. I would like now your professional judgment on what we need to appropriate now to meet all the bioterrorism threats.

Dr. KOPLAN. Thank you, Senator Specter. I am happy to offer my professional judgment. Of course, you will all recognize that it is not constrained by the competing priorities that the President and his advisors must consider.

Having said that, a major area for upgrade is State and local health capacity. You have heard that from, I think, your own respective States, wherever they are, and that this is really where things start in a bioterrorist event. It started in Palm Beach County, Florida; it started in New York City.

Senator SPECTER. Dr. Koplan, I have got 5 minutes. What is the cost?

Dr. KOPLAN. Okay. Basically, roughly between $15 and $20 million per State is needed to get them up to running speed for this.

Senator SPECTER. Total national?

Dr. KOPLAN. For a total of about $1.050 billion for States.

Senator SPECTER. What is next?

Dr. KOPLAN. Upgrading CDC capacity, including our biological capabilities and laboratories and chemical needs, is roughly $150 million.

Senator SPECTER. I am convinced of that. I have seen it myself. Next?

Dr. KOPLAN. The national pharmaceutical stockpile we want to enlarge. We want to add anti-botulism items. We want to increase trauma supplies, etcetera. That is about $640 million. We will add four more pushpacks to bring the total to 12 from 8 that we had before.

For the vaccine purchase that you have heard Dr. Fauci just describe, there are also some implementation figures that might be helpful for States. In other words, it is not just having the vaccine present in a warehouse. It is how do they get them out to commu-

nities. We can work with your staff to give an estimate of that number, but that will require a little more research.

Senator SPECTER. What is your professional estimate at the moment?

Dr. KOPLAN. I would guess it is probably somewhere between $600 and $700 million for the extra expenses beyond just producing the vaccine.

For laboratory security, principally at CDC, at four of our campuses that have biological agents present, roughly $96 million would be required for laboratory security improvement.

Then finally, for efforts related to the events of the last several months, where lots of expenditures have been made and lots of needs have been accrued by the localities in which these bioterrorist and terrorist events have occurred, roughly $50 million.

Senator SPECTER. Did you cover smallpox?

Dr. KOPLAN. Smallpox is handled within that vaccine, the area that I just mentioned, $600 to $700 million.

Senator HARKIN. $600 to $700 million.

Dr. KOPLAN. Plus the purchase, not including the purchase cost.

Senator SPECTER. So what would the total need be for the purchase of vaccines?

Dr. KOPLAN. Well, the purchase of vaccines, as Dr. Fauci just indicated, is the $500 million figure for purchasing these new vaccines.

Senator SPECTER. I had been informed that the smallpox vaccine would cost $1.4 billion.

Dr. KOPLAN. I am saying the purchase of the vaccine itself is roughly $500 million, but then there are other expenses in terms of getting it out to States and localities, having people prepared to use it, and having training for those people. There also has to be vaccinia-immune globulin.

Senator SPECTER. Then is the $1.4 billion figure accurate or not?

Dr. KOPLAN. I think that is a little high because of the negotiation and the lower price we got on the vaccine that was announced yesterday.

Senator SPECTER. How much would you take off the figure then?

Dr. KOPLAN. I would probably take off $600 million off of that, based on the way we have been able to package vaccine and get it up to 300 million doses.

Senator SPECTER. So $800 million instead of $1.4 billion?

Dr. KOPLAN. Exactly.

Senator SPECTER. The release by the Secretary yesterday on the expenditure of some $428 million, that has to be appropriated. The Department does not have that money, correct?

Dr. KOPLAN. I believe that has to be appropriated, correct.

Senator SPECTER. So he is contracting for it without authorization, without an appropriation from Congress, and I congratulate him for doing so.

You did not answer the question, Dr. Koplan, and you do not have to.

Dr. Fauci, the same question was put to you. What are the needs for NIH to have adequate funding for bioterrorism?

Dr. FAUCI. In our original request that is contained in the President's budget, Senator Specter, we had accelerated up to $92.7 mil-

lion. As things have evolved since the time of that submission I would have to give you my professional judgment of what we would need to meet what I feel are the scientific and public health needs that the NIH can address. As Dr. Koplan said, I would have to say that this judgment is not constrained by those other priorities of the President and his advisers.

But in my professional judgment we would have to do significantly more than that. If you look at bioterrorism prevention, treatment, vaccine and other basic research, not only in smallpox, anthrax, and other microbes, together with the secure facilities that we would need, what we call BL–4 facilities, to work with the material that we would ultimately have to work with, as well as other physical security measures and continuation of part of the smallpox vaccine program, it is going to depend on when we get it. But I will give you specific numbers, because if we could do it immediately it would be something that would be more front-loaded.

If you are talking about the number that we could clearly do—the kinds of research that I think are implementable right now—we are talking about a total additional number above the $92.7 million that ranges from $175 million to more than $200 million, again depending on when and how we get it.

If you add the kinds of things that we need——

Senator SPECTER. The question is how much do you need and can you put it to use now?

Dr. FAUCI. Right now, we could put to good use between $175 million and $200 million, in addition to the $92.7 million that we asked for.

Senator SPECTER. That sounds to an appropriator like $175 million. Will that meet your needs? If you are going to give us a range of $175 million to $200 million, we are not going to give you the top figure; we are going to give you the bottom figure. I just want to be sure that is what you need.

Dr. FAUCI. We could adequately spend up to $200 million.

Senator SPECTER. Dr. Koplan, on the figures you have given, is there room for a first installment or is that the money you need now to move ahead with an adequate response to bioterrorism?

Dr. KOPLAN. I think we are facing risks now and the sooner these funds beef up State and local health departments, the sooner we are better prepared.

Senator SPECTER. So you have a need to expend them now?

Dr. KOPLAN. Yes.

Senator SPECTER. Thank you.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

Senator Kohl.

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. Thank you, Senator Harkin.

Dr. Koplan, I would like to talk with you about the immunization program for the vast number of people who we would describe as the caregivers in the event of an outbreak—physicians, nurses, people who work in hospitals around the country, other local public health officials. I am assuming that in order for them to provide

the kind of service that would be necessary in the event of an outbreak they would need to be immunized beforehand.

Number one, is that true? Number two, what is the program that is on the table to immunize the caregivers of this country? Number three, how long does it take to provide that immunization to an individual, a day, a week, a month? How is this going to unfold and how quickly is this going to unfold?

Dr. KOPLAN. Thank you, Senator Kohl. We are trying to determine who would most benefit from vaccine. There are a range of both caregivers and non-caregivers who could potentially be exposed. One of the aspects of smallpox is that in the first 4 days after exposure to the disease you can still get the vaccine and be fully protected from it. So, unlike some other diseases where you have to get the vaccine days, weeks, or months ahead of time, smallpox is different. You begin to produce antibodies right away.

Another method of protection against smallpox is not just vaccine, but the type of isolation procedures that hospitals routinely use for a wide variety of other diseases and that can protect their staff, including the use of face masks protective against smallpox dissemination.

Nevertheless, having said those two things, what we are in the process of now, we have just put out a draft version of a national smallpox bioterrorism plan, if you will. That was created in cooperation with State and local health partners. What we are going to be doing is meeting, talking with them, with physician groups, nursing groups, etcetera, to determine just what you said, who are the groups that would most benefit from early vaccination with smallpox vaccine.

Senator KOHL. All right, I appreciate that. But if we have an outbreak tomorrow or next week, are the caregivers of this country prepared to provide their services?

Dr. KOPLAN. Yes. If we have an outbreak today—first of all, the outbreak begins with the recognition of a case or two, that is the way all outbreaks begin. At that point, local and State investigators would be on the spot, getting specimens, determining what is going on, and also identifying what had been exposed to that individual. All those individuals would be getting vaccine and we would go in increasing rings around that individual who had been exposed.

Senator KOHL. Yes, but don't those people need to be immunized in order to provide the kind of services that will be necessary?

Dr. KOPLAN. No, they do not. They can provide those services. I am not currently immunized and I would not hesitate to provide service to someone who came in with a rash or an illness, as long as I know that within 4 days after I have had that exposure I can get vaccinated.

Senator KOHL. You said that is true with respect to smallpox?

Dr. KOPLAN. That is true for smallpox.

Senator KOHL. What about other communicable diseases?

Dr. KOPLAN. Some of the other diseases that we worry about, rather than vaccines, we have antibiotics that are effective against them. But I think the key item in every one of these things that you are raising and appropriately raising is the speed of diagnosis. That is what makes all the difference in every one of these out-

breaks. It is how quickly you could identify those first cases, because particularly in diseases, unlike anthrax which cannot be spread from person to person. But some of the other diseases that we would worry about, such as smallpox and some others, are spread from person to person.

So the speed of that first diagnosis is crucial in limiting the amount of spread of disease.

Senator KOHL. Well, do we intend to immunize in advance those several hundred thousand primary caregivers around the country?

Dr. KOPLAN. I think that is a subject for discussion. As we get more doses of vaccine available, certainly more and more people can and ought to be considered. It is not just the primary caregivers. Once you get into a hospital emergency room, it includes maintenance staff and cleanup crews and people that come in and out, and there is turnover of all these individuals.

As I indicated before, the thing one has to keep in mind with something like smallpox vaccine is it is a live vaccine which is present on the skin surface. With its rates of side reactions, people who are immunosuppressed, who are HIV-positive, may have severe reactions to this vaccine. In addition, people working in hospital environments where there are sick people around may have to leave work for a period of time while that vaccination takes place because of the live virus present; they may not have to, but some may.

So these are all complicating issues when you talk about health care providers getting the vaccine. There is a tradeoff. If they absolutely need it, then they need to get it. But where the risk is unclear, there are also dangers attached to providing the vaccination, and it is these benefits and risks that have to be taken into balance and will be discussed with both clinicians and clinician groups and with public health people in the States.

Senator KOHL. Are you prepared to recommend that this group be immunized in advance at this time, next week, next month?

Dr. KOPLAN. No, I am not prepared to make that recommendation. But we are certainly eager to have discussions with both these people who would be involved and the people in the States and see what the consensus is on what policy would be best.

Senator KOHL. Thank you.

Thank you, Senator.

Senator HARKIN. Thank you, Senator Kohl.

Senator Stevens.

Senator STEVENS. Doctors, let me first start by making a short statement, and that is this. We are dealing with bills now that will probably not be signed until Christmas. Monies could not be released until at least January. We will be through at least one quarter of the fiscal year.

The figures you have just given the chairman and Senator Specter I assume were annual expenditures, or were they expenditures for several years?

Dr. KOPLAN. Those were annual.

Senator STEVENS. Could you give us a statement of how much you believe you need to pay out, not commit, pay out between now and May and between now and the end of September? I do not want it right now, but we are dealing with a lot of tight money

right now and we have got to stage it if we are going to get the money we need to you as it is needed. There is great fear that we are just dumping money out the window and people do not know exactly what it is for and therefore people are afraid that we are going to waste money. We all read the papers about the terrible big spenders around here and I usually head the list, but I do not believe we are. But we want to be very specific.

Now, my first question to you is, we have been visited, I think most of us have been visited, by a group that believes that they can develop a heteropolymer system that uses monoclonal antibodies to bind pathogens in the blood and transport them to the liver, where they can be cleansed and removed from the body.

Now, I do not know enough about the science, and I assume you do. But we have been told there is money in the budget, there has been money in the budget the last 2 years dealing with this. But we have been told that that process might be accelerated. I am particularly concerned with the people we send in harm's way, our military, and they said they could prepare what could be called a cocktail of such heteropolymers that could provide broad spectrum protection for people against a series of substances.

Now, do you know about this research and are either of you pursuing funding it?

Dr. FAUCI. The principle that you are referring to is a mechanical and physical chemical way, as you mentioned correctly, to bind to any organism, essentially, and get it cleared out of the body. The NIH, as in the past, enthusiastically now and in the future, will be happy to examine any proposal in the classical peer-reviewed way to determine if in fact it is something that can be and should be funded.

If we do not have a proposal in front of us, we cannot evaluate it. To my knowledge, that proposal has not reached us. But if it has, we would be more than happy to expedite looking at it.

Senator STEVENS. Well, I have been specifically requested to allocate portions of the defense budget to that immediately, because we still have the defense bill with us. I think that is why they are looking at the defense budget.

But we are also told that that research, with sufficient funding, now could be accelerated so that those substances might be available by 2003. If that is possible, we were further told that these substances could protect an individual for up to 60 days against the substance that might otherwise seriously harm or kill them.

I think we need to know about things like this because if this has less risk to the populace by using a temporary substance it might even bypass the problem we previously discussed of the risk to people with HIV or damaged immune systems from even things like smallpox.

All I can tell you is I hope you will look into it. I do not know what the cost would be, but clearly it would be much better to have people in the service have a vial that they could use, like we used to use morphine, and just self-administer it and have protection in the event they were told that substances had been released at them that might otherwise kill them.

I really think we are in a crisis period as far as they are concerned. Our people up here at home, we might have a better way

for civil defense than they do for defense militarily. So I would urge you to take a look at it.

Dr. FAUCI. If I can get something to look at, I would be happy to look at it, Senator.

Senator STEVENS. I will see that they get to you.

Dr. FAUCI. Thank you.

Senator STEVENS. I think we need someone's judgment before we move to earmark defense money for this. There is just not enough available to me so far.

Secondly, let me ask you this. I am running out of time. Could I have another minute?

Senator HARKIN. Yes, sure.

Senator STEVENS. I asked yesterday a series of questions about these substances in our building, about how far these spores can travel, have traveled, whether they have traveled further as minute particles than they would in the normal run of the mill anthrax, and what exposure we could expect our people to have if they go back into offices that may or may not have been exposed to this anthrax.

Now, my offices are on the fifth and sixth floor of the Hart Building. They are at the other end of the building from Senator Daschle. But clearly the question is what does the air system distribute and where do these things go. My friends from ranch country tell me they go to the ground. But these people have been leaving petri dishes around to see if spores are there. Everyone I have talked to says they may go to petri dishes, but they are going into the ground if it is there, and if it is not they are going where it is dark and dirty.

Now, we have not been looking where it is dark and dirty. We have been putting petri dishes out on the tables, as I understand it.

Can you clear that up for us? We really seriously have a group of young people who are going back into these buildings before Christmas probably and they are not satisfied with our explanations.

Dr. KOPLAN. Let me try. For one, I think there is frustration for all of us because we do not have all the answers and we do not have all the science for this. But for one, the EPA is responsible for the cleanup of the Hart Building and we are providing technical consultation.

Senator STEVENS. Doctor, they say you are responsible for the degree of safety in the buildings and determining whether it is clean or not.

Dr. KOPLAN. We are providing technical support to the EPA, and I will tell you everything I know.

Senator STEVENS. Do you accept responsibility for saying if the Hart Building is clean or not? Are you going to be the one that determines that?

Dr. KOPLAN. I think by statute the EPA is. We are working with them on a daily basis and this is an area that they have got longstanding expertise in, which is building cleanup and safety. We are involved in this to provide information on the anthrax.

Senator STEVENS. I am talking about the standards of what is clean.

Dr. KOPLAN. There are no standards, Senator.

Senator STEVENS. They are telling us that you are going to set them.

Dr. KOPLAN. Well, it is hard to set them in the absence of scientific information. This is why it is frustrating for all of us. But if I can continue, the issue here is to get rid of all the anthrax spores that we can through some process that gets rid of them. Your question is, well, how do you know where they are and how do you measure that?

The putting around of those petri dishes is appropriate because if you are on a ranch or you are on a farm, you look for anthrax in the soil or on cattle, but if you are in a room like this or in our homes or anywhere you might go, the spores exhibit a physical phenomenon: they drop to wherever they drop. They can drop in the plants and in the soil, yes. But they can also drop on a desk, and if there is a crevice on a piece of furniture they are as likely to be there as anywhere else.

It is not that they gravitate to soil. That is where they are found naturally. So when your folks outside talk about where you find it outside, yes, that is where it is naturally found, but not when it has been purposely spread in an office building.

Yes, it does spread through air ventilation systems and one of the things that has been done in Hart and other buildings has been to put petri dishes around in other places in the building to see where it has spread and to take specimens from walls, vents, filters, et cetera, to see where it has gone.

Really, the best measure of your first question of how far does it go, how do we know how fast it travels someplace, and where it goes, is to do that measurement in different parts of the building. That is what EPA and we have been working to do; to get those measures and see if it is there.

If you go and do a cleanup and it is still in places, then you have got to come back and do the cleanup again. I think none of us, whether it is CDC or EPA or the Capitol Physician, want to see you or any of your staff exposed to anything that can cause them harm. We have got to come to some determination of what is a safe level. Yes, we are working with our partners there to determine what is a safe level. We will come visit you in the Hart Building, too. We care about it for everybody. So we want a safe environment, a safe work environment.

The place will not be opened until it is deemed safe. You asked a question earlier of where these things line up and how you can find the spores; these petri dishes are the best route because that is what they grow on. But we will keep working with EPA until we can determine that you have got a safe work environment to go back into.

Senator STEVENS. I am overdoing it, but let us take the Daschle envelope. Air could carry that, it could go to the floor, people could walk on it and they could carry that. The cart that it was on could have carried it. A lot of things could have carried it around the building.

Let me say, I stayed in the building almost three days after I was there and I am one who believes it is clean now. Beyond that, the question is assuring other people it is clean. I still do not know

why other things were excluded. Petri dishes are one thing. Are you saying that you have tested some of the soils and the plants, you have tested some of the files and the drawers, you have pulled books off the shelf and tested them? That is not what we learned yesterday.

Dr. KOPLAN. Let me ask and I will get back to you on that. I will see exactly what they have tested, where they have done their swabs. If they have missed things that should be tested, they will have to be tested.

Senator STEVENS. Thank you very much. Thank you for your patience.

Senator HARKIN. Thank you, Senator Stevens.

Senator Landrieu.

OPENING STATEMENT OF SENATOR MARY L. LANDRIEU

Senator LANDRIEU. Thank you, Mr. Chairman. I appreciate you calling this hearing. I have prepared a statement that I will submit for the record, but I would like to take this opportunity to say a few things on the subject.

I realize that we are all on a learning curve here and really struggling to deal with something that is in some ways unprecedented in our Nation. Both of you have been wonderful to testify before our committees on several occasions and have been doing a very good job in helping the country prepare in the event of another attack.

Following up on what Senator Stevens said, could you just describe for the committee the link, the relationship or the communications you are having with our military infrastructure? While I appreciate that this is a public health issue, it is more than just a public health issue. It is not just your regular outbreak, obviously. It is not just an infection that has taken over the country. This is a purposeful attack with agents that we have had very limited experience with.

The questions that Senator Stevens asked are very much on point, I think: how clean is clean, how dangerous is the substance? Our military for many years has had a great deal of experience in bioterrorism, directed at protecting its own forces. All the information that the military has about protecting its own forces from this attack could be used very effectively in protecting the citizens of our Nation.

So my question would be, could you both describe for the committee your current communications and relations with the military and the Pentagon, so that we can both benefit from the expertise of the military and the CDC can try to come up with a plan that really works for the country? Dr. Koplan?

Dr. KOPLAN. Thank you. Thank you, Senator Landrieu. By the way, on your recent visit you advised us that it really is an anthrax attack, not an outbreak. I would like to let you know we use that expression now regularly ourselves, because it is not a naturally occurring disease outbreak.

Our links with the military actually go back some ways and so we have got a very good and close working relationship scientist-to-scientist and then at higher levels as well. The new Assistant

Secretary of Defense for Health Bill Winkenwerter and I have had regular discussions over this.

Our close ties are with USAMRIID, the Army Medical Research Institute for Infectious Diseases. In the earliest days of this anthrax outbreak, when our staff had to go to a 24-hour, 3 shift a day, round the clock cycle, they actually lent us some of their staff, came down, worked side by side with our people in our lab to get the job done. That is just an example. There is a close daily working relationship with USAMRIID, and we know the folks well and there is good communication and information gets exchanged.

As this thing progresses, there may well be the need for even more and broader interchange for information and for staff and for learning how things work.

Senator LANDRIEU. Mr. Chairman, the reason I raise this is as chair of the Emerging Threats Subcommittee, our jurisdiction is about helping the military be more prepared for these new asymmetrical attacks. So there may be a way for us to explore a more formal relationship between CDC and some of the experts within the Pentagon to really help step up this homeland defense so that these substances can be detected quickly, they can be analyzed more quickly, the communications can be made more effectively, and questions like Senator Stevens had can be answered in a much more urgent fashion, so that we can counter what we hope will be fewer attacks, but we are fairly confident there are going to be other attacks.

So I think a more formal relationship with the military and using their expertise, as well as leveraging the expertise of the CDC, is something I would like to pursue with you. I do not have a specific suggestion for this morning, but I just wanted to get that information.

Doctor, do you have anything to add?

Dr. FAUCI. Yes. Since we are a research institution, we have very good scientist-to-scientist interactions, particularly with individuals at USAMRIID and other groups that do biomedical research, prevention and public health out of the Department of Defense. It has been really quite good.

In fact, before you came in, Senator, I had mentioned that some of the collaborations, particularly in the arena of the development of the next-generation anthrax vaccine, is done in very close collaboration and cooperation with the Department of Defense. So from the scientific standpoint there is good collaboration.

I just might mention something that might be helpful to you in your formulation about the relationship between the military and civilian situations. Though we can learn an awful lot from them and I encourage us all to continue to make sure that the lines of communication are open, one of the things that is not fully appreciated is the rather significant difference in the populations that the military needs to think about and worry about when you are talking about bioweapons, strategic and tactical, versus bioterror in a very diverse civilian population.

If this were a theater of military operation and there was an anthrax attack and the attack was taken care of, you would have had very, very healthy young men and women between the ages of 18 and mid-forties or what have you. They would have been vac-

cinated, they would be very robust individuals. Whether or not there were two or three spores lying around, no one would care because of their mission.

Whereas in a situation in which you have civilians, where you have children coming into the building, pregnant women, older individuals, that is an entirely different ballgame. So that is really the reason why there is the frustration that Dr. Koplan alluded to, because there really is not any experience about what is totally safe in the setting that we are in right now.

Senator LANDRIEU. I appreciate that and I thank you. I will just close with this, that your points about the differences are well taken and I acknowledge that and I think it was well spoken.

PREPARED STATEMENT

But even given that, I think there are still, as we mentioned, some great leveraging that can be done between the military and the CDC as we stand up to this sort of new attack, or whatever we are going to sort of call it, to get the kind of information to the American people and get treatment and vaccines and deal with it in a much more expedited fashion. So I thank you and look forward to continuing to work with you on that.

[The statement follows:]

PREPARED STATEMENT OF SENATOR MARY L. LANDRIEU

Mr. Chairman, again, I would like to thank you for your leadership in holding this important hearing. As you well know, the subject of bioterrorism preparedness has been on the minds of all Americans. Stop at any newsstand in America and you will surely find the racks covered in newspapers and magazines with headlines that read, "How real is the threat?" or "Is America Ready?" Stop any American on the street and ask them to detail the symptoms and remedies for Anthrax or small pox and no doubt they will be able to. In this new world we live in, sights of HAZMAT suits and Cipro bottles are common.

The concern about the risk of exposure to deadly biological weapons is not just something we have read about or seen on television. For most of us here on the hill, our present circumstances remind us of how very real this threat is. From the time that the letter containing Anthrax was discovered in Senator Daschle's office, we ourselves, have had first hand experiences with nasal swabs, mail tests, fumigation procedures and antibiotic treatments. This experience forced us to question how prepared are we not only to respond to a bioterrorist attack but also to prevent against it. Finding the answers to these questions has not been easy. Like most other places in America, we were not unprepared, but we certainly were under prepared. We have made some good decisions and some not so good decisions, but most importantly, we have learned some important lessons. Our task now is to take those lessons learned and convert them into a plan for the next time, God forbid there ever is a next time.

Webster's dictionary defines the word preparation as "the process of making something ready for use or service or of getting ready for an occasion, test or duty." I mention this only because while we all use this word often, especially lately, it is important that we focus on what being prepared really means. In the event of a bioterrorist attack, our public health system must be ready to serve. This system has a duty to protect and preserve the lives of the American people. To be ready to perform that duty and that service, they will need guidance, assistance and resources.

Perhaps the first and most important step in the process of preparation is assessing the need for improvement. A recent article in the Washington Post asked this very question and what they found was this. A recent survey of city and county health departments found that 80 percent of them do not have comprehensive bioterror response plans. A little more than half of them have plans under development. Sixty-Two percent of these health centers responded that they were only "somewhat prepared" or not prepared at all to answer the public's bioterror questions since the September 11th attacks. A 1999 survey of the city and county health departments found serious gaps in the communication process between them and

the CDC. Sixty-Five percent of the CDC's e-mails were not successfully delivered to the departments. What's more, 55 percent of these public health agencies did not have the capacity to send alerts to multiple recipients like health agencies, the CDC and doctors. Finally, a 1998 study of 186 hospitals in Washington, Oregon, and Idaho found that 88 percent of them had no plan for attacks involving biological weapons.

These statistics show a collection of gaps that must be filled if we are to fulfill our promise to protect the American people from harm. Filling these gaps will require time, expertise and first and foremost, resources. In fiscal year 2001, the bioterrorism portion of the $3.9 billion CDC budget was a mere $181 million dollars. That is less than half of one percent. In this new world in which we now live, this is not enough. Yet just investing more money is not the answer. We must use these funds to make strategic investments in our public health infrastucture, national communication and coordination systems and disease and vaccine research.

Last year, Congress passed the Public Health Threats and Emergencies Act. This law, which I was proud to support, laid out a series of important initiatives to strengthen the nation's public health system, improve hospital response capabilities, assure adequate staffing and training of health professionals to diagnose and care for victims of bioterrorism, enhance our research and development capabilities and take additional steps to prevent, prepare and respond to the threat of a bioterrorist attack. While this bill became law, none of the programs it outlined were funded in fiscal year 2001. At the very least, we must invest the $1.4 billion authorized by this bill.

Mr. Chairman, as Chairman of the Armed Services' Subcommittee on Emerging Threats, I look forward to working with you, other members of this committee, members of the House and the Administration toward ensuring that the funding level for bioterrorism preparedness reflects its importance as a national priority. I am interested to hear from the witnesses today, especially those from the CDC and NIH about the extent to which they are collaborating with the Department of Defense and their experts in the area of bioterrorism. This threat of a biological weapons war is not new to them, they have had to have been prepared for such an attack, albeit under different circumstances, for quite some time. The resources, procedures and information that the DOD has to offer in this area are invaluable. I encourage members of this first panel to make use of this resource. Most importantly, I hope that they will work together with the DOD to reduce any duplication of effort and thereby maximize the potential of the resources and skill offered by all the relevant federal agencies.

Thank you.

Senator HARKIN. Thank you, Senator Landrieu.

Just a couple of follow-ups. I mentioned earlier—I do not know which one of you want to respond to this, but on the national pharmaceutical stockpile, are you planning to include Cidofovir in that? I do not know who is the proper person to ask that?

Dr. KOPLAN. Yes, there is a budget for Cidofovir in that.

Senator HARKIN. In the stockpile?

Dr. KOPLAN. Yes.

Senator HARKIN. Secondly, Senator Specter apologized; he had to leave to go to the Judiciary Committee. Both of us were discussing here the figures, Dr. Koplan, that you went over with him. There is just a little bit of confusion here on the smallpox development versus the smallpox vaccine, and we are trying to get a handle on that.

Without going into it because we want to move to our next panel, could you just submit to us again the details of what you just discussed with Senator Specter?

Dr. KOPLAN. Can I do that for the record?

Senator HARKIN. You want to do that now or do you want to submit it for the record?

Dr. KOPLAN. Can I submit it for the record?

Senator HARKIN. Please submit it for the record.

Dr. KOPLAN. Okay.

Senator HARKIN. Well, I am told by staff that we need to get this budget today.

Dr. KOPLAN. We will have it to you before the day is over. It is easier to see it written out on a line, and we will have it for you today.

Senator HARKIN. There is just a little bit of confusion on this, on a couple of those figures.

Dr. KOPLAN. We will have it on paper before the hearing is over, how is that?

Senator HARKIN. Rather than sitting here going back and forth, just give it to the staff afterwards.

Dr. KOPLAN. Great.

Senator HARKIN. Also, with those figures, Senator Specter also needed to know, just again we need to know time lines—how much now, how much you need later on, so we know the flow of the money.

Dr. KOPLAN. Will do.

Senator HARKIN. Lastly, do we have to provide money each year for upgrading State and local public health? You mentioned the figure of $1.050 billion. That was for upgrading State and local capacity. We are going to be hearing from some of the hospitals here on the next panel, but obviously there is a one-time up-front cost for training and that type of thing. But then there is going to have to be some ongoing costs.

Dr. KOPLAN. Actually, there is very little up-front cost for training because the training is ongoing for all these individuals. Yes, we would start right off with training, but the nature of the turnover in local and State health departments and the nature of new knowledge being imparted is such that training goes on literally 365 days a year for laboratorians and epidemiologists. So that is an ongoing thing.

Senator HARKIN. So you are looking at that $1.050 billion as——

Dr. KOPLAN. This is a yearly cost to keep our local and State health departments up to speed.

Senator HARKIN. So you are saying this committee has got to come up with an extra billion every year?

Dr. KOPLAN. Yes.

Senator HARKIN. Okay.

Dr. KOPLAN. In my professional judgment.

Senator HARKIN. I am sorry that Mr. Stevens left before that one. But anyway, we will make sure he hears that.

Thank you both very much again from a personal standpoint, but also speaking for this committee, we thank you both for your great leadership that you have shown in these trying times.

Barring any unforeseen circumstances, I doubt that we will be having you here again before the end of the year, but certainly when we come back in January we will want to have you back again to see where we are at that point in time, probably at the end of January, early February, come back and see if we need to make any adjustments in our budgets at that time.

Dr. KOPLAN. Thank you.

Senator HARKIN. We will be having supplementals.

Dr. FAUCI. Thank you very much, Mr. Chairman.

Senator HARKIN. Thank you very much, Dr. Fauci, Dr. Koplan.

Next, we have a vote coming up at 10:30. I am going to try to see if we can bring this next panel up: Dr. Ken Alibek, President of Advanced Biosystems; Dr. Joseph Barbera, Associate Professor and Co-Director of the Institute for Crisis, Disaster, and Risk Management at the George Washington University; and Joseph LeValley, Senior Vice President for Planning and Systems Development, Mercy Medical Center of Des Moines, Iowa.

We will start off in the way I have introduced: Dr. Alibek, President of Advanced Biosystems. Dr. Alibek, I might inform the audience, defected to the United States from the Soviet Union in 1992. Prior to that he was the Deputy Director of Biopreparat, the civilian arm of the Soviets' biological weapons program. Dr. Alibek frequently briefs U.S. military, intelligence, and medical officials about biological weapons and defenses. He is the author of "Biohazard," which describes his experiences running the Soviet bioweapons program. He holds M.D., Ph.D., and Doctor of Science degrees which he has received in the Soviet Union.

Dr. Alibek, welcome to the committee. Your testimony will be made part of the record and just please proceed as you desire.

STATEMENT OF KEN ALIBEK, M.D., PRESIDENT, ADVANCED BIOSYSTEMS, INC.

Dr. ALIBEK. Thank you. Mr. Chairman, thank you for inviting me to speak today. I know I have not much time, but I will try just to be absolutely short.

In my opinion, one of the biggest issues we need to resolve as soon as possible is what kind of research do we need to do in the field of weapons threat analysis and development of medical defense against biological weapons threat agents. I know we are focusing now on anthrax and smallpox. I fully support this work and I believe that anthrax and smallpox could be considered as an imminent threat to our Nation.

But at the same time, we need to keep in mind, unfortunately, the number of biological agents that could be used in biological weapons is very large. Just a short analysis done in the former Soviet Union showed that several dozen different biological agents could be used in biological weapons. Many of them have been developed in the form of biological weapons. For example, just a short enumeration probably would show you what is the real biological weapons threat.

In addition to anthrax, bacterial agents like plague, tularemia, brucellosis, glanders, melioidosis have been developed as biological weapons. Viral biological agents include smallpox, Ebola, Marburg, various encephalitis, and some other viral hemorrhagic fevers. There is a group of biological weapons based on so-called rickettsial agents: epidemic typhus, and so on and so forth. There is a group of so-called fungi biological weapons, including blastomycosis and toxidiumicosis.

Of course, I realize that if we start taking care of all these agents probably it would not be possible to find such a huge amount of money. But at the same time, we need to start doing some work to understand what is the real biological weapons threat. In my opinion, we need to rectify our knowledge, our understanding of the biological weapons threat. It would help us to develop a new con-

cept of biological weapons defense. When we work in the field of biological weapons defense or medical defense against biological weapons, we usually work in three major fields.

One field is so-called prophylaxis, or vaccine development; another field, so-called emergency prophylaxis is when we develop some medical means and approaches just to use for pre-exposure or post-exposure prophylaxis. I mean immediate pre-exposure, post-exposure. Then there is a third field, so-called treatment.

But when we discuss this issue, we focus very much on vaccines. I have nothing against vaccines, but what we need to keep in mind is that vaccines have been considered as the best defense against biological weapons by many countries to protect troops. Nobody considered vaccines for use in protecting civilian populations, because of some important reasons.

What we need to keep in mind is that vaccines usually take weeks and months just to take effect. In this case, for example, the just recent anthrax event, nobody discussed the necessity of using anthrax vaccine to vaccinate people who got infected.

In this case, of course, we need to spend more time just to see what kind of emergency prophylaxis means we could develop and use to take care of these infected individuals. We need to pay much attention to our treatment options and see what we can use to treat these individuals.

There are many other issues, but what I would like to say, when again we discuss the smallpox vaccine—I fully support this effort. We need to develop this vaccine because of two important reasons: because this infection is a very threatening, contagious infection and could cause epidemics and pandemics; but at the same time, this infection—this vaccine, I mean, this vaccine could be used not just for containing outbreaks and epidemics. It could be used for treatment, for so-called post-exposure prophylaxis. This vaccine is the only means we have got now just to protect against smallpox.

But at the same time we need to think what else we can do, because I do not envision any situation in which we are going to vaccinate the entire population of the United States against anthrax, for example, prior to any anthrax incident. I do not envision a situation in which you are going to vaccinate the entire population of the United States against many different infections.

In this case, of course it does not mean we do not have to work in this field of vaccines, but it means we need to focus much effort in the field of emergency prophylaxis and treatment, because there's not just a single way to protect, such as to develop and deploy vaccines.

One more issue I would like to touch on here. You know, the Soviet Union as a country has spent decades and decades researching and developing new biological weapons. My knowledge is coming from the Soviet Union, and my expertise in this field. Since I came to the United States in 1992, I have spent years and years discussing these biological weapons threat issues and possible approaches to biological and medical defense against biological weapons with many experts here in the United States—military experts, civilian experts. We discussed the different aspects of this problem.

You know what is getting obvious? Unfortunately, we have lost the knowledge and understanding of biological weapons threat

some time in the sixties and seventies. Since the seventies a lot has changed. We need to keep in mind two important things. Now when we discuss a biological weapon, or let me say medical defense against biological weapons, we are working in the field of developing protection against biological weapons developed in the seventies, early seventies and late seventies.

But you know, starting from the eighties a lot of new biological weapons have been developed. A lot of new genetically engineered agents and weapons have been developed. We are not addressing these issues now.

There is another problem when we talk about developing protection against biological weapons. In my opinion it is a major point. When we develop a new vaccine, it usually takes from 8 to 12 years to develop and get a new vaccine approved. But you know, my personal experience is that the development of biological weapons—I knew about many biological weapons developed in the former Soviet Union—usually takes from 3 to 4 years.

You can imagine in this case it is a sort of a race, with biological weapons appearing that are genetically engineered, antibiotic resistant, new agents, and so on and so forth. If you have got this time range for the development of protection, 8, 12 years, we will be increasing, widening the gap between our knowledge in the field of biological weapons defense and an actual situation in the field of biological weapons threat agents. In my opinion, this is important to address.

At the same time there is a group of scientists still in Russia. Some of them from the former Soviet Union are in the United States, in some European countries, Asian countries.

PREPARED STATEMENT

I am finalizing my talk. What we need to do in my opinion, we need to use the knowledge of these people, because many of them are underemployed now. Useing their tremendous knowledge in the field of biological weapons threat and defense probably would give us a lot of benefits here in developing a defense against biological weapons.

[The statement follows:]

PREPARED STATEMENT OF DR. KENNETH ALIBEK

TOPIC: BIOTERRORISM

Thank you, Senator Harkin and members of the Committee, for inviting me to testify for you today on the topic of bioterrorism. I am in a rather unique position to discuss these issues, since I developed biological weapons for the Soviet Union for nearly twenty years, until my defection in 1992. When I left the Russian biological warfare program, I had been serving as First Deputy Director of Biopreparat, the civilian arm of the biological weapons program, for four years. At that time, I was responsible for approximately 32,000 employees and 40 facilities, comprising over half of the entire Russian program's personnel and facilities. Since arriving to the United States, my personal and professional goal has been to make the greatest contribution I can to the elimination of the danger of biological weapons.

Biological Weapons Threat of Proliferation and Terrorism Following the breakup of the Soviet Union and the end of the Cold War, the threat of proliferation of mass casualty weapons has grown dramatically. In some ways, the danger posed by the proliferation of biological weapons and biotechnology is greater than that of nuclear proliferation. For example, the acquisition, manufacture, deployment, and movement of nuclear components or weapons is much more expensive and difficult to achieve than that of biological agents. A freeze-dried vial of anthrax can easily be

obtained and concealed, and the knowledge of how to turn that vial of anthrax into a biological weapon is in the possession of hundreds of scientists and technicians. The recent incidents of anthrax dissemination through the Postal Service have only served to demonstrate the reality of this threat.

The growing frustrations among scientists within the former Soviet bioweapons community add to the risks of proliferation. Despite initiatives directed by the United States government to employ some of these scientists and to shift the focus of their research to peaceful projects, more needs to be done. Many of these scientists are highly trained in biotechnology and their talents could be directed toward finding new methods of preventing or treating the diseases caused by these pathogens. Several former bioweapons scientists have emigrated to the West and are currently under-employed. We fear that in order to feed their families, others may offer their technical skills on the open market, which could provide our enemies with technical expertise or ready-made, engineered organisms. Some Russian microbiologists are reportedly teaching students from rogue states that are interested in this expertise. Other prominent scientists have simply dropped out of sight.

In a report to the Senate Permanent Subcommittee on Investigations in 1995, the U.S. Office of Technological Assessment identified 17 nations believed to possess biological weapons. It is estimated that at least 20 countries either have active research programs or were formerly involved in biological weapons research and production. In many cases, these are nations that are also engaged in chemical and nuclear programs, since they feel the necessity to protect themselves from hostile neighbors by any means necessary.

BIOLOGICAL DEFENSE AND TREATMENT OPTIONS

In the U.S. and other countries, growing fears of a biological attack by a hostile country or a terrorist group have prompted intensive efforts in the areas of consequence management, response planning, intelligence gathering, and nonproliferation of expertise. However, little effort has focused on new methods for treatment or prophylaxis of biological threat agents.

Unfortunately, the diseases caused by many biological threat agents, such as smallpox, Ebola, and Marburg are currently untreatable. For so-called treatable diseases, such as anthrax, plague and tularemia, current methods of treatment or medical prophylaxis are often ineffective. Antibiotic resistance is on the rise, and in many cases biological threat agents have been genetically engineered to increase their resistance to drugs.

Similarly, vaccines do not exist for the majority of biological threat agents. This situation is unlikely to change when we consider that it takes 3–4 years to engineer a new drug resistant or more virulent bioweapons, but it takes 10–12 years to develop and get Food and Drug Administration approval for a new vaccine. Even the few available vaccines are often ineffective against biological weapons for three reasons:

—Vaccines often require weeks to months to take effect;
—Vaccination of large portions of the population against numerous threat agents in advance of a biological incident is not feasible
—Biological threat agents can be engineered to circumvent the action of vaccines

NEW PARADIGM

We need to develop a broader appreciation of the scope of the threat posed by the major biological threat agents and possible medical and public health responses to them. This can only be achieved through extensive biomedical research aimed at developing new prophylaxis and treatment strategies.

New approaches are needed to both prevent and treat these pathogens, and our country needs to be at the forefront of medical research aimed at studying and developing novel approaches to combat disease. Recent advances in our understanding of the immune system are making it possible to create new tools to defeat invading organisms by boosting the immune response. These new means and approaches would supplement or replace drugs used to attack the invader. Tools to boost the immune system are not limited to infectious diseases, but can also be applied to the treatment of cancer, cardiovascular, autoimmune, and age-related diseases.

Research in this area should include investigations of the etiology and pathogenesis of infections caused by biological weapons, specific and nonspecific immunomodulation as a means of eliminating pathogens, and new antiviral and antibacterial drugs. Many of the treatments that could be developed based on this research could be useful not only for the purpose of medical defense, but also for the greater purpose of improving the general health of mankind.

INTERNATIONAL COLLABORATION TO CATALYZE THE DEVELOPMENT OF EFFECTIVE RESPONSES TO BIOTERRORISM

Countering bioterrorism will require efforts on an international scale. We should establish and maintain international collaborations of experts on bioterrorism and biodefense. The following research areas would greatly benefit from international collaboration:

—The potential of various biological threat agents
—Possible production and deployment methods used by terrorists
—Technical countermeasures to biological aerosols
—Analysis of possible genetic engineering of biological threat agents
—Epidemiology of infections caused by biological weapons
—Disinfection of large contaminated areas and buildings
—Medical microbiological, molecular biological, and immunological methods for the development of protection against biological weapons
—Research and development of novel therapeutic and prophylactic regimens for infections caused by biological weapons
—Signatures of possible production facilities

Addressing these issues will greatly enhance the international community's preparedness for a biological attack.

Senator HARKIN. Thank you, Dr. Alibek. That is a great suggestion. I read it in your testimony and that needs to be followed up on and I intend to follow up and find out what the administration is doing on that.

Dr. Barbera, welcome to the subcommittee. Dr. Barbera, your testimony will be made a part of the record in its entirety and I will ask you to summarize it if you could.

I just want to say again that Dr. Barbera is Associate Professor and Co-Director of the Institute for Crisis, Disaster, and Risk Management at GW University. Dr. Barbera.

STATEMENT OF JOSEPH BARBERA, M.D., ASSOCIATE PROFESSOR AND CO-DIRECTOR, INSTITUTE FOR CRISIS, DISASTER, AND RISK MANAGEMENT, THE GEORGE WASHINGTON UNIVERSITY

Dr. BARBERA. Thank you very much, Mr. Chairman. I will try to summarize. My statement is relatively short.

I have been an operational emergency medical responder to major disasters for the past decade for the Urban Search and Rescue system for the Office of Foreign Disaster Assistance. I responded to the Oklahoma City bombing and after the September 11th events. I was a responder to both the Pentagon and World Trade Centers.

I have additionally been involved through the hospital and through local preparedness efforts with the bioterrorism events that occurred recently here in Washington, D.C.

I am coming at this from a different angle than what we have heard in the prior testimony and that is from the operational medical perspective: how do we actually address bioterrorism and other types of mass casualty terrorism at the operational level, how do we institute medical care, how do we apply the principles, the scientific principles that you have heard talked about earlier?

I would like to say also that I think it is important that at this point we start to focus very much on hospital preparedness for mass casualties. This has not been something we have done in the past. It is something the public and the press have asked about: Why do we not have adequate preparedness at the hospital level for mass casualties?

What we have right now is hospitals trying to do reasonable preparedness for mass casualty events, and it is my belief that there is a wide gap between what is adequate and what is reasonable. The current medical economics are such that hospitals have very little left over to spend on things that do not have to do with the everyday practice of medicine. When I have talked to hospital administrators in the past about disaster preparedness, many of them have responded that their main concern is not the terrorism that could occur 3 months from now, it is whether or not their hospital will be in business 3 months from now due to medical economic constraints.

It is important to recognize that preparedness for mass casualty terrorism and mass casualty events from a hospital perspective has very little to do with what hospitals do on an everyday basis and what they do to prepare for the old-fashioned definition of a disaster, which is 1 to 10 or 20 casualties from a trauma event. In order to prepare for these things, I think it is time that we start to focus on how we treat hospitals as part of the public safety function in the American emergency response community.

As I have put into my testimony, right now when you need fire suppression you call 911 and you get fire response, which is a government entity. When you need law enforcement, you get police and that is a government entity. When you need mass casualty medical care, you get 911 and you get EMS, which is a government entity. But the patients end up at hospital facilities that are generally private, for-profit, not-for-profit, even public hospitals, that do not have a budget for mass casualty preparedness.

If we are going to adequately prepare for this, we need to pay attention to that, start to treat at a public policy level mass casualty medical care as a public safety function. We also have to recognize that hospitals are very much a vital asset in community emergency response and they deserve the same level of security and other attention that other government emergency response entities are given.

So how do we address this? I think you are taking a very important step here and I congratulate you on focusing on hospital preparedness for mass casualties. I think there are models out there for public-private emergency response partnerships that can be followed and I have referenced a paper that I did for the Harvard Kennedy School that addressed this specific subject.

I think that hospitals very much would be willing to develop even a contractual relationship with local community emergency response, to develop programs that include training and maintenance of those programs for mass casualty care and for specialty care, for true surge capacity for not just bioterrorism events, but an all-hazards mass casualty preparedness.

In closing, I would like to say very much that I think that we have a very strong medical foundation here at the hospital and the acute care medical communities across the United States. I have been part of the bioterrorism response entity here in Washington, D.C., over the past month and a half. I chair the D.C. Hospital Association Emergency Preparedness Committee. We have developed a mutual aid memorandum and a hospital mutual aid system in

Washington, D.C., between all of the hospitals in Washington, D.C., and including the four Federal hospitals in the D.C. area.

As part of our response, we established a daily conference call that ended up encompassing most of the hospitals in the National Capitol Region, most of the public health authorities in the area, and the acute care medical community. As the moderator of those conference calls, I was quite encouraged and inspired at how hospitals came together and worked very hard for community betterment during this.

PREPARED STATEMENT

I think that we have a possibility now or a very strong probability to develop programs that promote operational medical systems, not just the buying of equipment, not just seed money that will start programs that will then be another unfunded Federal mandate for hospitals to continue, but an opportunity to develop operational systems of information management, communication, true collaboration between the acute care medicine and public health entities, things that will be ongoing that will improve the medical care in the United States, not just for terrorism response but for all-hazards mass casualty events.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DR. JOSEPH A. BARBERA

Mr. Chairman and Members of the Subcommittee, I am Joseph A. Barbera, a residency trained, board certified emergency physician. I am Co-Director of the Institute for Crisis, Disaster, and Risk Management at the George Washington University, where I teach masters and doctoral emergency management courses, and I provide emergency medicine services through the George Washington University Hospital. One of my professional volunteer activities is chair of the Emergency Preparedness Committee of the District of Columbia Hospital Association (DCHA), a position I have held since the committee's inception in 1995. In this role, I have presided over the development and implementation of a comprehensive Hospital Mutual Aid System that provides effective coordination and communication between the District's hospitals in emergency preparedness and response. The four Federal hospitals in the National Capital Region, Walter Reed, National Naval, Malcom Grow, and the Veterans Administration Medical Center are all very active and vital participants in this process.

During my medical career, I have also had the privilege of experiencing disaster response to major incidents. I have participated in the FEMA and Office of Foreign Disaster Assistance Urban Search & Rescue programs for over a decade, including earthquake responses to Northridge California, Taiwan in 1999 and the Philippines in 1990. I have responded to major terrorism incidents, providing medical expertise to the search and rescue effort after the Oklahoma City bombing and, after September 11, to both the Pentagon and the World Trade Center incidents.

I have additionally experienced the specter of biological terrorism. I was the emergency physician on duty at George Washington University Hospital the day of the B'nai B'rith bioterrorism hoax in 1997. I was a medical controller for the TOPOFF bioterrorism exercise in Denver in 2000. Most recently, I was heavily involved in the recent anthrax dissemination incident here in the National Capitol Region. In my role for DC Hospital Association, I established a daily conference call that became the basis for information exchange between hospitals, acute care providers, and the multiple public health authorities in the National Capitol Region. We are currently developing a profession review of that incident response to capture the views of the hospital-based medical community.

I have been asked to speak to you today about the subject of hospital preparedness for mass casualty response. I would like to note that I provide this testimony from the medical perspective of a hospital-based emergency physician with extensive experience in emergency public health and emergency response. I have no remunerative relationship representing hospitals, or hospital associations, in this regard.

I would like to begin by congratulating and thanking you for focusing on this vitally important subject. As we face the specter of mass casualties from chemical, biological, incendiary or explosive attacks, the press and the public are continuously asking why the medical care community is not adequately prepared for these possibilities. Many vague reasons have been put forth, but the cold hard reality is that adequate preparedness is impossible without basic changes in public policy attitudes towards funding medical preparedness.

First, one must understand that the non-governmental medical system must be viewed as a "first responder" in mass casualty care.

Next, one must understand what mass casualty care entails. The medical infrastructure needed to care for one or ten injured or ill individuals is completely different from that required to care for hundreds or thousands of patients. The infrastructure for mass casualty care also has very little to do with everyday hospital practice. This is not a minor technicality to be recognized and understood only by medical planners. This is a fundamental financial reality that must be addressed by the highest level of political leadership at all levels of government. It is also critically important to understand the following key concepts:

—When you need firemen for fire suppression, you call 911 and the municipal fire department responds with the needed assets. All non-governmental assets are bit players. We stopped expecting private fire insurance companies to fund municipal fire services somewhere around two hundred years ago.

—When you need law enforcement to control a situation, you call 911. Police respond and become the primary force that provides law enforcement. Private security is only a bit player if involved at all.

—When you need acute medical care for hundreds or thousands of casualties, you call 911, but the response capabilities are completely different. Municipal services have little significant acute medical care capacity beyond triage and transport of patients. Definitive medical care in Washington DC, and most areas of the United States, is a function of primarily private sector assets. As such, all hospitals should be viewed as critical emergency response assets within a community, and accorded security considerations similar to that provided to governmental emergency response entities.

The next reality is that private medicine has been shaped by medical economic forces beyond the control of the medical and hospital community. Hospitals now survive by adopting "modern business practices" such as just-in-time inventory, bare minimum staffing patterns, closure of empty hospital beds. All these make smart business sense, but they have severely impacted health care surge capacity for both mass care and for specialty care of unusual victims such as critical care patients, ventilator patients, burn patients, patients requiring isolation, and so on. In an era of barely survivable medical economics, the government and the public have expected private medicine to pay on its own to cover the exorbitant costs of the community's mass casualty preparedness. It hasn't happened, which is why we are here today.

Mass casualty medical care must be recognized as a public safety function, and therefore as a governmental responsibility equal in importance to fire suppression, emergency medical services, public works, and law enforcement. Until public policy changes to address this financial reality, we have little chance of adequate preparedness for mass casualties. Hospitals, in their current financial circumstances, can at best make a good-faith effort at reasonable preparedness, and indeed they are doing so. The difference between adequate and reasonable is wide, and I believe it is unacceptable to the American public.

How can we address this gap?

Begin with a fundamental change in governmental attitudes towards hospitals, and I commend you for taking this important step. Government must actively solicit the hospitals' planning input through hospital group efforts such as the DC Hospital Association's Emergency Preparedness Committee. Government agencies must understand that they have an obligation to support hospitals in planning for mass casualties—Hospital's are in fact in the driver's seat of providing medical care. Government, including government public health entities, must allow hospitals to have significant input in developing the most effective ways for them to organize and to be assisted by governmental assets in preparing for and responding to mass casualty events.

A major fact of emergency management is that the planning process is far more important than any actual plan. The process must promote the development of effective planning and response relationships between key players, and this is even more important in areas such as healthcare, where many of the key resources are non-governmental. It again is a governmental obligation to assure that this objective is accomplished, and I believe this should be a goal of your legislative efforts.

Finally, government at all levels must accept that mass and specialty casualty care is a public safety function and must have adequate funding provided to hospitals who are willing to accept the responsibility for this community need. Hospitals do not need, nor should they accept, "seed money" that begins expensive emergency preparedness programs that result in additional unfunded Federal mandates. Hospitals need to become funded partners in community emergency preparedness, fully integrated into emergency response. Hospital mutual aid systems, effective collaboration between public health and the hospital community, mass decontamination capabilities, critical care surge capacity, improved information systems for communicating between hospitals and with key health officials are only a few of the requirements that would provide immense public benefit. Public hospitals, including our Federal hospital partners here in the Washington DC area, must receive the same financial attention.

Many hospitals, I believe, would be very willing to agree to a contractual relationship with the local community that adequately funds development, training, and maintenance of defined surge capacity and other specialized resources. Medical realities, such as the twenty- percent annual turnover in emergency department staff found in many hospitals, must be addressed in the training aspect of system maintenance. Many models exist for this type of public-private emergency response partnership, and have been described more fully in an article I co-authored for the Kennedy School of Government at Harvard University, titled "Ambulances to Nowhere: America's Critical Shortfall in Medical Preparedness for Catastrophic Terrorism."

In closing, I would like to emphatically state that this is not a time for political maneuvering, and it is not a time for shaping public perceptions of medical response competence through any route other than actually becoming competent in a planning process that could mean life or death for future terrorism victims in the United States. The coming together and voluntary commitment to community well-being that I witnessed by hospitals in the National Capital Region since September 11 have been both encouraging and inspiring. We have a very strong medical foundation upon which to expand our mass casualty preparedness. I urge you to thoughtfully develop a program that promotes creation of operational medical response systems that are effective, sustainable, and multi-use.

Mr. Chairman, that concludes my prepared remarks. I apologize that they are not more detailed, but I was invited to furnish this testimony only two days ago, and my schedule did not provide the amount of time I would have liked to further shape my comments. I would be pleased to answer any questions you or members of the Subcommittee may have at this time.

Senator HARKIN. Thank you very much, Dr. Barbera.

There is a vote on now. I think what I will do is I will hear Dr. LeValley's testimony, then we will take a break. You might get together with Dr. Koplan so he can get back and get these figures. Then I will come back here for a round of questioning. Senator Specter may come back with me at that time also.

So now we will turn to Dr. Joe LeValley, Senior Vice President for Planning and Systems Development, Mercy Medical Center in Des Moines, Iowa, again, hearing from people out in the field as to, again taking off from what you just talked about, Dr. Barbera, what we need in our local hospitals to be ready for any contingency like this. I am going to get into that more later when I get back to my questions.

Dr. LeValley, welcome again to the committee.

STATEMENT OF JOSEPH LeVALLEY, SENIOR VICE PRESIDENT FOR PLANNING AND SYSTEMS DEVELOPMENT, MERCY MEDICAL CENTER OF DES MOINES, DES MOINES, IOWA

Mr. LEVALLEY. Thank you, Mr. Chairman. My name is Joe LeValley. I serve as Senior Vice President for Planning and System Development at Mercy Medical Center in Des Moines.

I want to begin by saying it is an honor for me to be here representing our hospital and indirectly thousands of other hospitals. Mr. Chairman, as an Iowan it is particularly a pleasure to appear here before this committee. I and everyone at Mercy have enjoyed

the opportunity to work closely with you and your staff for many years and appreciate your longstanding support of health care in Iowa.

Mercy is a 691-bed tertiary hospital. We are involved in providing care in more than 50 sites, including physician clinics, nursing homes, hospice, and a dozen rural community hospitals. So I am going to try to bring the perspective as a non-clinician, the perspective of an administrator trying to coordinate with many others the care of Iowans in these issues.

One of the questions that America's hospitals have been asking since the national tragedy of September 11 is how ready are we to respond to incidents of terrorism involving biological, chemical, or nuclear materials. One answer is that we currently are well prepared to decontaminate, triage, diagnose, and treat a small number of victims of exposure to these dangerous materials. Our medical center, as an example, has one portable decontamination unit that can be utilized. We have one negative air flow room in our emergency department that prevents fumes and particulates from entering the rest of the hospital. We have a large emergency department with 38 exam and treatment rooms and a staff of more than 120 people. This emergency department cares for 56,000 people a year, the most of any in Iowa.

One reason we can claim to be ready for modest incidents is that we recognized even before September 11th the need to do more and we have implemented last spring an aggressive program to increase our preparedness. It involved training, new equipment, new haz-mat suits, new policies and procedures, clinical guidelines, security measures, several education programs, etcetera.

We also participate in the Metropolitan Medical Response System, which is a community-wide effort we are very proud of, that coordinates the planning for and response to these types of things. We have five departments represented on different committees of that collaborative effort.

Of course, Senator Harkin, we also hosted the community forum that you sponsored and facilitated, which was attended by people from throughout the community and the area in addition to the general public.

Despite our obvious pride in Mercy's capabilities and preparations, I do have to report that I do not believe we are prepared, nor any hospital is prepared, for mass casualties in the area of biological, nuclear, or chemical exposure. When you ask, well, how prepared are we, what is our level of preparedness overall, it is difficult to answer. It depends on what scale of preparedness do we want to be ready for, what scale of attack do we think is possible.

But, having said that, that it is almost an unanswerable question, there is no question that hospitals need to do more. An organization like ours, the largest trauma center in the State, needs more than one portable decontamination booth. If an attack were to occur, that booth takes care of one person every 8 minutes. That may not be adequate, probably would not be adequate in a mass exposure situation.

Many hospitals do not have even the basic level of the capability that Mercy has. So we know hospitals do need to do more and we are going to need the Federal Government's assistance to do that.

Some of this is occurring. We are pleased that the Des Moines area with this collaborative team has received a $400,000 Federal grant to get it started. But it is not nearly enough when you consider the number of providers and agencies who need that money in order to improve their capabilities.

So it is imperative the Federal Government provide additional assistance to America's hospitals, many of which already are suffering from declining reimbursement, increasing demands for care, and rising costs. Many of us have reached those capacity limits of having full beds and long waiting times in our emergency departments.

This problem is especially acute in Iowa, and the Senator is very aware of this issue, where we are severely underpaid by Medicare in a very unfair way. That constrains all types of issues for us: our ability to recruit and retain staff, to have adequate facilities, etcetera.

So I have included in my testimony a kind of a laundry list of things I think hospitals need. For time's sake, I will not repeat it here, but I think these are all critical things, not only the ongoing education and training that Dr. Koplan mentioned, but there are facility needs, there are equipment needs, that we have to address.

I would ask the Federal Government to address these things in two forms: an ongoing provision of fair and adequate payment and in specific grants to health care organizations and coalitions. Some of the bills that are being worked on include especially the second half of that and we appreciate that.

PREPARED STATEMENT

In closing, I want to say thank you. We appreciate Senator Harkin's and the committee's attention to this critical issue, and we certainly appreciate any support you are able to provide America's hospitals in dealing with these threats.

[The statement follows:]

PREPARED STATEMENT OF MR. JOSEPH LEVALLEY

Mr. Chairman and members of the Committee, my name is Joe LeValley and I serve as Senior Vice President for Planning and System Development at Mercy Medical Center in Des Moines, Iowa. I want to begin by saying that it is an honor for me to be here today, representing our hospital and, indirectly, thousands of other hospitals across our nation. Mr. Chairman, as an Iowan, it's a particular pleasure to appear before this committee. I and everyone at Mercy have enjoyed the opportunity to work closely with you for many years, and appreciate your longstanding support of health care providers in Iowa, and of the patients and families we serve.

Mercy Medical Center is a 691-bed tertiary medical center in downtown Des Moines. However, our organization is involved in providing care in more than 50 sites including physician clinics, nursing homes, hospice and a dozen rural community hospitals in central and southern Iowa. We are members of Catholic Health Initiatives, one of the nation's largest not-for-profit health care systems, and are affiliated with Mercy Health Network, a statewide network of hospitals and clinics in Iowa.

I have worked for Mercy hospitals in Iowa for 18 years. In my current role I am responsible for the strategic and facilities planning for Mercy-Des Moines and I oversee our Network of community hospitals. In contrast to several of the other witnesses, I am not a clinician. The perspective I hope to provide to the committee is that of an administrator who works closely with physicians, nurses and managers in all areas of the organization to try to ensure that our programs, services and facilities are adequate to meet the needs of more than 650,000 people living in the nine counties of central Iowa.

One of the questions that America's hospitals have been asking since the national tragedy of September 11, is: how ready are we to respond to incidents of terrorism involving biological, chemical or nuclear materials? One answer is that we currently are well prepared to decontaminate, triage, diagnose and treat a small number of victims of exposure to these dangerous materials. Our medical center has one portable decontamination unit that can be utilized in the Emergency Department garage with just 12 minutes notice, and we have one "negative air flow" room that prevents fumes or particulates from entering the rest of the hospital when caring for cases such as these. We have a large Emergency Department, with 38 exam and treatment rooms and a staff of more than 120 nurses, doctors and support staff. This ED receives and cares for 56,000 patients a year—the most of any hospital in Iowa.

One reason Mercy-Des Moines can claim to be ready for modest incidents is that we recognized, even before September 11, that we and the rest of the community needed to do more to prepare for the possibility of mass exposure to biological, chemical or nuclear agents. As a result, Mercy's clinical and safety leaders began an aggressive program to increase our preparedness. Since last Spring Mercy has provided hazardous materials training to all members of the staff of the Emergency Department. This training has totaled more than 600 person-hours. In addition, we have added new equipment, such as the decontamination booth, and about a dozen special "Haz-mat" suits to protect staff as they decontaminate and care for these patients. We have developed new policies and procedures, we have developed clinical guidelines for dealing with specific agents, such as Anthrax, we have stepped up our disaster drills, and we have increased our security measures for the hospital and its ambulances and helicopter. We also have hosted several educational programs for health care providers, have been active participants in the Metro Medical Response System—a community-wide effort to coordinate planning for, and response to, disasters such as we're discussing today. Mercy currently has representatives from Emergency Services, Infection Control, Safety and Security, Laboratory and Pharmacy serving on committees for this effort. In addition, Mercy representatives participate in the Iowa Department of Public Health's Disaster Preparedness Initiative—a statewide effort to create teams to respond to terrorist incidents. Lastly, as you know, Senator Harkin, Mercy hosted a community forum in October which you organized and facilitated, that was attended by emergency personnel from every agency and organization, in addition to the general public.

Despite our obvious pride in Mercy's capabilities, and the leadership we have shown in this important arena, I must report to the committee that we are NOT prepared—nor do I believe any hospital in America is prepared—for large scale disasters involving biological, chemical or nuclear agents. What is our level of preparedness overall? That is a difficult question to answer specifically, without defining the magnitude of the threat for which we want to be prepared. But I DO believe a large trauma center such as Mercy needs more than one decontamination room and one negative-air-flow treatment room. I know that the many hospitals that do not have even that basic level of capability must address this deficiency as well. There may be no upper limit to the resources that could be committed to increasing the health care system's preparedness. However, I believe the federal government does need to commit additional funds to assist hospitals in doing more.

Some of this is being done. For example, the Metro Medical Response System in Des Moines has received a $400,000 federal grant to improve the surveillance, communications, response and treatment capabilities related to potential terrorist acts. The Des Moines emergency workers and health care providers very much appreciate this support. However, it is not nearly enough, when you consider the multiple police departments, fire departments, hospitals, first responders and other agencies and organizations that are attempting to improve their capabilities.

It is imperative that the federal government provide additional assistance to America's hospitals, many of which already are suffering from declining reimbursements, increased demands for care, and rising costs of wages, supplies and pharmaceuticals. This is especially critical in Iowa, which is one of the lowest paid states in the nation by Medicare, and which cares for one of the highest percentages of Medicare recipients. The latest data available shows that the average hospital in Iowa has a negative Medicare margin of 6.5 percent. This enormous challenge is being exacerbated by plans to reduce outpatient payments to hospitals, and to reduce physician reimbursement by more than 5 percent.

I respectfully submit that health care providers—and hospitals specifically—need additional federal money to assist with the following critical needs related to our disaster preparedness:

—Community education
—Clinical training
—Development of clinical protocols and responses

—Development and coordination of community disaster response plans
—Improved communication systems
—Improved disease surveillance and reporting systems
—Purchase of decontamination and protective equipment
—Improvement of decontamination and treatment facilities
—Pharmaceuticals and medical supplies
—Mental health resources

This federal support should come in two forms. First and foremost, the ongoing provision of fair and adequate payment for the services provided by hospitals and doctors. Secondly, grants to specific health care organizations, to coalitions of providers, and to governmental entities to support needed improvements.

Related to these needs in Iowa, Governor Tom Vilsack has submitted, on behalf of the Iowa Department of Public Health, a request for a "Medical/Disaster Grant." This grant would be used equipment, vaccines, transportation support, communications improvements and many other areas related to potential terrorist events. A portion of this money would flow to hospitals, to assist them in their roles.

Also, as you may be aware, the American Hospital Association also has done some analysis related to these issues. The AHA's work is related more specifically to the needs of America's hospitals. Again, for the record, I have attached the AHA's report entitled "Hospital Resources for Disaster Readiness" to my printed statement.

In closing, on behalf of Mercy Medical Center, I want to say that we appreciate Senator Harkin's and the Committee's attention to the critical issue, and any support you provide to us in meeting these crucial needs. Thank you very much for the opportunity to testify. I would be happy to answer questions.

HOSPITAL RESOURCES FOR DISASTER READINESS

The American Hospital Association has developed the following overview of the needs of the nation's hospitals related to future mass casualty events. Many experts agree that it is a matter of "when" and not "if' such an event will occur. Without warning, hospitals in New York, Washington DC, Pennsylvania, Virginia, Maryland, New Jersey, and Connecticut were prepared to answer the call when it came on the morning of September 11th. America's hospitals will be there to do so again. The September 11th attacks, unfortunately, resulted in high mortality and few survivors. Hospitals were ready to respond but few patients appeared. The more recent spate of anthrax cases in Florida, New York, New Jersey and Washington, DC has been a further test of hospitals' readiness to address the increasing possibility of future mass casualty incidents.

However, the stakes have clearly been raised since the September 11th attack. Hospitals need to upgrade their capabilities. In a nuclear, biological, or chemical (NBC) attack, hospitals would be severely challenged without access to additional resources. The recent anthrax scare has shown that hospitals can adequately respond to an attack yielding a small numbers of patients, but questions remain about their readiness to deal with larger scale attacks.

This paper will provide a rough estimate of what each of the nations 4,900 acute care hospitals would require to increase their ability to respond to a NBC attack. We will distinguish between readiness resources required for the nation's approximately 2,700 metropolitan hospitals and 2,200 non-metropolitan hospitals. For metropolitan hospitals, we estimate the average number of total full-time equivalent (FTE) employees per hospital at 1,200, with 370 clinical staff. For a non-metropolitan hospital, we estimate the average number of total FTE employees per hospital at 300, with 90 clinical staff. The source of these hospital statistics is the AHA's Hospital Statistics database.

The resource estimates below are based on a scenario that includes an event with casualties of 1,000 individuals seeking care at a metropolitan hospital and 200 individuals seeking care at a non-metropolitan hospital. We estimate what these hospitals would need in order to sustain these intense demands for approximately 24 to 48 hours. After this period of time, we assume that the Centers for Disease Control and Prevention (CDC) Bioterrorism Preparedness and Response program, especially its National Pharmaceutical Stockpile program, would be mobilized, and provide additional medical supplies to the impacted community. It should be noted, however, that this program is not fully implemented and concerns about its weaknesses have been raised (See, Combating Terrorism: Accountability Over Medical Supplies Needs Further Improvement, GAO–O1–666T).

The AHA is also exploring a number of other options related to readiness, including the need for regional coordination of community-wide efforts to deal with an incident of biological or chemical terrorism; the need for educational efforts by Federal, State and local government to help hospitals and other members of the

healthcare infrastructure best utilize the resources outlined below; and the need to address changes in certain regulations, such as the Health Insurance Portability and Accountability Act (HIPAA), the Emergency Medical Treatment and Active Labor Act (EMTALA), and other requirements on hospitals that may actually impede our ability to prepare for and ultimately respond to acts of terrorism. Further, because health care workers in hospitals would be first responders in an outbreak resulting from biological terrorism, they may face a higher risk of infection than the general population. Therefore, the AHA, in consultation with public health authorities, will be addressing whether health care workers should be given priority with regard to inoculation against certain biological agents (such as smallpox and anthrax) that are considered to be potential terrorist threats. These issues will become agenda items for our readiness efforts.

In this document, we have included only those items that would be essential for the shortterm (24 to 48 hours) disaster response. However, we believe that what is ultimately needed, in both the short and long-term, is an operationally effective response system and the integration of hospitals into the community-wide response for mass casualty events. Because mass casualty events will, by definition, overwhelm the resources of a single hospital, they should be seen as community-wide concerns likely to require a broad array of community resources to supplement the health care system. Therefore, a communitywide perspective and community-wide planning is essential for readiness. Local government must be involved in such planning, including the public health department, police and fire department. Other community resources are likely to be called upon and should be included in community-wide planning, including public transportation officials, news media, telephone and communication systems, schools, churches, voluntary disaster relief organizations, restaurants and food suppliers.

In order to ensure the readiness of the nation's hospitals for such events, this paper will attempt to provide a credible roadmap toward that goal. Operationally effective response systems must be defined and developed so as to be sustainable over time. All related training also must be sustained over time.

The following key areas must be addressed to increase hospital readiness:

—Communication and notification
—Disease surveillance, disease reporting and laboratory identification
—Personal protective equipment
—Facility
—Dedicated decontamination facilities
—Medical/surgical and pharmaceutical supplies
—Training and drills
—Mental health resources

Communication and notification

Mass casualty incidents create a demand for public information and multiple means for communication with community first responder organizations. In most cases, at least some of the information will not be readily available while the incident develops. In our mass media and multi-media culture, every news and information source will seek access to the latest and most up-to-date information. Absent clear and credible information, speculation may reign, and increase the stress and pressure of the incident, especially on the hospital and its staff. Therefore, planned and structured arrangements for communication throughout the incident and during its response are critical components of hospital and community preparedness. For example, all organizations involved in the community preparedness plan for mass casualties, including hospitals, need to agree in advance on who will serve as the single, regional spokesperson. If a government official is designated as the spokesperson, health experts must be provided to assist the official with responses to medical questions. To minimize disruption of hospital patient care activities, press events should be conducted away from health care facilities, using regularly scheduled and pre-announced media briefing times.

Further, in a mass casualty incident, it is critical that hospitals have an ongoing, open channel of communications with the public safety community who may have first awareness of the incident. A community-wide network using the same channel is necessary. The network should be tested daily, with the test rotating across the various hospital and emergency medical services (EMS) shifts. Members of the public safety community, such as fire, EMS, public health departments, State, local and Federal law enforcement, and hospitals, normally rely on effective communications to provide emergency medical care, rescue accident victims, respond to natural disasters and investigate crime. One of the "lessons learned" from the experiences in the recent New York City attack, at Columbine High School in Colorado and in response to the Oklahoma City bombing is the need for greater coordination of public

safety communications. These types of communications may become even more critical in the case of an NBC attack.

One of the key issues regarding public safety communications is "interoperability." Interoperability refers to the ability of different public safety entities to communicate with each other, on demand, in real time. Common problems experienced by the public safety community include the failure of equipment in "dead spots," interference, insufficient equipment, outdated equipment and channel congestion. An array of technologies including pagers, cellular phones, mobile data terminals and mobile laptop computers are currently used. However, a recent report suggests that existing local land mobile radio systems are, on average, nearly 10 years old, with State agencies having considerably older infrastructures (See, Public Safety Wireless Network Program Analysis of Fire and EMS Communications Interoperability, April 1999).

Most public safety organizations, including hospitals, have experienced problems with interoperability. There is a critical need for funding to upgrade and modernize public safety communications systems and to address interoperability problems. In addition, public safety communications face a variety of issues related to spectrum. These are serious interoperability problems that arise from the fragmentation of public safety spectrum. The most effective way to better ensure interoperability is to incorporate the fundamental principles of the Incident Command System into each level of emergency preparedness planning. Additional spectrum may be required, as well as improved planning and management of the interoperability spectrum.

In case existing systems fail in an emergency, alternative and redundant communications systems (e.g., cell phone, two-way radio, ham radio, unlisted numbers, web-based, video conferencing, and use of human couriers) will be required as backup. Loudspeakers or bullhorns for communicating with the public outside the facility may also be required for the purposes of crowd control. Finally, translators and translated patient resource documents for non-English speaking patients will also be needed, as well as clear signage plans for directing patients to appropriate locations within the facility.

The following are resources needed for increasing preparedness and developing an adequate communications system for metropolitan and non-metropolitan hospitals.

—Coordination of public safety communications (fire, EMS, public health department, other hospitals, Federal Bureau of Investigation, Office of Emergency Preparedness, etc.)
— Alternative communications system if hospital communications fail/overload (e.g., cell phone, two-way radio, ham radio, unlisted numbers, web-based, video conferencing, courier system)
—Translators for non-English speaking patients and translated patient resource documents
— Loudspeakers/bullhoms for communicating with individuals outside the facility
— Signage for communicating instructions to patients and for designating various emergency functional areas

	Per hospital	All hospitals in category
Metropolitan hospitals	$75,000	$202,500,000
Non-metropolitan hospitals:	37,500	82,500,000

Disease surveillance, disease reporting and laboratory identification

A terrorist attack involving nuclear, biological or chemical agents could occur in an overt or covert manner. Most typical of terrorist actions to date is that of a sudden and highly localized event producing immediate casualties, such as an explosion. This is also the most likely scenario for an attack involving chemical weapons.

Scenarios involving the deployment of a biological agent are expected to occur covertly, with increasing numbers of patients presenting to hospitals and physicians offices over the course of hours to weeks with signs and symptoms that may be common to many diseases and conditions. Radiologic agents could be released in either a covert or overt manner.

Improving hospital disease surveillance and disease reporting, and the public health infrastructure will be critical to determining that a cluster of disease may be related to the intentional release of a biological or chemical agent. Particularly for biological agents, an effective medical response will be critically dependent upon the ability of individual clinicians, who may be widely scattered around a large met-

ropolitan area, to identify, accurately diagnose, and effectively treat an uncommon disease. To facilitate this level of readiness, laboratory diagnostic capability will need to be upgraded and laboratory personnel will require additional training.

The rapid identification of the chemical, biological or radiologic agents involved in any such incident is vital to the protection of the first responders and emergency medical personnel at local hospitals, as well as to the most effective treatment of resulting casualties. Further, readiness will require a special ability to track large numbers of patients and handle and display comprehensive amounts of real-time patient information, with the ability to integrate with systems currently used by Federal, State, regional and local agencies.

What follows are some of the improvements, equipment and tests that will be critical to ramping up hospital disease reporting, disease surveillance and laboratory identification capacity.

—Improvement of hospital disease surveillance, disease reporting, and public health infrastructure
—System to facilitate expedited disease reporting, dissemination of real-time treatment guidelines and access to experts
—Informatics
—Patient tracking system
—Detection instruments/monitors for detecting radiation
—Tests/assays for detection of chemical agents and toxic industrial materials
—Serologic/immunologic/nucleic acid tests for identification of biologic agents

	Per hospital	All hospitals in category
Metropolitan hospitals	$750,000	$2,025,000,000
Non-metropolitan hospitals	375,000	825,000,000

Personal protective equipment

Personal protective equipment (PPE) refers to clothing and respiratory apparatus designed to shield an individual from chemical, biological or other physical hazards. The "universal precautions" (gloves, gown, mask, goggles, etc.) used by medical personnel to prevent infections will generally provide protection from the biological agents commonly considered to be threats. However, in the event of a large-scale biological event, hospitals would have to provide at least this level of protection to all staff. A hospital's daily inventory of such items would be quickly exhausted and the replacement of these supplies and equipment would be necessary. This is particularly the case because hospitals would have to be prepared to receive not only patients who would be decontaminated in the field, but also patients who "walk in" without being decontaminated. Initial triage must be performed by health care workers in appropriate PPE. Today, hospitals generally are not stocked with suitable PPE to protect clinicians and other health care workers from exposure in the event of a biological or chemical attack, particularly one involving an unknown agent.

The highest level of PPE provides the utmost protection for the worker, but carries the disadvantages of being extremely costly to purchase and train staff members in its use, and is a very awkward ensemble in which to function. Other levels may provide appropriate protection levels and yet overcome some of the disadvantages. All levels of protection will fall under Occupational Health and Safety Administration (OSHA) regulations for respiratory protection (29CFR 1910.134) and personal protective equipment (29CFR 1910.132). A requirement for training hospital employees in the use of PPE also must be included in disaster planning.

Level A protection provides the highest level of respiratory and skin protection. The suit provides a fully enclosed environment for the health care worker, being chemical resistant and impermeable to gases and vapors. Chemical resistant boots and gloves also should be worn. It is used with either a self-contained breathing apparatus (SCBA) internal to the suit or a supplied-air respirator. According to OSHA this is the level of protection to be used with an unidentified agent. This level of protection is extremely cumbersome, hot to wear and may hinder communication.

Level B protection provides slightly less skin protection than level A, in that the suit does not provide a fully enclosed environment for the worker, but still a high level of respiratory protection. It is also chemical resistant, but does not fully protect against vapors, which may be harmful to the skin. Chemical resistant boots and gloves also would be required. At this level the SCBA tank would be worn outside of the suit, or a supplied-air respirator may also be used. Although less than level

A, level B protection is still cumbersome and warm, as well as limiting to communication.

Level C protection is also chemical resistant and splash proof, with chemical resistant gloves and boots required. At level C, a full- or half-face air-purifying respirator may be used. With this type of respiratory protection, it is essential that the chemical agent be identified, as the cartridges must filter that specific agent. There are some respirators available with stacked cartridges to address organic vapors and acid gas, and to provide high efficiency particulate air (HEPA) filtration. This latter system may prove to be effective against most agents expected to be utilized in a situation of chemical terrorism.

Level B protection will be appropriate for front-line clinicians in most health care applications. It provides a high level of protection, yet provides more ease of movement and comfort for the health care worker, while also being less costly than level A protection. Additionally, with SCBA or air-purifying respirators with full head cover, immediate knowledge of the specific identity of the agent is not required. For most agents encountered in a hospital setting, level B will be adequate, although not the highest level of available protection. However, level C protection, with stacked cartridges may also suffice. A health care organization must make its own determination concerning appropriate PPE based on regulatory requirements, evaluation of potential hazards, and consultation with local emergency response agencies. If, during the course of an incident, the contaminant is identified and determined to be a lesser threat than originally assessed, the level of personal protective equipment can be downgraded.

For metropolitan hospitals, we assume that a basic "universal precaution" level protection would be required for 1,200 FTE employees, with Level B protection available to 50 clinicians functioning in a front-line capacity—decontamination, triage, emergency room (ER), operating room (OR), laboratory, radiology, and custodial personnel—over the course of 48 hours in an event involving 1,000 patients presenting to the hospital. For non-metropolitan hospitals, we assume that the basic level of protection would be required for 300 FTE employees, with Level B protection available for 20 front line clinicians—decontamination, triage, ER, OR—over the course of 48 hours and in an event yielding 200 patients at the hospital.

—Gloves, gowns, HEPA masks (OSHA/NIOSH–approved high efficiency particulate), goggles, shoe covers—available to all employees with allowances for frequent glove, gown and mask changes (metro hospital $65,000, non-metro hospital $16,000)
—Fit-testing HEPA mask—at $75 per person for all employees (metro hospital $90,000, non-metro hospital $22,500)
—Level B protection for front-line clinical staff includes:
—SCBA operated in positive pressure mode
—Fit-testing and maintenance requirements for SCBAs
—Hooded, two-piece chemical resistant suit
—Chemically resistant gloves and boots
—Estimated cost of $7,000 per person; metropolitan hospital $350,000; nonmetropolitan hospital cost of $140,000

	Per hospital	All hospitals in category
Metropolitan hospitals	$505,000	$1,363,500,000
Non-metropolitan hospitals	178,500	392,700,000

Facility

Newly constructed and existing hospitals must comply with the Life Safety Code (LSC) developed by the National Fire Protection Association. The LSC is intended to provide a level of life and occupancy safety necessary to protect patients, personnel, visitors and property from fire, smoke and other products of combustion. It provides a process for inspecting, testing and maintaining fire protection and life safety systems, equipment and components on a regular basis. In addition, each hospital must develop policies and procedures that include written criteria evaluating various deficiencies and construction hazards.

In the case of a NBC attack the following additional items and capabilities must be contemplated:

—Lockdown capability to minimize access to facility and facilitate direct patient flow to specific points

—Other security measures such as perimeter checks, hospital-issued staff photo identification badges, visitor badging/identification and package handling.
—Auxiliary power source
—Increased storage capacity for fossil fuels to provide uninterrupted power
—Portable negative air machines and HEPA filters
—Large volume water purification equipment
—Expanded mortuary facilities to manage bodies with high contamination or infectivity potential
—Designated hospital locations for personnel quarantine
—Expanded patient isolation facilities, including separate air handling system
—Expanded storage space for stockpiles of PPE, pharmaceuticals and supplies.

	Per hospital	All hospitals in category
Metropolitan hospitals	$75,000	$202,500,000
Non-metropolitan hospitals	37,500	82,500,000

Dedicated decontamination facility

Patient decontamination is the process of removing or neutralizing hazardous chemical, biological or radiologic agents from an injured or otherwise exposed individual in order to reduce the risk to the individual and minimize secondary exposure to health care workers and other patients in the facility. Hospitals should have a minimal level decontamination facility for ambulatory and non-ambulatory patients for small events; the ability to ramp-up quickly for a medium level event; and access to a regional decontamination facility for a large-scale event.

An outdoor facility or area can be effective, particularly to prevent contaminants from entering a fixed health care facility. An outdoor facility also is suitable for handling any large influx of injured or exposed individuals. It also holds the advantage of not requiring a dedicated air-handling and ventilation system, as would be required in an indoor decontamination facility. There are several drawbacks, including the requirement for providing protection from inclement weather and providing additional lighting. Each hospital must consider all such relevant factors in making a decision regarding appropriate decontamination facilities.

—Hospital decontamination room, including:
—Dedicated entrance from the ambulance entrance
—Ventilation: negative pressure (minimum of 12 air changes per hour) and dedicated exhaust with HEPA filter
—Water supply: emergency eyewash and shower (with hot and cold water)
—Waste water containment: Floor drain directs decontamination water to a commercially available, 500-gallon hazmat-compatible (polypropylene) holding tank, with sample port, bypass valve and extra holding tanks.
—Electrical: Two explosion-proof pendant fixtures (not affixed to the ceiling), with two 48 × 1 inch 32W T8 tubes per fixture with full electronic ballast; external light switch, and; explosion-proof receptacles, protected by ground fault interrupters.
—Decontamination tables
—Storage: PPE, medical and other decontamination room supplies should be stored in a cabinet alcove outside the decontamination room. A hazardous waste drum should be in the room for contaminated patient clothing, etc.
—Provision for the storage and identification of patient clothing and personal items/valuables, pending possible disposal requirements.
—Provisions to extend decontamination into the parking lot or other large area using portable units, including:
—Outdoor shower systems with hot and cold water supply, with provision for separate showers for male and female patients
—Adequate containment for run-off waste water
—Separate tents for male and female patients
—Portable generator(s) for power and for heating/air conditioning based on weather
—Portable lighting units for use during evening operations
—Soap, dispensers, brushes, etc.
—Facilities for safe collection, containment, storage and disposal of contaminated materials
—Extra patient linen for decontaminated patients and hospital scrubs as change of clothing for hospital staff working in the decontamination room/area

	Per hospital	All hospitals in category
Metropolitan hospitals	$500,000	$1,350,000,000
Non-metropolitan hospitals	250,000	550,000,000

Pharmaceutical and medical/surgical supplies

Hospitals must be properly stocked with antibiotics, antitoxins, antidotes, ventilators, respirators and other supplies and equipment needed to treat patients in a mass casualty event. We assume that external sources of drugs and related supplies (e.g. CDC's National Pharmaceutical Stockpile) will be available within 24 hours of the detection of a biological or chemical agent. Therefore, hospitals would have to be prepared to sustain a 24-hour supply of pharmaceutical products at the most common dosage for the estimated number of patients and hospital personnel. Provisions and planning also must be made for appropriate dosages and formulations for children who may be victims. For medical/surgical supplies and equipment, a standardized formula must be developed to adequately determine stock requirements.

In addition to needed pharmaceuticals and medical supplies that are directly related to attacks using biological or chemical agents, hospitals may need to increase their in-house inventory of routine drugs, biologicals and medical supplies. As a cost containment initiative, many, if not most, hospitals have very tight inventory controls in place. If local transportation is disrupted or local warehouses destroyed, hospitals will need to be able to survive for 24–48 hours with on-hand pharmaceuticals and supplies for all purposes until relief supplies arrive. The need to increase their on-hand stock may be especially important for high-use items, such as insulin, that are taken daily by large numbers of people with chronic conditions. If local retail sources of such drugs become unavailable or local retail sources are unable to replenish their stock, chronically ill individuals who lose access to their home supplies are likely to turn to their local hospitals to access needed drugs and biologicals.

For pharmaceutical and other supplies used rarely in the normal course of hospital activity, particular attention must be paid to appropriate dosing, shelf life and stock rotation issues. A plan for pooling of resources through mutual aid agreements among area health care facilities should be considered for such rarely used products and supplies.

Suggested pharmaceuticals and related supplies

Bacterial agents: Ciprofloxacin, Doxycycline, Penicillin, Chloramphenicol, Azithromycin, Rifampin, Streptomycin, and Gentamicin.

Botulism toxin: Mechanical respiratory ventilators, and other associated supplies.

Cyanides: Cyanide antidote kits containing amyl nitrite, sodium nitrite and sodium thiosulfate.

Lewisite: British anti-lewisite.

Nerve agents: Atropine, Pralidoxime chloride, and Diazepam (or lorazepam).

Pulmonary agents: Oxygen ventilators, and Respiratory care supplies.

All agents: Resuscitation equipment and supplies, Vasopressors and vasopressin vials.

Other equipment and supplies

Mechanical respiratory ventilators (adult, pediatric, neonate), IV pumps and poles, IV supplies (for 1,000 patients)—IV Fluids-D5W, D5NaC1, D5 lactated Ringers (need one per initial patient) In-dwelling catheters (need one per initial patient in each size), IV sets (enough to handle one per initial patient)—Suction machines, Stretchers, Wheelchairs, Linens, and Bandages and dressings.

	Per hospital	All hospitals in category
Metropolitan hospitals	$600,000	$1,620,000,000
Non-metropolitan hospitals	300,000	660,000,000

Training and drills

Staff training is needed at all levels of the organization for all types of potential disasters: nuclear, biological, chemical and conventional. The training needs to be stratified by educational level, from general staff awareness to technician level. Fur-

ther, drills must be conducted at least twice a year, according to requirements of the Joint Commission on the Accreditation of Healthcare Organizations, (JCAHO), and involve all key staff. Additional disaster drills beyond those required by JCAHO, particularly those integrated into local/State/Federal disaster drills, would enhance the level of hospital readiness and staff competence in the event of a mass casualty incident.

—Training: Using Web-based format with hard copy materials for all levels of staff on mass casualty event awareness and preparedness (initial orientation, annually, periodic)

—Development of on-site disaster-response training courses (equipment, supplies, course manuals, trainers). This would include, but not be limited to, clinical training on biological and chemical topics involving staff from ER, urgent care, primary care, laboratory and others involved in emergency response. Should include training on pediatric casualties.

— At least two drills annually: Functional exercise, full disaster drill, and additional hours on development of the scenarios and logistics.

—Training on the use of personal protective equipment

—Training on set up and use of decontamination systems

	Per hospital	All hospitals in category
Metropolitan hospitals	$500,000	$1,350,000,000
Non-metropolitan hospitals	250,000	550,000,000

Mental health

Survivors of mass casualty events and responders to such incidents (fire, police, rescue workers, health care professionals, etc.) will suffer not only physical injury requiring medical care but also will undoubtedly undergo extreme psychological trauma. Thus the deployment of chemical, biological or nuclear agents against a population produces both acute and chronic psychiatric problems. In a disaster, several different groups would require mental health services, both direct and indirect:

—Individuals presenting at the door or brought to the facility by rescue personnel, including those who have specialized needs such as pregnant women, children, elderly, or those who have an underlying mental health problem that may or may not have been previously treated;

—Fire, police and rescue workers injured while attempting to save a life

—Injured individuals, including children, who have witnessed the death or serious injury of a family member or colleague;

—Family and friends of the missing, injured or dead. This group may suffer mental distress that may require immediate mental health services or physical treatment;

—"Worried well" individuals who may need reassurance that they are not ill;

—Administrative staff responsible for making decisions that affect the facility's ability to quickly respond to a mass casualty disaster;

—Communication/professional staff to handle media inquiries and present accurate and appropriate information so that the general public and institutions will be able to process the information; and

—Facility staff working the disaster to ensure they are mentally and physically fit. There would be an immediate on-site need for critical incident stress debriefing to be conducted for those providing trauma and triage care.

Beyond physical injuries, individuals who have survived a disaster also would be experiencing extreme emotional distress that could also manifest in physical conditions. This could include, but not be limited to, physical shock, hysteria, anxiety, fear, anger, frustration, and guilt, as well as an inability to communicate information critical to their treatment. For example, a survivor with a heart condition or asthma may require both immediate physical help and crisis intervention to be able to calm down and prevent further injury or distress. Finally, some individuals also may want to leave facilities to find loved ones or colleagues or to return to a safe place, whether or not they are physically or mentally able to do so. This might require close monitoring or short-term containment.

The following estimate was provided by the New York-Presbyterian Healthcare System, 525 E. 68th Street, New York, NY, whose recent experience provided some answers regarding this question. According to their estimate, triage and initial evaluation for one day of 1,000 individuals (assuming an average salary of $75,000) would require that 31.25 FTEs provide four direct service evaluations per hour. This

would be a direct cost of $9,375 per day. In addition, administrative services would cost $2,500 per day with total service personnel of $11,875. Other costs would include additional security, medications and administrative costs of $10,000, for a total of about $22,000 for a metropolitan hospital. We assume that a non-metropolitan hospital would bear about half the total cost of a metropolitan hospital.

	Per hospital	All hospitals in category
Metropolitan hospitals	$22,000	$59,400,000
Non-metropolitan hospitals	11,000	24,200,000
Totals: Metropolitan Hosp	3,027,000	8,172,900,000
Totals: Non-metropolitan Hosp	1,439,500	3,166,900,000
Totals		11,339,800,000

Senator HARKIN. Thank you, Dr. LeValley.

I want to call a brief recess here. When I come back I would like to cover just the following things. Dr. Alibek, I just want to ask you, do you think we are maybe overreacting? I want to just delve into that a little bit with you. Are we overreacting or not in this? We will get back to that when I get back.

Dr. Barbera and Dr. LeValley, I want to talk about this question you raised, Dr. LeValley, about what is the adequate level of preparedness. We cannot prepare for every possible contingency, so we have to prioritize. What is the first thing that we have to do and what does that cost, and what level of protection did we provide for the American people in our hospital systems across the country? Obviously, we just cannot cover everything, but we have to think about what is it that gives the maximum amount of protection to the American people in the realm in which we are working right now, and how much is that going to cost and how soon do we need to do it? So I am going to come back and ask you what the priorities are out there, since we cannot fund everything.

So we will have a brief recess. Maybe, Dr. Koplan, you can get those figures, because, as Senator Specter said, we have got to get this budget put together before the end of the week.

So we will have a brief recess and the subcommittee will be back in about 15 minutes.

[Recess from 10:42 a.m. to 11:04 a.m.]

Senator HARKIN. The subcommittee will resume.

Dr. Alibek, before I left I said I wanted to ask you a couple of questions. Again, I want to know if we are overreacting, because a couple of years ago, we had this Japanese cult that released some sarin gas in Tokyo in the subways and it just did not work on a broad basis. Even with the anthrax, it seems to be very difficult to do on a broad-basis.

Now that the initial wave has hit, people are now thinking about what we have to do. Are we overreacting? Is it very likely that biological weapons that were manufactured in the Soviet Union have been obtained by other nations?

You said that the former Soviet Union had genetically modified smallpox and other agents. Would the smallpox vaccine that we are talking about here, will it work against the modified smallpox?

Dr. ALIBEK. It would.

Senator HARKIN. It would.

Second, what do you think about this? Are we overreacting or not?

Dr. ALIBEK. I would like to say we are overreacting, but unfortunately I cannot say this. The problem is this: When we discuss biological weapons, what is the difference between a biological weapons threat, a bioterrorism threat, and some other threats we have already faced? We noticed that this anthrax threat was a long-term continuous threat. We saw how people reacted. The entire population was in a state of fear or scare.

What is important to say in this case is that this attack was the least effective attack you could imagine, because letter-borne deployment is not very effective. I would say it is the least effective. In this case, think what could be done if they are able to use some other techniques to deploy biological agents. I am not going to elaborate what kind of techniques they could use, but, believe me, there are many different techniques.

I do not want to be a bad messenger, but in my opinion it is sort of the beginning of the process. We will be seeing some new attempts to deploy biological agents in the future.

But when we say it was not very effective, for example the Japanese cult using sarin gas, and then the anthrax scare or attack here in the United States, in my opinion it is a first attempt. Even these first attempts showed how scary this thing could be. In this case, in my opinion we need to put it on a scale: What kind of consequences could we expect in case we have a large biological weapons attack somewhere in the mall, one of the malls, or metro systems, and so on and so forth. You can imagine what kind of damage, psychological and economic damage, this type of attack would bring to the United States.

In my opinion, we are not overreacting. We do what we need to do, and in my opinion we need to do more to be better prepared.

Senator HARKIN. I appreciate that.

One last thing. You mentioned the scientists that have a lot of expertise in this area. You mentioned in your testimony and in your written testimony, that they have a lot of expertise and that they could be used. Where are these scientists now? Are they still in Russia, are they here? Where are they?

What would it take to be able to enlist them? I think what you said is, because of the knowledge base they have, that knowledge could also be used to help develop defenses against biological weapons. Is that not what you said?

Dr. ALIBEK. Yes.

Senator HARKIN. Where are all these people?

Dr. ALIBEK. It is a very interesting question. Of course, maybe I am not an appropriate person to answer this question because I have never done intelligence work to find out where these people are. My knowledge is coming from my talks with some former Russian scientists and some discussions with some other people. For example, I know that many of them are here now in the United States. In my opinion, about between 70 and 100 scientists are in the United States.

Senator HARKIN. Are here?

Dr. ALIBEK. Yes, in the United States. Quite a significant number of people are in Europe, in Eastern and Western Europe; some of them are in Asia, Japan and some other Asian countries. We know about some scientists working as professors and faculty in Iran, teaching Iranian students. There was a rumor that some of them left for Iraq, but it was rumor. Of course, we cannot prove this.

There are quite a significant number still in Russia, and many of them are in the former Soviet Union countries, which are independent countries now.

I would say these scientists are scattered all over the world now. In my opinion it is important to discuss this issue of Russian scientists. We discussed smallpox, for example, and we know that in the United States we have got significant knowledge of smallpox. At the same time, a huge study was done on smallpox, regarding how to develop protection and how to develop biological weapons, in the former Soviet Union. A lot has been done with anthrax. These people have sophisticated knowledge about how to work with anthrax.

But at the same time, for many diseases like glanders, like melioidosis, brucellosis, tularemia, Ebola infection, Marburg infection, and so on and so forth—I can continue this enumeration endlessly—we have no sophisticated knowledge here in the United States. But these people, they've got this knowledge and they could be very good assets to help us understand what kinds of protection we can develop and understand the pathogenesis of these infections.

Just to prepare a good scientist in this field who is able to work under BL–3, BL–4 conditions and do this necessary work, it could take years and years or even decades, and it would cost millions of dollars. But we have got ready-made scientists and they are able to accumulate this knowledge here in the United States. In my opinion, they could be a perfect asset to help the United States develop protection against biological weapons and against bioterrorism.

Senator HARKIN. Thank you, Dr. Alibek. It seems to me we could make agreements with Russia. It would seem that they have as much interest in this as we do. But that is out of the realm of my subcommittee.

Dr. Barbera and Mr. LeValley, I asked you when I left to prioritize. Since we cannot do everything, what can we do now to help our local hospitals be at least somewhat prepared for what we know would be some of the major things that might happen? We know we cannot do everything, but what are the first things we need to do and ought to be paying attention to here with the money that we are appropriating?

Either one of you. Mr. LeValley?

Mr. LEVALLEY. Well, Senator, I think we all understand that, as I mentioned in my testimony, it is an unanswerable question. I think you are probably aware the American Hospital Association has done some work on some broad-based estimates using some pretty broad rules of thumb and came up with a figure of over $11 billion that hospitals could use to better prepare, based on the as-

sumption that we would want large urban centers like Mercy to be able to handle 1,000 casualties.

I think as we debate those kind of numbers, we can debate how many hospitals need to be ready for what level of care and what can the government afford, and all those are very legitimate issues.

One thing I might suggest to try to get to your issue of prioritizing. Rather than rely on my perspective, we may want to convene a group with the Iowa Hospital Association, for example, and get some clinicians and others together and provide you a written response to that question of how would hospitals prioritize. I might make that offer to you. I would be happy to coordinate that on your behalf, to pull some people together and get some additional minds other than mine in terms of the priorities.

From Mercy's perspective, I can tell you that if you took the American Hospital Association numbers, and I just did the calculation quickly last night in Mr. Waters' office, roughly about $3 million would flow to Mercy Medical Center. I can tell you as we sit here today that we could spend that $3 million to significantly improve our preparedness and not any of it would be wasted.

We have very real needs to improve our emergency department, to improve our security systems, to increase our pharmaceutical supplies and vaccines and all those things. I made kind of a laundry list here in my notes about laboratory and diagnostic capability expansion.

Compounding this problem of the terrorist threat is the fact that America's hospitals are experiencing capacity problems all across the Nation already. We have a bit of a crisis going on in hospital care to begin with. In Des Moines, not just Mercy, but all Des Moines hospitals have had numerous days in the last year or two where we have been full, with no beds available. We have had numerous days where emergency departments have been forced to turn away patients, divert patients to other places, because they did not have the capacity.

If an attack like this were to occur on a day when our beds were full and people are already being diverted, we would have a true catastrophe on our hands.

But to answer your question then, do we say as part of our terrorist preparedness that we want to expand the bed capacity and physical plants of all of our hospitals? That number would be enormous. So I think it is a very difficult policy question and we have lots of needs. Our commitment to you would be to put to very good use whatever funds you can come up with for hospitals to help us improve our preparedness.

Second, I would just hammer home this issue that, if we are going to have nurses in the future, if we are going to have physical capacity in the future to deal with our health care needs, we have got to have adequate reimbursement day in and day out. Think about trying to recruit nurses and the whole smallpox issue. Think about what we are going to have to be paying people in the future as these threats are elevated and emergency staffs and nursing staffs are being asked to take care of these kinds of risks. The costs of that are only going to rise, and if the government keeps reducing what they pay us, as currently proposed in the outpatient capital

process and the physician reimbursement process, we are really headed for disaster.

Senator HARKIN. That is on another track we are trying to address right now.

Mr. LEVALLEY. We appreciate it very much.

Senator HARKIN. But I see what you are saying. I think, to interpret what you just said, Mr. LeValley, it is hard to focus on building this extra additional capacity when the basic fundamental capacity and support structure is being eroded.

Mr. LEVALLEY. Absolutely.

Senator HARKIN. That is what we are facing.

Dr. Barbera, you spoke about what is adequate and reasonable. I am not certain I could define what is adequate. That is what I do not know. That is what we as appropriators are trying to get a handle on: What is adequate and what is reasonable?

You said in your testimony: "The difference between adequate and reasonable is wide and it is unacceptable to the American public." What are those parameters? I just do not know.

Dr. BARBERA. I do not think we know what adequate is, but I think what we need is an objective process to decide what we think it is and whether or not we are going to make a conscious decision whether we are going to try to reach that or not.

I can tell you somewhat what reasonable preparedness is. We as the hospital community in the District of Columbia have recognized for a while that mass terrorism is a possibility, a very real possibility. In 1995 we developed a hospital mutual aid system. We recognized from research and other things, multiple things.

One thing is, in major mass casualty events 80 to 85 percent of patients get to hospitals without EMS, even in the best-trained EMS system. So contaminated patients and others are going to show up at hospitals no matter how well prepared our hospital community is.

We recognize also that in most mass casualty events the regional hospital capacity is rarely exceeded. It is a problem of medical needs being in places where there are not the medical resources. We saw that in Oklahoma City, where many of the casualties arrived at St. Anthony's 5 minutes from the Murrah Building, whereas hospitals were prepared and standing by only a few minutes further on and got very few patients.

So we developed a mutual aid system so that we can call each other for help and we can offer assistance, recognizing that you can move medical staff, nursing staff, and equipment better than you can move critically ill patients. So we have tried to maximize what we have here in the District. Indeed, when we had a fire in the Foggy Bottom Metro Station across the street from George Washington University's main entrance and we did not know whether it was accidental or terrorist, we activated the system and had plenty of capabilities that could have responded if we suddenly had 200 badly injured, smoke-ingesting patients who came up from the Foggy Bottom Metro stop.

That is part of what we would call reasonable. At George Washington University Hospital, we developed a low budget mass casualty decontamination system. We made some assumptions and we

moved forward, so that we can wash off a significant number of patients quickly. Those are some of the things that are reasonable.

But in terms of adequate, we truly need a surge capacity, and a surge capacity is not regular business. If you are using your surge capacity on a regular basis, it is not surge capacity. Anyone who looks at the business of anything says if you develop capacity and you are funding capacity that does not bring you anything back that is a stupid business idea. And medicine and hospitals can no longer afford any sort of those types of ideas.

Senator HARKIN. But if I might interrupt you, for surge capacity you just need locations, sites, you need facilities that can be requisitioned, is that not the idea for quarantine purposes and treating purposes?

Dr. BARBERA. On a regular day most hospitals are close to their capacity for critical care patients.

Senator HARKIN. I understand that.

Dr. BARBERA. So you need locations, you need equipment, you need staff that can provide critical care services. We saw with September 11th in the D.C. area and I think in the New York City that area hospitals stepped up. Hospitals from the Baltimore area called our communications system and offered their services de novo. Hospitals will do what they can. But if these are bioterrorism events or things that are going to go long term, we have to look at what you are going to do to hospitals.

You can close down your operating rooms and use the post-operative area, the post-anesthesia or recovery room area as a critical care area, but you have just killed off your operating income for the hospital. How long can you do that, and is there a mechanism to recover that if you have done that for the community's benefit?

What happens if you have accepted large numbers of contagious patients potentially with contaminants on them? How do you convince the public that it is time to come back to your hospital, that it is clean? And do you recover in some manner the business losses that you have for doing that? This is not looking at profit. This is looking at maintaining an everyday capacity in your community.

These are difficult questions. So I would say you would like to prioritize these things, starting with what are relatively cost-effective mechanisms to develop a surge capacity across the region that is sustainable and multi-hazard. That is why we used our mutual aid system. We also have to prioritize the protection of hospitals, their staff and current patients from patients who are coming in that could inadvertently be a threat to the facility or staff.

We have to look at the security interests of hospitals. We all recognize that the terrorism modus operandi is secondary hits, and we also recognize that they are not like in the old days, where there were some general rules, so the hospital could very well be the secondary hit. Hospitals do not have extra money to have standby security capacity.

So there are a lot of these issues. I think we can prioritize them based on cost-effective considerations, such as how do we maximize what we have using information systems and communications systems, how do we have an integrated system between public health and emergency medicine and the hospitals and emergency management, how do we bring regional and Federal resources in to assist

the hospitals, how do we work closely with the U.S. military medical capacity and the hospitals?

I think we have developed a model here in Washington, D.C., using the mutual aid system, with Walter Reed, Malcolm Growe, the National Naval Medical Center, and the Veterans Hospital. We have offered help to each other when we have had problems internally at hospitals.

So there are things we can do, but there are adequate things that we have not defined yet.

Senator HARKIN. Thank you very much, Dr. Barbera, Mr. LeValley, Dr. Alibek. Thank you very much for being here and for your expert testimony. I appreciate it. You have given some good suggestions we are going to follow up on.

One thing we have really got to work through with the Centers for Disease Control and with hospitals around the country is that there have to be plans in effect for these kind of surge capacities. There has to be some plans in effect, maybe not in every locality, but at least I think in major metropolitan areas, where the rate of contagion can be more rapid than, let us say, in a dispersed area. I am not certain that we have those kind of plans in effect right now.

Mr. LEVALLEY. If I might, Senator, I think every hospital does have a disaster plan.

Senator HARKIN. Oh, I understand that.

Mr. LEVALLEY. I think at least in Iowa the coordination and cooperation between hospitals is wonderful, as we saw in Sioux City with the 232 crash. There is good response capability for 100, 200 casualties. I think it is when we get up into those big numbers that everything is really at risk.

Thank you.

CONCLUSION OF HEARINGS

Senator HARKIN. Thank you very much.

The subcommittee will stand in recess until Tuesday morning, when we will have a hearing on cloning.

[Whereupon, at 11:26 p.m., the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

○