HOMELAND SECURITY: IMPROVING PUBLIC HEALTH SURVEILLANCE

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS AND INTERNATIONAL RELATIONS

OF THE

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HOMELAND SECURITY: IMPROVING PUBLIC HEALTH SURVEILLANCE

MONDAY, MAY 5, 2003

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS AND INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:01 p.m., in room 2154, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Murphy, Janklow, and Bell.

Staff present: Lawrence Halloran, staff director and counsel; Kristine McElroy, professional staff member; Robert A. Briggs, clerk; David Rapallo, minority counsel; and Jean Gosa, minority assistant clerk.

Mr. SHAYS. A quorum being present, the Subcommittee on National Security, Emerging Threats and International Relations hearing entitled, "Homeland Security: Improving Public Health Surveillance," is called to order.

As we convene here today, the world is conducting an involuntary, live-fire exercise of public health capacity against bioterrorism. Severe acute respiratory syndrome [SARS], emerged from the microbial hothouse of the Far East through the same vulnerabilities and vectors terrorists would exploit to spread weaponized, genetically altered disease.

The global response to SARS underscores the vital significance of sensitive disease surveillance in protecting public health from natural and unnatural outbreaks. It also discloses serious gaps and persistent weaknesses in international and U.S. health monitoring.

The lessons of the West Nile virus and mail-borne anthrax have not gone unheeded. Substantial enhancements have been made to the accuracy, speed, and breadth of health surveillance systems at home and abroad. The limited impact of SARS here can be attributed in part to increased preparedness to detect, control, and treat outbreaks of known and unknown diseases.

But the public health surveillance system at work today against SARS is still a gaudy patchwork of jurisdictionally narrow, wildly variant, and technologically backward data collection and communications capabilities. Records critical to early identification of anomalous symptom clusters and disease diagnoses are not routinely collected. Formats for recording and reporting the same data differ widely between cities, counties, and States. Many key records are still generated on paper, faxed to State or Federal health au-

thorities, and entered manually one or more times into potentially incompatible data bases.

In a world made smaller by the speed of international travel and the rapid mutation of organisms in our crowded midst, the interval between local outbreak and global epidemic is shrinking. Virulent, drug-resistant organisms easily traverse the geographic and political boundaries that still define and inhibit public health systems.

Efforts to build a more modern "system of systems," envision routine collection and rapid dissemination of real-time data from public and private health systems and laboratories. Early warning capabilities would be enhanced through the fusion of innovative syndromic surveillance—automated screening of emergency room traffic, pharmacy sales, news wires, and other public data streams—for potentially significant signs of an outbreak.

Pieces of this planned health monitoring system can be assembled at different times and places, but no fully national system yet integrates the observations and communications needed to protect public health from rapidly emerging biological hazards. Successfully operating the elaborate, elegantly sensitive surveillance network of the future will require unprecedented levels of human skill, fiscal resources, medical information, and intergovernmental cooperation.

At this moment, sophisticated radars scan the skies and the seas to detect the approach of forces hostile to the peace and sovereignty of this Nation. A similarly unified, sensitive system of disease sensors is needed to detect the advance of biological threats to our health and prosperity.

Testimony today will describe civilian and military programs under way in the United States and abroad to overcome the natural and man-made barriers to health monitoring. We deeply appreciate the dedication and expertise all our witnesses bring to this important discussion, and we welcome their participation in our oversight.

At this time, we will call on Mr. Bell, who is the acting ranking member today.

Mr. BELL. Thank you, Mr. Chairman.

I would like to thank you and those who are providing testimony before the committee here today.

Today's hearing is critically important to this Nation's security and the safety of its health in general. We are all aware of the need to detect the outbreak of disease and respond immediately and effectively. This could be no clearer than in my congressional district, which is home to the world's largest medical center in the world in Houston, TX.

Public health surveillance has been described as "the cornerstone of public health decisionmaking and practice." The events of September 11, 2001, and the subsequent anthrax attacks raise the profile of this issue significantly, so much so, President Bush proposed the creation of "a national public health surveillance system to monitor public and private data bases." He argued that the anthrax attacks of October 2001 prove that quick recognition of biological terrorism is crucial to saving lives; and he proclaimed an urgent need to integrate the Federal interagency emergency response plans into a single, comprehensive, governmentwide plan.

But what concerns me most is that there has been no evidence of any attempt to follow through on this proposal. Additionally, the administration's fiscal year 2004 budget slashes funding in core Centers for Disease Control functions.

I would hope that our witnesses can clear up the discrepancies between the administration's rhetoric and its proposed funding levels, and I look forward to your testimony.

Thank you, Mr. Chairman.

Mr. SHAYS. Thank you, Mr. Bell.

At this time, the Chair would recognize Mr. Janklow.

Mr. JANKLOW. Thank you very much, Mr. Chairman. I am going to be extremely brief.

If you go back to the period of time just a couple of short years ago when those anthrax letters were mailed around the country, they had the anthrax outbreak, the situation down in the Carolinas, the reality of the situation is, from and after that point in time, phenomenal things have been accomplished.

But as you indicated, Mr. Chairman, in your opening remarks, we still have a patchwork in this country that we have a responsibility to overcome very, very quickly. We have cities that have public health laboratories and counties with public health laboratories. We have prisons with public health laboratories. We have States that have public health laboratories; we have private health laboratories.

The Federal Government has Indian health service laboratories, they have public health service laboratories, they have military laboratories. We have a whole host of different laboratories, reporting centers in this country, and still a large amount of it is based upon paperwork. And it is incredibly important, it is really incredibly important that in today's day and age, when it is not that difficult to put together reporting systems based upon electronic means—and not facsimile, but far more modern electronic means—that this be done in the most expeditious manner.

The Centers for Disease Control frankly have accomplished phenomenal efforts in terms of working with local communities, working with States and communities over the last couple of years. But notwithstanding all the accomplishments that have been made, Mr. Chairman, the fact of the matter is, we are not where we have to be, we are not where we want to be, and we are not where we should be. And so anything that can be done to speed that process up can only be of a beneficial nature to the people of America.

Thank you very much, Mr. Chairman, for giving me this opportunity.

Mr. SHAYS. I thank the gentleman for this statement.

Mr. Murphy.

Mr. MURPHY. I will wait and ask questions.

Mr. SHAYS. Wonderful to have you all here. You all are such wonderful, active members of this committee.

Before recognizing our witnesses, let me just get some housekeeping in place here, and ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record, and the record remain open for 3 days for that purpose. And without objection, so ordered.

I ask further unanimous consent that all witnesses be permitted to include their written statements in the record. And without objection, so ordered.

At this time, we will recognize our first panel. We have two panels. Our first panel is Dr. David W. Fleming, Deputy Director for Public Health Science, Centers for Disease Control and Prevention; and Dr. David Tornberg, Deputy Assistant Secretary of Defense for Clinical and Program Policy, Department of Defense.

Gentlemen, as you know, we swear in our witnesses, all our witnesses. If you would stand, raise your right hands, and then we will take your testimony.

[Witnesses sworn.]

Mr. SHAYS. Note for the record that both our witnesses have responded in the affirmative.

I should have asked, is there anyone else that might help you respond that might have to say something publicly? If so, we will swear them in.

We will start with you, Dr. Fleming, and then we will go to you Dr. Tornberg.

Let me just tell you what we do. We do a 5-minute, and then we roll it over for the next 5 minutes. Stop sometime between the first 5 minutes and the second 5 minutes. Please don't go over the second 5-minute.

I've never figured out what would happen if you did.

Dr. FLEMING. I don't want to be the first. Thank you.

Mr. SHAYS. I'm using a little poetic license. It's happened once or twice.

OK.

STATEMENTS OF DAVID FLEMING, M.D., DEPUTY DIRECTOR FOR PUBLIC HEALTH SCIENCE, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND DAVID TORNBERG, M.D., M.P.H., DEPUTY ASSISTANT SECRETARY, HEALTH AFFAIRS, U.S. DEPARTMENT OF DEFENSE

Dr. FLEMING. Mr. Chairman, members of the subcommittee, I'm Dr. David Fleming. I'm the Deputy Director of CDC for Public Health Science. Good afternoon. On behalf of CDC, thank you for inviting us here today. We very much appreciate your leadership and attention to the issue of public health surveillance.

You know, this weekend when I was preparing my testimony, my 10-year-old asked me what I was doing. And when I told her I was working on a talk about public health surveillance, she said, Wow, I didn't know anybody was interested in that. And, you know, she had a point. Public health surveillance isn't an issue that most people know they should care about; and for that reason, we doubly appreciate your interest in this issue. And in some ways it's funny.

Mr. SHAYS. Given her great insight, would you give her full name for the record.

Dr. FLEMING. Sure. Absolutely. Her name is Whitney Lynn Fleming.

Mr. SHAYS. Well, she gets it.

Dr. FLEMING. Thank you.

And it's funny, because I think all of us would be fairly concerned if we walked into our personal doctor's office and he or she suddenly started treating us without taking a history or without doing a physical or without doing any diagnostic testing.

For public health, our patient isn't a person, it's the community. And just as clinicians need to know about blood pressure and about blood chemistries to diagnose the patients, public health practitioners must have the eyes and the ears and the tools to get the information that's needed to diagnose what's going on in their communities.

Although the range of information that's needed to monitor community health is broad, today we are focusing on one piece, the piece that's needed to respond to a biologic threat in a community, to detect an epidemic or a bioterrorist event. And the problem here is that in the early phases of an outbreak, affected people don't turn to public health because no one realizes there is an epidemic. Rather, one by one, affected people seek health care for their symptoms. And to overcome this problem requires a system that, first, recognizes and diagnoses cases as they occur; second, transfers information about those cases to the public health system, where, third, it's analyzed, investigated, and acted on.

Now, in this country this critical function is performed by our reportable disease surveillance system. Every physician, every laboratory in this country is required to report specific diseases and conditions to their public health authorities. And, you know, remarkably this system generally works. Thousands of disease reports are initiated each day and investigated each day, resulting in the detection of routine and exotic epidemics.

This is the system that identified the anthrax attacks, and odds are it's the system that will identify the next bioterrorist attack on this country. Is it perfect? No. It is the best in the world. But not all reports are complete, not all are timely, and not all are appropriately acted on. It is, however, the core of our detection capacity, and it is the one to work on to make us more prepared.

And there is good news here. The bioterrorism resources recently appropriated for building public health capacity have strengthened the system through a wide range of activities, such as increased provider training, improved laboratory diagnostic capacity throughout the country, better linkages between the clinical system and the public health system, and improved public health department 24/7 ability to receive and investigate reports. And these investments are paying off. Our remarkable success in detecting and responding to West Nile last summer and SARS right now are good examples.

In addition to these general improvements, let me just mention three specific enhancements that we are working on, and all of them capitalize on the fact that we are at a critical moment of opportunity regarding the use of information technology.

First, our current system emphasizes that providers recognize an event so that they can report it. In today's electronic age, there is a new potential that some of you have already alluded to, to use preexisting electronic data bases like nurse call lines or pharmacy records to check for clustering of events that might indicate an unrecognized problem. This type of monitoring is sometimes called

syndromic surveillance, and it can supplement our existing disease reporting system. It holds promise for potentially detecting some kinds of events sooner and for providing a richer set of information to monitor and respond to any recognized problem.

Second, we are working to improve the transfer of information from providers to public health. Though our National Electronic Disease Surveillance System [NEDSS], program, CDC is moving to move reporting from a paper system to an electronic system by establishing secure connectivity, by agreeing on those critical data standards, and by developing public health expertise that is necessary to make this system work.

And, third, we are working on our ability to integrate real-time information from a wide range of sources. You know, our detection methods have to be sensitive, but the price for that is the potential for false alarms. Creating the capacity to rapidly look across a range of inputs to see if one is confirmed by the others is an increasingly critical capacity. And the scope and speed with which a bioterror event could evolve also puts a premium on our ability to monitor the emergence of an epidemic and the response capacities that are needed to fight it.

I know the committee is also interested in surveillance at the international level. Let me just quickly say that the detection and tracking of SARS is an example of the international system working right, particularly given the resources that are available in most of the affected countries, and particularly given the fact that the very basics that we are beginning to take for granted here, like laboratory diagnostic capacity and personnel trained in case investigation and response are the rate-limiting need in most of the developing world.

So, in conclusion, public health surveillance is as critical to public health as clinical information and diagnostic testing is to the practicing physician. The basic elements of our system to detect a bioterrorist event are operational and increasingly robust as a result of the recent investments that we have made. More can be done, however. In particular, enhancements with a strong information technology component, accessing existing electronic data bases, facilitating electronic reporting, and improving our ability to rapidly analyze a wide range of information sources, once only dreams, are now possible. The challenge now is to make them a reality.

Thank you very much. And I would be happy to answer questions.

Mr. SHAYS. Thank you, Dr. Fleming.

[The prepared statement of Dr. Fleming follows:]

Testimony
Before the Committee on Government Reform, Subcommittee on National Security, Emerging Threats, and International Relations, United States House of Representatives

CDC's Public Health Surveillance Activities

Statement of

David Fleming, MD

Deputy Director for Public Health Science
Centers for Disease Control and Prevention
Department of Health and Human Services

For Release on Delivery
Expected at 9:00 am
on May 5, 2003

Good morning, Mr. Chairman and Members of the Subcommittee. I am Dr. David Fleming, MD, Deputy Director for Public Health Science at the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to update you on CDC's public health surveillance activities. I will describe the function of our current surveillance systems, update you on recent efforts to build surveillance capacity in state and local health departments, and discuss the status of our global disease surveillance activities.

As the nation's disease prevention and control agency, CDC has the responsibility on behalf of the Department of Health and Human Services (HHS) to provide national and international leadership in the public health and medical communities 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. The ongoing response to the outbreak of Severe Acute Respiratory Syndrome (SARS) demonstrates the crucial importance of watchfulness to detect problems and control the spread of disease.

Public health surveillance is the ongoing collection, analysis and dissemination of public health data related to disease and injury. It is a crucial monitoring function for CDC and its partners, both domestically and internationally. These ongoing data collection and analysis activities help us detect threats to the health of the public. Without our public health surveillance systems, we might not identify outbreaks or other important problems in time to prevent the further spread of disease. We cannot investigate problems, identify their causes, and implement control measures if we have not detected them. Recent events, including the SARS outbreak, have underscored this essential role of public health surveillance. For most of our surveillance data, the initial source of information is provided by health care professionals; a physician's ability to recognize, for example, a suspected case of SARS and his or her responsibility for reporting it to the state

or local health department has been critical toCDC's ability to recognize unfolding disease events. Indeed, identification of cases of SARS relies on heightened awareness among health care professionals who recognize that the respiratory syndromes they were seeing were actually an unusual illness, not influenza.

Current Surveillance Systems

One key to successful defense against any threat to the health of the public, whether naturally occurring or deliberately caused, continues to be accurate, timely recognition of a problem. Awareness and diagnosis of a condition by a clinician or laboratory is a key element of our current surveillance system. Clinicians and laboratories report diseases to State and Local health departments, which share information with CDC. CDC works with our public health partners to define conditions that should be reported to public health departments. Health departments share these definitions and guidelines with health care providers, infection control practitioners, emergency department physicians, laboratorians, and other members of the health care system to ensure accurate and timely reporting.

Our surveillance systems generally use paper or facsimile reporting by health care providers to health If a case of illness is particularly unusual or severe (such as a case of anthrax or rabies), the provider may call the local health department immediately. As mentioned, health care provider recognition of the illness and awareness that certain health events require immediate notification of public health authorities, is critical to our ability to detect problems and mount a public health response. Such reporting requirements are mandated at the state level. For routine public health surveillance, this largely paper-based system is burdensome both to providers and health departments,often resulting in reports which are not complete or timely. In addition, the volume of paper reports and the need to enter the information collected into various information

systems leads to errors and duplication of efforts.

These shortfalls influence more than our ability to detect an event; surveillance also plays a pivotal role in event management. Surveillance data help us to determine where cases are occurring and who is affected (e.g., particular age groups or occupations such as children or postal workers), when cases are occurring (i.e., are cases still occurring; are the numbers increasing or decreasing with time?), and matching such information to the laboratory data about the particular agent, to trace its origin as well as to identify whether cases in different geographic locations might have resulted from the same source. Such information is vital to directing our investigation and control efforts, but it requires a well-designed system to input and analyze the voluminous data required, such as the thousands of swabs tested for anthrax.

Integrated, Electronic Surveillance Information Systems

Given the crucial function of public health surveillance, we have recognized the need to take advantage of information technology advances to bring our surveillance systems into the 21st century. First, I will describe the overall direction that we are headed to transform our public health surveillance systems, and then I will describe some of our short-term efforts to enhance current surveillance systems in light of the threat posed by emerging and re-emerging infectious diseases and terrorism.

CDC and its partners have recognized the need to build more timely, comprehensive surveillance information systems that are less burdensome to data providers. Several years ago, we initiated the development of the National Electronic Disease Surveillance System (NEDSS). The ultimate goal of NEDSS is the electronic, real-time reporting of information for public health action. NEDSS will include direct electronic linkages with the health care system; for example, medical

information about important diagnostic tests can be shared electronically with public health as soon as a clinical laboratory receives a specimen, or makes a diagnosis. In the future, NEDSS coupled with a electronic real-time reporting of births and deaths (vital statistics) and computerized medical records, not only in hospitals but also in ambulatory care offices, could facilitate immediate awareness of unusual illnesses such as anthrax or smallpox, as well as our ability to detect more subtle problems that may be dispersed across the country.

NEDSS integrates the numerous existing surveillance systems using a standards-based approach, with standards for data, information architecture, security, and information technology. This adherence to standards will ensure that data need only be entered once, at the point of care for a patient, without a need for re-entry of data by our local and state partners. Use of standards is critical to ensure that our public health partners can use technology more effectively and collaboratively. The NEDSS strategy provides for State implementation of the CDC-developed version of NEDSS or state systems compatible with NEDSS. Currently, 30 States have requested installation of the system and four have been installed to date.

As NEDSS progresses, we are ensuring that the data standards we use are compatible with those used in the health care system generally so that we can make sense of health-related data and therefore detect potentially related cases across the country. Moreover, NEDSS is fully consistent with applicable aspects of HHS Secretary Thompson's recently announced consolidated health informatics (CHI) standards which are health data interoperability standards established under one of the Administration's electronic government projects covering the federal health care enterprise. In addition, a standard information and high-level security architecture will enable public health partners to share data in a secure fashion, which is critical for identifying problems that cross jurisdictional boundaries. And finally, the reliance on industry voluntary consensus standards for information technology ensures the availability of

multiple commercial products to meet the needs of our public health partners, including state-of-the-art analytic tools and geographic information system capacity.

CDC's Public Health Information Network (PHIN) initiative transforms a broader continuum of public health practice. Essentially, PHIN expands the NEDSS approach of standards-based systems integration and applies it to other functions of the information life-cycle of public health PHIN will electronically enable real-time data flow, computer assisted analysis, decision support, professional collaboration, and rapid dissemination of information to public health, the clinical care community, and the public through a common integrated and standards-based framework for public health systems and functions to reduce reporting burden by using existing electronic clinical data, monitor the nations health through continuous detection and evaluation of threats, and provide information and decision support to the public and public health professionals.

Near Term Surveillance Efforts - Building State and Local Surveillance Capacity

The Nation's public health surveillance capability requires a strong foundation of surveillance capacity at all levels of local, state, and federal public health and the ability to rapidly, consistently, and securely exchange and share such data and information to detect events and take appropriate public health actions. With Congressional support, CDC has been working with State and local health agencies to build and enhance surveillance and epidemiological capacity for many years largely through categorical disease grant programs and providing technical assistance. Following September 11, 2001, Congress appropriated $918 million for State health agency grants to enhance terrorism preparedness and response. Two of the five focus areas for these grants in FY 2002 and again this fiscal year are: 1) enhancing epidemiological and surveillance capacity, and 2) developing and leveraging information technology and systems to support various public health functions. Guidance for this funding directs partners to use

voluntary industry health data interoperability standards, such as those announced by Secretary Thompson, when they invest in information technology to support preparedness efforts. The use of these standards permits states to address immediate needs while still considering interoperability of systems.

Recognizing the urgent need for increased capacity, CDC and its public health partners initiated various activities to improve their ability to detect events of importance to the health of the public. Funding for countering terrorism and other public health emergencies has enabled state and local health agencies to increase their public health surveillance capacities. In addition to hiring qualified epidemiologists, several states have improved their ability to detect and respond to disease reports. For example:

- Michigan has begun implementation of a secure web-based disease surveillance system to improve the timeliness and accuracy of disease reporting.
- Missouri has implemented a new hospital tracking system to detect possible outbreaks by monitoring the number of admissions and ambulance diversions at hospitals. This system provides a way for hospitals to obtain instant messages and alerts.
- Pennsylvania is developing an early warning system, using symptom data from emergency departments, as a way to detect unusual patterns of illness and automatically alert hospitals and public health agencies when the incidence of disease exceeds a critical threshold. This system enables the earliest possible response and intervention before an outbreak or epidemic spreads.
- Virginia, Maryland, and Washington DC are working on a similar capability as that described for Pennsylvania.
- New York City has a well-established surveillance system of nontraditional data sources of pre-diagnostic indicators for surveillance and event detection.

The latter three efforts and "syndromic surveillance" projects undertaken by academic colleagues, and the Department of Defense represent a novel approach to early detection surveillance. Syndromic surveillance is an investigational approach to early detection of outbreaks through the monitoring of real-time, electronic data that are screened for indicators of disease as early in the course of illness as possible. Although promising, this approach to public health surveillance has not undergone rigorous evaluation and validation for its usefulness and value. There is still much to be learned about the most useful data sources, analytic strategies, and methods for presenting the information from the multiple possible data sources to State and local health department partners in coherent usable format. This is particularly critical because state and local partners have limited human resources to do follow up investigations on "alerts," many of which may be false alarms. CDC has taken a leadership role in developing a systematic approach to evaluating syndromic systems, and believes it is critical to undertake such evaluations before these systems can be recommended for widespread use.

Other related activities useful for early detection of emerging infections or other critical biological agents include CDC's Emerging Infections Programs (EIP). CDC funds EIP cooperative agreements with state and local health departments to conduct population-based surveillance and research that goes beyond the routine functions of health departments to develop "next generation" surveillance science, and often involve partnerships among public health agencies and academic medical centers. Of note, NEDSS supports many EIP information system needs.

In addition, CDC has established other networks of clinicians-- whether infectious disease or travel medicine specialists, or emergency department physicians-- whose functions are to serve as "early warning systems" for public health by providing information about unusual cases

encountered in the clinical practices of its members. It is important to note that these relationships, particularly between health care providers and local health departments, are the foundation on which our surveillance systems operate. The state and local health department is the front-line of defense for the public health system.

Emergency Preparedness

In addition to these efforts, CDC is enhancing its capacity to detect unusual clusters of illness, whether from intentional threats or naturally occurring problems such as SARS, by building upon a long history of successful surveillance collaborations with healthcare providers. Through a collaboration with our public health partners and the American Association of Health Plans (AAHP), CDC is working with epidemiologists and experts in informatics at Harvard Pilgrim Health Care to create a system of access to real-time electronic ambulatory care data through the National Bioterrorism Syndromic Surveillance Demonstration Program (NBSSDP).

This program, which expands a successful project operating in Massachusetts since late 2001, targets geographically oriented information about possible clusters of specific health events to State health departments within 24 hours or less. The program makes use of information both from local health plans and from a national telephone triage system, in which nurses screen calls from health plan members. The systems currently participating in the program serve over 20 million people throughout the U.S. Expansion to local health plans in Minnesota and Colorado are first, with on-line reports to health departments and CDC from sites outside Massachusetts scheduled to begin on or about May 1. Incorporation of nurse call data from all 50 states is expected soon thereafter, to be followed by data from health plans in Texas and California. To ensure that the needs of the public health system are integrated into this program at every stage, an advisory group with active participation by State health officials guides the implementation of

data collection and reporting activities.

In addition to early warnings of a bioterrorist attack, this system should prove invaluable in facilitating the daily surveillance work of State and local health departments. CDC is working to make parts of this system available now to address our public health partners' needs for managing possible responses to the SARS epidemic.

Global Disease Surveillance

Since 1994, CDC has been engaged in a nationwide effort to revitalize national capacity to protect the public from infectious diseases. The emergence of SARS, a previously unrecognized microbial threat, has provided a strong reminder of the threat posed by emerging infectious diseases. In March 2003, the Institute of Medicine (IOM) published *Microbial Threats to Health: Emergence, Detection, and Response,* a report describing the spectrum of microbial threats to national and global health, factors affecting their emergence or resurgence, and measures needed to address them effectively. Although much progress has been made, especially in the areas of strengthened surveillance and laboratory capacity, the IOM recommends much remains to be done both domestically and internationally.

In many countries, participation in disease surveillance outside of their borders is not a major health priority. For these countries, control of endemic diseases - major killers of children - is a far more urgent need. From a global health perspective, however, the capability of these countries to recognize and report disease outbreaks is crucial because new diseases are most likely to emerge in poor rural areas where disease rates are high. The WHO International Health Regulations that are currently being revised are expected to address countries' abilities to detect and respond to events of international health importance.

CDC is intensifying its efforts to work with the World Health Organization (WHO) and other partners to create a comprehensive global network that detects and controls local outbreaks before they grow into worldwide pandemics. Currently, there are Field Epidemiology Training Programs (FETP's) in 30 countries throughout the world that support disease detection activities and provide an essential link in global surveillance. These FETP's have been developed under the auspices of CDC and with the support of WHO. They are modeled after the Epidemic Intelligence Service (EIS) training program which focuses its attention on epidemiology and surveillance and their application as a means to control an outbreak and to prevent further disease spread. Additionally, there is a concerted effort to develop and expand other fledgling regional disease surveillance networks that include less developed nations as members. These networks, which can build on the established FETP's or on their model, include the Caribbean Epidemiology Center's disease surveillance network, the Amazon and Southern Cone networks in South America, the Integrated Disease Surveillance and Epidemic Preparedness and Response Project in Africa, and the Mekong Basin Disease Surveillance system in Southeast Asia. In the years ahead, these regional disease surveillance networks are likely to grow in number and geographical scope. Over the long-run, these networks can expand, interact, and become the building blocks of a worldwide "network of networks" that monitors priority diseases of global concern, including pandemic influenza, drug-resistant diseases, and diseases cause by biological agents. They will also provide early warning of new and re-emerging threats.

CDC has also created two International Emerging Infections Programs (IEIPs)--one in Thailand (established in 2001) and one in Kenya (scheduled to open in 2003)--that are modeled on the domestic EIP Programs described earlier that have been so successful in the United States. The IEIPs will serve a double purpose: fostering the next generation of international public health leaders while providing high quality disease surveillance data and rapid response capacity for new and emerging diseases. A pilot IEIP site– established in Bangkok in 2001 as a collaboration

with the Thai Ministry of Public Health (MOPH)– is currently serving as a regional hub for CDC's SARS control activities in Asia, coordinating the shipment of diagnostic specimens from Taiwan, Thailand, and Vietnam, and deploying staff, as requested, to Hong Kong, Laos, and Taiwan. When SARS occurred in Thailand on March 11, carried by an arriving airline passenger, the IEIP was able to respond within minutes by isolating the passenger at the airport and implementing strict infection control procedures at the hospital. These procedures remained in place over the subsequent 3 weeks and no health care workers or other community members became infected. Within hours the IEIP began assisting the Thai MOPH, and WHO to contain transmission at other hospitals, implement a nationwide SARS surveillance system, and train public health workers in appropriate control measures.

Further, there is an FETP located in China (CFETP) which has taken a significant lead on the management and control of the SARS outbreak there. Teams of epidemiologists and other scientists were assembled to investigate and direct the national response to the ongoing epidemic. A CFETP trainee is included on these teams. These trainees have had a role in coordinating the surveillance efforts required to track and stem the outbreak of cases. Chinese health officials credit the ability to draw on the FETP staff and trainees and their medical expertise regarding epidemiology and surveillance with helping to prevent the uncontrollable spread of SARS in at least one of China's most densely populated provinces.

Additionally, two years ago, during the anthrax investigation in the United States, the Bangkok IEIP responded to requests for advice, diagnostics, and testing of suspected materials not only from the Thai MOPH, but also from U.S. embassies in other Asian countries. Global programs like the IEIP and the FETP's builds in-country public health expertise to diagnose or rule out known diseases and to recognize and report new or unusual illnesses to the global community.

Conclusion

In conclusion, CDC is committed to working with other federal agencies and partners as well as state and local public health departments to protect the public's health. To this end, our best public health strategy against illness, regardless of cause, is the development, organization, and enhancement of public health surveillance systems and tools.

Our public health surveillance systems provide a critical piece of the public health infrastructure for recognizing and controlling deliberate bioterrorist threats as well as naturally occurring new or re-emerging diseases and other threats to health. We have made substantial progress to date in enhancing the nation's capability to detect and respond to problems that threaten the public's health. Recognizing that there is no simple solution for our surveillance needs, we have supported augmenting the staff in state and local health departments, as well asspecial projects to explore the usefulness of various clinical data sources. We are undertaking a critical review of current efforts to determine what would be feasible and useful to implement more broadly. We are implementing the National Electronic Disease Surveillance System, which will provide direct linkages with the health care system, improving the timeliness, efficiency, and usefulness of our surveillance efforts. These cross-cutting efforts to build the surveillance infrastructure will be useful to detect any problem, not just potential bioterrorist events; the ongoing use of this surveillance infrastructure will ensure that it is familiar and functional should bioterrorist events continue to occur. A strong and flexible public health infrastructure is the best defense against any disease outbreak.

As we have seen recently, infectious diseases are a continuing threat to our nation's health. Although some diseases have been conquered by modern advances, such as antibiotics and vaccines, new ones, such as SARS and West Nile Virus, are constantly emerging. SARS reinforces the inextricable link between U.S. health and global health, and that fulfilling CDC's

domestic mission -- to promote health and quality of life by preventing and controlling disease, injury and disability –requires global awareness and collaboration with domestic and international partners to prevent the emergence and spread of infectious diseases.

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

Mr. SHAYS. Dr. Tornberg.

Dr. TORNBERG. Good afternoon, Mr. Chairman, distinguished committee members. I am grateful for this opportunity to discuss the activities of the Department of Defense military health system, and to focus today on those activities engaged in medical surveillance.

The military health system, with over 8.7 million beneficiaries, has a global mission that's continually involved in health surveillance. Our medical treatment facilities are daily collaborating, planning, training, and participating in homeland defense operations with our civilian community partners. Our military bases coordinate in the development of mutually supportive surveillance, defense, and consequence management plans. These efforts will be part of the Joint Services installation pilot project demonstrations.

Integral to this project is ESSENCE II, the electronic surveillance system for early notification of community-based epidemics. This program is a cooperative venture between the Defense Advanced Research Projects Agency [DARPA], and the Johns Hopkins University applied physics laboratory.

ESSENCE II is an outgrowth of ESSENCE I, which was developed for DOD-GEIS. ESSENCE II monitors the National Capital Area and performs syndromic surveillance based on school absenteeism, pharmacy prescription, over-the-counter transactions, emergency room and hospital clinic visits, and other disparate data sources to detect natural disease outbreaks or possibly covert biological weapons attack. A rapid display of clusters of suspicious symptoms or findings provides decisionmakers with outbreak information not currently available. This program shows great promise for providing early detection and response to numerous public health challenges.

Medical surveillance of our new recruits and our Active Duty population presents us with the unique opportunity to detect the emergence of infectious illness. This knowledge can impact public health strategies by national authorities. In the past 2 years, virus isolates from military sources have twice driven the composition of the influenza vaccine used throughout the Nation in both the military and civilian communities.

Development of vaccines to counter the relentless spread of old and newer biologic threats is a major contribution by Department of Defense laboratories. Current studies include working on improving vaccines for anthrax, Venezuelan equine encephalitis, plague, botulism, and toxins such as staphylococcal enterotoxins, and ricin.

Medical oversight and surveillance of our military members from the moment they are recruited until the day they die provides unprecedented opportunity to monitor the potential impact of occupational, environmental, and geographical exposures. The defense medical surveillance system, a longitudinal surveillance data base, allows the Department to capture and then track significant events and exposures throughout a members' accession, training, deployment, and retirement. Improved occupational environmental surveillance programs protect forward-deployed service members' health by providing improved monitoring. The Theater Army Medical Laboratory, the Navy's Forward Deployable Preventive Medi-

cine Unit, and the Army's Center for Health Promotion and Preventive Medicine provide rapid analysis and risk assessment information.

To facilitate rapid biologic identification, DOD has supported development of the Ruggedized Advanced Pathogen Identification Device [RAPID], as we call it. This device is a miniaturized polymerase chain reaction [PCR], technology. It's a bioagent detection system that can frequently identify the cause of the outbreak or bioterror attack within 2 hours. This process could possibly take 4 days using standard laboratory techniques to identify agents.

DOD has implemented weekly tracking of field clinic visits for various diseases and nonbattle injuries during deployments, and has increased such daily monitoring for current operations in all field clinic reports through command channels at least daily on the current situation, so notification of an outbreak or development of an unusual pattern is relatively immediate. The value to the Nation of these systems extends beyond DOD to industrial agents whose work forces parallel those in the military by providing valuable insight and methods to prevent or mitigate long-term disability.

The Department of Defense partners with a number of civil, military, and international partners. The Armed Forces Medical Intelligence Center, an arm of the Defense Intelligence Agency, performs classified and unclassified global medical intelligence to arm theater commanders with the latest environmental, biological, and medical threat assessments. Their unclassified assessment is available to citizens and agencies.

Enhanced Federal agency sharing and knowledge exchange is achieved by assigning military epidemiologists to the Centers for Disease Control. Public health service experts are also assigned from CDC to DOD. This sharing of our joint resources and expertise enhances the national response to both local and global threats.

In like manner, we have detailed a military medical specialist to the World Health Organization. In the recent severe acute respiratory syndrome outbreak [SARS], the Department detailed a military expert in epidemiology to CDC from DOD-GEIS—and GEIS, as we know, is the Global Emerging Infection Surveillance response system—to provide our unique perspective. Additionally, DOD-GEIS experts were detailed from our laboratories in Indonesia to Vietnam in the outbreak's earliest days. Our experts contributed essential knowledge in the acquisition of specimen collection and biologic identification, and provided skill in transporting specimens. The existing infrastructure of the GEIS global laboratory influenza-based surveillance program was rapidly expanded to facilitate the transport of these specimens.

A daily executive summary is issued by DOD-GEIS to communicate not only news with respect to general SARS issues, but also specific DOD information on possible cases, policy guidance, referenced laboratory resources, and surveillance data from ESSENCE and other DOD sources. DOD and service-specific clinical disease control and air evacuation guidance has been disseminated to our forces. To date, we have had no active confirmed cases of SARS.

GEIS's mission is directed by Presidential Directive 7, and includes support of global surveillance training and research and response to emerging infectious disease. Recognized by the Institutes of Medicine in 2001 as a critical, unique resource of the United States in the context of global affairs, and as the only U.S. entity that is devoted to infectious disease globally that has broad-based capacity in the overseas setting, DOD-GEIS stands as our commitment to surveillance for emerging infectious diseases in direct support of our national security efforts.

Emerging infections, as has been discussed, are a threat to global security and have the ability to harm U.S. interests through reversing economic growth, fomenting social unrest, and complicating our response to refugee situations.

Biological terrorism and warfare are additional concerns. The recent emergence of SARS and the inextricable progress of the HIV/AIDS epidemic in Africa have provided ample evidence of the economic and societal damage that infectious disease can cause.

During our continuing operations in Afghanistan and Iraq, the military health system has applied the lessons of 12 years' experience since the first Persian Gulf operations. Through a force-held protection strategy, the Department promotes and sustains the health of our service members prior to deployment, protects personnel from disease and preventable injury during deployment, and provides comprehensive followup treatment for deployment-related conditions. A deployment health surveillance program with pre and post-deployment health assessments validates each individual's medical readiness to deploy, and addresses health concerns upon his return.

Improved deployment health protection measures are designed to counter an increasingly broad range of threats. Such measures include the fielding of new biological and chemical warfare agents, detection alarm systems, and the operational testing of integrated electronic medical surveillance and emergency response networks. Current vaccines and antimalarial drugs and research on the next generation of vaccines and pharmaceuticals are but some of the many efforts we are engaged in.

DOD has coordinated with the VA to address deployment, health-related concerns of both service members and veterans in developing a post-deployment health guideline. This practice guideline and the use of it through electronic information sharing through the Federal Health Information Exchange provides significant improvement in the care of our veterans' health.

The military health system participates in the National Science Foundation's multiagency project to prioritize national research agenda for information systems to detect and respond to natural outbreaks or intentional release of biologic agents that target not only humans but plant and animal resources. Economic and health strains and vulnerabilities are being mapped, while requirements for information systems to track, alert, and notify disturbances are being developed. A national strategy involving combining Federal and civil agencies to combat bioterror will strengthen the national response.

In conclusion, I am proud to say that the Department of Defense military health system is a solid partner in support of the national

public health security through daily medical surveillance and support of the continuing war on terror. I believe that you will find that the military health surveillance has many complementary and overarching systems that cooperate with both other Federal agencies and the civilian medical community. These activities are enhanced through outstanding programs such as DOD-GEIS and the ESSENCE I and II programs.

Thank you, Mr. Chairman, and distinguished committee members.

[The prepared statement of Dr. Tornberg follows:]

Dr. David Tornberg, MD, MPH
Deputy Assistant Secretary of Defense (Health Affairs)
Subcommittee on National Security, Emerging Threats, and International Relations Hearing on Homeland Security: Improving Public Health Surveillance

Introduction

Good morning Mr. Chairman, Distinguished Committee Members, I have been asked to provide this committee with information on the activities of the Military Health System in support of global public health security.

The Military Health System (MHS), with over 8.7 million beneficiaries, constantly monitors health data. About 1.4 million beneficiaries are active duty service members, many deployed or stationed frequently with their family members outside the United States. Over 300,000 new recruits from many areas of the world attend military basic training each year in an intense, controlled, close quarters environment. This creates a need for understanding health issues from around the globe, providing a unique population with challenges in preventive medicine, immunization issues, and potential for outbreaks of infectious disease. Thus, the MHS has to deal daily with public health issues on a large scale; with many unique health threats associated with training, plus operations in overseas and often austere environments with poor sanitation, encountering endemic diseases, etc. Due to these military health threats, DoD has developed extensive health protection measures and capabilities, such as in vaccine development, disease prophylaxis, and medical and environmental surveillance.

Protecting Our Military Forces

A Presidential Review Directive (NTSC-5, 1998) regarding military and veteran health protection was set up to review and make recommendations on Military/Federal Health Issues providing extensive detail and recommendations for DoD health surveillance activities for the health protection of Service members and veterans. These activities relate directly to global public health security due to requirements for protection of Service members in a worldwide deployed environment with constant infectious disease and potential bioweapons threats.

In 2000, the Institute of Medicine (IOM) published a review entitled, "Protecting Those Who Serve," which focused on military health protection, particularly during military deployments. IOM made the following six recommendations, which are all being implemented by DoD:

1. Use a systematic process to prospectively evaluate non-battle related risk (and injuries) associated with deployments
2. Collect and manage environmental data, personnel locations, and biological samples to facilitate analysis of deployment exposures and to support clinical care and public health activities.
3. Develop the risk assessment, risk management, and risk communication skills of military leaders at all levels.

4. Accelerate the implementation of a health surveillance system that spans the service life cycle and that continues after separation from service.
5. Implement strategies to address medically unexplained symptoms in populations that have been deployed.
6. Implement a joint computerized patient record and other automated record keeping that meets the information needs of those involved with individual care and military medical public health.

These issues all relate to global public health security, as protection of our citizens worldwide requires attention to public health issues which may be unique to specific foreign environments, as well as to those common to all developed countries.

A Global Surveillance System

DoD's surveillance activities are enhanced through the DoD Global Emerging Infections Surveillance and Response System (DoD-GEIS). The Department has for more than 100 years been a global leader in addressing public health research and operational issues. The primary thrust has usually been to counter threats to U.S. forces that need to operate in locations with infectious diseases that are not considered a major threat to citizens residing within the 50 states. A 1992 report of the Institute of Medicine entitled, "Emerging Infections: Microbial Threats to Health in the United States," urged a broader role for the DoD in recognition of its substantial globally distributed infectious disease research laboratory network. This overseas highly developed infrastructure, unique in the federal government, has been key to the development of new drugs to prevent and treat malaria and of vaccinations against diseases including hepatitis A, Japanese encephalitis, and infectious diarrhea.

Subsequent to the IOM report, the CDC and NIH, in strategic planning documents, also recognized the critical role DoD overseas labs could play in advancing the detection and response to emerging infections. A Presidential Decision Directive (NSTC-7) issued in June 1996 formally expanded the role of DoD "to include support of global surveillance, training, research, and response to emerging infectious disease threats." It called on DoD to "strengthen its global disease reduction efforts through: centralized coordination; improved preventive health programs and epidemiological capabilities; and enhanced involvement with military treatment facilities and United States and overseas laboratories."

The program has been in operation more than five years. To ensure that the program is yielding optimal benefits, the Institute of Medicine was asked to evaluate the entire effort in 2000-2001. While many recommendations were offered, the IOM concluded that DoD-GEIS is "a critical and unique resource of the United States in the context of global affairs. It is the only U.S. entity that is devoted to infectious diseases globally and that has broad-based laboratory capacities in overseas settings." The powerful capabilities of DoD-GEIS were seen as more than an opportunity to enhance

military health and readiness or even the health of Americans in general. As highlighted in the recent National Intelligence Estimate, "The Global Infectious Disease Threat and its Implications for the United States," emerging infections are a global issue. They have the capability to harm U.S. interests abroad through destabilizing key institutions, obstructing trade and human migration, slowing or reversing economic growth, fomenting social unrest, and complicating our response to refugee situations. Biological terrorism and warfare are additional concerns. The recent emergence of SARS in Asia and the inexorable progress of the HIV epidemic in Africa have provided ample evidence of the economic and societal damage that infectious diseases can cause. Thus, DoD-GEIS is seen as a key contributor to not only military readiness but also to international public health and U.S. foreign policy. The IOM evaluation of DoD-GEIS was not only of value internally to the Department of Defense but numerous recommendations formed a basis for elements of the Global Pathogens Surveillance Act of 2003 (S. 871) which Senators Biden, Domenici, Hagel, Lugar, Feingold, and Kennedy introduced into the Senate on 10 April 2003 and which is now with the Foreign Relations Committee.

The DoD-GEIS operates in two primary realms, the five overseas tropical medicine research units and various elements of the Military Health System. The overseas medical research units are located in Peru (NMRCD), Egypt (NAMRU-3), Kenya (USAMRU-K), Thailand (AFRIMS), and Indonesia (NAMRU-2). Including foreign national professionals and contractors, they employ collectively over 600 persons. In addition DoD has benefited greatly from arrangements with the Centers for Disease Control and Prevention that have placed senior public health experts at NMRCD, NAMRU-3, and NAMRU-2 for long-term assignments. These overseas assets are backed up by an extensive DoD infectious disease research and surveillance infrastructure located at institutions including the Walter Reed Army Institute of Research (Silver Spring, MD), the Navy Medical Research Center (Silver Spring, MD), the US Army Center for Health Promotion and Preventive Medicine (Aberdeen Proving Ground), the US Army Medical Research Institute for Infectious Diseases (Fort Detrick, MD), the Armed Forces Institute of Pathology (Washington, DC), the Naval Health Research Center (San Diego), and the Air Force Institute for Environmental, Safety, and Occupational Health Risk Analysis (San Antonio, TX). As a result, an unprecedented level of networking and synergistic collaboration has been fostered between these overseas and domestic elements and other institutions within the U.S. government and overseas.

The DoD overseas medical research units are among the most advanced biomedical laboratories in their respective regions. They conduct projects in over 30 countries around the world. The GEIS program at the overseas laboratories has several foci. Global influenza surveillance is one critical emphasis because of the historic morbidity and mortality associated with influenza. In the great Spanish influenza epidemic of 1918 over 43,000 U.S. servicemen died of influenza. The German Chief of Staff, Eric von Ludendorff, cited influenza outbreaks towards the end of the World

War I as a detriment to German Army success. All five DoD overseas medical research units participate in global influenza surveillance in conjunction with AFIERA (Air Force Institute for Environmental, Safety, and Occupational Health Risk Analysis), CDC, and WHO. The yield of this program has been notable. In the 2001-2002 and 2002-2003 influenza vaccines, the viral isolate for one of the three components (the Panama strain) originated from a DoD-GEIS surveillance specimen collected in Panama. The original selection by the FDA of another component, the New Caledonia strain, was heavily influenced by DoD's first isolation of this strain in the hemisphere by public health surveillance the Navy's Peru lab was conducting on Peruvian naval recruits. In this manner DoD-GEIS has benefited not only the Service personnel who receive this vaccine each year but also the tens of millions of other recipients. A strong influenza surveillance program is also valuable for bioterrorism surveillance since many agents in that group would initially present as influenza-like illnesses. Similarly, the recognition of new respiratory agents such as the agent of SARS is enhanced by global influenza surveillance.

Surveillance for drug-resistant malaria is also a focus of the DoD-GEIS overseas medical units. DoD has traditionally been a world leader in the development of antimalarial drugs and the overseas labs have been the backbone of the relevant clinical field trials needed to obtain licensure. DoD-GEIS funds the WHO Collaborating Center for Malaria Drug Development at the Walter Reed Army Institute of Research. Through DoD surveillance the distribution of drug-resistance can be tracked and methods of prophylaxis and treatment optimized. Similarly, diarrheal disease has historically been a major problem for military and other international travelers. The spread of antibiotic resistance has been rapid. Through structured surveillance DoD has been able to monitor these trends and optimize treatment approaches.

The greatest challenge for global infectious disease surveillance is dealing with the unexpected, especially when the unexpected is a new agent not previously described and for which specific laboratory tests are not available. Often these new agents are only recognized when the problem becomes distinctive enough that an astute clinician recognizes something unusual and is prepared to take public health action. Often and unfortunately, delays are an inherent part of this method of recognition and response. DoD-GEIS has endeavored to foster early detection through implementation at all of its overseas programs syndromic surveillance activities. In some cases individual patients who fit a specific syndromic pattern, for example fever with jaundice, are subjected to a predetermined algorithm of laboratory tests. In other cases, a broader, more rapid and affordable net is cast with the focus being on recognition of abnormal symptom patterns that manifest at the community level. For example, the NAMRU-2 lab in Indonesia has established an electronic syndromic disease network of networks called EWORS (Early Warning Outbreak and Recognition System). These networks are in Indonesia, Laos, Viet Nam, and Cambodia. The symptom patterns of patients presenting at sentinel clinical sites are captured in a standardized way and

downloaded electronically each day to a centralized site for analysis through use of a specially developed software tool. Through this method NAMRU-2 has been able to detect or characterize numerous outbreaks of problems such as dengue hemorrhagic fever. The value of the EWORS approach has been appreciated by other governments such as those in Poland, Panama, and Peru that have asked for GEIS help as they try to establish similar mechanisms in their countries.

The Right Resources in the Right Place

DoD public health security builds on a strong cadre of preventive medicine and public health officers and personnel stationed at military installations across the globe who serve as our first line of defense in the identification and control of infectious diseases that may pose a risk to our Service members and our mission. These dedicated professionals constantly monitor the disease patterns in their local area, make notification when something seems awry, and implement measures to help control the situation. In most cases, the military preventionists work closely with their civilian counterparts at the local or state level to develop and implement control measures. The efforts of the local public health experts should not be discounted. Not only do they serve as the first-line of defense when an outbreak occurs, but they often identify a problem before electronic surveillance triggers are reached.

The Defense Medical Surveillance System is located at the U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM) and captures data from the MHS and other sources. It is unique, in that it links multiple military data bases, most notably the MHS, personnel, deployment, reportable disease, and serum repository systems. CHPPM manages EPICON, a rapid response cell that can mobilize to investigate any disease outbreak. CHPPM also has teaching materials for the prevention of medical illness and injury. As 9-10 individuals suffer from disease and non-battle injuries for every wounded soldier, sailor, airman, Marine, or Coast Guardsman, prevention of non-battle disease and injury is paramount to the success of any military mission. CHPPM (through the Deployment Environmental Surveillance Program), Air Force (through the Air Force Institute for Environmental, Safety, and Occupational Health Risk Analysis) and Navy (through the Navy Environmental Health Center) programs monitor environmental, bioweapon, industrial, and infectious disease threat analysis and mitigation.

An example of mobile environmental and clinical laboratory capability is provided by the DoD development of the Ruggedized Advanced Pathogen Identification Device (RAPID) to provide field commanders with portable, rapid, specific biological agent identification capability. This system identifies infectious agents in as little as 2 hours, enabling commanders and health care providers to make laboratory-based decisions that govern intervention and prevention in a timely manner. DoD has currently deployed nearly three hundred fifty of these $60,000 units.

The Armed Forces Institute of Pathology (AFIP) has one of the world's best laboratories for anatomic and microscopic pathology. AFIP works in concert with both DoD and civilian experts to analyze the histological patterns for any disease process, and it is a world-renowned pathologic reference facility. AFIP also manages the Office of the Armed Forces Medical Examiner, which monitors all military deaths and assures that appropriate autopsies are conducted to determine cause of death.

The Uniformed Services University of the Health Sciences (USUHS) operates Preventive/Occupational Medicine and Tropical Medicine Residencies and Fellowships, as well as public health training and research for medical and graduate students. Physicians from around the world study at the DoD medical university. USUHS participates in manning several of the remote laboratories that provide tropical disease information and research.

The Armed Forces Medical Intelligence Center (AFMIC) has both classified and unclassified information on the medical threats and health issues potentially facing our deployed forces anywhere in the world. This information includes endemic and epidemic disease occurrence, health care capabilities, disease and animal vectors, and pests and reptiles important to disease transmission. This center provides critical intelligence for unit medical planners to ensure that proper medical information and prophylactic medications are dispersed to deploying forces. This information is not only vital to medical planners, but it is also used by the military leadership of deploying forces in developing their risk assessments at all unit levels.

A National Role

Mr. Chairman, you'll be pleased to hear that DoD is a solid participant in a National Science Foundation-sponsored multi-agency working group[1] to develop the National strategy and vision for informatics systems for surveillance of infectious diseases and bioweapon use against humans, plants and animals. This agenda will recommend research priorities for development, integration, and coordination of disparate data systems to give decision makers at all levels timely, accurate and dependable surveillance information.

ESSENCE and Syndromic Surveillance

Within the structure of the Military Health System GEIS program syndromic surveillance has also been a focus. In 1999 GEIS launched ESSENCE, the Electronic

[1] AFMIC (Armed Forces Military Intelligence Center), CDC (Centers for Disease Control and Prevention), CIA (Central Intelligence Agency), DoE (Department of Energy), DHHS (Department of Health and Human Services), DoT (Department of Transportation), NASA (National Air and Space Administration), NIH (National Institutes of Health), NIMA (National Imaging and Mapping Agency), NIST (National Institute of Standards and Technology NOAA (National Oceanographic and Atmospheric Administration), NSA (National Security Agency), State Department, USDA (United States Department of Agriculture), USGS (United States Geological Survey)

Surveillance System for the Early Notification of Community-based Epidemics. This effort, inspired by earlier work by the City of New York, initially sought to create for the National Capital Region a near real-time method for detecting unexpected changes in health. The means used were to capture electronically every day the ambulatory medical diagnoses issued by providers at over 100 DoD primary care clinics within 50 miles of the White House. The multiple public health jurisdictions in the National Capital Region made implementing such a system in the civilian sector much more of a challenge than was the case in the City of New York. Because DoD had in place a networked electronic medical information infrastructure, it was feasible to pilot such an initiative rapidly and at very low cost. Immediately following the events of September 11, 2001, it was possible to scale up the ESSENCE effort to involve daily capture of outpatient diagnoses from over 300 DoD medical treatment facilities around the world. The numerous diagnostic codes are reduced to several broad categories thought to point towards syndromes associated with naturally occurring outbreaks or bioterrorism.

Using historic data and mathematical methods, epidemiologic aberrations in temporal trends are sought and prioritized for alert. ESSENCE has been recognized as a leader in this new approach to public health surveillance. In recognition of this DARPA funded the creation of ESSENCE II, a civil-military operational research and development partnership involving GEIS, the Johns Hopkins University Applied Physics Lab, and other academic and corporate partners. The objective is to create for the National Capitol Region a more powerful tool for detecting and characterizing outbreaks as early as possible. In addition to tracking civilian and military health care system ambulatory data, the ESSENCE II consortium is evaluating complementary surveillance sources such as over the counter and DoD pharmacy data, nurse hotline data, and ICU data. The Defense Threat Reduction Agency and the DoD Program Executive Office for Chemical and Biological Defense have also provided funding to further improve and extend this enhanced model of surveillance to a test bed in Albuquerque, NM and to nine DoD installations.

In-Garrison Health Surveillance

DoD-GEIS has also focused on strengthening the key elements of the Defense Medical Surveillance program for the in-garrison health system. A key focus has been on laboratory based surveillance of respiratory diseases. The Air Force Institute for Environmental, Safety, and Occupational Health Risk Analysis and the Navy Health Research Center have expanded their respiratory disease public health laboratories. Through an annual tri-service meeting, the GEIS-supported work of these labs is coordinated to ensure that it is synergistic, as comprehensive as feasible, and cost-effective. AFIERA focuses on global surveillance of respiratory viruses especially on etiologic determination of agents causing disease. AFIERA receives specimens from Army and Navy overseas research units and numerous MHS laboratories around the world. AFIERA's valuable work is reflected in their featured

role each year at the FDA meeting to select the annual influenza vaccine components. The NHRC laboratory focuses on population-based surveillance, especially in tri-service DoD training centers, for bacterial and viral respiratory diseases. This has allowed DoD to detect and characterize problems in basic training centers so that appropriate prophylaxis and other disease controls can be put into place rapidly. After the first Gulf War it was recognized that a weakness in DoD surveillance was the lack of rapid surveillance for cause of death. Through funding to the AFIP, GEIS has been able to establish an effective mortality surveillance system to ensure that all active duty deaths are fully documented and that unexplained deaths, potentially due to emerging infections, are rapidly investigated.

Value of Partnerships

DoD has always recognized that global surveillance is a goal we cannot achieve alone. Partnerships with WHO and its regional offices in other nations and the building of trust have been a key element of the DoD philosophy. Many countries, in confidence, have brought issues to the attention of GEIS and the overseas laboratories because they respected the integrity of the GEIS scientists, the spirit of collaboration, and the capabilities of the DoD network to produce high quality results rapidly. DoD-GEIS is a member of the WHO-led Global Outbreak Alert and Response Network or GOARN. As such it receives privileged information each week on significant public health events around the world. From time to time it is asked to support responses to these events such as the recent SARS outbreak. The integration of DoD-GEIS into these WHO-led responses is facilitated by having these elements awarded status as a WHO Collaborating Center. This multiyear process involves, in part, demonstrated international collaboration. Currently DoD supports WHO Collaborating Centers for Emerging Infections at NAMRU-2 and NAMRU-3. The other overseas labs are in the application process. U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) is also a WHO Collaborating Center for Viral Hemorrhagic Fevers with DoD-GEIS providing funding to the diagnostics laboratory.

To facilitate WHO-GEIS collaboration in the GOARN and in other venues, the Navy detailed a preventive medicine physician to WHO in June 2001. DoD provides the primary financial support to enable this officer to serve a vital civil-military liaison function at the WHO. Thus, most mornings we have at the table in Geneva, where emerging outbreaks are discussed, a DoD epidemiologist who can help focus DoD-GEIS resources towards important emerging global problems. During operations in Kosovo this was useful and most recently this has proven critical as we have faced the SARS crisis in the midst of the major deployment to the Middle East theater of operations. Through this office many valuable activities are developing including a NATO conference on influenza pandemic planning that was held in Saint Petersburg, Russia just a few days ago. The head of the AFIERA division that oversees GEIS influenza surveillance was partnered with a Russian scientist as co-sponsors.

Partnerships with specific WHO regional offices have been a major focus of GEIS. A major focus here has been capacity building projects often focused around outbreak investigation training. Most of the overseas laboratories have found that the sponsorship of outbreak investigation training for host nation professionals is a useful way to add eyes and ears to the GEIS network and to build mutual trust and confidence. Doing this in conjunction with WHO further adds to the strengthening of the global network and the acceptance of DoD's role. The Combatant Commands have over the years seen that supporting GEIS-related humanitarian assistance projects is a valuable tool for engagement. Over the last five years the Southern Command humanitarian assistance program has funded GEIS to donate equipment and provide training to establish electronic laboratory networks for disease surveillance in over 20 countries of the Caribbean and Latin America. In this way the reach of DoD-GEIS has been extended well beyond traditional boundaries.

Military Health System Vaccine Program

Vaccines are important tools in protecting the health of the men and women who serve their nation in uniform. The biological threats may spread in a number of ways including person-to-person in recruit training, airborne transmission on the battlefield, through contaminated food or water, or from the bite of an infected mosquito during deployments. Vaccines provide a safe and effective means of countering the threats to personal health and military readiness. DoD uses a wide array of vaccines to help mitigate the impact of biological threats. These Vaccines prevent infections, such as tetanus, typhoid fever, measles, yellow fever, smallpox, and anthrax, to name just a few. The DoD Military Vaccine Agency serves to coordinate the use, risk communication and safety monitoring of vaccines both in garrison and in operational settings in an effort to keep units operationally ready and reduce the risks from disease.

In addition to effectively using available vaccines, DoD has an extensive research effort ongoing to develop new and better vaccines to protect our Service members. The United States Army Medical Research Institute of Infectious Diseases has a staff of 450 physicians, veterinarians, microbiologists, pathologists, chemists, molecular biologists, physiologists, and pharmacologists, and the technical and administrative staff necessary to support the research. Current studies include work on improved vaccines for anthrax, Venezuelan equine encephalitis, plague, and botulism, and on new vaccines for toxins such as staphylococcal enterotoxins and ricin. Research on medical countermeasures to viral hemorrhagic fevers and arboviral illnesses also is conducted.

Topical Response

Response is a critical and challenging element of the DoD program. Over the last five years various elements of the DoD-GEIS network have supported responses such as those to outbreaks of Rift Valley Fever in Kenya and Yemen. SARS illustrates in perhaps the most comprehensive way the ranges of assets DoD-GEIS can coordinate and bring to bear on a problem. From the earliest days, having a DoD officer assigned to WHO headquarters has been of great value. As the complexity of the SARS situation grew, especially with the ongoing deployment, we found it advantageous to detail a DoD epidemiologist to the CDC SARS operations center in Atlanta. This individual has been a key point of coordination for numerous issues.

Though DoD has yet to register a "suspect" or "probable" case of SARS, much preparation has been accomplished. DoD and Service-specific clinical, diagnostic, disease control, and air evacuation guidance has been disseminated. PACOM has issued a directive on travel restrictions to East Asia. The existing infrastructure of the GEIS global, laboratory-based respiratory surveillance program was rapidly expanded to facilitate transport of acute respiratory disease specimens to capable laboratories. Through coordination with CENTCOM, new laboratory-based respiratory disease surveillance sites were established in Oman, the Kyrgyzstan Republic, Qatar, and Kuwait. These will provide surveillance for not only SARS but also all other respiratory agents in theater. AFIERA coordinated laboratory actions with CDC, provided instructions for specimen collection and shipment, and sent supplies to the new surveillance sites. Both AFIERA and NHRC are working with CDC to ensure optimal specimen processing and the implementation of appropriate assays as soon as they are available. A daily Executive Summary is issued by DoD-GEIS to communicate not only news with respect to general SARS issues but also specific DoD information on possible cases, policy guidance, reference laboratory resources, and surveillance data from ESSENCE and other DoD sources. CDC has recognized the extensive capabilities of USAMRIID to contribute to the national SARS response. USAMRIID assets are being used to evaluate the effectiveness in the laboratory of multiple antiviral drugs. With GEIS funding, the USAMRIID diagnostics laboratory is also developing and evaluating diagnostic methods for SARS. DoD vaccine experts have also been involved with early planning for the development of a vaccine against the causative agent. The overseas laboratories are well positioned to support the SARS response effort. NAMRU-2 in Jakarta has been somewhat compromised in this effort since it was largely evacuated after the Bali bombing last fall. State Department restrictions have curtailed movement of DoD officers remaining at the laboratory. Nevertheless, almost immediately after SARS was reported from Viet Nam, NAMRU-2 host national staff traveled to Viet Nam bringing to collaborators materials for specimen collection. NAMRU-2 has been designated by the Indonesian Ministry of Health as the "official" facilitator of laboratory diagnostics for SARS in Indonesia and has coordinated specimen handling protocols and testing with CDC. In this role it shipped specimens from nine "suspect" Indonesian patients to CDC on 9 April 2003. On 17 April 2003, NAMRU-2 sent additional specimens to CDC including one from Indonesia's first "probable" case. It has established a network of

20 referral hospitals from across Indonesia to ensure proper, safe management of specimens and relevant information. On 16 April 2003, it held a workshop for 40 SARS network participants. NAMRU-2 participates on the Indonesian National SARS Task Force and will establish in-country testing if proper safety conditions can be assured.

Conclusion

The Military Health System surveillance capability covers a wide-reaching, complex network of domestic and deployed programs which support clinical care and public health activities. The focus on prevention spans the career of Service members from accession beyond retirement and includes individual as well as population health initiatives.

DoD-GEIS is a tri-service program of DoD designed to make well-coordinated and efficient use of a wide range of complimentary assets for DoD emerging infections surveillance and response. It works closely with CDC, WHO and its regional offices, and many host country governmental and non-governmental entities. Value has been added in numerous ways to benefit not only the health of DoD personnel and other citizens but also to address a broad range of national security interests. DoD-GEIS has helped enhance control of influenza, improve medical threat assessments, guide DoD drug development, strengthen the capability for prompt detection of disease outbreaks including those due to bioterrorism, and reduce post-deployment importation of disease back to the U.S. Its initiatives have helped recognize emerging problems in training settings and validate methods of disease management. DoD-GEIS is well situated to continue serving as a vital partner in the federal consortium of partners dedicated to addressing the continuing threat of emerging infections.

I believe that you will find that our military health surveillance has many complementary and overarching systems that cooperate within DoD and the civilian medical community. These activities are enhanced through the DoD Global Emerging Infections Surveillance and Response System (DoD-GEIS).

Mr. SHAYS. I am stunned by the timing of your speech. You had 5 seconds left. Thank you. It was a thoughtful statement. Both of your statements were very helpful.

I am going to recognize Mr. Janklow, and then we will go to Mr. Bell and Mr. Murphy. We are going to do 10-minute segments.

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

Dr. Tornberg, the system that you described, DOD-GEIS, is that suitable for civilian use in America?

Dr. TORNBERG. It is, sir. It's a developing system. The ESSENCE II is in fact a system that is involved with the civilian community. ESSENCE II is a lab data base analysis and recognition that we are conducting in conjunction with Johns Hopkins. It is based on the National Capital Area and the 21 jurisdictions surrounding it.

Mr. JANKLOW. Dr. Fleming, as I look at your testimony, you cite 30 States that have asked for funding under the NEDSS strategy. Is the NEDSS strategy, is that an end result or is it just part of a process?

Dr. FLEMING. N.E.D.S.S., or NEDSS as the jargon, is a program that's designed to transfer at the State and local and national level from a paper reporting system to an electronic reporting system.

Mr. JANKLOW. Can you tell me why 20 States have not yet requested funding for that?

Dr. FLEMING. In fact, there may be a misunderstanding or a misinterpretation. All States are getting funding for NEDSS. Some States, approximately 20, have bought into the concept, but are using the standards that have been developed to develop their own software and process for making this happen. Thirty States have said, no, we don't think we have that technical capacity, and we want to jointly invest in the system that CDC is developing that will allow this to happen.

Mr. JANKLOW. Sir, help me with this. And I understand, you know, interest in open architecture and competitive marketplaces. But why in the world would we be encouraging what looks like maybe one system, based upon 30, that CDC is developing—30 States, in reporting—major reporting jurisdictions, and then 20 more separate ones that all have to be tied together?

Frankly, sir, what sense does that make?

Dr. FLEMING. The fundamental principle that NEDSS is operating on is to say that, independent of whether systems are homegrown or developed outside, that they have to conform to an agreed-upon set of strict standards that assures interoperability.

Mr. JANKLOW. That makes my point, sir. I mean, that's the very point that I'm making.

If you have strict standards and criteria that people have to meet, why aren't the other 20 part of the first 30 and all in the same system? Is there a reason, other than good feelings or, you know, good relationships that this is being done?

Is this a sovereignty issue or is it a competency issue or what, sir?

Dr. FLEMING. I think it's actually a good public health practice issue.

At the end of the day, these systems will be indistinguishable and transparent from each other as far as enabling the needed transfer of information. But the reality is—is that in different juris-

dictions there are different needs and issues such that it does make sense for a particular jurisdiction adhering to a set of standards to say, we want to be able to customize this to meet not only the national needs but our local needs as well.

Mr. JANKLOW. Doctor, if I could, and I'm referencing page 6 of your written testimony: You give examples of different States, the Michigan example, the Missouri example, the Pennsylvania example, and then Virginia, Maryland, and Washington, citing that they are buying into the Pennsylvania example.

Where you have an example like, let's just take Michigan. Michigan is implementing a secure Web-based disease surveillance system to improve the timeliness and accuracy of disease reporting. Why would that be any different than what Missouri is doing?

And I know the answer is going to be Missouri is doing it, too. But why do they all have to be done in different ways? Because what we are going to end up with is, some jurisdictions are going to be more comprehensive and more thorough than others. And when we're dealing with national information that's coming from all over America, different jurisdictions are going to be reporting or not reporting certain data based on what it is they decide to do.

Dr. FLEMING. Let me draw a distinction. First, I understand the point that you're making. And rest assured that CDC, as well as State and local governments, are working very hard to prevent what you are talking about from happening.

Mr. JANKLOW. But it doesn't indicate here it's happening. And I'm not trying to interrupt you, sir, but the testimony here indicates that may not be happening.

But go ahead, please.

Dr. FLEMING. And there are really two different systems that we are talking about. In my oral testimony I talked about the reportable disease system that is standardized across the country and which NEDSS is seeking to make electronic with strict standards.

In addition, with the availability of electronic medical records and other electronic data bases out there, there is now a new potential as you heard about, for example, in essence to, independent of that system, develop syndromic surveillance that accesses these data bases.

We are right now at a stage where pilots and demonstrations and experiments are needed in that syndromic surveillance part of how we detect diseases. We do not yet know for sure how effective that system will be or what the best way to do it is. In that context, we are allowing innovation at the State and local level, under the guidance of CDC, to assess different ways of conducting not this reportable disease surveillance that NEDSS is standardizing, but rather this new enhanced, complementary approach of syndromic surveillance.

Mr. JANKLOW. Doctor, given the history, I will call it in the nonwarfare sense, whether it's botulism, whether it's measles, whether it's other types of clusters—I remember an incident involving the Schwan's trucks several years ago with respect to the ice cream that was nationwide in scope. CDC and the systems in America have done a tremendous job of getting on top of that, meningitis, very, very quickly.

What's the difference between the system in place for that and the systems you are describing now, sir?

Dr. FLEMING. OK. And it's two different approaches that are complementary, that are both designed to try to detect one of these events as soon as they are happening. The system that's a standard system that detects the salmonella outbreak is one where people with salmonella go to see their physician, a diagnosis is made, those cases are reported to the health department, and as a result of cases coming in from multiple physicians, there's a recognition that there is an outbreak of salmonella that is happening, and the appropriate investigation is occurring.

Now, there are some conditions. Let's take anthrax as an example, where before someone gets to the point where it would be possible to diagnose the disease anthrax, they have several days of milder symptoms that are influenza-like, if you will, with fever and other illnesses. One potential way of jump-starting our recognition of an anthrax attack would be not to wait for people to come in at the stage where you could diagnose anthrax, but by monitoring reasons that people are coming into emergency rooms or in pharmacy records, seeing that there is a sudden upswing in the nonspecific seeking of attention for an influenza-like syndrome.

Mr. JANKLOW. But isn't that done now?

Dr. FLEMING. Actually, that's what we are talking about trying to implement with respect to this jargon, "syndromic surveillance." Which is to say, is it possible to implement systems that could pick up earlier in the course of an epidemic some of these nonspecific illnesses that aren't yet diagnosed, and by seeing an uptick, put the public health and the clinical health system on alert? We are right now in the phase, though, of figuring out how best to do that.

Mr. JANKLOW. One thing that the Department of Defense excels at is educating their people. They have a worldwide system that's in place.

Recognizing that the traditional method that we follow in this country is to bring a lot of people together for a conference, would it not make sense to start using to a far greater extent, for example, satellite television, recognizing that in a lot of instances it will be video one-way and audio two-way, but that you could really reach an awful lot of people and, frankly, a lot of general public?

I think where you are dealing with, especially the new world we live in of terror, the more the general public knows, the more equipped we are as a nation, one. And, two, the better it is in terms of reporting things to their physicians and their medical providers. I mean, it isn't like grandmas and mothers can't look at the symptoms. By the time you get to be a grandma, you know them pretty well. The school of hard knocks has taught you an awful lot.

Is there any approach being looked at to more effectively use—like direct broadband, direct broadcast satellites, as opposed to specialty satellites like SS and direct TV?

Dr. FLEMING. You are absolutely right that with the new technologies we have available to us, we need to be creative and make sure we are staying ahead of the curve of how best to communicate——

Mr. JANKLOW. Are you doing any of that?

Dr. FLEMING [continuing]. With people. And so there are a number of avenues that CDC, along with State and local health departments, are doing. One you mentioned is that many people now have access to the Internet, and one of the most effective ways to educate people is by putting information on Web sites, including interactive Web sites. CDC's Web sites gets millions of hits each month. And you can watch it uptick when West Nile comes, or with SARS, when SARS came. So people are using the Internet.

Second, we need to take advantage of distanced-based learning techniques, as you have alluded to, via satellite transmissions, Webcasting, via even old-fashioned, if you will, videocassettes that allow people to learn at the time that they are able to do it, rather than going to the expense of bringing people all into the same place. There are many of these kinds of technologies that are now available to us, and we need to be smart and use them, and we are trying.

Mr. JANKLOW. Thank you.

Mr. SHAYS. I thank the gentleman.

Mr. Bell.

Mr. BELL. Thank you, Mr. Chairman.

Dr. Fleming, we've obviously all heard about the anthrax scare in 2001. We read constantly about the threat of bioterrorism, and we pick up a newspaper or turn on the television just about every day to hear another story or see another story about SARS and the spread thereof.

I think, given all of that, everybody recognizes the need, the very pressing need, for a national surveillance system. And many, certainly, on this side of the aisle are quite curious to see the cut to CDC in the President's budget to offset a $550 billion tax cut, or what would appear to be a cut in order to offset the $550 billion tax cut—and I'm very curious as to why these cuts to CDC—what impact the cuts would have on the efforts to establish a national surveillance program.

Dr. FLEMING. Thank you, Congressman. I think there has been a bit of confusion about the nature of the reductions you are talking about. In fact, in the President's 2004 budget compared to the President's 2003 budget, there was actually a proposed increase of $125 million in chronic disease, $50 million for HIV prevention, $10 million for a public health information network, initial development, $5 million for health statistics, $17 million for pay raises.

What happened though is that the President's 2003 request was modified by Congress and increased. So if you look at the President's 2004 request compared to what it was that Congress authorized in 2003, there is this difference.

From our perspective, it does make sense for the President to operate off the budget that he proposed in 2003. And in that budget there are not any programmatic reductions. Obviously, when the budget comes to you all, you are going to need to sort this out as far as what you authorized in 2003 compared to what you authorized in 2004.

Mr. BELL. What about moneys spent on the National Electronic Disease Surveillance System?

Dr. FLEMING. The dollars that were requested by the President in 2003 for that system match the dollars that were requested by the President in 2004 for that.

Mr. BELL. That's been going down every year since 2002, has it not?

Dr. FLEMING. I could get back to you on the record with the specifics. My understanding is that the amount has been constant, with the exception of an earmark that was deleted. But let me get back to you on the record.

[The information referred to follows:]

FY 2002 Actual—$27.8 million
FY 2003 Enacted—$28.6 million
FY 2004 Request—$27.6 million

Mr. BELL. Well, let's discuss in a more positive light what progress has been made in bringing the 100 district surveillance systems together under a more comprehensive program.

Dr. FLEMING. There has been remarkable progress made. Let me say that more can and needs to be done, but within the last year many States have begun actually operationalizing a system where clinical laboratories in their jurisdictions are now automatically and electronically forwarding disease reports so those reports are coming in a more complete and timely fashion. And States like Hawaii have performed brilliant analyses of this that show that they are now better able to detect outbreaks more rapidly and more efficiently than they were before.

In addition, there has been absolute commitment at CDC and agreement with our State and local partners that we need to establish a uniform set of standards for developing our information technology systems, and especially those systems that are relevant to biosurveillance.

And so, over the last year, for the first time there is a comprehensive list of standards that all of the public health partners have bought into that said, as we move forward, these are the standards that we agree we're going to abide by to assure that a clinical laboratory that reports to multiple jurisdictions only has to do it one way because there will be one set of standards and to assure that, as information passes from one jurisdiction to another, that passage will be transparent, because it will be sent and received in a standard format.

In addition, there has been good initial work done on what we are calling the public health information network, which is the underlying information architecture that we need to do all of our business, not just surveillance, but also alerting of providers through routine e-mail communications and training and informing the public. So, we build one system with multiple functionalities rather than multiple independent systems. We have gone a long way.

Mr. BELL. OK. But we don't have one system right now as we sit here today; is that fair?

Dr. FLEMING. That is correct. We are moving toward that single system. But we need to recognize that we were starting from a baseline of many disparate systems, and we need to keep the trains running as we move forward.

Mr. BELL. Sure. And I agree with that and I understand that. But what challenges still exist in order to get to that one system? Because I assume from your comments that is the ultimate goal.

Dr. FLEMING. There are several challenges. I won't deny that resources is certainly part of it. Information technology and these systems are expensive. And in this era where there are finite resources available, tough decisions are going to have to be made.

Second, though, we need to look critically at the human capacity, because in fact you can have the best computers and the best information system in the world, but unless there is somebody sitting behind that computer that is knowledgeable and competent and trained and knows how to act on that information, you haven't bought anything. And I think at CDC we are most concerned perhaps about whether or not there is this pipeline of trained public health professionals out there to use this new technology.

And, in fact, there may not be. So, a major area that we are looking at in conjunction with our State and local health departments is, what does need to be done with respect to schools of public health and other educational institutions, preparing public health professionals to assure that the work force that we are generating is one that is competent and knows how to take maximum advantage of the system that we are building?

Mr. BELL. Dr. Fleming, given the fact that, as you state, resources are one of the challenges we face, is it fair to say, when the amount of money is decreasing that is being spent on the surveillance system, we are not going to get there anywhere fast toward the one system?

Dr. FLEMING. Moving toward the one system certainly is going to be both resource and people-dependent.

Mr. BELL. What kind of money are we talking about?

Dr. FLEMING. Right now, we are engaging with OMB according to the Klinger-Cohen Act to develop the business case for exactly what it is with respect to this overall vision that we are going to need in the next few years. When that process is complete, we will have a specific target amount that will be needed, and we will get back to you with that. We are working through exactly that issue right now.

Mr. BELL. So we don't even know how much it would cost at this point in time?

Dr. FLEMING. We need to complete our discussions with OMB and under the rules of the Klinger-Cohen Act.

Mr. BELL. Is there any kind of estimate available at this—has anyone made any sort of estimate how much one system might cost?

Dr. FLEMING. Let me get back to you on record for that.

Mr. BELL. I'm sorry?

Dr. FLEMING. I will get back to you on the record.

[The information referred to follows:]

Estimate For FY 2004

$95 million for combined Public Health Information Systems/Global Detection/Communications.

A comprehensive Public Health Information Network could seamlessly connect people across our nation with CDC, other HHS agencies, state and local public health agencies, healthcare organizations, and many other stakeholders. This network could serve as the backbone for: emergency health alerts, distance learning, knowledge management, disease detection, reporting and surveillance functions, health tracking, secure data transmission, and many other functions important to public health. The public health information network could not only create and disseminate the information to promote health and safety in this country, but is a cost-effective means to support global public health advances. The Public Health Information Network is already in development, but funding could allow us to scale up and speed up its implementation.

Mr. BELL. I would appreciate it.

It is not your impression—and, Dr. Tornberg, you can comment on this as well—that the administration has stepped away from its earlier desire to see this national surveillance system? Do any of you all get that impression?

Dr. FLEMING. Dr. Tornberg can comment. I certainly do not. If anything, the administration, and especially the Vice President's office, has been very supportive of the notion of doing what needs to be done to make sure that we have a surveillance system that's competent and, particularly, a surveillance system that can detect not only naturally occurring events but bioterrorist events as well.

Mr. BELL. Dr. Tornberg.

Dr. TORNBERG. I would agree. I think that there is a full commitment to providing a national surveillance system. I have not detected any variance from that point.

Mr. BELL. Has everybody made it clear that more money is going to have to be committed to the project if we are going to be able to realize one system?

Dr. FLEMING. We made it clear that resources are needed to make systems work and that we need to balance the expectations for what those systems are against the resources that are available.

Mr. BELL. Thank you very much.

Mr. SHAYS. I thank the gentleman.

Before recognizing Mr. Murphy, what I'm wrestling with is one country, 50 States, thousands of local governments, and the comment is made, it's a question of resource and people. It's not a question of legislation that would allow you to mandate one system throughout?

Dr. FLEMING. Mr. Chairman, I don't think so.

Mr. SHAYS. OK. We will come back to it.

OK, you've got it, Mr. Murphy.

Mr. MURPHY. Thank you, Mr. Chairman. Actually, you were reading my mind. My mind is working along the same lines.

In Pittsburgh, we have a system called the Real-time Outbreak and Disease Surveillance System [RODS] system, which has been operating pretty well. And in southwestern Pennsylvania—and, also, Utah used some of this during the last Olympics where they do monitor those very things you were talking about, over-the-counter supplies and pharmacies, etc. And that's one sort of system, and you are looking at others.

I just want to make sure I understand this. Are you at this point testing different systems that are being used to determine which one is the best system? Have you determined that yet as different universities are involved in these functions?

Dr. FLEMING. The RODS system that you are referring to would fall into that category of syndromic surveillance systems, where in fact right now a number of different systems—ESSENCE would be an example; ESSENCE I and II would be examples—are being tried in different jurisdictions. I personally think that the outcome of this is not going to be that one of those systems is going to be proven best, but alternatively we will see the aspects of each that provide the most functionality. And by combining the best of all of them, we will create that, if you will, one system that serves our needs.

But we are really right now in a phase of piloting and demonstrating and, to a certain extent, experimenting, because this is new ground for the public health community.

Mr. MURPHY. So you are working with different places like the University of Pittsburgh and others to monitor the kinds of parts that are in place, so you can pull out of each one what's the best?

Dr. FLEMING. Exactly right. And in addition, I mean, a key to these—the underlying notion here is that these systems can detect problems more effectively and more rapidly in some instances than our existing reportable disease system, and can be a complement to it.

That's a concept that has not been totally proven yet, and before investing a whole lot of resources in a nationwide system, we do need to see the evidence that these systems are able to do what they, in theory, might be able to.

Mr. MURPHY. Let's walk through what happens next. Say you come up with a national system that's been working in the cities and rural areas, etc. The thing about bioterrorism, it moves slow enough that you can detect and then implement strategies to quarantine, to have public education, to immunize, whatever. But, of course, the drawback is that it also moves slow enough that it can be spread throughout the Nation in a matter of a few days before anybody has a sense that they need to take some steps.

When that happens—and we have had some other hearings here, for example, with NORTHCOM, some wonderful hearings and discussing some of the aspects taking place.

But let's go—let's say there is some disease that begins to be picked up in multiple cities around the country, it's spreading by whatever mechanism, through contact, it's around. Can you walk us through what happens once you get this data, in particular, the plans in place to notify physicians and hospitals, coordinate efforts, get products to communities, notify the Defense Department, even to the level of local emergency responders, EMS people, etc?

Can you walk us through what happens once you identify that there appears to be something out there?

Dr. FLEMING. It's a complicated question. Let me try to answer it in a couple of ways.

First and most basically, the health department needs to be the nerve center for making this happen. What we are talking about is gathering the information through the surveillance systems to allow competency in making the decisions that need to occur. Then, the different arm needs to come in action. The health department, as you have said, works with providers and works with appropriate policymakers to make the right things happen.

A fair amount of the dollars that have gone out over the last year for enhancing bioterrorism preparedness have been put in place through plans and exercises, exactly the kind of thing that you're talking about. So even as we speak, health departments around the country are, in fact, making plans, drilling, making sure that they have the ability to connect with the providers that they need to connect with, testing that, making sure that they're connected with the policymakers and others.

Mr. MURPHY. Is this part—there'll continue to be drills around the Nation? There's funding available for that aspect that commu-

nities can also apply and work with health—because you also have State health departments in some—I know in Pennsylvania many counties don't have a health department. They have to rely on the State. It's a slow system. And so it will require some drills and exercise to take care of that. Is that a part of the States as well?

Dr. FLEMING. Absolutely correct. And let me point out that one of the ways that we are really focusing on using these resources is to invest them in the same systems that are used every day to detect naturally occurring outbreaks and to mount the responses that are necessary to combat those. So in addition to exercises and drills, in fact, we are, because of Mother Nature, constantly being drilled in this country and around the world through the natural everyday public health emergencies that our health departments are facing.

Mr. MURPHY. Was this 5 or 10 minutes that I have?

Mr. SHAYS. Ten minutes.

Mr. MURPHY. Ten minutes? Oh good. Let me continue to pursue this.

With this kind of data out there, the question becomes one of Big Brother and how do you protect confidentiality of records. And let me add to this, a lot of hospitals are concerned now about HIPAA regulations and problems with confidentiality. So now they can't get the information that they need to track what's happening with patients.

Let me continue to build this. As we're working on such things as other aspects of pharmaceutical care for the elderly, without some openness of sharing some records, you run the continued risk of the problems that there are with prescription and nonprescription drugs. Some estimates have been out there about 10 percent—I'm sure you're aware that about 10 percent of emergency room admissions they say are related to some pharmaceutical problems; perhaps the person took the double doses they weren't supposed to. Perhaps a physician did not know what else was being prescribed. They didn't know that the patient was taking over-the-counter products. Someone forgot their medication for 2 days, they took it all at once. The list goes on. And in aspects where pharmacists have data available or where the pharmacy benefits manager may have information available of what else that person is on, it helps them prevent a lot of those accidents.

Now, we're looking, too, here at collecting data on symptoms. If it is just looking at sales, numbers for what's happened with antihistamines and pharmacists, that's one thing, but ultimately you have to get down to the level of who has this? That's been part of the elegance of tracking SARS around the world, that you were able to track it down to a hotel in Hong Kong, ninth floor, who was there, and tracking them around the world. Clearly you're going to need some sort of records like this, too, but it has to be looming over people's minds of—on the one hand they want to know if there are symptoms in a town, they want action to be taken to identify that, but also protect confidentiality. How do you walk that line?

Dr. FLEMING. OK. An excellent question. Let me say first that I think most people in public health would not see it as public health versus privacy, but rather only by protecting privacy can we expect

this information to be made available, and so we're on the same side of this.

There's a couple of strategies that are used. First there are some kinds of surveillance where you don't need identifying information, and so the first question that we always ask in any of these surveillance systems is can we get what we need without having identifying information there, and if so, let's not get it.

But as you pointed out, there are some places where, in fact, identifying information is needed so you can track back to the individual or the individual's provider to get more information to assure that the right things are happening to that person and to take the appropriate actions in the community.

This is an issue that public health has been dealing with, you know, for 100 years. And, in fact, on a day-to-day basis, personal identifying information is routinely relayed from the medical community to the public health system, and that information is guarded very carefully both from a legal standpoint and from a security standpoint so that there have been few, if any, breaches in the history of public health where an individual's confidentiality has been compromised, and that's by maintaining attention to the sanctity of privacy and, when information that is identified is obtained, making sure that it's used wisely. That's the answer.

One last thing about HIPAA is that there is a lot of confusion out there, obviously, and we're working in the health care sector, but HIPAA, in fact, does give an exemption to public health, so—providing information from the clinical sector to the public health sector for public health purposes and says in that situation it is OK to transfer identifying information.

Mr. MURPHY. Well, I certainly hope as all this is gathered a great deal of training information is available to physicians, hospitals, emergency responders, police, etc., because a lot of them still don't know what to do.

And let me ask one final quick question. Who is ultimately in charge when a disease outbreak is determined? Who is the top of the chain of command?

Dr. FLEMING. Well, the President, obviously.

Mr. MURPHY. I mean, is it where the thing occurs first? Oftentimes first responders, whoever's first on the scene in that community, is now in charge either nationwide, or it begins in some State——

Dr. FLEMING. I'm sorry. I misunderstood your question. Health is a State's right, and so it will be the State health department at which there is legal jurisdiction for the health events going on in the State. If an event crosses State boundaries, then it becomes also from a legal perspective a Federal jurisdiction issue.

Mr. MURPHY. And so such actions as quarantining, other information then becomes through—Health and Human Services, HHS and CDC begin to take control and begin to tell States what they should do in communities and travel, etc?

Dr. FLEMING. The short answer is yes. The more accurate answer is that we really do have a good partnership in public health, and so CDC and State and local health departments routinely, every day, in the absence of who is in charge, make critically important decisions about what needs to be done.

Mr. MURPHY. Thank you.

Thank you, Mr. Chairman.

Mr. SHAYS. I thank the gentleman.

In our two panels we have the national looking at the civilian and the military, and then we have basically State and local and international, and we're also looking at the private in our second panel.

I was just curious, Dr. Tornberg, as you're hearing the questions being asked to Dr. Fleming, besides thinking what you're going to do this evening or tomorrow or on the weekend as it related to this hearing, what kinds of things go through your thoughts? I'm just trying to figure out how you interface with CDC.

Dr. TORNBERG. Well, we interact extensively with CDC and I have with Dr. Fleming on issues. The collaboration extends not only to CDC, but to a host of other Federal agencies and the World Health Organization. As I indicated in my earlier statement, we have representatives assigned to CDC, military epidemiologists. We are currently assigning an individual to represent—Dr. Winkenwerder—at the—to Dr. Gerberding's office as we speak.

So the collaboration is very close, and there's an ongoing active discussion. Particularly with the SARS outbreak, there's been really intense collaboration between CDC and the World Health Organization and our assets, the assets of DOD-GEIS, in addressing this issue, and I think we have a really fine working relationship.

Mr. SHAYS. Now, if there wasn't the terrorist threat, you'd still be in business, and why would that be true? In other words, if you never had to worry or—not just the terrorist threat, but a sanctioned military effort on the part of an adversary to use biological agents, if you didn't have that concern, whether it was sanctioned by a government or individual terrorist attack, one used against the military or one used against civilians, would you still be in business, and why?

Dr. TORNBERG. Yes, sir, we would be. In fact, our ongoing efforts and our fight to preserve the health and safety of our personnel demands that we be very active and proactive in this arena, as we have been from the earliest days of the Department of Defense. Our forces are expeditionary in nature and exposed to a host of——

Mr. SHAYS. I get the gist of that. Thank you. That's clear to me.

Let me ask you, Dr. Fleming, though, so you have Dr. Tornberg, who's focused on a national and international, tell me how your focus becomes international in terms of the fear—in other words, we have representatives from our military all around the world. Is your focus international as well as national?

Dr. FLEMING. Absolutely. And it is for several reasons. The spector of infectious disease is perhaps the most obvious threat. A case of drug-resistant tuberculosis or SARS is simply a plane ride away in today's world. And one of the best ways to prevent the emergence of both known and unknown diseases in this country is to make sure that we have a strong global network and a U.S. presence, a CDC presence, overseas fighting those diseases in the countries that they're occurring, minimizing the chance that they will come here.

Mr. SHAYS. How many laboratories would CDC have overseas?

Dr. FLEMING. CDC's primary expertise is in people and epidemiologists, so we have a handful of field stations, but in my opinion, the real international resource, the resource that CDC provides for the world, is in the trained epidemiologists, and we currently have approximately 60 CDC medical epidemiologist in various countries working with local ministries of health on critically important issues, be it polio eradication, or HIV prevention, or surveillance for infectious diseases.

Mr. SHAYS. Dr. Tornberg, how many—is that classified information?

Dr. TORNBERG. No, sir, it's not. We have five overseas laboratories.

Mr. SHAYS. And where are they located?

Dr. TORNBERG. We have a laboratory in Thailand, in Jakarta, Indonesia. We have one in Peru, Kenya and Cairo.

Mr. SHAYS. OK. Now, getting to where Mr. Bell is, in Congress, we have to wrestle with a constituent who will say we need to do this, and they want a State law because they don't like what their—they want a Federal law because they don't like what their State is doing, and we get into this issue of, you know, do we overrule State law and have a uniform law. And I try explain that you sometimes can end up with a common denominator, and you might want a stronger law in one State versus another.

But when you get into health care and you get into this issue of collecting data, I'm really unclear as to what restraints there are. I mean, is there an untold story here that Republicans don't want to get into this because there is the States rights issue, and Democrats may not want to get into this because of the personal privacy? I mean, is party ideology, conservative or liberal, getting into play here besides the issue of resources and people-dependent and money, because I'm thinking, good grief, we're not going to have a vaccine for every potential pathogen, every potential illness inflicted on us. So one of the ways that we are going to deal—and we wouldn't want to necessarily even if we could, because there's always some side effects with that.

So we want to—it seems to me our strategy is identify quickly, isolate it, contain it, and deal with that as we find it. And I'm unclear from you, Dr. Fleming, as to, you know, are we going here and there, or are we just trying to say, well, given this disparate kind of system we have, we'll make the best of it? Or should we say this is absurd, this is ridiculous, we want to have unified information, we want to have every local community send it up to the State on real time, we want it available to the Federal Government on real time, just like K-Mart might know what they have in their inventory and what they sold in the last 15 minutes? In my mind, that's kind of the way I'm thinking, but I'm not sensing that's the way the Federal Government's thinking.

Dr. FLEMING. First off, I think—just so that you'll know, I have about 20 years experience. Most of that is actually working at the State level. I have been at CDC for about 3 years, and so I have a little bit of history here. And I think if you'd asked me this question 20 years ago, I would have said you're absolutely right, because I would think that the rate-limiting step is the fact that peo-

ple don't want to work with each other, and we can do it more quickly if we mandate it.

That has changed dramatically, particularly in the last couple of years, such that there is now essentially uniform agreement that what the vision you just articulated is where we need to be heading. So the rate-limiting step isn't that people don't agree to that, the rate-limiting step is getting there through resources and planning and people, as we've talked about.

Mr. SHAYS. And you said we don't need a law. You said CDC has the power to mandate a standard form, standard information. Do you have the capability under law to say we want it within an hour of your knowing, etc?

Dr. FLEMING. I'm sorry, I may have misunderstood your question. When I said we don't need a law, it is not because we have the authority to mandate it, but rather because it's my perception that it doesn't need to be mandated; that the system out there agrees with the vision and is trying to move toward it. We don't need the stick in this instance to get people where they need to be. They are there on their own. There is so much logic to it, and now there's now the information technology that enables it to happen, that with more and more people working at the State and local level, seeing the need for cross-jurisdiction communication and coordination, there is essentially uniform agreement out there that this is the way we need to go.

Mr. SHAYS. If it's not a law requiring it, and someone doesn't provide it, then is there any liability?

Dr. FLEMING. Well, first off, in individual States, as you know, there are laws that mandate the provision of this information, and those are enforced generally through the licensure acts so that an agency or a laboratory that does not submit required information can be acted upon through their licensure. So there is a governmental stick, if you will. I'm just saying I don't see the need for a Federal stick.

Mr. SHAYS. Let me go through just—you said our surveillance—on page 2 of the statement I had—it was 3 on another one, so I guess a different copy—but it said our surveillance systems generally use paper facsimile reporting by health care providers to health—if a case of illness is particularly unusual or severe, such as in the case of anthrax or rabies, the provider may call the local health department immediately. You had the word "may," which I think is interesting. Then you say, as mentioned, health care provider recognition of the illness and awareness that certain health events require immediate notification of public health authorities is critical to our ability to detect problems and mount a public health response. Such reporting requirements are mandated at the State level. But aren't they mandated in different ways, different timeframes, etc?

Dr. FLEMING. There is currently some State-to-State variability around the specific conditions and the timing. I think my experience has been that the right things are happening, though, so regardless of whether you say a case of anthrax should be reported immediately in one State or within an hour in another State, if you look across States, the bottom-line message is the same, is that there is a common list of conditions for which immediate action is

warranted, and then another category of diseases for which you can have a little bit more time to do the steps.

I'm not trying to make it sound like it is a perfect world out there. What I am saying, though, is that tremendous progress has been made such that, at least in my opinion——

Mr. SHAYS. You know, I agree with the tremendous progress, and I do think that if you can get things to happen voluntary—and I'm going to just roll my 5 minutes over and start a second round of just 5 minutes, if I could. So I'm going to begin the second round of questioning.

I guess this is what I'm wrestling with. I kind of have been listening to Representative Bell, and I'm thinking, as he's asking these questions, we are safer than we were before September 11, but we don't feel as safe because we had a false sense of safety before September 11.

But we've had—you know, SARS is an interesting kind of process here that just kind of makes us alert to the fact that both of you are dealing with defense against the pathogens that may attack us. You know, for the nonscientist, me, the nondoctor, me, when I hear there are mutations of SARS, and you think, you know, this thing is like an interesting threat to say the least, I'm just wondering, what in the world it is going to look like in a year or two? Will Mr. Bell or Mr. Janklow or Mr. Murphy and I be able to say a year from now when there is an outbreak, one—excuse me—if there is an illness in one place and an illness in another place and an illness somewhere else, and they don't see the severity of it, but if you put it all together, we would see it clustered, will we know within an hour of that, or will we know 5 days later? And if one or two States don't have the same requirements, will it be incomplete information? Or are we going to have a good system in a year from now?

That's kind of what I'm asking. And I'd like, Dr. Tornberg, even though this isn't your direct responsibility because it's CDC, I want you to tell me what you think is going to happen, and then I want you, Dr. Fleming, to tell me what you think.

Dr. TORNBERG. I think we are moving clearly in the direction that you described. Will that be a year from now? Difficult to say. But the recognition time of a syndromic event is really somewhat based on the kinetics of the event itself and how rapidly it travels. But we clearly are moving in that direction and would hopefully have that capability and make this a much safer place.

Mr. SHAYS. What would be wrong for me to say that we should be able to say, all right, we will have it ready in a year, or we will have it ready—what is the puzzlement that says that we won't? I mean, what—if everybody realizes we should have it, why are we talking this way?

Dr. TORNBERG. Well, what we are gaining in part of the growth phase—and we are in—with syndromic surveillance itself, and that's what we're talking about, we are in the toddler stage, if you will, in the development and the maturation of the process, and it's clearly a process that has to mature from a—data acquisition is part of the problem, but a bigger part of the problem is the analysis of the data we have, because there's, as we discussed, many disparate sources of information, and there can be data overload. The

key in the challenge is to analyze that data to allow it to be—have a meaningful pattern, and subsequently to allow us to——

Mr. SHAYS. You're telling me that it is going to be very difficult, and it is just not going to be adding numbers. I hear you.

Dr. TORNBERG. We can't identify aberrations if we don't know our baseline. That's critical for early detection. And we are very much right now in the phase of developing our baselines and noting exceptions from that.

Mr. SHAYS. Well, basically I'm just trying to make—this is kind of like telling me we have a learning curve?

Dr. TORNBERG. Yes, sir.

Mr. SHAYS. OK. And you're not able to tell me how long that learning curve is going to take.

Dr. TORNBERG. I would be hard pressed to give you a year timeframe on that, but certainly within several years.

Mr. SHAYS. Dr. Fleming.

Dr. FLEMING. In some ways I don't think it is a yes/no answer either. We have already around the country a system that works and that does identify these events. It does need to be improved, but how long that takes depends on what level of improvement and what we are trying to get to. A year from now our system will be better than the system we currently have today, and if we at CDC are doing our job right, 2 years from now it'll be better than the system a year from now.

Mr. SHAYS. OK. Let me just real quickly, in the 40 seconds I have left, have you explain to me what would be a good system, a really good system. In other words, is the analogy of a K-Mart being able to tell me what's in their inventory, what's sold in the last—real time, is that just totally unrealistic?

Dr. FLEMING. Absolutely not. Real time is an aspect of this. But the true measure of a system is how responsive it is not in detecting the event, but in responding to the event and putting the actions in place that need to be put there to keep people healthy. And so my definition of the perfect system, if you will, is a system that is rapid enough such that the preventive actions that need to be put in place will happen before individuals become sick or die.

Mr. SHAYS. Thank you.

Mr. Bell, do you have any questions you want to ask?

Mr. BELL. Can we do another round?

Mr. SHAYS. Yes, another 5 minutes, and then we're going to——

Mr. BELL. Thank you, Mr. Chairman.

I'm curious, Dr. Fleming, because in your original statement you said that there are reports, or your—I believe it was your strong-held belief that there are reports that are not completed or acted upon.

Dr. FLEMING. That's correct. The system we have is not yet perfect. It works, it's good, but it can be improved.

Mr. BELL. But let's say someone in Texas sees a case of SARS and decides not to, for whatever reason.

Probably wouldn't be true today, but several—a couple of months ago—and chooses not to report that. Then certainly it would be your strong desire that they would report it, but if they didn't, there's absolutely no law in place to punish that individual in any way, shape or form, correct?

Dr. FLEMING. Certainly within the State of Texas, providers are licensed and are required by law to report.

Mr. BELL. To you.

Dr. FLEMING. No, to the State health department.

Mr. BELL. OK. And so—good. That's helpful. Where is the breakdown coming in the reporting mechanism then?

Dr. FLEMING. There are several places. First off, I think not everybody that's sick sees a doctor, so there's illnesses out there that may never be diagnosed.

Second, some of the diagnoses that happen are—happen in such a way that the provider forgets to report. It is just—you know, it's not a willful act, but it just doesn't happen. The NEDSS system that we're putting in place, which basically says when a provider, clinician or a laboratory, as part of their clinical records, indicate they have just diagnosed this case of salmonella or E. Coli or whatever it is, they don't have to report it to the health department at that point. The computer system automatically recognizes it as a condition that requires reporting and automatically instantaneously transports it to the health department. That's a big part of the fix of the system.

The third part is to make sure that when that report is received, that there's somebody at the health department to look at it and to investigate it. The bioterrorism resources that have been made available go a ways in making that happen.

Mr. BELL. As the chairman alluded to, what would be—I'm just curious. What do you all see as the downside to having some sort of law that would mandate reporting to have that in place?

Dr. FLEMING. Well, first, I do think that there are different diseases that are of greater or lesser importance in different parts of the country. And so, for example, some of the fungal diseases that are common in the Southwest need to be reported there, but because they're not prevalent in other parts of the country don't need to be reported there. There is need and room for local flexibility. In addition, within the confines of a system that's trying to accomplish these agreed-upon goals, there is some flexibility about the best way to get things done. And in one—in all aspects of the government, the thing that will work best in one part or one jurisdiction isn't necessarily the thing that'll work as well in another. So we need to allow, in my opinion, for local flexibility around the process so that the agreed-upon outcomes that we're striving for can be achieved as best as possible.

Mr. BELL. And one final question. It would appear, going back also to the—if we can get there in 1 year, it would appear that would be somewhat impossible. We don't know how much—as far as having one unified system, we don't know how much that would cost as we sit here today. You said you'll get back to us on that. If that price figure comes back, and it's obvious with the money that is presently allotted there's no way to get there, or do you all plan to advocate for more funding to go toward a national surveillance system?

Dr. FLEMING. We will make it clear within the administration and to you what can be done for what level of resources, recognizing that it's you all's decision where the tradeoffs need to come from.

Let me just make one other comment, if I might. I would hate for you to leave thinking that we're talking about only one system; there's only one thing that needs to be done. Public health surveillance, including infectious disease surveillance, is a system of systems. We're talking about one today. But clearly the vital records system in this country for looking at births and deaths; the systems that we have in place for figuring out who's been vaccinated and who isn't, vaccine registries; the system that on a real-time basis surveys people out there to find out what they know about SARS, etc., are also critically important parts of our surveillance. And so we need to be thinking about ensuring that the system of systems is as robust as possible, not focusing on only one element.

Mr. BELL. Thank you, Mr. Chairman.

Mr. SHAYS. I thank the gentleman.

Mr. Janklow.

Mr. JANKLOW. Thank you, Mr. Chairman.

Dr. Fleming, I've got several questions. I'm going to try to be really quick with them. One, does DOD have a good—in the words of the chairman—a truly good system?

Dr. FLEMING. The ESSENCE system has promise. I mean, I would say it's in evaluation, so I can't tell you yet.

Mr. JANKLOW. How long has it been in evaluation?

Dr. TORNBERG. ESSENCE II has been in operation, I believe, for the last 2 years.

Mr. JANKLOW. Dr. Fleming, in your testimony you talk about several years ago you initiated development of the NEDSS System. How long does it take to develop a system? Aren't we talking about two things? One, we're talking about software; and, two, we're talking about baseline or the data for the information you're going to gather on the software and how it is going to be utilized, correct?

Dr. FLEMING. That is correct.

Mr. JANKLOW. In terms of developing the software, when—how long did it take to do that?

Dr. FLEMING. The software development process takes about a year to 18 months, but you also need to have the standards, agreement on what that software needs to do, and in addition——

Mr. JANKLOW. Excuse me. I thought you had the standards, and you've already told people what they're going to be that they have to meet to come out of the system.

Dr. FLEMING. No. Right. But what I'm saying is those needed to have been developed, in essence, before software can be developed.

Mr. JANKLOW. How long have they been out?

Dr. FLEMING. It's an iterative process. We started work on it several years ago, and they're still being refined.

Mr. JANKLOW. Let me ask if I can, picking up on Mr. Bell's question from before, can you tell me what hasn't been done because you haven't had enough money? What hasn't been done? What's lagging?

Dr. FLEMING. There's two things. One is the capacity on the clinical laboratory side, to computerize and send their information. So even if a public health department is equipped to receive information, that information can't be received if it can't be sent on the clinical side.

Mr. JANKLOW. Why do you think it can't be sent? What's holding that up?

Dr. FLEMING. There's a wide range of systems that are out there, and, in fact, some aspects of the health care system still aren't computerized.

Mr. JANKLOW. Isn't that what we started out talking about today? Does that take a mandate to get that done? If we've still got some aspects of the health care system that aren't computerized, and if there are no mandates in place, how's it ever going to get there?

Dr. FLEMING. I was hearing the question about mandates relative to a mandate on the public health system from the Federal level relative to the State level. There's a separate question about the need for electronic medical records and the development of clinical standards to create those records. That's a bit beyond my domain of expertise, but it is an active part of this, active part of this process.

Mr. JANKLOW. But, sir, aren't we—what—we're talking about a reporting basically, either a diagnosis or a symptom; isn't that correct?

Dr. FLEMING. It's actually a bit more complicated, when you think about the range of information that is being collected in the health care setting.

Mr. JANKLOW. I understand. But when we're talking about looking at this from a national sense, aren't we really talking about, one, diagnoses that have been made, and, two, symptoms that would lead one to the conclusion someplace else as you gathered this from all over that there may be a problem that we need to look into?

Dr. FLEMING. I think you might hear from the clinical sector that they would want that system integrated into their overall way of doing business so that they did not have to go off just for this purpose to enter information. But rather it needs to be part of the therapy that's being given and the monitoring of the patient.

Mr. JANKLOW. Doctor, if you had the money you needed, how long would it take to get a system in place?

Dr. FLEMING. Again, there is a working system in place. We do have the ability to detect these events. We can make substantial progress over the next year to 2 to 3 years, but I don't want to make it sound like it is an on/off——

Mr. JANKLOW. Are people like me then unnecessarily concerned that we don't have a coordinated system in place?

Dr. FLEMING. I think that I've tried to express the level of concern we have, which is we see that this is important, and substantial progress has been made. The system is working. We can make it better. It's not broken, but it can be improved.

Mr. JANKLOW. In terms of improving it, are we where we need to be in a world that deals with terrorism focused toward us?

Dr. FLEMING. That's the critically important question we need to address, as we've been talking about. There are things that can and do need to be done to improve our security.

Mr. JANKLOW. Is that a yes or a no, sir?

Dr. FLEMING. Ask your question again, please.

Mr. JANKLOW. Pardon?

Dr. FLEMING. Ask your question again.

Mr. JANKLOW. In terms of the world that we live in where terrorism is directed toward us, are we where we need to be?

Dr. FLEMING. No.

Mr. JANKLOW. OK. Thank you.

Mr. SHAYS. Let me just—before we go to our next panel, this is Emerging Infectious Diseases. I think it is a peer review journal tracking and analysis disease trends, and it's done by the CDC; is that right? In the first article it has Planning Against Biological Terrorism: Lessons From Outbreak Investigations. Is this an article you're familiar with at all?

Dr. FLEMING. I've not looked at it.

Mr. SHAYS. In the first paragraph it says, for six outbreaks in which intentional contamination was possible, reporting was delayed for up to 26 days. We confirm that the most critical component for bioterrorism outbreaks detection reporting is the frontline health care professional and the local health departments. Bottom line, though, it—you know, I'm going to take a better look at this article. Well, actually I have to take a look at it. I haven't looked at it other than that quote. But you can't respond to that issue of——

Dr. FLEMING. I would also need to review the article to respond in detail.

Mr. SHAYS. Well, why don't we just submit it for the record then.

[The information referred to follows:]

Planning against Biological Terrorism: Lessons from Outbreak Investigations

David A. Ashford,* Robyn M. Kaiser,* Michael E. Bales,* Kathleen Shutt,* Amee Patrawalla,* Andre McShan,* Jordan W. Tappero,* Bradley A. Perkins,* and Andrew L. Dannenberg*

We examined outbreak investigations conducted around the world from 1988 to 1999 by the Centers for Disease Control and Prevention's Epidemic Intelligence Service. In 44 (4.0%) of 1,099 investigations, identified causative agents had bioterrorism potential. In six investigations, intentional use of infectious agents was considered. Healthcare providers reported 270 (24.6%) outbreaks and infection control practitioners reported 129 (11.7%); together they reported 399 (36.3%) of the outbreaks. Health departments reported 335 (30.5%) outbreaks. For six outbreaks in which bioterrorism or intentional contamination was possible, reporting was delayed for up to 26 days. We confirmed that the most critical component for bioterrorism outbreak detection and reporting is the frontline healthcare professional and the local health departments. Bioterrorism preparedness should emphasize education and support of this frontline as well as methods to shorten the time between outbreak and reporting.

Bioterrorism is the intentional use of microorganisms or toxins derived from living organisms to cause death or disease in humans, animals, or plants on which we depend. In 2001, *Bacillus anthracis* was disseminated through the U.S. postal system (1). Before that event, concern about bioterrorism had led to preparedness efforts, including strategic planning (2). As part of these efforts, we examined investigations conducted by the Centers for Disease Control and Prevention's (CDC) Epidemic Intelligence Service (EIS). EIS was established after World War II, in part to protect the United States against bioterrorism. We reviewed characteristics and trends of EIS investigations conducted from 1988 to 1999 (3). Outbreak investigations from 1946 to 1987 had already been reviewed (4). We focused on field investigations involving agents that could potentially be used for bioterrorism because understanding how these outbreaks were detected and reported might improve early detection and reporting of bioterrorism.

Each EIS field investigation follows an official request from a state or international health agency. States and international health agencies receive reports of cases or outbreaks from many sources, including local public health agencies, hospitals, healthcare providers, private citizens, or other federal or international agencies (4).

We describe lessons learned from outbreak investigations that involved biologic agents with potential for bioterrorism. In addition, we review investigations in which intentional contamination was considered as a potential cause of the outbreak.

Methods

A standardized form was used to collect data from each investigation from 1988 to 1999. Trip reports submitted by EIS officers after the investigations served as primary sources of information. We focused on outbreaks caused by biologic agents with high potential for bioterrorism, such as *B. anthracis*, *Yersinia pestis*, *Francisella tularensis*, variola virus, viral hemorrhagic fever viruses, *Clostridium botulinum* toxin, *Vibrio cholerae*, *Rickettsia rickettsiae*, encephalitis viruses, *Brucella* species, *Burkholderia mallei* and *B. pseudomallei*, and others according to our preparedness plans (2). We also identified outbreaks in which bioterrorism or intentional contamination was considered. Because each outbreak represented possible bioterrorism, we examined outbreaks in which the etiologic agent remained unidentified. From the trip reports, we abstracted information on possible bioterrorism, causative agent, location, time from first case to first report of the outbreak, and source of recognition and reporting of the outbreak.

We defined the source of recognition and reporting as the person, persons, or institution that originally brought the outbreak or health emergency to the attention of health authorities, as recorded in the trip report. While diagnosis and reporting may be ongoing during an investigation, the initial recognition of an outbreak is a singular event that can occur at the peripheral or primary care setting or at the local, state, or federal level.

We defined the beginning of the outbreak as onset of illness in the first case of the outbreak cluster. Diagnosis of the first illness in an outbreak may occur before the epi-

*Centers for Disease Control and Prevention, Atlanta, Georgia, USA

demic is recognized and is often determined retrospectively. Epi Info 6 software (CDC, Atlanta, GA) was used to enter the data from the abstractions of the trip reports. SAS software, release 6.12, (SAS Institute Inc., Cary, NC) was used to generate descriptive statistics.

Results

Several agents have been identified as likely to be used in bioterrorism (2). Of the 1,099 investigated outbreaks, 44 (4.0%) were caused by an agent with potential for bioterrorism (Table 1). *V. cholerae* was responsible for 18 outbreaks, *Y. pestis* for 11, viral hemorrhagic fever for 7, *Bacillus anthracis* for 3, and *C. botulinum* toxin for 3. *F. tularensis* and *R. rickettsiae* accounted for one outbreak investigation each. The causative agent was not identified in 41 (3.7%) investigations.

The 44 outbreaks involving an agent with potential for bioterrorism and the 41 caused by unknown infectious agents are summarized by location, year, disease agent, and conclusion (Table 2). All botulism outbreaks (two in the United States) were linked to contaminated food. Ten of the 11 plague outbreaks occurred in U.S. areas of known endemic plague in animals. Of the 18 cholera investigations, 4 were in the United States and involved nursing home patients, imported food, raw fish, and contaminated food on an international flight. Twelve (29%) of the 41 outbreaks caused by unknown agents involved cruise ships.

Intentional use of infectious agents to cause harm to civilians (i.e., bioterrorism) was considered in six investigations (Table 3) (5–8). Although the event did not occur during the period of this review, we included an outbreak of salmonellosis associated with contamination of a salad bar in Oregon in 1984. Several years after the investigation, contamination was (during the study period) determined to be intentional.

Healthcare providers were the source of 270 (24.6%) reports, and infection control practitioners were the source of 129 (11.7%). Together, these two categories of healthcare professionals were the most common source of outbreak recognition and reporting, accounting for 399 (36.3%) reports. Health departments accounted for 335 (30.5%) reports. Some of these 335 outbreaks may have been originally reported to local health departments by clinicians or clinical laboratories, but the original reporting source may have been missing from the trip report. Other sources of recognition and reporting of these outbreaks were existing surveillance systems (55, 5.0%), foreign ministries of health (30, 2.7%), nongovernmental organizations (22, 2.0%), the World Health Organization (16, 1.5%), and the Indian Health Service (12, 1.1%). Forty-nine (4.5%) outbreaks were reported by other sources, such as private clinics, laboratories, or private citizens. More than one reporting source was found in 58 (5.3%) cases. In 123 (11.2%) outbreaks, no mention was made of the recognition and reporting source, the method of recognition and reporting was unclear, or both the source and the method of recognition and reporting were unclear.

Table 1. Epidemic Intelligence Service field investigations involving unknown agents and potential agents of bioterrorism, 1988–1999

Agent	Frequency	% of investigations (n = 1,099)
Unknown infectious agent[a]	41	3.7
Vibrio cholerae	18	1.6
Yersinia pestis	11	1.0
Viral hemorrhagic fever virus	7	0.6
Bacillus anthracis	3	0.3
Clostridium botulinum	3	0.3
Coxiella burnetii	1	0.1
Francisella tularensis	1	0.1
Total	85	7.7

[a]In these cases, the outbreak was considered to be caused by an infectious agent because of the characteristics of the illness and outbreak.

The number of days from the beginning of the outbreak to the date the problem was first identified by the agency requesting CDC assistance was 0 to 26 days (Table 4). The time from the date the initial patient became ill to the date the initial contact was made to the requesting agency for the unexplained critical illness investigation was 26 days (Epi-Aid 99-59). The number of days from the date the problem was identified by the requesting agency to the date of initial CDC contact was 0 to 6 days.

Discussion

Investigations from 1988 to 1999 included outbreaks caused by *B. anthracis* spores, *V. cholerae, Y. pestis, F. tularensis*, *Coxiella burnetii*, Venezuelan equine encephalitis virus, viral hemorrhagic fever virus, and *Clostridium botulinum*; all of these agents might pose a bioterrorism threat, were responsible for 4% of all outbreaks from 1988 to 1999, and are not common causes of outbreaks investigated by CDC. A single case of illness or death caused by any of these organisms should suggest intentional exposure (or accidental exposure in which the perpetrators inadvertently exposed themselves to the causative agent.)

However, not all bioterrorism has involved or will involve these high-threat (formerly identified as weaponized) agents. In 1997, a laboratory worker intentionally contaminated his co-workers' food with a strain of *Shigella* stolen from the laboratory (9). While the *Shigella* strain did cause severe gastroenteritis and several hospitalizations, the use of this strain deviates from the popular idea of a bioterrorist's preferred weapon. However, viewing the bioterrorist's preferred weapon as a high-threat, aerosolizable, infectious agent that may cause immediate, widespread outbreaks may mislead preparedness efforts.

Table 2. Trip reports, involving unknown infectious agents or potential agents of bioterrorism (ultimately not considered bioterrorism), the Centers for Disease Control and Prevention, January 1988–December 1999

Report no.	Y	Location	Etiologic/agent	Conclusion
90-56	1990	Texas, USA	Unknown	Rash and fever in children, no discernable cause
93-02	1992	Wyoming, USA	*Coxiella burnetii*	Q fever in two bentonite miners
94-02	1993	Georgia, USA	*Clostridium botulinum*	Botulism outbreak linked to contaminated food
94-32	1994	Five states, USA	Unknown	Cluster of cases, no discernable cause
94-42	1994	Texas, USA	*C. botulinum*	Botulism outbreak linked to contaminated food
94-86	1994	Connecticut, USA	Sabia virus	Accidental infection with Sabia virus in laboratory worker
94-88	1994	Bolivia	Machupo virus	Bolivian hemorrhagic fever outbreak
95-16	1994	Utah, USA	Unknown	Contaminated solution used in grafting procedure; source undefined
95-40	1995	Palau	Dengue type 4 virus	Dengue type 4 virus outbreak
95-55	1995	Kikwit, Zaire	Ebola virus	Ebola hemorrhagic fever outbreak
95-61	1995	South Dakota, USA	*Francisella tularensis*	Tick-borne tularemia
98-23	1998	Kenya, Somalia	Rift Valley fever virus	Rift Valley fever outbreak
98-28	1998	Argentina	*C. botulinum* toxin	Botulism outbreak linked to contaminated food
98-35	1998	Uganda	Rift Valley fever virus	Rift Valley fever virus outbreak
98-55	1998	Texas, USA	*Bacillus anthracis*	Exposure to live spore vaccine for anthrax
98-83	1998	Kazakhstan	*B. anthracis*	Reemergence of anthrax, Kazakhstan
11 investigations involving plague	Multiple	10 investigations in USA (Oklahoma, Arizona, New Mexico, Texas, California); one in India.	*Yersinia pestis*	Mostly in areas of endemic plague in animals
18 investigations involving cholera	Multiple	4 investigations in USA (Mississippi, Maryland, Hawaii, California), 14 elsewhere	*Vibrio cholerae*	Cholera in two nursing home patients, outbreak involving imported food, outbreak involving consumption of raw fish, and outbreak involving contaminated food on international flight
12 investigations involving unknown agent on cruise ships	Multiple	Cruise ships	Unknown	Gastroenteritis outbreaks in which infectious agent was not identified by laboratory testing
26 additional investigations involving unknown agent	Multiple	24 in USA, 2 elsewhere	Unknown	Gastroenteritis outbreaks, acute illness after surgical procedures, and other outbreaks in which no infectious agent was identified by laboratory testing

In 1984, the outbreak of salmonellosis associated with intentional contamination of a salad bar in Oregon was not initially considered intentional (8); however, further investigation proved that it was. Intentional contamination may resemble naturally occurring outbreaks, may spread slowly through a population, and may involve endemic pathogens. Because of the potential similarity between naturally occurring and intentional outbreaks and the increased threat of bioterrorism in the United States, the index of suspicion for intentional exposure should be high.

Despite advances in the identification of pathogens, outbreaks of unexplained illnesses continue to occur. In this review, we found 41 outbreaks in which the causative agent remained undetermined. Intentional contamination should be considered in these cases because 1) unusual or not easily explained outbreaks are more likely to be caused by intentional contamination, 2) outbreaks resulting from bioengineered pathogens may have unusual or unexpected characteristics, and 3) bioengineered pathogens may not be easily detected by existing assays. For these reasons, outbreaks with unexpected or unusual clinical or epidemiologic characteristics should be pursued with added urgency, and investigators should consider the possibility of previously unidentified or newly engineered pathogens.

While CDC is often notified about outbreak investigations by a state or national health department, the origins of these reports are diverse and include local health departments, surveillance systems, physicians, veterinarians, infection control practitioners, organizations (e.g., the U.S. Food and Drug Administration or the World Health Organization), laboratories, private citizens, ship doctors, vessel sanitation programs, and others. We found that physicians and infection control practitioners reported more than one third of outbreaks. This estimate is probably

Table 3. Epidemic Intelligence Service investigations in which bioterrorism or intentional contamination was considered a cause

Report No.	Outbreak	Conclusion
84-093	Salmonellosis, Oregon, 1984	A total of 751 persons became ill with salmonella gastroenteritis. Religious group deliberately contaminated salad bars. *Salmonella enterica* Typhimurium strain found in laboratory at commune was indistinguishable from outbreak strain (5).
97-008	*Shigella dysenteriae* type 2, Texas, 1996	Diarrheal illness in hospital laboratory workers who ate pastries, anonymously placed in break room. Identical strains of *S. dysenteriae* type 2 were isolated from stool cultures of case patients, from recovered muffin, and from laboratory stock culture, part of which was missing.
98-006	*S. sonnei*, New Hampshire, 1997	Seven laboratory workers at local hospital became ill with gastroenteritis. Most cases caused by strain of *S. sonnei* that was highly related to a stock culture strain maintained by the hospital laboratory. Possibility that first two cases were caused by intentional contamination could not be excluded.
99-025	Anthrax hoaxes, 1998	Centers for Disease Control and Prevention received reports of alleged anthrax exposure; letters were sent to health clinics in Indiana, Kentucky, and Tennessee and to private business in Tennessee; three telephone threats of anthrax contamination of ventilation systems were made to public and private buildings; all threats were hoaxes.
99-059	Unexplained critical illness, New Hampshire, 1999	A 38-year-old woman was admitted to a hospital with fever, myalgia, and weakness; severe illness and death occurred 32 days after hospital admission; serum specimens indicated *Brucella* species. Patient's history of multiple febrile illnesses suggested unspecified autoimmune process.
99-94-1	Encephalitis cluster, New York City, 1999	Several residents were hospitalized with illness of unknown etiology characterized by fever, encephalitis, axonal neuropathy, and flaccid paralysis (unpublished data: Epi-1 report); increase in deaths of New York City birds, especially crows; human and bird tissue samples were positive for West Nile–like virus.

low because the reports that were recorded as originating from local or state health departments may actually have been brought to the attention of health departments by frontline practioners. Because of the importance of this frontline in detection and reporting, preparedness efforts must include education and support of these healthcare professionals. The clinical laboratory should have the capacity and legal latitude to use all appropriate testing. This capacity should include Gram stain of tissue smears for agents such as *B. anthracis*.

Trip reports (Epi-2) are summaries, not finalized data and are written for the state and local health departments and CDC and the U.S. Department of Health and Human Services. They are primarily internal documents and are not independently peer reviewed or standardized; however, each investigation may use standardized techniques. In general, problems we encountered were not inaccuracies (when a subset of trip reports were compared to the articles that followed them) but rather incompleteness of data we were interested in reviewing. We suggest that trip reports include standardized data collection on certain variables important in evaluating the effectiveness of detecting and reporting outbreaks (e.g., source of outbreak detection, date of the first case diagnosis, and date the outbreak was recognized).

Because we cannot rely on astute healthcare practitioners alone, existing national health surveillance systems should be modified or strengthened to increase their effectiveness in identifying bioterrorism (10). Systems already in existence for laboratory-based reporting should be enhanced for use in bioterrorism surveillance. Improved surveillance for unexplained critical illness and death may also be an important component in improved health surveillance for bioterrorism (5).

In addition to healthcare providers and public health departments, other persons and organizations may identify and report outbreaks. For example, veterinarians may be the first to see evidence of bioterrorism because pets and livestock may be more susceptible than humans to agents released in the environment or because a large susceptible

Table 4. Number of days from beginning to notification for outbreaks in which bioterrorism or intentional contamination was considered

Report no.	Investigation	Beginning of outbreak	No. of days from first case to problem identification	No. of days from problem identification to initial CDC contact
84-93	Large salmonellosis outbreak caused by intentional contamination of restaurant salad bars, Oregon	9/15/84	6	4
97-008	Shigellosis outbreak in hospital laboratory workers, Texas	10/29/96	1	1
98-006	*Shigella sonnei* outbreak in laboratory workers, New Hampshire	9/20/97	17	3
99-25	Anthrax hoaxes	10/30/98	0	0
99-59	Unexplained critical illness, New Hampshire	3/24/99	26	1
99-094	Encephalitis cluster with paralysis of unknown etiology, New York (West Nile virus)	8/9/99	14	6

[a]CDC, Centers for Disease Control and Prevention.

animal population may be present in the affected area (11). Detection of disease in lower animals may be essential to detecting a bioterrorism event because most of the bioterrorism threat agents are zoonotic disease agents, causing disease in both humans and lower animals. The West Nile virus outbreak, while naturally occurring, is a good example of the importance of animal disease surveillance because detection of illness and death in birds was important to identification of the outbreak.

Other potential resources include persons not in the healthcare field. Employers may notice a high rate of illness in their employees, or schools may report a larger than usual absentee rate. Enhancing surveillance systems, providing a mechanism of instant reporting to the proper officials, educating healthcare professionals and others in the community, and strengthening knowledge and skills for thorough outbreak investigations will improve collective preparedness for bioterrorism. In the future, shortening the time from detecting to reporting an outbreak to public health authorities, including CDC, will be essential to an effective response. National health surveillance systems are an important adjunct that, with further development, may allow for early detection of bioterrorism. Finally, education about bioterrorism should go beyond a mere description of the threat agents and strive to enhance the epidemiologic and investigative skills of healthcare professionals, including laboratory personnel, especially those in primary care settings, who are likely to be the first contact for people and communities affected by acts of bioterrorism.

Dr. Ashford is an epidemiologist in the Meningitis and Special Pathogens Branch, Centers for Disease Control and Prevention, where he serves as a subject matter expert for several zoonotic diseases. His research interests include the epidemiology and control of zoonotic diseases and bioterrorism preparedness.

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Address for correspondence: David A. Ashford, Centers for Disease Control and Prevention, 1600 Clifton Rd., Mailstop C09, Atlanta, GA 30333, USA; fax: 404-317-5220; email: dba4@cdc.gov

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Mr. SHAYS. You both have been wonderful witnesses, and we realize we're also wrestling with this. I think that what I am wrestling with is that I see this as the whole package. So when you talk about your not being able to talk about the technology to present this, you know, rather than its—you know, some of these are paper transactions. For me, I don't really—I don't like the feeling that I'm getting that we're not—I guess what I'm beginning to think is who's in charge? I don't mean that in a disparaging way, but who is taking ownership of this? Ultimately who takes ownership of making sure that this reporting happens quickly, that it's not paper transactions, that we're asking for the right things? Who ultimately, in your judgment, has that responsibility?

Dr. FLEMING. Well, the short answer is that CDC can and is taking a leadership role in this, and if I haven't conveyed that clearly, I sincerely apologize. I want you to know that our organization is committed to making this happen.

Mr. SHAYS. I get a feeling that you're content that a lot of progress is being made. And maybe what I'm hearing as well is that from a scientific standpoint, you know, we just—we study it, we check it, and we just—and so it'll happen when it happens. That's kind of the feeling, that we're making progress, but that's the kind of feeling I'm getting. From a politician and public policy standpoint, I'm thinking should we be tasking you to just make sure in a year or two it's done. And then you're probably saying, hello. You know, what do you mean it's done? So the process begins, you know, continues here.

Any last comment that you'd like to make before—OK. You both have been excellent witnesses, and I thank you.

Excuse me. Let me just say this. Is there anything, Dr. Tornberg or Dr. Fleming, that you want to put on the public record before we adjourn? A question maybe you had prepared for that you think we should have asked, and we just didn't have the common sense to ask it?

Dr. TORNBERG. No, sir. I think both my oral and written statement cover the areas that we would like to address for the committee's attention.

Mr. SHAYS. Dr. Fleming.

Dr. FLEMING. No. We will get back to you on the record on the issues that we talked about.

Mr. SHAYS. OK. And on this article.

Dr. FLEMING. Yes.

Mr. SHAYS. OK. Thank you both very much.

Let me just announce the second panel. I'm going to ask three people to come up to be sworn in: Ms. Mary Selecky, Dr. Seth L. Foldy, and Ms. Karen Ignagni. And then afterwards I'll invite Dr. Julie Hall to sit down at the desk as well. We're swearing in three of our four witnesses.

[Witnesses sworn.]

Mr. SHAYS. And at this time we'll also invite Dr. Julie Hall, medical officer of the World Health Organization, to join us. Evidently we didn't make it clear to the World Health Organization we swear our witnesses in, and they have a policy as an international agency not to be sworn in. So we'll accept the way it is.

And Ms. Selecky is Secretary, Washington State Department of Health, president of the Association of State and Territorial Health Officials.

Dr. Seth L. Foldy—am I saying it right?

Dr. FOLDY. Foldy.

Mr. SHAYS. Foldy—commissioner of health, city of Milwaukee; Chair, National Association of County and City Health Officials, Information Technology Committee.

And Ms. Karen Ignagni is president and CEO of American Association of Health Plans.

And Dr. Julie Hall, as I said, is medical officer of the World Health Organization.

We'll go in the order that you're sitting. And again, 5 and then another 5. Your testimony is very important to us. And I think that I would say that if you want to ad lib a bit, and given that you sat through this first panel, that you may want to jump in and make some points, because I think some of the questions we've asked you you're well prepared to answer.

So we'll start with you, Ms. Selecky.

STATEMENTS OF MARY C. SELECKY, SECRETARY, WASHINGTON STATE DEPARTMENT OF HEALTH, PRESIDENT, THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS; SETH L. FOLDY, COMMISSIONER, MEDICAL DIRECTOR, CITY OF MILWAUKEE, HEALTH COMMISSIONER, CHAIR, NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS, INFORMATION TECHNOLOGY COMMITTEE; KAREN IGNAGNI, PRESIDENT AND CEO, AMERICAN ASSOCIATION OF HEALTH PLANS; AND JULIE HALL, MEDICAL OFFICER, WORLD HEALTH ORGANIZATION

Ms. SELECKY. Thank you, Mr. Chairman, distinguished——

Mr. SHAYS. Is your mic on?

Ms. SELECKY. Thank you, Mr. Chairman and distinguished members of the subcommittee. My name is Mary Selecky. I'm the Secretary of Health in Washington State, and I'm honored to be testifying before you today as president of the Association of State and Territorial Health Officials. And also having been a local health department director for 20 years and having the experience of, on the ground, working local, State and working with our Federal colleagues, we certainly can address some of the issues that came up earlier.

I certainly would like to thank the committee for your past support of work that goes on with public health, but most particularly your attention to the issue. It has not been in the recent past that we've had the opportunity to bring public health issues before you. This hearing focuses on one of our most important, although invisible and forgotten, public health tools, and that is public health surveillance. It's not something people think about every day. As early as 1878, Congress recognized that this is an important issue when it authorized the U.S. Marine Hospital Service to collect morbidity reports concerning cholera, smallpox, plague and yellow fever from U.S. Consuls overseas.

Now the diseases may have changed, but the issues are very, very similar. In 1928, all States, the District of Columbia, Hawaii

and Puerto Rico were participating in national surveillance and reporting on 29 diseases. And in 1950, ASTHO, my organization, created its affiliate, the Council of State and Territorial Epidemiologists [CSTE], to determine and work together, States, local and Federal, to see which diseases should be reported to the U.S. Public Health Service. All States now voluntarily provide information to the Centers for Disease Control and Prevention [CDC] on nationally notifiable diseases.

One of the core functions of State health departments is to collect, analyze, interpret and disseminate public health data. States do this to identify health problems, determine the programs or other responses needed to address the problems, specific health concerns, and evaluate the effectiveness of the responses. Health departments depend upon the receipt of quality public health data to identify and track emerging infectious diseases such as already mentioned, SARS and West Nile virus. Equally important, although often overlooked, is the collection of public health surveillance data that identifies the burden and causes of the Nation's leading causes of death. That's chronic diseases, heart disease, diabetes, injury and risk factors. We may have more attention paid at times to communicable disease, but we must do the same with the noncommunicable.

State health departments have a unique role to play in public health surveillance. Public health threats do not respect political boundaries, be it the local level or the State level. Reporting of disease entities, therefore, needs to be uniform within any given State in order to work with Federal and local colleagues to assure an adequate immediate response to public health emergencies. In many parts of the country, only the state Health Department has the sophisticated laboratory and highly trained laboratorians, epidemiologists and other public health professionals needed to tackle the most serious public health challenges.

I had that personal experience. I was in northeast rural Washington, Colville, Washington, up in Representative George Nethercutt and formerly Speaker Tom Foley's district. We didn't have the levels of sophistication that perhaps our colleagues in Seattle did, and, in fact, Seattle might be very busy with the work going on with their own communicable diseases. Work we did from our rural community was dependent on our State colleagues helping us and opening the door, if needed, to the Federal kinds of resources available.

In this testimony I'd like to make four points. Since the 1988 Institute of Medicine's Future of Public Health Report recognized the inadequacy of our public health infrastructure in general, and public health surveillance in particular, we've made great strides, and you have heard some of those. Substantial congressional investments in preparedness funding have enabled States and local to expand our surveillance capacities.

We must continue our efforts to integrate and coordinate public health surveillance systems. You've already heard that.

While tremendous efforts are focused on developing high-tech surveillance systems, and technology is critically important, a computer without the right software and without a trained user is just an expensive paperweight. We must proceed with caution and en-

sure that any new systems are tested by local and State health agencies and determined to be usable and effective.

Despite the progress made since the Institute of Medicine report, much more needs to be done, and you've already heard some of that. We have a number of health professionals, and Dr. Fleming already mentioned that, that are due to retire in the next 5 years. We must pay attention to our work force.

To illustrate my points about the importance of public health surveillance, I'll give you three quick examples from Washington State. SARS, in Washington State today we have 24 cases; 22 of those are suspected, 2 are probable. That's a fairly high number across the United States when you look at our map. The systems that we have in place now were dealing with rapid identification; using common case definitions; the reporting mechanisms we have in place from our local health departments, from our clinicians to our local health departments, to us at the State and us in real time to the Federal Government, so that we all got a handle on this. We've been able to use the systems that we have enhanced over our State's emergency preparedness efforts.

West Nile virus. Washington State has not yet been hit with a human case occurring in our State. We know the mosquito is there. We've had dead birds. We've had dead horses. But for West Nile what we're doing right now is we're doing that real-time educating. We are using Webcast. We're using our information systems to enhance what people need to watch for, how to diagnose, how to report to our colleagues at the local level, and what it is we need to do as a State and work with the Federal Government at the Centers for Disease Control and Prevention [CDC].

And one other example is E. Coli O157:H7. Washington State unfortunately has a lot of practice. It was Burger King back in the early 1990's. It actually was a number of cases in 1985. Our public health lab created the 1-day test, what used to take 5 days, in Washington State. We were working together with the scientists at the Centers for Disease Control, because the real-time reporting, that happens through PulseNET, through our public health laboratory system, and then to capitalize on that with the National Electronic Disease Surveillance System really means that we deal with this very quickly.

Last summer we had a multistate outbreak that had to do with a meat packer in Colorado. We worked very closely together with the systems that are in place to make sure the public is protected.

In closing, I want to reiterate a few points. First, thank you to Congress for investments. They hadn't come in the near past. The investments have become more real more recently. They must be sustained. State and local public health working together with our partners at the Federal level need to have that investment.

Second, public health work force issues must be addressed, whether it's through our schools of public health, whether it's through routine training available using, for example, Webcast satellite downlinks or whatever the case is.

And the third is the continuing effort to coordinate the systems. A clinician and a local community is the first place where this starts, the local health department connectivity to that local clinician and to us at the State and at the Feds.

Now, there are systems in place, and the reason you don't have a one-size-fits-all is the fact that you have had things develop; whether it's in Pittsburgh or an area of Texas, we've got to have common standards so that we can report commonly.

Again, thank you for the opportunity to be here, and I'd be happy to answer questions when we're done with the panel.

Mr. SHAYS. Thank you Ms. Selecky.

[The prepared statement of Ms. Selecky follows:]

Statement of

MARY C. SELECKY

SECRETARY
WASHINGTON STATE DEPARTMENT OF HEALTH
And
PRESIDENT
ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Before the

SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS, AND INTERNATIONAL RELATIONS

of the

UNITED STATES HOUSE OF REPRESENTATIVES

Hearing on

"HOMELAND SECURITY: IMPROVING PUBLIC HEALTH SURVEILLANCE"

MAY 5, 2003

Representing

THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
(ASTHO)

Mr. Chairman and distinguished members of the Subcommittee, my name is Mary C. Selecky. I am the Secretary of the Washington State Department of Health, and I am honored to be testifying before you today as the President of the Association of State and Territorial Health Officials (ASTHO). I would like to thank the Chair and subcommittee members for your past support for public health matters, including public health preparedness.

This hearing focuses on one of our most important, although often invisible and forgotten, public health tools – public health surveillance. As early as 1878, Congress recognized the important of surveillance when it authorized the U.S. Marine Hospital Service to collect morbidity reports concerning cholera, smallpox, plague, and yellow fever from U.S. consuls overseas. These data were to be used for instituting quarantine measures to prevent the introduction and spread of these diseases into our nation. By 1928, all states, the District of Columbia, Hawaii, and Puerto Rico were participating in national surveillance and reporting on 29 specific diseases. In 1950, ASTHO created its affiliate, the Council of State and Territorial Epidemiologists, one of the group's purposes was to determine which diseases should be reported nationally to the Public Health Service. All states now voluntarily report nationally notifiable diseases to the Centers for Disease Control and Prevention (CDC).

One of the core functions of state health departments is to collect, analyze, interpret, and disseminate public health data. States do this to identify health problems, determine the programs or other responses needed to address specific public health concerns, and evaluate the effectiveness of the responses. Health departments depend upon the receipt of quality public health data to identify and track emerging infectious diseases such as

SARS and West Nile virus. Equally important, although often overlooked, is the collection of public health surveillance data that identifies the burden and causes of our nation's leading causes of death - chronic diseases (such as heart disease and diabetes) injury, and risk factor analysis.

State health departments have a unique role to play in public health surveillance. Public health threats do not respect political borders. Reporting of disease entities, therefore, needs to be uniform within any given state in order to work with federal and local colleagues to assure an adequate, immediate response to public health emergencies. In many parts of the country, only the state health department has the sophisticated laboratory and highly trained laboratorians, epidemiologists and other public health professionals needed to tackle the most serious public health challenges. As a former health officer for the Northeast Tri-County Health District in rural eastern Washington state, I know firsthand about the importance of the critical synergies that must be in place to assure that all citizens are protected. Just as there are differences in capacities among states, there are differing response capacities within communities in every state. As a local health official, I worked hand in hand with the state health department on foodborne outbreaks and other public health emergencies. Local, state, and federal health agencies, including the CDC, each have a distinct and important role in public health surveillance activities.

In this testimony, I would like to make four points:

1) Since the 1988 Institute of Medicine's *Future of Public Health Report* recognized the inadequacies of our public health infrastructure in general, and public

health surveillance in particular, we have made great strides in strengthening these areas. Substantial Congressional investments in preparedness funding have enabled states to develop surveillance capacities that are being used to address potential terrorist and naturally occurring public health threat emergencies.

2) We must continue our efforts to integrate and coordinate public health surveillance systems.

3) While tremendous efforts are focused on developing high-tech surveillance systems, and technology is critically important to enhancing our capabilities, a computer without the right software and without a trained user is just an expensive paperweight. We must proceed with caution and ensure that any new systems are tested by local and state health agencies and are determined to be usable and effective.

4) Despite the progress that has been made since the Institute of Medicine issued its report, much more needs to be done. As our affiliated organizations – the Council of State and Territorial Epidemiologists and the Association of Public Health Laboratories -- have indicated, we face a serious shortage of trained public health laboratorians and epidemiologists. A significant portion of our present workforce is expected to be lost in the next 5 years to retirement or other career opportunities. We can have all of the sophisticated equipment in the world, but without trained professionals to gather, analyze, interpret and disseminate data, our public health surveillance system will falter. We need to address workforce issues at the same time as we address hardware, bricks and mortar, and other aspects of our infrastructure.

To illustrate my points about the importance of public health surveillance, I would like to offer three examples from Washington state.

SARS – The public health system relies on physicians to identify possible SARS cases. The SARS epidemic has required extensive interaction between local and state health agencies and physicians to relay the rapidly changing knowledge about the epidemic. Health care providers must know in real time what to look for and what to do to manage suspect cases and protect their patients, the public and themselves. We have used traditional public health mechanisms – a notifiable condition regulation that requires reporting of new and emerging diseases, basic communication tools such as telephones and fax machines, and trained local and state staff to answer questions and investigate cases. We have also begun to use systems that have been developed as part of our state's emergency preparedness efforts. We take part in frequent conference calls with the CDC and with local health agencies to relay information, answer questions and assure consistency of approach. We also use the national Health Alert Network to disseminate official messages from the CDC across the public health system, and through local health agencies to physicians. These new systems have greatly enhanced our surveillance and response efforts for SARS.

West Nile virus – Washington has not yet been hit as hard as many other states, but we know the disease is coming. West Nile virus has been identified in birds, mosquitoes and horses in our state. We expect a significant increase in animal cases and a number of human cases this year. We are preparing for this by developing communication and

response plans at the state and local level, by training local health staff on surveillance and control measures, and by communicating with physicians on how to recognize and report the disease. We are using the same surveillance and response systems and staff for West Nile virus that we do for other communicable diseases and for potential bioterrorism threats.

E. coli O157:H7 – Washington has a lot of experience identifying and responding to this foodborne disease, but these outbreaks are certainly not limited to Washington. A large multi-state outbreak last year highlights the need for standardization of surveillance systems and information. Twenty-eight people across seven states were sickened in an outbreak associated with ground beef from a meat packer in Colorado. Close work between local and state health agencies and the CDC allowed rapid assessment of the extent of the outbreak and identification of the likely source. The successful response to this outbreak was a result of physicians who recognized E. coli O157:H7 and knew how to report the case; trained local and state epidemiologists who knew how to do investigations; and systems such as the National Electronic Disease Surveillance System and the PulseNet laboratory network that facilitated the rapid sharing of standardized information across the country.

In closing I want to reiterate some key points. First, thanks to Congress' early recognition of the importance of public health surveillance and its commitment to provide funding to strengthen our surveillance capability; we now are able quickly to identify and address some key threats to the public health. Great progress has been made in this area,

but much more can and must be done. Second, public health workforce issues must be addressed immediately. Without adequate numbers of well-trained public health professionals involved in our surveillance efforts, we run the risk of not being able to rapidly detect and address public health emergencies. Third, we must continue to coordinate our existing surveillance systems and ensure that new surveillance approaches work before asking state and local health departments to use them. And finally, because of decades of neglect of our nation's public health infrastructure, continued federal investments in public health surveillance at the federal, state, and local levels are urgently needed. The preparedness funding of last year was a critical beginning, but it cannot be a "one shot" effort. Sustained support is essential.

Thank you for this opportunity. I would be pleased to answer any questions you may have.

Mr. SHAYS. And Dr. Foldy.

Dr. FOLDY. Yes. Good afternoon, Mr. Chairman, members of the subcommittee. I'm Seth Foldy, health commissioner of the city of Milwaukee, WI, and I speak today on behalf of the National Association of County and City Health Officials, which represents the Nation's nearly 3,000 local public health agencies. I'm glad to share a local perspective with you regarding the urgent need to support and to upgrade America's disease surveillance capabilities.

I share your urgency. I certainly hear it. My remarks will be tailored considerably, given the advanced level of discussion you've already achieved previously. I believe I understand some of the sources of your impatience and some of your confusion about how to proceed.

I would be remiss not to begin by just pointing out that the reporting of diseases to public health is but one part of the surveillance network and the surveillance resources that are greatly needed. Among those, of course, are resources for global surveillance, such as WHO has provided. I shudder to think what SARS would have been like in the United States without the advanced warning, or "heads up," from the World Health Organization and the critical importance of the public health laboratory in permitting public health to speedily confirm what might be an epidemiologic suspicion.

We have heard it often from Washington out in the hustings; we have heard it asked, "Does the United States have the ability to fight two wars simultaneously?" And perhaps the most important—more important—and cogent question is "Do we have the ability to fight two, three or four epidemics simultaneously?" In the last few weeks, severe acute respiratory syndrome [SARS], has been added to the plate of local health departments not through—who do not have different divisions to deal with each of these problems, but it is one team typically who are all struggling with smallpox vaccination, West Nile Virus, influenza season—on its way out, we hope—resurgent HIV and AIDS and sexually transmitted infections, and increasing rates of obesity, diabetes and asthma.

It is important for the committee to understand that the local health departments are the eyes and ears for surveillance of the Nation. They are also the hands and feet for the emergency public health response. Without the local public health agencies being a true part of the picture, we have a giant public health entity without eyes, ears, hands or feet. However, the local public health agency is at the bottom of the funding chain, often at a low priority for local tax dollars, and, very importantly, many are now downsizing during the current fiscal crisis. You need to be aware of this.

Also, because the authority for communicable disease reporting really derives in common law from local police powers and nuisance enforcement, there is typically no extrinsic funding or little extrinsic funding for disease surveillance at the local level, the most fundamental process that you are speaking about today.

We thank you very much for soliciting the local public health view from NACCHO. The international SARS epidemic has clearly underscored the importance of disease surveillance, and you can just look at how everyone at USA Today is trying to learn how to read an epi curve. It also underscores the importance of having in-

tegrated and flexible disease surveillance, and it points out weaknesses of our current system and opportunities for improvement.

In terms of integration, Milwaukee began enhancing disease surveillance systems long before we were worried about bioterrorism. It really dates back to a massive outbreak of a common but then little known bug called Cryptosporidium. This waterborne outbreak sickened more than 400,000 people suddenly in our city. We had little idea that an outbreak was taking place. Traditional surveillance systems would not report a disease that was not mandated for legal reporting. Similarly, a spate of deaths during the 1995 heat outbreak makes it clear that it was also under the radar of health surveillance systems.

This makes it clear that health surveillance can't be designed for one problem in isolation of others, and in particular, that very finely defined health surveillance systems that might be applicable for the agents we think are going to be responsible for a bioterrorism attack will really not serve us well. We need integrated systems that bring together information of various types, various diseases that are integrated in the public health world and not set up as some separate entity, some separate department of government.

In terms of flexibility, you're going to hear in my presentation that ideas and innovations are bubbling up as well as down, and the creation of very highly standardized systems is important. What we really hope to achieve, I think, in our Nation today are standardized methods of coding information and standardized ways of transmitting information that—such that the information can talk to itself, and agencies and information systems can talk to each other in such a way that it actually encourages innovation.

What is important is if you were, for example, to ask the Federal Government to mandate that all health care providers begin to report certain information immediately up at the Federal level, and that all local health providers and State departments do the same, the easiest way to do that is to create a single Web-based entry system where we all spend all of our time filling in the blanks on the instrument that has been provided from above. But what that denies us the opportunity to do is to create flexible instruments we carry into the field that, because of standard transmission of health care information, can then up link to the Federal system.

That is a decision, an important decision, that has to be made, and yet I agree with you. We cannot dilly dally too long in seeking the right balance between mandates and innovation. The weakness of the traditional reporting systems have been pointed out, although they remain absolutely crucial. They are slow. They often give us incomplete information. They rely on paper forms that often sit around in piles, which should surprise no one. Furthermore, it is increasingly being pressured by the fact that a laboratory specimen obtained in Milwaukee may well be analyzed in Atlanta or in Santa Cruz, and that information somehow has to find its way back to the doctor's office and subsequently to the local public health authority.

I agree very much with Dr. Fleming's catalog of improvements in the traditional reporting system: educating the providers, improving our laboratory infrastructure, creating a 24/7 response. But, in addition to this, I think the real low-hanging fruit for the tradi-

tional disease surveillance system is electronic laboratory reporting.

There are huge numbers of laboratories out there. If each of their laboratory information systems could report data in a standardized fashion so that it would find its way to and through the different health information systems that come between them and the local public health authority, this information could reach quickly, be routed to us, could automatically alert us, could be stored, displayed, analyzed, and tracked, greatly reducing the work of local public health.

My colleague, Rex Archer in Kansas City, has established such electronic lab reporting with a large number of laboratories in Kansas City and has demonstrated increased timeliness of reporting, increased completeness of reporting, reduced time wasted. However, as with all surveillance and public health, we know that it also gives us more complete reporting. He is chasing a lot more disease than he ever knew about before, and that has its real implications.

The real point here is that the standardization of electronic health information is really a critical step. HIPAA really created a basement, a foundation for doing this by creating accountability, about confidentiality, security, and mandating certain standardization; and we really need to let this take root.

The second topic that has been discussed is enhanced or syndromic surveillance. We know that we can look at a lot of different patterns of illness such as symptoms in emergency departments, pharmacy dispensing, test orders. It is very important to recognize that this is a young science, easily oversold, hard to prove how well it works. However, it is very important that we begin to explore these capabilities. This will require again standardized health information, information that can flow electronically so that we are not adding constantly to the workload of busy health care providers.

In addition, it requires connectedness; and I will tell you a brief story from Milwaukee. On their own initiative, because they needed it for their own reasons, all of the local emergency departments established a secure, live Internet site that told them when different emergency rooms were on divert status. When we learned about that this resource was in each of our emergency rooms, we politely asked access to the system and have used it since to post alerts to the emergency medicine community. My pager goes off when more than three emergency rooms at a time go on ambulance divert. I can draw down statistics to see why emergency rooms are going on diversion and what the temporal pattern is.

And, most recently, we have solicited the emergency rooms to provide us with daily updates of certain types of diseases, not on an ongoing basis, because they don't have the labor to do this continuously, but on an as-needed emergency basis. We performed such surveillance for bioterrorism-like syndromes during the All-Star game last summer. But beginning with the SARS epidemic, given this experience, we were able within 3 days to have 13 emer-

gency rooms in our community both screening their patients routinely for possible SARS-related symptoms and then providing us with daily counts of what they were seeing.

Mr. SHAYS. Thank you, Dr. Foldy.

[The prepared statement of Dr. Foldy follows:]

NATIONAL
ASSOCIATION OF
COUNTY & CITY
HEALTH OFFICIALS

1100 17TH STREET, NW, 2ND FLOOR
WASHINGTON, DC 20036
(202) 783-5550
(202) 783-1583 FAX
WWW.NACCHO.ORG

Statement of

Seth L. Foldy, MD
Health Commissioner
City of Milwaukee, Wisconsin

on behalf of the

National Association of County and City Health Officials

Before the

Subcommittee on National Security, Emerging Threats, and International Relations
House Committee on Government Reform

Hearing on "Homeland Security: Improving Public Health Surveillance"

May 5, 2003

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Seth Foldy, MD, Health Commissioner of the City of Milwaukee, Wisconsin. I am pleased to speak with you today on behalf of the National Association of County and City Health Officials (NACCHO). NACCHO is the national organization representing the nation's nearly 3000 local public health agencies. I chair NACCHO's Committee on Information Technology and am glad to share with you from the local viewpoint what we are learning about disease surveillance and how the nation can do it more effectively.

When a disease outbreak or other public health emergency occurs, local public health agencies provide the eyes, ears, hands and feet to find the cause and prevent further harm. We are usually the ones who first detect and investigate unusual occurrences of disease and execute a response. It is important for state and federal governments to alert us to potential problems, but such alerts are useless unless we have the ability to do disease investigation and response on the ground.

Today, the number of threats we face is increasing, as are the number of tools potentially available to help us address them. It will take many years of sustained investment to modernize our local public health workforce and our systems to enable us to do justice to these challenges. It will also require active, sustained involvement by the local public health community in the development of statewide and nationwide disease surveillance systems. Such systems cannot and will not function effectively unless they are designed to account fully for the processes and realities of local public health work.

The need for improved surveillance systems is critical not just to detect a bioterrorism event, but also to detect emerging communicable diseases, such as Severe Acute Respiratory Syndrome (SARS). We can never assume that the diseases we will be trying to track next month will be the same diseases that have concerned us over the past several years.

The Objectives of Disease Surveillance

The purpose of disease surveillance is the same, whether the disease is SARS or smallpox. Our objective in all cases is to detect the occurrence of an infectious disease as early as possible so that we can act to prevent its spread and minimize the number of persons affected. The sooner

we know that a disease outbreak may be occurring, the sooner we can act to confirm and contain it.

There are many ways we might learn that a communicable disease outbreak is threatened or in progress. In the 2001 anthrax event, the public health system was alerted by the diagnosis and prompt reporting of a single case of an unusual disease in Palm Beach, Florida. In the 1993 Milwaukee outbreak of *Cryptosporidium parvum,* a water-borne parasitic disease that ultimately killed more than 50 in my city, it was several days before public health authorities realized that a generalized outbreak was underway. Traditional surveillance did not awaken public health. Rather, it was calls from pharmacists running out of anti-diarrheal medications and laboratories besieged by requests for stool cultures.

These two examples illustrate the two differing types of disease surveillance: 1) direct observation, diagnosis and reporting by astute clinicians or from laboratory results; and 2) observation of community-wide patterns that indicate a possible disease outbreak. An effective disease surveillance system uses both strategies, which then function synergistically and optimize our ability to contain outbreaks. Both strategies require establishing systems that enable flows of information and health data within communities to permit timely recognition of local events. They must also adapt to the increasingly regional and national nature of laboratories and health care databases, since a sample obtained in Massachusetts may be analyzed in Atlanta. Ideally, surveillance occurs actively, with continuous scanning of patterns of disease and near-real-time notification of aberrations, rather than waiting for outbreaks to become obvious.

Disease Surveillance: The Past and the Future

The nation's traditional approach to disease surveillance has been slow and cumbersome. States establish lists of reportable diseases. Physicians and laboratories confirm the diagnosis of a reportable disease and record the information manually on paper. The paper is sent to the local or state health department, which processes it and determines whether it needs to be sent elsewhere and whether action needs to be taken. Often the paper forms are missing crucial pieces of information, such as the address or phone number of the patient. If it is necessary to contact

the patient to gather further information about how the disease might have been acquired or spread, someone must chase down that information before contact can be made. It can take a long time before these pieces of paper add up to the identification of a disease outbreak. Valuable time for preventing the spread of the disease is lost.

Traditional legally-mandated disease reporting that is based on the definitive diagnosis of illness and relies on clinicians making the effort to notify public health authorities may be too slow and unreliable for some of today's challenges. It has been estimated that each hour delay in the recognition of an airborne anthrax attack might cost hundreds of millions of dollars due to missed opportunities to limit exposures and offer prophylactic treatment. Moreover, the traditional model will not detect emerging communicable diseases that too new for mandated reporting regulations.

Imagine how different it would be with real-time, electronic systems instead of paper and fax or mail. Physicians, hospitals and laboratories record information one time in their electronic record, but uniform data standards permit that data to flow through interoperable information systems to serve the needs of pharmacies, labs, billing departments and public health authorities. Information of interest to public health is automatically identified, filed, stored, counted, analyzed, and displayed. Computers programmed with algorithms recognize an unusual pattern of symptoms, laboratory tests, or diagnoses, sounding a virtual alarm at the text pager of a health department physician or epidemiologist who logs in via the nearest computer, examines the data promptly and determines whether further investigation is needed. Patterns of time, location and population affected are rapidly assessed by working backward through electronically linked information

Disease Surveillance: Today

Our present approach to disease surveillance is beginning to move beyond the limitations of paper-and-pencil reporting of specified diagnoses. However, several steps separate us from the vision described above. Much health care information remains in paper records. Existing electronic health data systems do not produce information in standardized ways in order to

permit another system to receive or comprehend it. Information systems at local, state and federal public health agencies are often rudimental and outdated.

The Health Insurance Portability and Accountability Act (HIPAA) is setting the stage for such interoperability. Despite some provider anxiety about HIPAA regulations, they lay the foundation for interoperable health information systems by requiring common data standards and defining appropriate security and confidentiality. Creation, refinement and adoption of information standards useful for public health are being facilitated by CDC's Public Health Information System functions and requirements. The recent adoption of a first set of uniform health information standards across federal agencies is another exciting development.

Most successful models are being developed and tested at the local level. For instance, the Kansas City Health Department receives electronic notification of reportable lab results from multiple medical laboratories who share the same Laboratory Information System vendor. This is called electronic laboratory reporting and it is probably the technology most likely to produce immediate improvement in traditional disease surveillance. Kansas City's health officer reports that this reduced lag time in disease reporting and increased the receipt of complete information, enabling faster response with fewer wasted resources. Like most improvements in surveillance, however, this system generates more reports of disease that require public health follow-up. This is a desirable result, but it demonstrates that surveillance is the tip of an iceberg that leads to many other types of local public health responsibilities.

In Milwaukee, many hospital emergency rooms have voluntarily reported daily counts of defined symptom syndromes electronically to my health department using a Regional Emergency Medicine Internet application. We are using that system now to perform surveillance for symptoms associated with SARS. This is one form of what is known as syndromic surveillance. We do not receive personally identifiable information, but each hospital has a way to help us locate the persons with symptoms if necessary. While it is simple to use, it does require extra data collection and data entry by Emergency Department personnel. Because the system operates on the World Wide Web it was fairly easily adopted by other communities for

the SARS epidemic. More information on this project is available at www.frontlinesmed.org/sars-sp.

Syndromic surveillance cannot definitively establish that a particular disease is causing an outbreak. It alerts local public health to the need for more investigation. But we can alert clinicians and laboratorians to be on the look-out to help us pin down a diagnosis. Similarly, such surveillance may be helpful in tracking an ongoing situation, and we have used it during heat waves for this function.

Syndromic surveillance relies on our ability to compare current trends to what is "normal". Longitudinal experience and statistical algorithms are needed to exploit the potential of such systems. When algorithms are too sensitive, false alarms strain public health resources. If they are too insensitive, important events are missed. Development of good algorithms for syndromic surveillance is a science in its infancy. There are many syndromic surveillance systems being touted, but most still require rigorous evaluation and fine-tuning over time.

The ideal system automatically collects and transmits accurate, meaningful information without requiring busy health care providers to vary from their usual routines. That is why electronic medical records and interoperable electronic health information hold the greatest promise for enhanced disease surveillance.

The evolution of regional and national health care, insurance, pharmacy and data management companies has led to the creation of large regional and national health data systems. One possible approach to disease surveillance is to establish a regional or national center that analyzes health trends in such systems. These systems need to be tested to see if local events can be detected and meaningfully interpreted by remote analysts. Corroboration is best performed by local professionals who know and understand the community. In order to confirm an outbreak, a local professional may need to talk to physicians, emergency room staff, pharmacists or patients. No data are ever 100% accurate. Sometimes unusual patterns of disease may emerge and they represent simply an aberration or a coincidence, not an outbreak requiring intervention. A local public health authority must interpret surveillance data in a local context and prepare a local

response. As surveillance systems are established, they must integrate intimately with the work practices of the local health offices that will need to respond to them. There is no way to build an effective national surveillance system that relies on weak and overtaxed local health departments. Neither can such systems be effectively designed without taking into account the day-to-day work processes of local public health investigation and outbreak response. Indeed, the challenges of maintaining a high level of response capability for anthrax, smallpox, and SARS are sorely challenging the capabilities of many excellent local departments.

Recommendations for Improving Disease Surveillance

We are in a very exciting developmental period for disease surveillance. We are just beginning to explore the possibilities for applying sophisticated information technology in public health, a field that has lagged other sectors in technology resources and proficiency. Indeed, just a few years ago, before Congress funded the Health Alert Network program, many local public health agencies did not even have Internet access. However, public health offers a century of proven experience in disease control. Give us the proper data in usable form, and we will know how to interpret it and what to do about it. The best approach is to give public health agencies, led by the Centers for Disease Control and Prevention, the resources and ability to mine the technologic expertise of other federal agencies and the private sector. Keep disease surveillance under explicit public health leadership and direction. Remember that improving technology and information systems is not an end in itself, but a tool to assist public health science and achieve public health objectives.

There are essential roles both for federal leaders and local communities in disease surveillance. It is appropriate for federal leaders to develop a vision and specifications for an integrated, interoperable system with multiple uses, the goal of CDC's Public Health Information Network project. However, the federal government must consult early and often with the local public health agencies that will be using the system developed and must provide them the resources to participate in it. Receiving, managing, and responding to information produced at the federal level profoundly affects work processes at the local level. National initiatives (and state initiatives funded by federal programs) rarely recognize, anticipate, or prepare for this. National initiatives creating new information management demands must be accompanied by meaningful

investment in the local public health personnel and training that will make the national initiative work. Otherwise, the entire enterprise will not be effective.

Investment and incentives for creating interoperable health information systems should be supported at the federal level. Similarly, nodes of innovation in disease surveillance at the local level also should be encouraged and supported. I have mentioned Milwaukee and Kansas City; many other communities have created innovative surveillance and communications systems funded by the Health Alert Network program and other funds dedicated to local use. Local centers of innovation provide models that can be evaluated by national authorities and replicated if promising. Funding and equipping local public health departments to be partners in the development of disease surveillance will yield better outcomes than simply requesting "input". Finally, it must be noted that a strong surveillance system with a weak local public health response system is little better than no system at all. Continued investment in daily public health functions at the local level remains a critical national need.

In addition to supporting the CDC Public Health Information Network, federal policy-makers should continue to provide policy and incentives for the rapid adoption of interoperable electronic information systems in health care. This will create streams of data and produce faster and better surveillance systems of the future, as well as potentially reduce health care costs and improve health care quality. Obviously, the security and confidentiality of personal health and financial information must be scrupulously maintained in such systems or else the public will not feel confident and safe. However, I believe such security and confidentiality are technically achievable, if they are supported by an adequate policy and regulatory framework.

Thank you for your interest and for your support of the critical enterprise of disease surveillance. I will be pleased to answer any questions or provide further information for the record.

Mr. SHAYS. Dr. Hall.

Dr. HALL. I am Dr. Julie Hall.

Mr. SHAYS. I am going to have you move it a little closer.

Dr. HALL. OK.

I am Dr. Julie Hall. I am a medical officer with the World Health Organization. I work in the headquarters in Geneva where I work as part of the Global Outbreak and Alert Response Team and have helped to coordinate the international response to SARS.

Mr. Chairman, Congressman Bell and members of the subcommittee, on behalf of the World Health Organization and Dr. David Heymann, Executive Director for Communicable Diseases, thank you very much for the opportunity to brief you today on improving surveillance for infectious diseases at the global level and to brief you on the lessons that we are learning particularly with regards to SARS. Dr. David Heymann asked me to convey his regrets for not being able to be here in person today.

I have submitted a written statement for use by the committee. At the back of that written statement there is several charts that I will refer to during my verbal testimony.

As has already been mentioned before, the threat of infectious diseases, of emerging and reemerging diseases is an ever present threat. And the first slide at the back of the written testimony shows a map of the world and a number of the infectious diseases that have emerged or reemerged in the past 5 years. It doesn't, as you will note, show SARS on there.

The threats of infectious diseases is indeed an issue of security. Infectious diseases have the potential to damage not just the health of the population but to cause social disruption, particularly when frontline staff or health care facilities are affected, as is the case with SARS, and also to cause economic damage, again something clearly evidenced with SARS.

Our traditional defenses against infectious diseases cannot always be relied upon. National borders do not protect against the emergence of diseases. And the second slide at the back there will show very graphically how quickly, within days, SARS had spread from one hotel in Hong Kong to over eight different countries around the world.

Anti-microbial drugs, one of our previous defenses against infectious diseases, are becoming increasingly ineffective as antibiotic resistance increases; and scientific advancements in the development and productions of vaccines cannot always keep up with the pace of change for infectious disease. So the emergence of an infectious disease in one part of the world is a threat to the entire world; and our key defense is early detection, early dissemination of that information, and early implementation of the protective measures that are required to stop the spread of disease.

The aim of global surveillance then is to provide the world with a window of opportunity early in the course of the disease when it is possible to potentially control and eliminate that disease.

Surveillance at the global level allows the compilation of data from different sources. This is particularly important when looking at the emergence of a new disease, because quite often it is a jigsaw puzzle. Piece A may come from one country, piece B in terms of information may come from another. Surveying the world and

having surveillance at the global level allows these pieces to be put together, and in the case of SARS this was absolutely crucial. We knew with SARS that there was ongoing problems in Guangdong. This was in early February. We knew also that there were problems with H–5 influenza in Hong Kong. So when one single case occurred in Vietnam, we were alert to a potential problem of pandemic proportions.

Surveillance at the global level also allows us to put out the early warnings that have been so effective in terms of controlling SARS, and it allows us to get a global picture to assess the need for further action, whether that be at global level in terms of producing travel advisories or at local level to provide international support to countries that are affected by the disease.

How does global surveillance work? Well, it works in much the same way that you have heard how surveillance works at local level, at State level, and at national level. There are four key components: the gathering of information, the verification of that information, further assessment of that information, and then a response is mounted. And it is key that surveillance should not be seen as separate from response. The two things are interlinked and critically important.

In terms of global surveillance, we have a number of systems in place at WHO to collect the information. The first and about a third of our information comes from the WHO system itself. WHO has a headquarters in Geneva. It also has six regional offices and 141 country offices, and this provides a great deal of information about the emergence and reemergence of diseases of potential international harm.

In addition to that, Health Canada runs the global public health information network that constantly scans nearly 1,000 media feeds and electronic discussion groups to look for hints of the emergence of diseases; and this gives us real-time and very accurate information of what is going on all around the world.

Another key source of information for us is through the Global Outbreak Alert and Response Network. This is a network of over 150 different organizations from around the world—laboratories, epidemiology groups, other health institutions; and, again, this can provide key early information.

However, much of the information that's received at WHO comes in the form of rumor, and this must be verified. WHO is in a good position to be able to do this with its 141 country offices and regional offices who work quickly with local health authorities to verify information that has been provided to us. This can allow rapid confirmation that an outbreak is occurring and the ability to share information, but it can also provide rapid ability to refute information and clarify the situation, and that can ensure that panic does not ensue unnecessarily and economic damage does not occur. On a daily basis, the information that is received by WHO is assessed in terms of its risk for international health concern; and additional information such as geographical, political, and other social information is included as part of that process.

Responses can be mounted very rapidly by WHO, and within 24 hours we are able to get field teams into virtually any country around the world. We are also able to disseminate the information

very quickly through our cascade of country offices, through the production of information on our web, and other sources of information. If assistance is required by any country, any member state of WHO, this can be coordinated by WHO and with its headquarters and assisted by regional offices and the country offices itself.

Expertise and field teams can be quickly organized, as I mentioned before, by calling upon our partners within the Global Outbreak Alert and Response Network of who CDC is a key player. WHO's neutrality and ability to get laissez-passer status to any member of our international team means that we have privileged access to 192 countries around the world.

The fourth slide at the back of my written presentation gives an overview of the extent to which WHO and the activities at WHO has been coordinating in response to SARS. This included not just operational support in terms of field teams in Hong Kong, Vietnam, Singapore, Beijing, and now to be in Taiwan as well, the production of supplies and the creation of logistic bases in Vietnam, Thailand, Manila, and rapid response capabilities in Geneva, but it is also being—a considerable amount of energy and effort has gone into international collaboration, laboratory collaboration. Twelve laboratories around the world have collaborated to identify the virus in record time, clinical collaboration to share information, epidemiological and environmental collaboration as well. WHO has produced recommendations for the control of the disease, management of the patients, and prevention of international spread.

However, there are areas for development, and these fall into two areas. Developments are needed in terms of capacity and developments in terms of commitment.

In terms of capacity, global surveillance will only be as good as the national surveillance systems that it depends upon; and, as you can see in the final slide that's attached to the written statement, in terms of FluNet and other surveillance systems, there are clear holes in many countries around the world that need to be supported and developed if we are to have a truly global system.

We also need commitment to global reporting, transparency, and commitment to global collaboration, for these are the key things that will defend us against infectious diseases. The true cost of SARS will be if we don't learn the lessons of SARS; and the true benefits that we have seen from SARS and the lessons that we have learned are that rapid detection, rapid implementation of protective measurements and also multilateral global collaboration can protect us from infectious diseases.

Mr. SHAYS. Thank you very much.

[The prepared statement of Dr. Hall follows:]

Statement by Dr. Julie L. Hall
Medical Officer
World Health Organization

5 May 2003

Before the
Subcommittee on National Security, Emerging Threats, and International Relations
Committee on Government Reform
U.S. House of Representatives

The role of global surveillance in protecting nations from the evolving infectious disease threat

This statement provides a brief overview of the dynamics of the infectious disease threat, explains the role of global surveillance as a defense strategy, and describes the systems now in place for detecting outbreaks early and mounting a strong response. The example of severe acute respiratory syndrome, or SARS, is used to illustrate the strengths and weaknesses of these systems when confronted with an especially challenging new disease. Lessons learned from the evolving SARS outbreak are then used to assess global capacity to respond to other infectious disease threats, most notably the next influenza pandemic and the possible deliberate use of biological agents to cause harm. Priority areas for urgent improvement are identified and discussed.

The dynamics of the infectious disease threat

Continual evolution is the survival mechanism of the microbial world. Infectious disease agents readily and rapidly multiply, mutate, adapt to new hosts and environments, and evolve to resist drugs. This natural propensity to change has been greatly augmented by the pressures of a crowded, closely interconnected, and highly mobile human population, which has given infectious agents unprecedented opportunities to exploit. The result has been an equally unprecedented emergence of new diseases, resurgence of older diseases, and spread of resistance to a growing number of antimicrobials over the past three decades.

As adversaries, microbial pathogens have particular advantages in terms of invisibility, mobility, adaptability, and silent incubation periods that render national borders

meaningless. Infectious agents, incubating in symptomless air travellers, can move between any two cities in the world within 36 hours and slip undetected past any border. They can also be transported over long distances by migratory birds, again rendering national borders meaningless. Disease vectors, hidden in cargoes or riding in the cabins or luggage holds of airplanes, can likewise enter new territories undetected and establish permanent residence there. Vulnerability to these threats is universal and has been amply demonstrated in practice.

Some examples A few recent examples illustrate both the geographical sweep of the infectious disease threat and the specific ways in which emerging and re-emerging diseases strain global and national capacity.

- The threat posed by drug resistance is ominous and universal. Health care in all countries is now compromised by the shrinking number of effective first-line antimicrobials and the need to resort to more costly, and often more hazardous, alternative drugs, when available. Drug resistance to common bacterial infections is now so pervasive that it raises the specter of a post-antibiotic era in which many life-saving treatments and routine surgical procedures could become too risky to perform.

- A new strain of epidemic meningitis emerged in 2002, defying emergency preparedness as conventional vaccines proved to be ineffective. The new strain struck again in early 2003, necessitating emergency arrangements with the pharmaceutical industry and funding agencies to produce sufficient quantities of an effective and affordable vaccine. Despite this effort, the supply has been inadequate to protect all at-risk populations. The result: close to 6,000 cases of a diseases that causes permanent brain damage in up to 20% of cases, and more than 800 deaths.

- The invariably fatal variant Creutzfeldt-Jakob disease, first recognized in 1996 and probably transmitted to humans through beef, has defied the best scientific efforts to develop a treatment or cure. Although the number of cases has been small, the new disease shook public confidence in the meat supply in ways that are still being felt.

- Year by year, the highly unstable influenza virus is a reminder of the ever-present threat of another lethal influenza pandemic that could stretch global capacity – in terms of manpower, hospital beds, vaccine development and production, and supplies of antiviral drugs – to its limit.

These developments have eroded past confidence that high standards of living and access to powerful medicines could insulate populations in wealthy countries from infectious disease threats abroad. They have also restored the historical significance of infectious diseases as a disruptive force – this time cast in a modern setting characterized by the close interdependence of nations, rapid international travel, and instantaneous communications. As a result, outbreaks of new and epidemic-prone diseases have consequences that extend far beyond the sphere of public health to affect economies and, in some cases, disrupt social stability. These consequences likewise extend beyond the individually affected countries to have repercussions felt around the world.

The role of global surveillance

Defense against the infectious disease threat ultimately depends on early detection and rapid intervention. For emerging diseases to be contained and epidemics prevented, protective and preventative measures need to be instigated quickly. Because of the world's interdependence and high mobility, the window of opportunity to prevent international spread is often very short and an outbreak in one corner of the world can quickly become an epidemic in another.

Global surveillance provides a mechanism by which information about potential biological threats can be gathered from all parts of the world, analyzed and disseminated rapidly. It provides an early warning system for the international community and can give unaffected areas the time that would not otherwise be available to prepare and prevent further spread of the disease. The pooling of information from different countries also allows a more comprehensive picture of an emerging threat to be developed than would be available from one single national source. Such information often provides vital early clues about the nature of an emerging infection and the types of control methods that are most likely to be effective.

Ideally, national and local surveillance systems would be the strong base of this global system and give it great sensitivity and speed. However, national surveillance systems around the world, in wealthy as well as developing countries, suffer from a long history of underfunding. In many developing countries, including those where new infectious diseases most frequently emerge, surveillance is patchy outside large disease control programmes, such as those for AIDS, tuberculosis and malaria, and reporting is slow, incomplete and unreliable. As a further problem, some countries are reluctant to reveal the presence or true magnitude of an outbreak for fear of the economic consequences. In a sense, then, the practical measures being taken by WHO to institute and improve global surveillance and international response are currently having to compensate for weaknesses in many national systems while also encouraging improvements in those national systems. Action simply must be taken, however, given that we all live in a world where biological threats, including emergence of new diseases, more virulent forms of old diseases or deliberately released pathogens, are real possibilities.

Systems now in place

Since 1997, WHO has been building up an integrated operational system for strengthening global defense against the transboundary threat posed by outbreaks and epidemics. The system is centrally co-ordinated by a team at WHO headquarters in Geneva and supported by a "virtual" network architecture. This Global Alert and Response system gives priority to prompt detection and rapid containment of outbreaks, with improved surveillance as the cornerstone. Defense relies on a three-pronged approach: combating known risks, detecting and responding to unexpected events, and continually improving global and national preparedness. The system is constantly being strengthened as experience is gained, new mechanisms are developed, and new electronic

tools become available. The whole system benefits from the presence of WHO offices in 141 countries and the fact that 192 countries are member states of WHO.

Global Outbreak Alert and Response Network (GOARN) In April 2000, WHO formally launched the Global Outbreak Alert and Response Network (GOARN) as a mechanism to link together, in real time, 110 existing organizations and networks which together possess much of the data, expertise, and skills needed to keep the international community alert to outbreaks and ready to respond. By electronically linking together existing networks the World Health Organization is able quickly to learn of significant events and to mobilize verification and response activities in spite of WHO's limited resources.

From January 1998 through March 2002, the WHO has investigated 538 outbreaks of international concern in 132 countries. The most frequently reported outbreaks were of cholera, meningitis, haemorrhagic fever, anthrax, and viral encephalitis. During the past two years, WHO, working with partners from the Global Outbreak Alert and Response Network, has launched broad and effective international containment activities in Afghanistan, Bangladesh, Burkina Faso, China, Cote d'Ivoire, Republic of Congo, Egypt, Ethiopia, Gabon, Hong Kong SAR, Kosovo, India, Madagascar, Pakistan, the Philippines, Saudi Arabia, Sierra Leone, Senegal, Singapore, Sudan, Tanzania, Uganda, Viet Nam, and Yemen.

The U.S. government continues to be a valuable partner for WHO in developing global alert and response capabilities and participating in the GOARN network. Various U.S. government agencies contribute to this effort, in line with their specialized capabilities and the particular threat being addressed. Most extensive is WHO's long tradition of reliance on the practical experience, technical expertise, and staff resources of the Centers for Disease Control and Prevention (CDC) to conduct a range of fundamental activities needed to contain the international spread of infectious diseases. This collaboration has become even closer and more vital as the number of outbreaks requiring an international response continues to escalate. The recent establishment of the Global Emerging Infections Surveillance and Response System (GEIS) within the Department of Defence is another especially welcome resource for expanding the global reach of surveillance, research, training, and access to high-quality laboratory support. USAID also supports WHO surveillance activities, particularly the strengthening of national capacities.

Such practical assistance can be invaluable. For example, when an outbreak is caused by a previously unknown or highly pathogenic organism, certain activities, such as sampling and analysis for definitive identification of the agent, must be carried out by experienced specialists and frequently require the security of biosafety level III or IV laboratories. In this regard, the WHO global network of more than 270 collaborating institutes and laboratories with expertise in infectious diseases, including 40 housed in CDC, provides a vital resource. Moreover, the sharing of such resources is a far more cost-effective option than attempting to build highly specialized capacity in an enlarged number of countries.

Real-time disease intelligence One of the most powerful new tools for gathering epidemic intelligence is a customized search engine that continuously scans world Internet communications for rumors and reports of suspicious disease events. This is the Global Public Health Intelligence Network (GPHIN), a computer application developed by Health Canada and used by WHO since 1997. GPHIN operates as a sensitive real-time early warning system by systematically searching for key words in over 950 news feeds and electronic discussion groups around the world. Human review and computerized text mining are used to filter, organize and classify the more than 18,000 items it picks up every day, of which around 200 merit further analysis by WHO.

In outbreak alert and response, every hour counts, as the window of opportunity for preventing deaths and further spread closes quickly. GPHIN has brought tremendous gains in timeliness over traditional systems in which an alert is sounded only after case reports at the local level progressively filter to the national level before being formally notified to WHO. GPHIN currently picks up – in real time – the first hints of about 40% of the roughly 200 to 250 outbreaks subsequently investigated and verified by WHO each year. While the early alert to outbreaks of genuine concern is most important, GPHIN also allows WHO to step in quickly to refute unsubstantiated rumors before they have a chance to cause social and economic disruption.

During outbreak response, WHO uses a custom-made geographical mapping technology to assist in the location of cases and rapid analysis of the epidemic's dynamics. This epidemiological mapping technology is also used to predict environmental and climatic conditions conducive for outbreaks. An event management system, introduced in 2001, is now used to gather and communicate data throughout the course of outbreak investigation and response. The system generates a dynamic picture of operations, aids organization of logistics, and provides a systematic way to prepare better, respond faster, and manage resources more effectively.

Preparedness mechanisms: stockpiling of supplies For outbreaks of some diseases, control depends on the rapid immunization of populations that can number in the millions and has, in the past, completely exhausted vaccine reserves and created international crises. For epidemic meningitis, WHO established in 1997 a coordinating mechanism, engaging research institutes and manufacturers, that maintains an emergency stockpile of vaccines and other supplies, oversees their distribution, and also works to forecast epidemics and reduce the price of vaccines. To date, 9.8 million doses of meningococcal vaccine have been distributed through this mechanism. In 2001, a similar mechanism for yellow fever vaccine facilitated the emergency management of a large urban outbreak, averting an estimated 30,000 deaths. Most recently, WHO, assisted by industry and the Bill and Melinda Gates Foundation, has made a new meningitis vaccine available to African countries just months (instead of the usual years) after detection of an emerging epidemic caused by a new strain of the pathogen.

Privileged access to countries WHO staff, consultants, and expert advisers have privileged access to all 192 member states. This privilege allows WHO, in the interest of safeguarding international health, to transcend the prevailing political reality in which access to critical expertise might be denied because of one country's political relationship

with others. On many occasions, the Organization's ability to secure UN laissez-passer status has proved decisive in getting CDC and other U.S. experts quickly and smoothly into countries where, for diplomatic reasons, entrance might otherwise be delayed or denied. This ability to obtain privileged visa status can be extended to all security-cleared partners who become members of a WHO response team.

WHO also has unique and permanently positioned geographical resources. These include six regional offices and an additional 141 country offices, located within or in close proximity to ministries of health. Although the size of these offices varies according to the disease situation in the country concerned, all offices are staffed with medical experts and often with epidemiologists, and all have the essential logistic equipment, including vehicles and local communications, needed for the prompt on-the-scene investigation of a suspected outbreak. In the event of an outbreak of urgent international concern, WHO country offices facilitate the arrival of international assistance by arranging flights, customs and immigration clearance, and accommodation. All offices are now electronically linked to WHO and thus to its global network of institutional resources and collaborators.

SARS: an especially demanding test of global capacity

SARS demonstrates dramatically the global havoc that can be wreaked by a newly emerging infectious disease. It has also been an extremely demanding test of the effectiveness of WHO and its partners in GOARN to mount an adequate response, get teams and supplies into countries, and ensure adequate monitoring and reporting. The urgency of SARS has further challenged WHO to set in motion high-level international scientific and medical collaboration in which natural competition for publication and prestige is set aside in order to identify the SARS causative agent with unprecedented speed and to develop diagnostic tests and effective treatment protocols.

At this moment, public health authorities, doctors, nurses, scientists, and laboratory staff around the world are struggling to cope with SARS at a time when some hope remains that the disease might still be contained. Economists and market analysts are simultaneously struggling to calculate the present and future costs, initially estimated at $30 billion in the Far East alone. Public panic is widespread, some government officials have lost their jobs, and social stability has been jeopardized in some of the hardest hit areas. Hospitals, schools, and borders have been closed, and several governments have advised their citizens not to travel to hard-hit areas. "Hot zones" of particular concern have included Toronto, Hong Kong, Singapore, Taiwan, Beijing and, increasingly, much of the rest of China. With the exception of Taiwan, all of these areas belonged to the first wave of outbreaks, prior to the WHO global alert issued on 15 March. Viet Nam, another country in the initial wave of outbreaks, became the first country to control its SARS outbreak on 28 April.

SARS is the first severe and easily transmissible new disease to emerge in the 21st century. Though much about the disease remains poorly understood and frankly puzzling, SARS has shown a clear capacity for rapid spread along the routes of international air

travel. WHO regards every country with an international airport, or bordering an affected area, as at potential risk of an outbreak.

On 21 February, SARS was carried out of Guangdong Province, China by an infected medical doctor who had treated patients in his home town. He brought the virus to the ninth floor of a four-star hotel in Hong Kong. Days later, guests and visitors to the hotel's ninth floor had seeded outbreaks of cases in the hospital systems of Hong Kong, Viet Nam, and Singapore. Simultaneously, the disease began spreading around the world along international air travel routes as visitors at the hotel travelled home to Toronto and elsewhere, and as other medical doctors who had treated the earliest cases in Viet Nam and Singapore travelled internationally for medical or other reasons.

The number of probable SARS cases passed the 6000 mark on Friday 2 May, with 27 countries reporting cases from five continents. More than 400 deaths have occurred. China is reporting a cumulative total of probable cases that is approaching 4000 as each day's nationwide reporting adds at least 100 new cases. Although outbreaks in Hong Kong, Singapore, and Toronto show signs of having peaked, new cases and deaths continue to be reported. Taiwan, with a rapidly growing number of cases and deaths, is a worrisome new development.

A particularly serious threat SARS needs to be regarded as a particularly serious threat for several reasons. The disease has no vaccine and no treatment, forcing health authorities to resort to control tools dating back to the earliest days of empirical microbiology: isolation and quarantine. The virus comes from a family notorious for its frequent mutations, raising important questions about the future evolution of outbreaks and prospects for vaccine development. Epidemiology and pathogenesis are poorly understood. All available diagnostic tests have important limitations. If tests are poorly conducted or results wrongly applied, patients excreting virus and thus capable of infecting others can slip through the safety net of isolation and infection control. The disease continues to show a disturbing concentration in hospital staff – the human resource vital to control. A significant proportion of patients require intensive care, thus adding to the considerable strain on hospital and health care systems. Evidence is mounting that certain source cases make a special contribution to rapid spread of infection. SARS has an incubation period that allows rapid spread along international air-travel routes.

With the notable exception of AIDS, most new diseases that emerged during the last two decades of the previous century or have become established in new geographical areas have features that limit their capacity to pose a major threat to international public health. Many (avian influenza, Nipah virus, Hendra virus, Hanta virus) failed to establish efficient human-to-human transmission. Others (*Escherichia coli* O157:H7, variant Creutzfeldt-Jakob disease) depend on food as a vehicle of transmission. Diseases such as West Nile fever and Rift Valley fever that have spread to new geographical areas require a vector as part of the transmission cycle. Still others (*Neisseria meningitidis* W135, and the Ebola, Marburg, and Crimean-Congo haemorrhagic fevers) have strong geographical foci. Although outbreaks of Ebola haemorrhagic fever have been associated with a case-

fatality rate in the range of 53% (Uganda) to 88% (Democratic Republic of the Congo), person-to-person transmission requires close physical exposure to infected blood and other bodily fluids. Moreover, patients suffering from Ebola during the period of high infectivity are visibly very ill and too unwell to travel.

The SARS response To date, the global response, coordinated by WHO and strongly supported by CDC, has been designed to rapidly seal off opportunities for SARS to establish itself as a common disease. The initial emergency plan, mapped out in mid-March, called for an attack on the ground and in the "air". On the ground, WHO sent teams of experts and specialized protective equipment for infection control in hard-hit hospitals to countries requesting such assistance. In the "air", WHO used the model of its electronically interconnected global influenza network to quickly establish a similar "virtual" network of 11 leading laboratories, connected by a shared secure website and daily teleconferences, to work around the clock on identification of the SARS causative agent and development of a robust and reliable diagnostic test. This network, in turn, served as a model for similar electronically linked groups set up to pool clinical knowledge and compare epidemiological data. WHO also decided to issue daily updates on its website to keep the general and travelling publics informed and, to the extent possible, counter rumors with reliable information.

On 15 March, based on information from WHO country offices and GOARN partners, followed by risk analysis by the WHO headquarters operational team, WHO issued a rare emergency travel advisory designed to alert national authorities, medical personnel, and travelers to an emerging threat that was quickly taking on international dimensions. Global vigilance was immediately heightened, with the result that most countries subsequently reporting cases have managed, through prompt detection, isolation and good infection control, to prevent the scale of transmission experienced in the SARS "hot zones". On 2 April and again on 19 April, WHO issued the toughest travel advisories in its 55-year history when it recommended postponement of all but essential travel to designated high-risk areas.

WHO teams continue to provide operational support and specialized expertise in the most seriously affected areas. Requests for additional country assistance continue to be received, most notably from authorities in China. Abundant additional support is available to all through information posted at the WHO website (www.who.int/csr/sars). Guidance ranges in nature from forms for collecting and reporting data, through guidelines for clinical management and infection control in hospitals, to the materials for local production of diagnostic tests. The evolution of the outbreak is constantly and closely monitored and daily updates are posted on the website. On 17 April, exactly a month after its establishment, the laboratory network announced conclusive identification of the SARS causative agent: a new coronavirus unlike any other known human or animal virus in its family. The laboratory reagents needed to calibrate, standardize and assure the quality of laboratory tests are being made available by WHO, at no cost, to laboratories designated by ministries of health.

Learning from SARS: how to prepare for other emergencies caused by infectious diseases

When the first suspected SARS cases began appearing in the U.S., many hospital staff cited the WHO advisory, and their subsequent high-level of awareness, as one reason why cases were quickly detected and isolated, with the result that further transmission was either avoided entirely or kept to a very small number of cases. A second explanation offered for the comparatively mild and well-contained SARS situation in the U.S. is the high level of nationwide planning and preparedness that followed the deliberate distribution of anthrax-tainted mail in the US postal system in October 2001.

The International Health Regulations provide the legal framework for global surveillance and reporting of infectious diseases and a mechanism by which measures to prevent international spread can be enforced. The regulations, which are currently undergoing a substantial revision, will be discussed by Ministers of Health at the World Health Assembly later this month. The SARS outbreak provides firm evidence of the need for such regulations and concrete examples of the areas in which revision and updating are urgently needed.

The novel nature of the SARS virus created an extra step in the containment response: scientific identification and characterization of the causative agent to allow development of a diagnostic test, treatment protocols, and a scientifically sound basis for recommending control measures. Experience with SARS has shown that, with strong global leadership by WHO, scientific expertise from around the world can work in a very effective collaborative manner to identify novel pathogens. This function would be invaluable in the event of the deliberate release of a biological agent or during future emergence of a novel or poorly understood pathogen.

WHO is continuing its aggressive containment activities aimed at preventing SARS from becoming a widely established threat. The immediate scientific priorities include developing a robust and reliable diagnostic test, improving our understanding of the modes of transmission and identifying effective treatment regimes. If, in spite of best efforts, the disease does become endemic, WHO and its international partners will have to settle in for a long and difficult fight. In this case, existing mechanisms developed for other public health emergencies, such as the Medicines for Malaria Venture, the Global Alliance for Vaccines and Immunization, the Global TB Drug Facility, and the International Coordinating Group for meningitis and yellow fever, would have to be looked to as possible models for ensuring the rapid development of SARS drugs and vaccines and equitable access in all at-risk countries. Use of the influenza network as a model for the SARS laboratory network suggests that such an approach brings great speed as well as efficiency.

Lessons for the future

Just as the SARS response has been guided by lessons learned during preparedness planning for the next influenza pandemic and for a possible bioterrorist attack, both of these types of potential public health emergencies will benefit from lessons learned as the international response to SARS continues.

The response to SARS has already brought to light a number of positive lessons as well as highlighted a number of challenges for future preparedness planning. The SARS experience has shown the capacity of global alerts, widely supported by a responsible press and amplified by electronic communications, to improve global vigilance and awareness at all levels, from health professionals and national authorities, to politicians and the travelling public. The quick detection and reporting of the first cases in South Africa and India are indicative of the high level of global awareness and the vigilance of the world's health systems. The present climate of high alert also helps explain the speed with which developing countries – from Namibia to Mozambique – have readied their health services with preparedness plans and launched SARS campaigns, often with WHO support, to guard against imported cases.

The SARS experience in Viet Nam has shown that immediate political commitment at the highest level can be decisive. Viet Nam demonstrated to the world how even a very poor country, hit by an especially large and severe outbreak, can triumph over a disease when reporting is prompt and open and when WHO assistance is quickly requested and fully supported.

And finally, stimulation of very rapid, high-level research has been seen clearly to be a key component of an effective response.

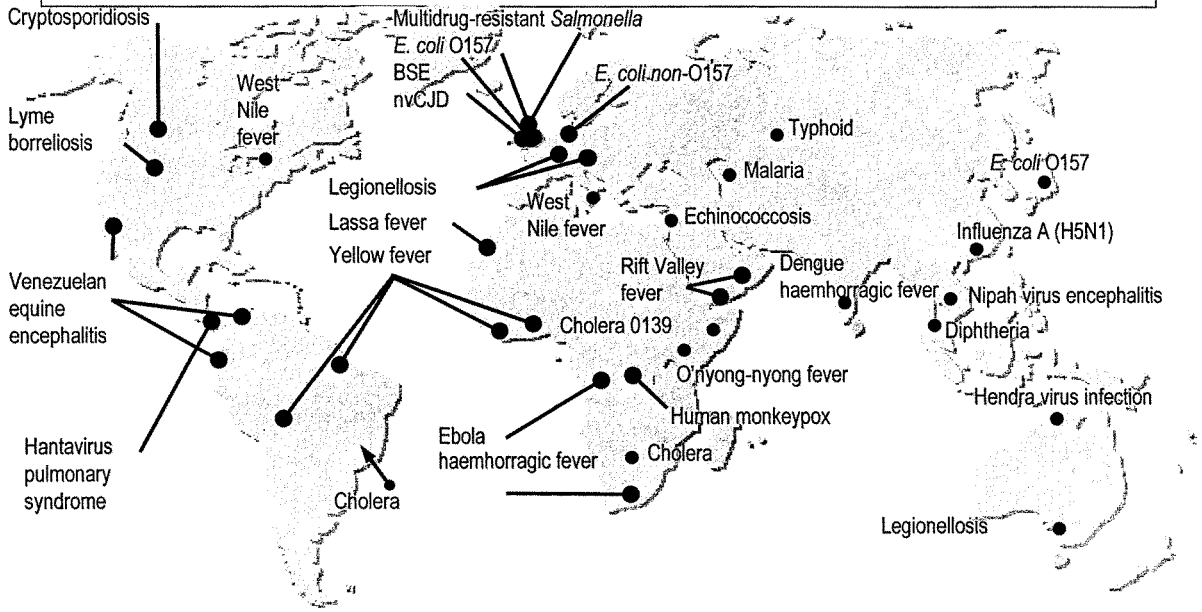
The key challenges to be addressed in future planning are those of surge capacity and transparency. Inadequate surge capacity in hospitals and public health systems has clearly been a major problem, especially when health care workers have themselves been victims of the disease and are the frontline troops at risk. The shortage of expert staff to co-ordinate national and global responses to a rapidly evolving public health emergency is also an issue needing investment and attention.

SARS is now known to have begun in mid-November in a southern province of China. Cases during the earliest phase of the SARS outbreak there were not openly reported, thus allowing a severe disease to become silently established in ways that made further international spread almost inevitable. This is the most important lesson for all nations: in a globalized, electronically connected world, attempts to conceal cases of an infectious disease, for fear of social and economic consequences, must be recognized as a short-term stop-gap measure that carries a very high price – loss of credibility in the eyes of the international community, escalating negative domestic economic impact, damage to the health and economies of neighboring countries, and a very real risk that outbreaks within the country's own territory can spiral out of control.

The SARS experience also has some lessons about the importance of international collaboration and strong but politically neutral global leadership. Though exceptional in terms of its impact, severity, rapid international spread, and many puzzling features, SARS is only one of around 50 internationally important outbreaks to which WHO and its partners respond in any given year. The high level of medical, scientific, political, and public attention focused on SARS is helping the world to understand the severity of the infectious disease threat and the importance of international solidarity in the face of this threat. It is also helping the world to understand the importance of global leadership and of politically neutral and privileged access to all affected countries. Finally, the response to the SARS outbreak is helping the public to understand that WHO's activities of global coordination, capacity development, communications, and mobilizing expertise enable rapid response and actually save lives. To date, in the vast majority of countries, these activities have helped health authorities confronted with imported cases prevent a SARS outbreak and thus avoid the devastating consequences seen elsewhere.

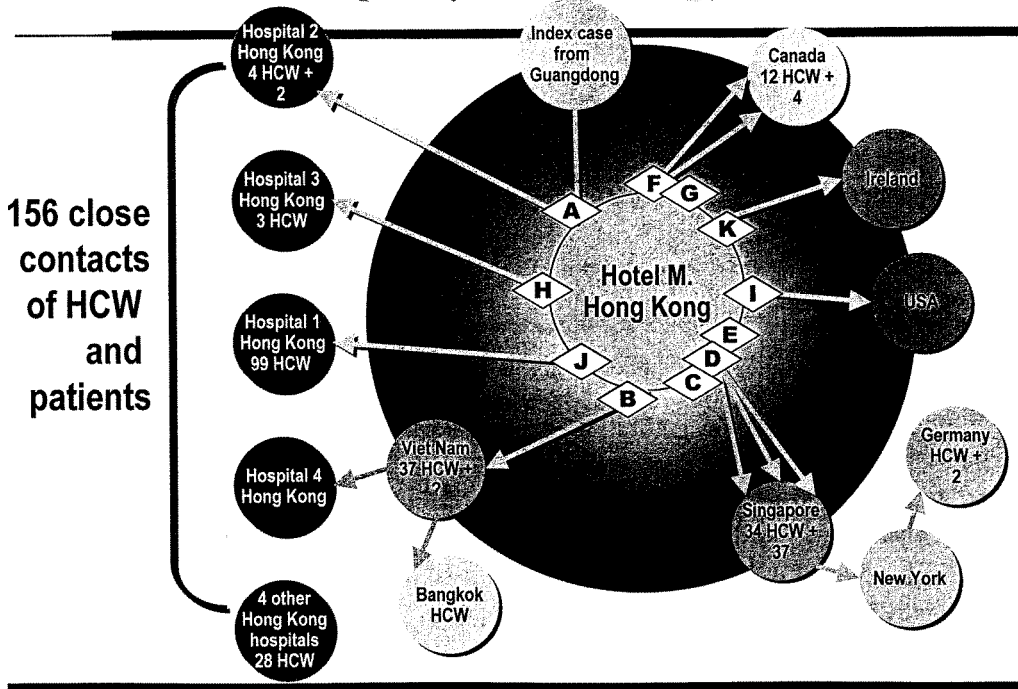
Improving infectious disease surveillance and response is indeed a matter of "national security, emerging threats and international relations" as this Subcommittee's name implies. Global public health security will continue to require effective leadership and action at a global level by WHO and its partners.

Emerging/re-emerging infectious diseases,1996–2003



WHO Global Alert and Response Operations

SARS: chain of transmission among guests at Hotel Metropole, Hong Kong, 21 February



As of 26 March, 249 cases have been traced to the A case

Source: WHO/CDC

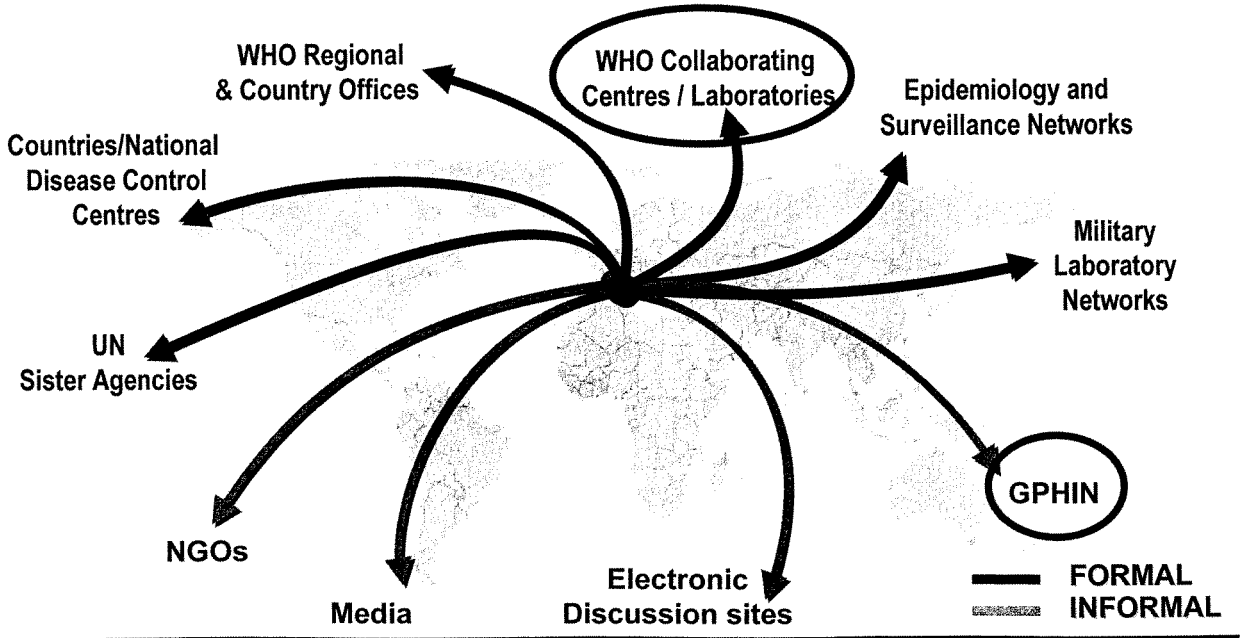
Global Alert and Response network
Epidemic Intelligence

Real time gathering of information related to outbreak events
Multiple first sources: 1 Jan 2001 to 31 Dec 2002 (N=436)

GPHIN	**39%**
WHO system	**34%**
ProMed	**8%**
Other*	**19%**

Other sources including GOARN partners, UN, NGOs, news media..

Partnership for global alert and response to infectious diseases: network of networks



April 2003 World Health Organization

Global Response: SARS

Operational support:

- Field teams
- Logistics and supplies

International collaboration:

- Laboratory
- Clinical
- Epidemiology
- Environmental

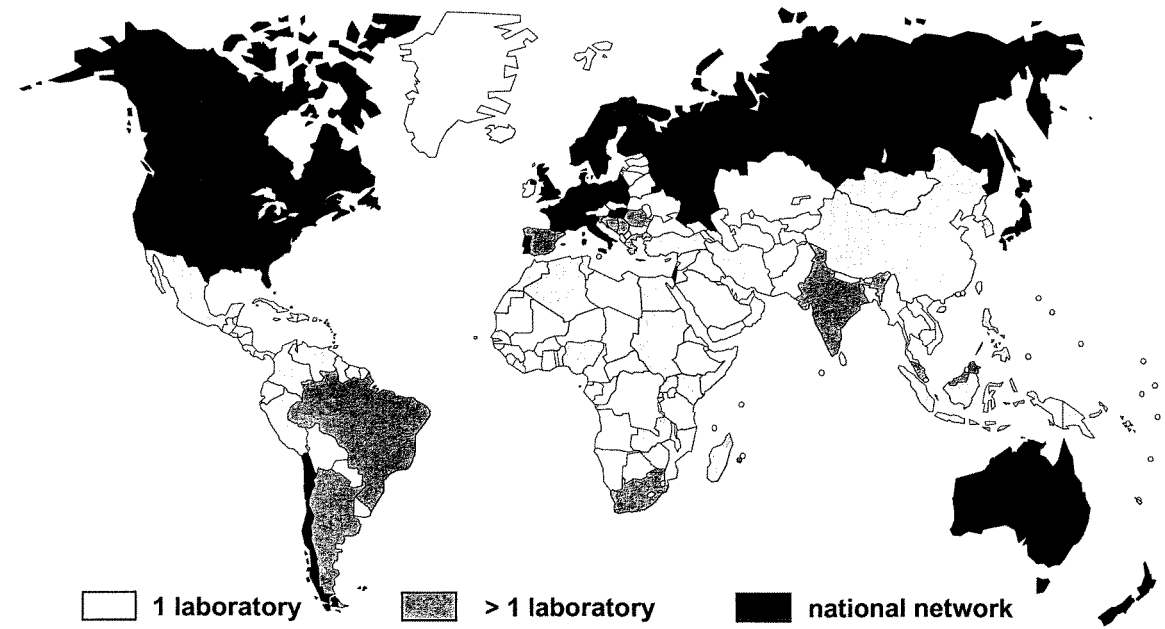
Recommendations:

- Control of disease
- Management of patients
- Prevention of international spread

Communication:

- Information
- Risk

FluNet: Global surveillance of human influenza, participating laboratories, 2003



April 2003

World Health Organization

Mr. SHAYS. I'm just going to say to our last witness that sometimes when I have discussions with my staff I am right and sometimes they are right. They think they are right more often. You can be a really major player here. I say I pronounce your name Ignagni, and one of my staff says it's Ignagni. Who is right?

Ms. IGNAGNI. Well, the Italian is Ignagni. So——

Mr. SHAYS. Neither of us are.

Ms. IGNAGNI. The Anglicized version is Ignagni. Thank you, sir.

Mr. SHAYS. Thank you.

Ms. IGNAGNI. Mr. Chairman, thank you for the opportunity to testify. I want to commend you and the members of the subcommittee for taking this leadership. It is my pleasure and honor to be part of these distinguished panels, and I hope we might make some contribution to the endeavor of improving our Nation's homeland readiness. As you will see, our members have unique capacities to contribute to this readiness effort, and I am pleased to have the opportunity today to discuss those capabilities.

What distinguishes us in the health plan arena, irrespective of plan model, insurance type, or what have you, are four characteristics: First, we are providing coverage to defined populations, and the meaning of that is that we can get a sense of statistical significance of symptoms and what they mean as a percentage of a particular universe.

Second, we have real-time de-identified data that we are reporting into a system. I make that point because, in response to Mr. Murphy's question earlier about HIPPA and patient confidentiality, we have taken steps in our program to make sure that we are fully compliant with HIPPA; and I will describe that more fully in a moment.

Third, we have case managers collecting information from patients that are going into the system.

And, finally, we have rapid-response outbound calling technology, so, to the extent messages need to get quickly to patients, we have the ability to do that.

What we are testing in our program, which is described fully in our testimony, is whether or not we can leverage these capabilities to strengthen the public health surveillance systems, which has generally depended upon passive collection of data. What you have been talking about throughout the afternoon is in fact collecting data once individuals go to emergency rooms, once they go to the hospitals, once public health gets ahold of those individuals in terms of collecting that information. There is often a gap between the time individuals have symptoms and the time they actually seek treatment. So we are trying to see whether or not we can contribute to the transition to real-time data collection.

After the tragedy of September 11, our members began an intense process of discussing how we could contribute to the effort to improve homeland readiness. We realized these unique capabilities could lead us to making a substantial contribution. We spent a great deal of time collaborating among our medical directors who are on the ground providing health care services to large numbers of people throughout the country and collaborated with the CDC, with ASO, with the county organizations; and indeed, we put together a very large advisory committee, including with inter-

national representatives, to make sure that the design of this particular proposal is rigorous and effective.

What we began with is a process that draws data from plans covering more than 20 million people in 50 States. Since we have begun, and we are only months into it now, several health plans in Texas have been added to the system, and we are in major discussions with national plans all around the country. But I wanted you to get a sense of where we start in terms of a baseline.

Here is how it works. There are five steps. First, there is a criteria established; and I am pleased to tell you, in light of the discussion earlier, that we are in compliance with the NEDSS system, the CDC system. So that's the first thing. You know what you are looking for.

Second, each night a computer program at the participating plans captures clinical encounters for the preceding 24 hours, and it meets those specific criteria. These aggregate—and I want to stress—de-identified data are reported to a research center at Harvard University. The research center has a program that contains specific thresholds for notifying public health of particular occurrences. Now, obviously, I'm oversimplifying in an effort to make this as clear as possible, but there are decision rules in this program that flag certain collections of symptoms.

Fourth, an epidemiologist will then analyze any spikes in information to make sure that the computer program has worked as expected, that we are not overly sampling particular clusters of symptoms, etc.; and the epidemiologist then will coordinate the reporting of a specific disease or illness in geographic areas, the manifestation of those, to the appropriate public health agencies and departments. For example, if the epidemiologist gleans that there are five individuals in a particular geographic area with pneumonia, that might be in compliance with the threshold and that might indicate that is something that needs to be reported. So that would be basically the way the system works.

The public health departments then, my colleagues on the panel, in receiving this information would make a decision as to whether or not that would engender further investigation. Do they need to have more information about particular patients and the symptoms that are occurring in particular geographic areas?

The system has several important features, as you can see. Specific populations are being measured. It is done in real-time. The system can be modified to capture new symptoms. So it's very interactive, if you will, to the extent that—to the extent when SARS became something that was not anticipated when we designed the system, we are now in discussions with CDC in terms of moderating the system and modifying it so we can capture those symptoms as well. The data are already being collected, so we don't have to actually go out and collect new data.

And then, finally, I do want to stress, because of the emphasis in the questioning earlier, that we are in full compliance with HIPPA confidentiality rules.

Health plans have for a number of years been at the forefront of population-based care, and what we are trying to do is to take a leadership role in constructing a system that can be expanded, and we hope that we can make a significant contribution to our home-

land readiness. We have a lot to learn. We think that we can contribute something important, something unique, and we are going to be working very, very closely in our advisory committee with representatives from the organizations who are represented very well on this panel to make sure that the design is adequate and we are doing what we need to do to make sure that we can add a new contribution to the important efforts that were already described this afternoon.

Thank you, Mr. Chairman.

Mr. SHAYS. Thank you.

[The prepared statement of Ms. Ignagni follows:]

Testimony

Homeland Security: Improving Public Health Surveillance

Karen Ignagni
President and CEO
The American Association of Health Plans

Submitted to the
U.S. House of Representatives
Committee on Government Reform
Subcommittee on National Security, Emerging Threats,
and International Relations

May 5, 2003

Good afternoon, Mr. Chairman and members of the Subcommittee. I am Karen Ignagni, President and CEO of the American Association of Health Plans (AAHP). Thank you for the opportunity to be here today to discuss the role of private health plans in the development and operation of regional and national bioterrorism and acute illness surveillance systems. AAHP is the principal national organization representing more than 1,000 health plans which provide coverage for more than 170 million Americans nationwide.

We are excited about the role that health plans can play in national and local efforts to improve America's overall emergency preparedness and response, and protect our homeland from health-related terrorist threats. The Congress, the Department of Health and Human Services, the Department of Homeland Security and other federal, state and local government agencies, as well as the medical and scientific communities, state and local policymakers, and public and private organizations, have been working together to address homeland security issues. A key element of these collective efforts is the integration of all resources that can contribute to the early identification of a bioterrorist event and improve coordination and communication with federal, state, and local public health organizations. Coordination and mobilization of all resources is essential if we are to create and maintain an effective public health infrastructure responsive to potential catastrophic events.

America's health plans are positioned to help advance this coordination of resources because they have unique capabilities to provide real-time data and other relevant information that can be an important part of the development of a national and state emergency preparedness and readiness strategy. These capabilities include:

- Large well-defined populations that allow public health officials to know where illnesses are concentrated (and also where they are not);
- Real-time de-identified data for the early detection of disease clusters, infections or potential biological and chemical exposure;
- Real-time symptom data from health plan nurse call centers;
- Nurse case managers who log valuable information from follow-up medical care, post-hospitalization, health care visits, and home care visits; and

- Rapid-response outbound call technology that can deliver customized public health messages to health plan members, network providers and employers.

My testimony today will highlight the critical importance of strengthening our nation's ability to respond to bioterrorist attacks through effective surveillance systems. I will also review questions that have been raised about passive surveillance systems being prone to chronic underreporting and delays in the receipt of data by public health authorities. Finally, I will discuss the experiences of private health plans that are working with CDC to contribute to the development of early warning health surveillance systems.

The opportunity to strengthen public health surveillance programs

The events of September 11, 2001 and the subsequent anthrax contamination have made the nation keenly aware of the need to be better prepared and responsive to potential future terrorist attacks. The Institute of Medicine's (IOM) Forum on Emerging Infections' 2002 report, *Biological Threats and Terrorism- Assessing the Science and Response Capabilities,* emphasizes the importance of countering bioterrorism with effective surveillance and early detection. Surveillance mechanisms are seen as critical elements in strengthening our ability to respond to a bioterrorist attack. Delays in detection would further spread communicable diseases and prevent or delay the introduction of effective treatment, increase morbidity and mortality, and heighten public fear.

The IOM report stresses that comprehensive surveillance for bioterrorism will require integrating human resources, laboratory resources, and information management in innovative, legal, and acceptable ways that allow for early detection and characterization of threats.

In addition, the Department of Defense identified four key elements of surveillance systems that are needed to maximize patient survival:

1. Facilitating the rapid recognition of a bioterrorist attack;
2. Assisting in determining the site of exposure;
3. Maximizing efficient delivery of targeted (and perhaps scarce) medical countermeasures to the infected population; and
4. Assessing containment and mitigation.

The expansion and improvement of early warning systems for bioterrorism will likely have the additional benefit of strengthening the public health infrastructure for detection of naturally occurring infectious disease outbreaks as well as new emerging diseases. The advantages of this improved public health surveillance is a theme heard throughout the public health community and reinforced by the Director of the Centers for Disease Control and Prevention (CDC), Julie Gerberding, MD, MPH, who commented last year on the demonstrated benefits of bioterrorist planning and funding in improving the surveillance and public health response to West Nile Virus. Such systems can be utilized or easily modified to track and alert public health officials about other infectious disease outbreaks such as Severe Acute Respiratory Syndrome (SARS).

While we know the importance of early warning systems to our nation's domestic readiness effort, there are significant challenges ahead. The General Accounting Office's (GAO) recent report, *Infectious Disease Outbreaks-Bioterrorism Preparedness Efforts Have Improved Public Health Capacity, but Gaps Remain*, suggests that public health surveillance programs, especially those capable of detecting possible bioterrorism attacks, are "inadequate." The GAO's report emphasized that state and local public health authorities rely primarily on passive surveillance systems that are prone to chronic underreporting and significant time lags between diagnosis and receipt of the data by public health authorities. Initiatives underway by public health authorities to develop active electronic surveillance systems have largely focused on hospital and emergency rooms where access to data has been challenging, the number of institutions that must develop customized surveillance procedures is large, and the uncertainties about which hospitals serve specific communities are problematic.

The GAO found that the level of preparedness in states and cities was varied, and generally lacking in terms of regional planning. States and metropolitan areas are focused on their specific populations, but there is little coordination across regional areas or state lines. Since infectious disease (naturally occurring or deliberately spread) knows no jurisdictional boundaries, the lack of regional and/or national surveillance capacity represents a significant gap in our current level of homeland security.

Challenges to improving local, state, federal, and international health data collection and reporting

Infectious disease is mobile, and prior to an onset of symptoms, *invisible*. The recent Severe Acute Respiratory Syndrome (SARS) and West Nile virus epidemics have illustrated the advantage of uniform cross-border and cross-region health data reporting and analysis, and the danger of restricting or limiting that flow. Collaborations on a variety of fronts will be needed to establish "best practices in real-time surveillance" that can be integrated and applied in a myriad of settings required for effective detection of possible bioterrorism events. None of the systems currently being developed are likely to be adequate in and of themselves. The best solution will probably be a "system of systems" that is sensitive enough to detect specific conditions and even small outbreaks.

Collaborations among various levels of government (federal, state and local) and the private sector will help to prevent and provide earlier detection of potential bioterrorist attacks. Active public health surveillance systems designed by the private sector utilizing sophisticated data collection and computerized modeling programs are currently being developed for specific diagnosis and symptoms (e.g., influenza-like illness) and are being rapidly adapted to meet the challenge posed by the threat of bioterrorism. This work can be leveraged to meet the needs of homeland security. There is a necessary tension between the desire for a "uniform" system and the advantages of developing a variety of approaches that will lead to effective options that meet the wide-ranging needs of the international public health community and homeland security, as well as the local public health authority.

Private health plans are working with the CDC to contribute to the development of early warning health surveillance systems

Soon after the tragic events of September 11, we began discussions with our member plans about their skills and experience and how we could leverage that to contribute to public health preparedness. In our fact finding process, it became clear that health plans had a unique set of skills and competencies based on their integrated care coordination systems, large defined populations and comprehensive data sets that could provide a substantial public health benefit. Our community

realized that we should be an important component of an early warning health surveillance system. Much of this information includes coded diagnoses in automated medical records, information collected by telephone assistance/triage centers, and other data (automated vital signs, encounter clinician notes, laboratory data, etc.). This type of information is sufficient to identify, within a day, at least some new clusters of respiratory, gastrointestinal, neurological, and other illnesses experienced by health plan members.

Once our community identified its potential contribution to homeland readiness, we began discussing how we could help support the work of the CDC. This resulted in the collaboration of several health plans and AAHP with CDC to create a national bioterrorism syndromic surveillance demonstration program that utilizes existing automated data maintained by health plans covering more than 20 million people in 50 states. The primary goal of the program is to develop and implement standards, protocols, infrastructure, and analytic tools for detecting and reporting unusual geographic and temporal clusters of symptoms or complaints of acute illness that might represent the initial warnings of a bioterrorism event. The initial work to develop and evaluate the effectiveness of an early warning health surveillance system is being funded through a grant from CDC.

The national demonstration program involves AAHP, and four health plans or physician groups – Harvard Pilgrim Health Care/Harvard Vanguard Medical Associates (Massachusetts), HealthPartners (Minnesota), Kaiser Permanente Colorado, and UnitedHealthcare's nurse call center, Optum. Through additional funding from the Texas League of Health Departments, Scott and White Healthcare System (Texas), and the Austin Regional Clinic (Texas) are participating in the demonstration project and are included as additional sites providing data to the project.

The demonstration program includes a rapid response capability to identify unusual clusters of symptoms or illness from daily encounters, to notify the right public health officials of these clusters, and to facilitate the ability of public health officials to obtain detailed clinical information about specific cases when needed. Health plans report only aggregate de-identified data to the surveillance system – counts of episodes of illness or symptoms within specific geographic areas – thus providing maximum protection of patient confidentiality. In cases where unusual clusters are identified, the state or local public health team will decide if additional information is needed. This

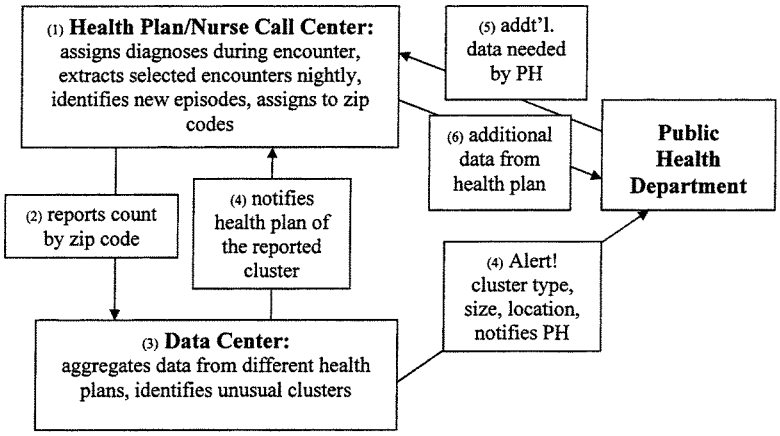
system is being developed in a manner that will facilitate the participation by other health plans and medical groups that possess real-time encounter level information.

Diagnoses recorded during routine ambulatory care, including office visits and nurse telephone triage calls, may provide important information on disease outbreaks before their occurrence is detected through emergency room visits, or hospitalizations. For instance, evidence suggests the increase in winter respiratory illness in a community can be detected two weeks earlier in the ambulatory setting than through hospital admissions. The operation and use of nurse telephone call centers may dramatically improve the early detection of bioterrorism and infectious diseases. Professionally staffed call centers provide symptom triage, health information, case management, and care coordination for health plan enrollees. These call centers are local, statewide and national in scope and operate extended hours – many operating twenty-four hours a day, seven days a week. By utilizing the available ambulatory care and nurse call center data, health plans are in a unique position to identify the earliest indicators of sentinel bioterrorism events or emerging infectious diseases.

Health plans participating in the study disclose health information to a research data center which in turn analyzes the information and identifies unusual clusters of medical events, such as a concentration of a specific disease or illness in a geographic area. This system is based on one created by investigators who have dual appointments at Harvard Pilgrim Health Care/Harvard Vanguard Medical Associates and Harvard Medical School, in collaboration with the Massachusetts Department of Health through an earlier bioterrorism preparedness grant from the CDC. This demonstration initiative takes advantage of the health plans' ability to use their existing automated data systems to rapidly identify health plan members that may be part of an important disease cluster. Typically, each night, a computer program at the participating health plan extracts the clinical encounters for the preceding 24 hours that meet any of more than a thousand specified criteria, such as cough, fever, or a rash. These criteria and their associated disease groupings (syndromes) were developed in collaboration with the CDC and the DOD. The system then eliminates visits for illnesses that had previously been identified, and links the relevant information about the new illnesses to the individual's zip code. The health plan's information system then sends a daily report to the data center using secure Internet communications.

The disclosure of information to the data base is pursuant to research waivers obtained from health plan Institutional Review Boards (IRBs) or privacy boards. The privacy rule allows disclosure of health information for research projects either by written authorization or by a waiver of the authorization requirement approved by an IRB or privacy board. This daily report lists only the aggregate count of new illnesses or symptoms in each zip code, thereby affording important privacy protections. The data center combines reports from different health plans and searches for unusual clusters of different syndromes (respiratory, gastrointestinal, etc.). The system takes into account factors such as seasonal occurrences, day of the week, and other factors that influence the number of complaints and cases cared for on a particular day. It also takes into account past information about patterns of illness and health care delivery in each zip code. Because the number of health plan members in each area is known, it is possible to adjust the observed counts of the new illnesses and consider the number of people who are at risk for being affected. Because this work is automated, many thousands of possibilities are analyzed. It would not be possible to do this cluster detection work manually because the numerous mathematical computations would be too difficult.

The decision rules built into the automated system allow the data center, a research unit of Harvard Medical School in the Brigham and Women's Hospital, to determine whether the number of cases is sufficient to warrant notifying the relevant health department about the type, size and location of the cluster. The data center uses aggregate information to inform public health departments that, for example, there are four people with pneumonia in a particular zip code. In general, the disclosure of aggregated health information by zip code is not identifiable information subject to the privacy rule. The public health department is informed about who to contact at the health plan to obtain additional information about individuals who are part of the cluster, and their illness. The data center will also notify the health plan about the information reported to the public health department and direct it to review the relevant clinical records, which are always stored and maintained at the health plan.



These communications between the public health departments and the health plans are covered by existing public health reporting laws and are consistent with the confidentiality protections of the HIPAA privacy rule. This enhanced collaboration between health plans and public health organizations builds on existing relationships and a long history of reporting information to public officials when a public health problem is identified. Because of this new early warning health surveillance system, we have the ability to identify illnesses that otherwise would have been missed and report them much earlier.

In summary, the new system has several valuable features from a public health perspective:

- health plans provide coverage to over 170 million Americans; many have some electronic information, e.g. nurse call centers, that could be useful for this type of surveillance;
- the source population will be known, which allows greater flexibility for detecting illness clusters than is possible when only the affected individuals are known, as is the case for most systems based on emergency room visits or hospitalizations;
- it is relatively simple to modify the syndrome definitions or to create new syndromes when new potential threats may arise, because the health plans retain diagnosis-level data and other information that may easily be added (for example, we are now working with CDC to modify the system to help identify SARS outbreaks);

Mr. SHAYS. Before asking Mr. Janklow to begin his questioning, I am just going to make an observation. I made the analogy of Kmart, and my counsel said the challenge is—I'm not sure I'm doing it justice. But it's if Kmart had to get a lot of mom and pop operations into their network, they might not be able to do it in real-time. And I thought that is very intuitive, I think.

One of the things that I'm noticing with health care is that—I use the word stepchild as if stepchild is a bad thing, but not always getting the attention that it deserves. We did one major tabletop experience in Bridgeport, and the fire, the police, they all—there were weaknesses in the connection, but our local health care providers were really caught without communications, without resources, and so on.

So maybe what I'm hearing from the panelists are, my gosh, this is where we were and this is where we are, so we have made such great progress. But I think, in terms of the consequence, if there was an induced terrorist activity planned, located in certain ways, that we wouldn't be happy with the results. So that's kind of where I'm—I'm kind of wrestling with this, because I feel like there is almost a sense of contentment on the part of our panelists because we have made a lot of progress.

Mr. BELL. Mr. Chairman, Kmart also went bankrupt. So I don't know if that's really one that we want to be using.

Mr. SHAYS. That was another one, but then my staff spared me that analogy since I was the one who brought it up. And I will just say, Ms. Ignagni, I gave you the opportunity to be right with the chairman, and you declined.

Ms. IGNAGNI. But, sir, you swore me in.

Mr. SHAYS. That's true, I did. What a good answer.

You have the floor.

Mr. JANKLOW. Mr. Chairman, thank you very much.

You know, I've—the hearing today, Homeland Security: Improving Public Health Surveillance, you know, and I recognize that public health surveillance, adequately done, truly contributes to homeland security. But I want to focus my questions, if I can, to the war on terrorism, you know; and I realize that, with respect to West Nile and SARS and hepatitis and measles and mumps and rubella and polio and I mean all kinds of other reporting things, the system works pretty good.

When I say pretty good, I am making that with a small P and a small G, because, Dr. Foldy, I couldn't agree more with you: Because we are a Nation of 1,700 different sovereigns all the time, nobody is going to tell me what to do. So we have thousands of people that feel that way, and so that's why some are in paperwork and some aren't even reporting, and I think it's far worse than some of our colleagues at CDC think it is.

But I'm going to focus on homeland security, if I can. World War II from start to finish for us took 3½ years. How many years is it going to take for us to design a reporting system that will catch deliberate acts of terrorism? Because if the good Lord doesn't or nature spreads diseases around, there's a pattern that WHO, that the whole world can figure out rather quickly. It's when human beings are deliberately helping the process move that we have never really

been tested, ever, as to whether or not we have the ability to deal with it.

Doctor, let me ask you first. If 1993 were replicated in Milwaukee, you would be on top of it in literally minutes if not hours, if not minutes. Isn't that correct?

Dr. FOLDY. That's correct.

Mr. JANKLOW. And I have to believe throughout this country there are processes all over. What does it take to get them together to come up with a system? And you are next, Ms. Selecky.

Dr. FOLDY. I have little doubt that a deliberate act of bioterrorism would be detected within days. We've done things like make sure doctors know what they are looking for, make sure labs can do——

Mr. JANKLOW. But I'm talking about process, sir.

Dr. FOLDY. But what we want to do is shorten that window to hours——

Mr. JANKLOW. Can it be done without mandating it in some form? And I don't know if States do it or counties do it, the Federal Government does it. But isn't it possible to really get from here to there in a—recognizing a world war, is it possible to get from here to there during the war without mandating something?

Dr. FOLDY. I'm sure there will be mandates. I would add to those mandates, helping the health care sector move from paper and pencil to electronic——

Mr. JANKLOW. Isn't that the most important thing?

Dr. FOLDY. The latter? Yes.

Mr. JANKLOW. Yes, sir.

Do you agree with that, Ms. Selecky, that the most important single criteria is how do we get from paper to electronics?

Ms. SELECKY. I would add a criteria that has to do with the knowledge base of the people who are using——

Mr. JANKLOW. I agree with that. I understand getting the right people and training them. I appreciate that. But is that—is there anything—let me put it this way. Is there anything more important than the ability to get it from paper to electronics?

Ms. SELECKY. When we think about the health care system in this State, in this Nation, you look at relying on a local clinician, whether they are in a community clinic or a private office, to get the word to a local health department. And——

Mr. JANKLOW. And that's under the normal system, the way nature spread diseases.

Ms. SELECKY. Well, even under a bioterrorism event. Actually, the city of Seattle and the city of Chicago this next week will be participating in TopOff2, the top officials exercise. I just spent my morning with the Federal Cabinet in preparation for the work that will go on. In Washington State it will be a radiological——

Mr. JANKLOW. Can I interrupt you for 1 second? You are getting prepared for that tabletop. When they hit you with terrorism, you're not going to have—you're not knowing it's coming, what day, what hour, and what teams to assemble.

Ms. SELECKY. No disagreement. And these aren't tabletops. We actually are doing exercising. And you are right, we do have information ahead of time. The point is, where are the flaws in the system or the weaknesses.

Mr. JANKLOW. OK.

Ms. SELECKY. The learning from this is what's essential in that whether——

Mr. JANKLOW. Will that be shared with people all over the country?

Ms. SELECKY. Yes, the results of that will be. Yes.

Mr. JANKLOW. OK.

Ms. SELECKY. In terms of the communicable disease, for example, that will be used in the Chicago venue—and it will be pneumonic plague—it's a matter of what systems are in place, are people reporting electronically now? No, not everywhere; and it will be as important in a rural area as it will be in an urban area.

Mr. JANKLOW. Excuse me for a second.

Ma'am, you look shocked. You are sitting there looking at me shocked. Is there a reason? Ms. Ignagni.

Ms. IGNAGNI. Well, I didn't mean to interrupt. But you did read me correctly. And it's not shock. It's I think that there is something in addition to the electronic issue. But I would be happy to wait until our colleagues finish answering their question. But you registered my being perplexed as I was thinking about your question. I think there is something that we have been missing all afternoon, frankly. But I don't want to be rude and interrupt your——

Ms. SELECKY. No. If you've got it, go for it.

Ms. IGNAGNI. Well, no. I don't know if I have it. I wouldn't want to be presumptuous. I'm the only one on the panel that isn't a physician. But in my humble opinion, in looking at the reports by the Institutes of Medicine, the General Accounting Office, the World Health Organization reports, where we are going wrong in our country in terms of bioterrorism readiness is that for too long we have thought of the health care system as what happens in the hospital.

Now that's a very important part of the health care system, but I can tell you that what we did—and we're just beginning our demonstration program. But we did a dry run in Massachusetts, and what we found is that people were reporting symptoms into our system a full 2 weeks before people ended up in the hospital. So, sir, when you asked the question is there something more important than electronic, I was sort of shaking my head and intuitively going through all this information. And I didn't want to sound presumptuous in sharing with the committee the idea that I do think the comments that have been made, particularly by the GAO about their reliance on passive reporting, is something that we really have to get our hands on and we have to figure out how do we go to real-time. It's not just about electronic, though.

Mr. JANKLOW. If I could ask that the three of you from American organizations, and just whoever wants to answer first or only—be the only one, what do we need to do to fix this? If your children's lives depend on it, your neighbors' lives depen on it, is this a congressional fix? Is it a Presidential fix? It is a health community fix?

I've heard people say that lawyers and judges can't fix what's wrong with the legal system, and that doctors and hospitals can't fix what's wrong with the medical system. It takes outsiders who have a different perspective, who are really not the producers but the consumers that contribute.

Let me ask you. What does it take to fix this? Because we are all frustrated.

Dr. FOLDY. Well, until the information can flow rapidly, we are missing an essential part of the fix. Ms. Ignagni brings this up.

The next point, which is do we really know—there is a lot of science that needs to be done and needs to be done ideally——

Mr. JANKLOW. You said—I think your quote was, young science easily oversold.

Dr. FOLDY. So, for example, she raises one of many very interesting and answerable questions: What part of the health system or other human behavior——

Mr. JANKLOW. OK. But, sir, how do we get there?

Dr. FOLDY [continuing]. Serves as an early detector.

Mr. JANKLOW. We are in the third year of the war. How do we get there? How do we wind this up?

Dr. FOLDY. I would like to see a lot of the best people in Federal agencies, including the different agencies within the Centers for Disease Control, be given an office and some money and some contact with the best people in informatics, intelligence, Defense Department, even financial systems. I mean, I can draw cash out in Taiwan, but I can't see surveillance figures in my own den. And there is a lot that can be learned quickly if people can be brought together, apply sustained attention to the problem over the next few years, while having—starting to get the electronics information that——

Mr. JANKLOW. If I could ask you, sir, if you would just submit to the committee a list of who you think ought to be at that table by organization.

Dr. FOLDY. My local perspective, and therefore very imperfect perspective.

Mr. JANKLOW. Sure.

Dr. FOLDY. Yes.

Mr. JANKLOW. Ours is perfect, sir. Yours isn't. No, we understand that. In the most base sense, we all understand that.

But if you would, because you can tell by our questions, all of us, we don't know what to do, but we don't think what's being done necessarily is working. If someone is going to attack us tomorrow, are we ready? The answer is, no, we are not if they are going to be spread around—if they were to spread this around. We have seen what hoof and mouth disease can do to Europe, to the livestock industry. I can't believe that something wouldn't be akin to human beings if they had the same type of disease for people. I know they do have that one, but I'm not talking about Banks disease.

Thank you, Mr. Chairman.

Mr. SHAYS. I would just point out, though, that's one form of terrorism; and that's not just the attacks on human beings but the attacks on livestock could be devastating.

Mr. Bell, you have the floor.

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

First of all, Dr. Shelley Hearne could not be here to testify today,

and I would ask unanimous consent for her written testimony to be submitted for the record.

Mr. SHAYS. Without objection. And she is with——

Mr. BELL. Trust for America's Health.

Mr. SHAYS. Thank you.

[The prepared statement of Dr. Hearne follows:]

Testimony of Shelley A. Hearne, DrPH
Executive Director
Trust for American's Health
Washington, DC

Regarding Homeland Security: Improving Public Health Surveillance

Submitted to the
Committee on Government Reform
Subcommittee on National Security, Emerging Threats, and International Relations
United States House of Representatives
May 5, 2003

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to submit testimony on the importance of improving public health surveillance as an essential step toward bolstering our homeland security. My name is Dr. Shelley Hearne, and I am the Executive Director of the Trust for America's Health (TFAH) and the Chair of the American Public Health Association (APHA) Executive Board. TFAH, a nonprofit, non-partisan advocacy group, is dedicated to protecting the health and safety of all communities from current and emerging health threats by strengthening the fundamentals of our public health defenses.

A strong public health defense begins with disease surveillance, which is why today's hearing is so important. Public health surveillance, also known as health tracking, not only helps us monitor and mitigate potential chemical and bioterrorist attacks, but also is crucial to unlocking the mysteries behind chronic and infectious diseases. Tracking disease is one of the most vital weapons public health officials have in the fight to prevent and control threats to the country's health.

Public health surveillance is defined as "the ongoing, systematic collection, analysis and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know."[1]

A comprehensive disease tracking system monitors the occurrence of disease and can inform the rapid identification of outbreaks or "clusters" of cases and analysis of geographic variations and temporal trends. With this information in hand, public health investigators can search for the sources and routes of exposure to determine why the outbreak occurred, how to prevent similar outbreaks in the future, and, if the outbreak is ongoing, how to prevent others from being exposed. Concurrently, action must be taken to control the spread of the disease and minimize further illness and death, even when clear cause and effect have not been fully identified.

[1] Thacker, S.B. and Berkelman, R.L. Public Health Surveillance in the United States. Epidemiology Review. 10: 164-190 (1988).

The public health community overwhelmingly agrees: health tracking works. Unfortunately, up until now, we have lacked the resources and national resolve to make effective, comprehensive health tracking a reality. The new threats of potential chemical and bioterrorism, combined with emerging health crises like severe acute respiratory syndrome (SARS) and West Nile Virus, mean that health tracking is even more essential. Now is the time for Congress to make it a national priority.

Even limited health tracking efforts have already helped us make advances toward improving the health of communities. For example, through health tracking information, we have been able to better understand how West Nile Virus is spread.

The good news is that as we are working to prevent these possible and emerging health dangers through public health surveillance, we can put this same tool to work to curb and control existing chronic disease epidemics, from cancer to asthma to diabetes. Seventy percent of Americans will die from a chronic disease. At the same time, according to the Centers for Disease Control and Prevention (CDC), approximately 70 percent of these illnesses are preventable through strong public health measures.

As we work to improve public health surveillance efforts, we must also realize that our entire public health system is in urgent need of revitalization and modernization. It is no secret: the current system is painfully under prepared to meet the public health threats that Americans face today.

In the past, the U.S. public health system served as the world leader in stamping out diseases like yellow fever, typhoid, influenza, and cholera. Just as the world is looking to our country for leadership in the war against terrorism and the worldwide SARS epidemic, the United States also should be at the forefront of the global war against modern disease.

Instead, we find our public health defense system ailing: the 2001 CDC report *Public Health Infrastructure* stated the current U.S. public health infrastructure "*is still structurally weak in nearly every area.*" The report calls for a system of "public health armaments," including a "skilled professional workforce, robust information and data systems and strong health departments and laboratories."

In a separate report, the General Accounting Office (GAO) found that "the 1999 West Nile virus outbreak, which was relatively small, taxed the federal, state and local laboratory resources to the point that officials told us that CDC would not have been able to respond to another outbreak had one occurred at the same time." According to the GAO report, coordination between state, local and federal authorities, communication systems, disease surveillance, staffing and laboratory capacity are areas that require immediate improvement.

In order to provide public health surveillance that bolsters homeland security, we must focus on: national authority and commitment to disease tracking standards and reporting systems; rapid communication links with all health agencies, hospitals, first responders and laboratories; modern and compatible equipment; and a trained workforce. Sadly, many of these elements are missing currently. Consider:

- The lack of national coordination -- mandated standards, support and enforcement. CDC does not have a command and control mentality with respect to surveillance. The most recent example is the agency's unwillingness to require that SARS be considered a reportable disease in every state. In fact, most of the nation's disease tracking systems

suffer from the lack of national standards and uniform structures, resulting in a patchwork approach to surveillance. Often, the CDC is in the unenviable position of having to cajole state health departments to provide important data about cancer, birth defects, and many other chronic diseases and conditions.

- The data collected may never be analyzed or disseminated. The 2001 Pew Environmental Health Commission's *Transition Report to the New Administration: Strengthening our Public Health Defense Against Environmental Threats* found that there is virtually no "synchronization in the collection, analysis and dissemination of information. In addition, much of the data that is collected is never analyzed or interpreted in a way that might identify targets for further action."[2]

- Inadequate resources. At a time when the public health system needs substantial investments and a 21st Century overhaul, the Administration had proposed over $100 million in cuts to the CDC budget for FY 2004. At the same time, state budget deficits are leading to massive cuts in chronic and infectious disease prevention, putting vital programs at risk and there is no way for the CDC to fill those gaps.

Together, these factors present a dangerous and, frankly, unacceptable way to watch guard the health of the nation. The result is that our public health and homeland security face serious risks.

Public health officials know how to reduce these risks: watchfulness, rapid response, research and action are the trademarks of an effective, responsive public health system. The response of the CDC to the global SARS epidemic is testament to why a coordinated public health game plan can and will save lives. At the same time however, it is important to note that SARS has barely touched U.S. shores, so the preparedness of the entire public health system --local and state health departments, hospitals, and laboratories--remains largely untested.

In fact, it is worth remembering that the anthrax attacks in Fall 2001 exposed and exacerbated the weakness in the public health infrastructure. Lack of a national response plan and deficiencies in our public health apparatus made a terrible situation even harder to manage.

While improvements are urgently needed in virtually every aspect of the U.S. public health infrastructure, Congress can and should take these immediate steps:

- Increase funding for the Nationwide Health Tracking Network to $100 million. We are encouraged that in the Administration's budget request to Congress calls health tracking a "major focus" of its environmental health program. We are equally encouraged that the Congress has taken the lead in providing initial funding for the Nationwide Health Tracking Network in Fiscal Years 2002 and 2003. It's time to take this critical surveillance tool to scale. A fuller description of a Nationwide Health Tracking Network is described in Attachment A.

- Substantially increase funding to enhance the information and communications systems related to public health surveillance. Specifically, provide full funding for the National Electronic Disease Surveillance System (NEDSS), which serves as CDC's architectural backbone of surveillance. As former CDC Director, Dr. Jeffery P. Koplan wrote in 2002,

[2] Pew Environmental Health Commission. Transition Report to the New Administration: Strengthening our Public Health Defense Against Environmental Threats. Johns Hopkins School of Public Health. Baltimore: 26 (January 17, 2001).

"As the initiative [NEDSS] proceeds, it will reshape the way public health is practiced with unprecedented access to high-quality and timely surveillance data.[3]

- Chronic under-funding has led to a network of health agencies that have trouble communicating with each other, let alone with the public. As we have learned with SARS, communicating with a shaken public is key to alleviating natural fears that arise with an emerging illness. The Health Alert Network (HAN), a federally coordinated system between the CDC and state/local health departments, has the potential to fill this current communications gap. By using advanced technological tools, HAN will allow for real-time coordination in situations where even seconds matter. HAN plays a vital role in the nation's state of readiness and timetables to completion and activation must be accelerated and linked to state and major metropolitan health departments.

- Given the importance of CDC for protecting the public's health, restore at least FY 2003 funding levels to all programs at the CDC. The proposed cuts are unwise at a time of a global epidemic caused by "Mother Nature" and in light of potential biological and chemical terrorist attacks.

- Ask the Department of Health and Human Services to convene a national summit on the future of the American public health system and the resources needed to build a robust, integrated 21st Century infrastructure that can play a "double duty" role by enhancing preparedness for the full spectrum of health threats from chemical terrorism to cancer and from biological attacks to birth defects.

Mr. Chairman, the unimaginable happened on September 11, 2001 -- an act of intentional terrorism on American soil. The unimaginable struck again in the past few months with SARS outbreak -- this time an act of nature. An effective public health defense requires us to be prepared for the epidemics we already know and those we have yet to imagine. Health tracking and reviving our public health system are vital to our nation's security. The health of the American public deserves no less.

Thank you again for the opportunity to submit this testimony on behalf of Trust for America's Health.

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[3] Baker, Edward L. and Koplan, Jeffery P. "Strengthening the Nation's Public Health Infrastructure: Historic Challenge, Unprecedented Opportunity," Health Affairs, Volume 21, Number 6: 16 (November/December, 2002).

ATTACHMENT A:

Fundamentals of the Nationwide Health Tracking Network

1. *Establishing essential data collection systems for chronic diseases and conditions and potential links to environmental factors:* The network would build on existing health and environmental data collection systems for infectious diseases and ensure uniform coverage in all 50 states.

2. *Developing an Early Warming System:* A network would serve as an Early Warning System to alert communities immediately of health threats to the population. The same system used to alert officials in the event of a terrorist attack could also help in detecting possible disease clusters.

3. *Creating Rapid Response Teams:* Such teams able to deliver instant information are crucial to communities in crisis. The network would coordinate federal, state, and local health officials to quickly investigate situations of concern.

4. *Addressing Unique Local Health Problems:* The seventeen states and cities and three Centers of Excellence established through the 2001 health tracking funding serve as excellent models for a broader Nationwide Health Tracking Network. Local and state health departments are often the first line of defense in protecting the health of communities.

5. *Creating Community and Academic Partnerships:* Relationships with communities and academic centers will help ensure that data collected is accessible and useful on a local level. Collaborating with research groups will aid in training the local workforce, analyzing data, and developing links between tracking results and preventative measures.

Mr. BELL. I want to go back for just a minute to this idea that was discussed with the previous panel of trying to create one unified system for reporting; and you all, I think, were all present during that testimony. I'm curious as to where you would rate the importance and if you are as troubled as I am by the fact that we at the present time don't know how much it would cost and really don't have any time line for getting there, and the amount of money being committed toward spending on that type of surveillance system is decreasing rather than increasing. And I will begin with you, Ms. Selecky.

Ms. SELECKY. As the other nonphysician on the panel and a person of great practicality, as many of us are, the issue is that we really don't have sort of a uniform system like you would call a Kmart, regardless of whether they went bankrupt or not. There are multiple plans, they're private and public, and having a one system fits all doesn't cut it in this country very often. That's why I think that you hear us talking about common standards so that the information that's collected can speak and give us the information that we need to take quick and rapid action. That's one.

Two, I think that your colleague who was here earlier talked about a reporting system in southwestern Pennsylvania that's been under development, that works there, works under the State laws of the State of Pennsylvania, is a good model for many of us to look at as to whether it would work in Washington State or in other States, and learn the best things from it, as long as we all have the common format of reporting in a way to get the information again real.

In Washington State, we still have very rural parts of the State that don't have Internet or electronic reliable capability, so that we do have to have redundant systems. And you would falsely rely on the ability for everybody to have access to T–1 lines, etc. We are not the only State like that. There are other rural States like that, also. Cell phones don't work in many places. Fax machines usually can be relied on. The Internet goes down when that backhoe digs up the one line to Ferry County or whatever the case is. So we have got to make sure that we continue to work on what the reality is.

The reality is, are people informed at the closest level to where a client shows up with a symptom, be it at a doc's office, a clinic, or an ER—is that person informed to get that information to the folks who need to have it at the local level, as they see increasing activity get the information to the State level and we work together with the Feds? We would all like to have it done in that real-time, rapid way that allows us to rely on the electronics. But having experienced the earthquake in Washington State, we could not then rely on the electronics. We did have to rely on the person-to-person reporting. You've always got to have both of those things in place.

So by virtue of the fact of making sure that what's in place now works, that you parallel, then grow it up, the infant system Seth talks about that needs to be developed across the Nation with common standards, that would be my goal.

Mr. BELL. Dr. Foldy.

Dr. FOLDY. I think this was well summed up. I do sometimes—and I'm not a software engineer—but I do sometimes look at the

way the Internet was able to develop. Nobody could figure out ever to design something that is like the Internet, but once people learned that they were going to—that they had the benefit of communicating through a few very simple standards so that it didn't matter what kind of computer you were on or what kind of browser you were using or anything else, the kind of capabilities that developed out of that were very great. So I have some hope for that.

I do think that Ms. Selecky's points are very well taken about not overestimating the capability of the people in the field at either the State or the local level. I hasten to remind the committee that, prior to Congress creating specific health alert network funding that was earmarked to local health departments, the majority of health departments had no Internet connections in this country. We do have a severe backlog of information infrastructure and people development, bringing them along both in terms of skills, technical, epidemiological, and laboratory in our local health departments. It is not impossible—it is impossible to overlook that deficiency, because there is no State or national organization that has the people to fill in where local health departments need to play their role. So you are looking also at strengthening the infrastructure at the local level so that a lot of information isn't simply released that results in an inadequate response.

Mr. BELL. Dr. Hall.

Dr. HALL. I think the most important thing, as I said before, is about commitment and also about capacity. I think that the most important take-home message really is that a disease occurring anywhere in the world within hours can affect any other country around the world. And when we have a map that looks like this, the very back of the written statement, where we have great big holes in terms of surveillance around the world, then nowhere in the world, no matter how good their national reporting and surveillance system is, is going to be safe from the threat of infectious diseases.

So I think it's about investing in capacity, both in the countries that already have some in terms of improving the capacity they have but key to it is investing in capacity in areas where there simply is nothing, where we would not be able to—it would take a very long time before we detected that a problem was emerging in that area. And it's about investing in the commitment to that and investing in the commitments of transparency in terms of reporting from all those countries and constantly building up capacity so that all around the world we at least have a basic minimum level so that we can find out exactly what's happening.

Mr. BELL. And Ms. Ignagni.

Ms. IGNAGNI. Thank you, Mr. Bell. We crossed this bridge as we were developing our demonstration program, and we would not have developed it without a consensus on what was being measured, how we were going to measure, and how we were going to retrieve data. It simply wouldn't provide anything that was useful. And that's caused me to listen to my colleagues, and I think the comments have been very, very thoughtful, and I largely agree with them.

I do think, however, there is an opportunity to achieve uniformity in a productive way here without necessarily killing the innova-

tion and the public health kinds of activities. You'd want to be nimble at the local level, and I think that's—if I could draw out what I heard—while at the same time having some consistency across different systems and States to measure, because we know that there are no geographic boundaries for infectious disease.

Our community has committed to transparency. We are the only stakeholders in the health care arena measuring anything, which may surprise you in light of 5, 6 years of discussions about so-called patient protection. We are not measuring in any other areas. So for us, perhaps we crossed this bridge a long time ago, and we have consensus in our community about measuring. But I do think it's important now to think about drawing that out across the delivery system and particularly in this area.

Mr. BELL. Ms. Selecky and Dr. Foldy, a number of national associations and organizations, one being the American Public Health Laboratory Association, have found that financing for many State health laboratories would be reduced this year and that few cities had enough hospital space to quarantine patients in the event of a large-scale outbreak of an infectious disease like SARS. I'm curious if you share those beliefs; and, if so, what recommendations would you make to rectify the situation.

Ms. SELECKY. The answer is, yes; and the recommendation is continued and increased support to State and local public health is absolutely needed from Congress. This is not about a part of the body disease. It's not about a singular kind of action. It's about the investment in the public health system. Our laboratories need to have up-to-date information but up-to-date equipment.

Technology changes quickly. What used to take days to grow a culture on now can have rapid testing within hours. We've got to have those kinds of investments. The bioterrorism preparedness money helped us make a major shift, but there needs to be continuation on that and particularly our work with our facilities. You know, our hospitals in this country have come down to a much smaller operating margin. There isn't much room available for the emergency kind of planning that goes on.

Again, Congress has done some investments. We in public health at the State and local level are working very closely, for example, in Washington State, with our 91 hospitals to work at the community level to deal with surge capacity. You don't make beds overnight, but you can work on plans how to deal with people if you have a major event.

Mr. BELL. Dr. Foldy.

Dr. FOLDY. I would concur. I would also add that issues like isolation are particularly thorny for local government. I believe that Wisconsin is typical of many States where the responsibility for bearing the cost of isolation lay in the local jurisdiction, which means that a single case of tuberculosis can wipe out the budget of a small health department overnight. It seems somewhat ridiculous. Those kinds of costs need to be socialized in some manner over a larger territory than the small local jurisdiction.

Mr. BELL. Thank you, Mr. Chairman.

Mr. SHAYS. I thank the gentleman.

Dr. Hall, when I look at that map at the back, it has surveillance of human influenza. And I look at India and it has one—I guess

just greater than one laboratory. But how many? Not many? It's not a network. Is that your point?

Dr. HALL. Yes. I mean, what's missing there is, yes, a national network so that all areas within that country can be detected, that some polls can be taken from patients and that they can be assessed and evaluated properly.

Mr. SHAYS. I look at the two largest in terms of population, China and India, and that they don't have a network system yet. Walk me through really—I'm not looking in great detail, but I will tell you I am somewhat haunted by—maybe others as well, but this was one story, the story of the mom leaving Hong Kong, going to Toronto. She's infected. She dies. Her son dies. I mean, what a horrible—not only do you lose your life, but someone who you brought into life loses their life. And that could have been prevented—correct—had we known sooner in China, had China participated sooner and acknowledged the problem, correct?

Dr. HALL. Well, certainly what we have seen is that within 24 hours of that occurring, of the cases landing in Toronto, WHO put out a global alert. And since the global alert, because of the heightened vigilance all around the world, with the exception of Taiwan we haven't seen that rapid transmission of disease anywhere else. So, yes, the early detection and the early release of information and the heightened vigilance that has occurred has meant that, while cases have occurred, say, in the United States, they are isolated cases, and we haven't seen that level of transfer.

So that the real lesson of SARS is that the more transparent countries are, the quicker they report the cases, the quicker the international assistance can get there to look and help with the diagnosis if that's necessary, then the greater the window of opportunity for the rest of the world to be able to protect themselves against these diseases that can in a matter of hours fly around the world.

Mr. SHAYS. Right. What I'm trying to sort out, though, is we up on the panel are thinking we could do so much better. But you say we have a network; and we are looking at this network and saying, it could be so much better. Correct?

Dr. HALL. Um-hmm.

Mr. SHAYS. So even when I look at the dark-colored parts and all of Russia and the Scandinavian countries and most of Europe, I'm looking at some of the European nations I guess not—I am—you do agree that, when you look at this network, this network could be so much better. Correct?

Dr. HALL. Absolutely. Yes. I mean, it's just an example of just the FluNet, but it's pretty reflective of surveillance on the global level for virtually any disease.

Mr. SHAYS. When you talked about early detection and early intervention. And I think that's kind of where my colleague Mr. Janklow and I are wrestling, as well as Mr. Bell. The question is, we have a system now that may not provide for early intervention. When you look at those countries that have a network, what don't they have? In other words, you could compare to the network ones and say, compared to China and India, you know, they are way ahead. But what don't we have in the United States, as far as you can tell?

Dr. HALL. I mean, I think the rest of the panel have been explaining exactly where the problems are.

Mr. SHAYS. But I'm using your—I'm taking advantage of your global view to say how much better it could be.

Dr. HALL. Right. I mean, I think the key issues are about the timeliness of reporting and standardizing reporting as well, so that you get a similar report from all around the world. And that I'm sure will probably apply to the States within the United States. So that you can actually compare and you can compile that information to get a much better picture.

Quite often, in the emergence of a disease—and this would be the same, the bioterrorist threats—it's unknown, it's different, it follows a pattern you have not seen before. So what is key is to be able to rapidly piece little pieces of the jigsaw puzzle together? And I would imagine that in the United States, as most countries around the world, suffering the problems of reporting in a standardized manner so it can be compared from different bits of the States and reporting in a timely manner so that those pieces can be very rapidly put together in a better picture.

Mr. SHAYS. Now, you talk about a learning curve, but I'm struck by the fact that—I've been chairman now for 9 years of either—the first 4 years was overseeing CDC and FDA and HHS, among other departments and agencies; and now I'm involved with my colleagues on the national security side. But there is some real compatibility. I mean, thank goodness I had that knowledge to bring in here.

One of the things I wrote down is, you can't push science. You know, when we were looking at Gulf War illnesses, they said, you know, it make take 10, 15 years for us to understand why people are sick. And I'm thinking up here, well, they are dying and they are sick and so on, and it's going to take 15 years. And it's like, we can't push science.

But I wonder, this isn't pushing science. This is different than pushing science. This is saying we have information. We need to find a way to identify it sooner. We need to find a way to identify the illnesses sooner, have a standard. This to me isn't science. This is like logic. And yet I think I'm hearing scientists saying, thinking like that this is going to be a long process.

Ms. Ignagni, how are you reacting to what I'm saying?

Ms. IGNAGNI. I think it is like putting down pylons. If you think about creating the architecture, doing something here that collects the system of systems, you really just—in constructing a building, you construct buildings the same way all around the world and all around our country. And so, just to be very simple about it, I think you are on the right track. I think that what we've learned is there's a real value in consistency.

I think Dr. Hall is making a very compelling point here. I think what—our colleagues from the States and the local area are sending messages, let's figure out a way to have the consistency of drawing the data but at the same time not quash their ability to be nimble in reacting to that. And I think that—so the question is, where do you put the fulcrum on those two—on the continuum? And I think you are on the right track.

Mr. SHAYS. I also am thinking that—and this is a slight exaggeration. But health departments have been so beaten down in terms of the contest with other departments in the cities and in the States that they have low expectations, and they have learned to be very patient people. Maybe the science tells you to be patient, but it strikes me that the expectation should be a lot higher; and I didn't really come to that conclusion until really wrestling with the first panel now and the second. There is really no reason why—I mean, some of this, as I am struck thinking about it, is some of this is just common sense stuff. And Ms. Selecky, do you want to just comment?

Ms. SELECKY. We in public health have to be ready to move on a moment's notice, because communicable disease does not work. We can't——

Mr. SHAYS. Does not what?

Ms. SELECKY. Does not wait. Excuse me. We can't wait for someone to say, here is the perfect system that is going to be used nationally. So that's why I think you have things that grow up like the one that's in southwest Pennsylvania, as was described earlier, or other places, in the local community to say how do we get our arms around Milwaukee, Seattle, eastern Washington, whatever it is. How do we get ourselves to talk to one another in real-time to work on instant reporting of something that is a terrorist event? It's an unusual disease that's showing up. We are all starting to see it, and we need to move on it.

I guess I'm struggling with how to answer your questions about should we nationalize and have a common data reporting system. How do you then get everybody using the same software in the local doctor's office that's part of a health plan who also have four or five other health plans there because they have requirements, the local health department, who is part of the city infrastructure, or the county infrastructure? And we can't wait for that, because communicable disease does not wait.

Whether it is electronically, whether it is by the telephone, whether it is by paper, public health is impatient to get the information. The sense of urgency is that our science is based on early detection, quick action and prevention. Otherwise, we wouldn't have some of the good health that we do experience in this country or the ability to begin to look at the work that the World Health Organization, all of a sudden connected to me in my job in Washington State and in my community.

So if we haven't talked about urgency, it's about—it's not about the sense of urgency of participating in a good, thoughtful discussion about what's the best system. The urgency exists by virtue of a public health or an organism problem that we have to act on, regardless of what system exists.

Mr. SHAYS. Go ahead.

Dr. FOLDY. Well, just since—over the last several years, we have done everything possible we can do without spending a lot of money; and that included getting 15 local health jurisdictions to all report to a one-stop location and which can rapidly take in the report, determine that something is going on.

Our first—you know, E-coli operated—the first five cases came from five suburbs. Fortunately, they all report to one location. We

could put it together and act immediately. Our use of this regional emergency medical Internet, it simply fell into our hands.

With more resources, we can do great things. However, my local tax base, as the support for my department has gone from 45 percent down to—it's starting to approach—I'm sorry—55 percent, starting to approach 40. The State is cutting back. We are really looking at hard times and sustaining these systems can't go on indefinitely.

Mr. SHAYS. My time has run out. But, Dr. Hall, what would you like to say?

Dr. HALL. Just to say that certainly, from our point of view at Global Alert and Response, we spend far too much time being reactive and not enough time being proactive; and that is simply because of a lack of investment in the system. It means we have enough money to buy the brakes, but we haven't got enough money or time to get the motor to stick it all together. And what you see—that systems I'm sure all around the world building up, building on experience like we have built on the experience of ebola and meningitis outbreaks and other things but never quite enough time to glue that together so that you actually have a system that is stream—that means that information can flow very quickly and very rapidly.

Ms. IGNAGNI. Mr. Chairman, can I make a quick comment?

One of the things that I think has probably been implicit in the discussion, particularly from the previous panel, but wasn't said very specifically is that in the last couple of years there has been a dramatic progress in the ability to unite the systems and create a system of systems. What now we have the capacity to do, like we do in defense where we have command centers tracking what's going on around the country, the Secretary has created a command center in terms of getting the information in, looking and arraying the information. If you go into that command center, what you see are different geographic locations and the ability just to put up on the wall where blips are coming up.

And I think perhaps what you have been hearing this afternoon is a reflection on how far that has gone and come from where we were. But I think, just as we have learned in this country that we need to take a new approach to thinking about defense as well, I think that the consensus in the public health community is that we need to think more like that in public health. So I think that there has been a dramatic progress over the last couple of years and now it's the question of how we get to where you are suggesting we need to go, and I believe that there is tremendous consensus about that objective, and I think we can do it. There is probably more interest in achieving that now post SARS and some other experiences than there was a year or so ago throughout the country.

Mr. SHAYS. Thank you very much.

I appreciate the patience of my colleagues. I don't always do this, but Dr. Kelley, Colonel Kelley, do you have any observation you would want to put on the record? I would have to swear you in, but if you would like to, I would be happy to have you come up. So the answer first has to be yes or no.

Colonel KELLEY. Yes.

Mr. SHAYS. OK. And with the indulgence of the committee, I would just swear you in. If you would raise your right hand, please.

[Witness sworn.]

Mr. SHAYS. I appreciate you, Dr. Kelley, staying for this hearing. I know your superior was here. I mean—but what observation would you like to make?

STATEMENT OF PATRICK W. KELLEY, M.D., DR PH, COLONEL, MEDICAL CORPS, DIRECTOR, DEPARTMENT OF DEFENSE, GLOBAL EMERGING INFECTIONS SURVEILLANCE AND RESPONSE SYSTEM

Colonel KELLEY. I think I would like to make several observations.

You know, money can go only so far. But what we really need is leadership to make it clear that these are our priorities that need to be followed. In our various organizations, civilian and military, there are many, many issues that we are trying to balance back and forth and prioritize. We have to prioritize not only budgets but time, and it's very critical I think that our leaders understand that this needs to be a priority.

I think one thing we have to realize, too, is that surveillance implies a response. I can't put a precise figure on this, but I would guess for every dollar you spend on surveillance you need several available to fund the response that is implied by the generation of this new information, and I know various health departments outside the military that find that a particular challenge. Now that their surveillance systems are getting better, they have to—they find themselves constrained in reacting to the wonderful data that they are generating.

Mr. SHAYS. We will note for the record that Ms. Selecky and Dr. Foldy were nodding their heads continuously as you were talking about that.

OK, anything else?

Colonel KELLEY. No, sir. Thank you for the opportunity.

Mr. SHAYS. Well, you are welcome. But thank you for staying, and thank you for your good work as well.

Is there anything? Mr. Janklow, any other comments you want to make again?

Mr. JANKLOW. Could I ask a couple quick questions, Mr. Chairman?

Mr. SHAYS. You sure can.

Mr. JANKLOW. With respect to the—Dr. Foldy, if I could ask you—and let me ask you, Ms. Selecky, first. In the State of Washington, are you satisfied that you are where you want to be in the State with respect to the reporting system for State purposes?

Ms. SELECKY. No, and the reason I say no is because we all can do better; and I think that last comment is part of that. You not only need the way you do the reporting, you need to have the foot soldiers to do the work at both the State and local level. The communications system's in place to work to make sure that the public and private people across the State are getting the information to take the action. Can we do it better? Absolutely. We need to upgrade electronic capability across the State. We have already reviewed our reportable diseases in Washington State. We updated

them just 2 years ago. We updated our quarantine and isolation rules just in December. We have those kinds of tools. But we have to continue to work on the common data, elements that all of us will agree on come together in Washington State. We are doing better than we were.

Mr. JANKLOW. Are there a set—do you have common data elements in place?

Ms. SELECKY. We have common reporting from all our private providers as well as public providers in and around the list of communicable diseases that includes emerging diseases like SARS, and in real-time in Washington State we have those kinds of reports to know what we have going on with that. Whether it's E-coli from spouts—we have that from this summer—E-coli from lettuce—it was multi-state. We had it this summer. It's about getting that information to move into action.

When I hear you all talk about and when we talk about a common system, I get concerned that we are waiting for the perfect system when what we really need to have are the foundations to be able to use whatever system exists.

Mr. JANKLOW. When I talk about electronics, ma'am—I understand an earthquake can be disruptive. But I don't see a national earthquake coming. I mean, if anything, it would be very regional in terms of its scope; and so I don't know of another effective means other than electronics in war. If we have to go to paper, we can. But to the extent we go to paper, we've lost. Once we have to take the war dealing with someone deliberately injuring our people with bacteria or a toxin or a virus, at that point we have lost.

So what I'm wondering is, putting a system in place, what does it take to do it? Because electronically the world is there. It's there. The kids know it. Napster knows it. The only people that don't know it most of the time are the governments and the adults, but the kids have figured it out, whether it's with their chatrooms or whatever.

Second of all, I don't think it's that difficult. I realize there could be arguments, but I don't think it's that difficult to come up with a list of sicknesses, diseases, symptoms, differential diagnosis, whatever you want to call it, that are reportable events.

The third thing is, there has been a huge amount of Federal money, of national money, our money, that has gone in in the previous couple of years. All the States received very sizable grants, one for their laboratories and two for their planning for this type of thing. And so I understand it's not enough, but it's a huge amount of money if it was somehow coordinated better than we all coordinate it.

So I realize our time is up on this stuff, but I just—the point that I'm trying to raise is, is there—and I realize we need more trained people and we need more money. But, absent those things, is it OK the way the States and local governments are doing it? Or is there something that all of us can do in a national wartime scope that would make this more effective and more efficient in terms of the wartime side of this issue?

Ms. SELECKY. One of the things we clearly do have to work on, and are working on, are secure ways of getting this information

sent between State and local; and that is using the common standards you heard Dr. Fleming talk about. So we are working on that.

You are saying, speed it up. You are saying, get it done because we are in a wartime kind of thing. It's not about laissez-faire. And I would absolutely agree with you, your point about it makes sense to come up with a common list of diseases. States have those. States work with State and local. We are based on that. So that one you rest assured on.

Your point about the earthquake is well made. What we have to do is not falsely rely on it as the exclusive way of doing things. The investments made by Congress over 2 years have moved us along, but I want to have a digital signature in every clinician's office at some point, that clinician can have someone enter the data from their office, from their outlying remote clinic or from their ER room so that the local health department and the State health department have access to that immediately and we transmit it to the Feds.

Mr. SHAYS. We can keep going on and on and on, but I think this is probably a good time to stop. You have been a wonderful panel. You have helped put the whole thing together for us, and we appreciate your participation. Thank you very much.

With that, we will adjourn the hearing. Thank you.

[Whereupon, at 4:59 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

1100 17TH STREET, NW, 2ND FLOOR
WASHINGTON, DC 20036
(202) 783-5550
(202) 783-1583 FAX
WWW.NACCHO.ORG

NATIONAL
ASSOCIATION OF
COUNTY & CITY
HEALTH OFFICIALS

June 3, 2003

The Honorable Christopher Shays, Chair
Chair, Subcommittee on National Security, Emerging Threats and International Relations
House Government Reform Committee
B-372 Rayburn House Office Building
Washington, DC 20515

Dear Representative Shays:

I was encouraged and impressed by the interest in disease surveillance expressed by members of the Subcommittee on National Security, Emerging Threats and International Relations at the hearing of May 5, 2003. Representative Janklow, in particular, had asked me for my expert perspective concerning what would most rapidly improve our nation's system of disease surveillance. I submit the following for your consideration and for the record of the hearing.

Summary of Recommendations

1. Keep the development of national disease surveillance under the leadership of the Centers for Disease Control and Prevention (CDC).
2. Provide the CDC with additional dedicated funding and staff to accelerate the development of standards, implementation guides and other requirements for interconnected health information and surveillance systems.
3. Encourage CDC to employ industry leaders in this acceleration process.
4. CDC should convene local, state, federal and healthcare stakeholders within the next few months to identify *one* high-priority base set of surveillance and directory information for which standards are already available. This set should then be broadly disseminated to public health agencies, health care providers and information systems developers and venders. This will allow the needed partners to begin immediately to modify their health information systems to exchange this information. This process should be repeated on a regular basis as further standards and information needs become clear.
5. CDC or another agency should measure on an ongoing basis the proportion of health care providers and public health agencies capable of transmitting and receiving this information electronically and report to Congress on a regular basis.

6. Identify funding specifically to assist local and state health departments with the development and/or purchase of compatible, interconnectible information systems to enable transmission, receipt and utilization of this information.

Discussion

As I mentioned during the hearing, local public health agencies perform most the work of communicable disease surveillance and outbreak control. Legally, disease surveillance is a police power typically derived from local or state laws. Disease reporting occurs primarily at the local and state level, with national sharing based on cooperative voluntary agreements.

Because local agencies bear the most immediate responsibility to respond to disease outbreaks, it is critical that they have immediate and total access to information related to persons in their jurisdictions. The main goal of a surveillance system is *not* to accumulate data at the national level, but to assure timely detection and response at the *local* level.

Nevertheless, a purely local system of disease surveillance is untenable for several reasons. First is the increasingly national and international nature of food production, commerce and travel. One producer of contaminated products (or one terrorist group) may generate simultaneous outbreaks across scores of communities. A national system of reporting could speed the recognition of a common source, and thus more rapidly control dangerous exposures to the public. Second is the increasingly regional and national scope of medical and laboratory services. In the past, local providers reported to local health officials, but now hundreds of providers around the country must somehow route reports to nearly 3000 local jurisdictions. A system for routing reports is required to assure speedy receipt of disease reports. Third, speeding reporting, analysis and action means replacing paper reports with rapid electronic messages. This goal requires the adoption of national standards for recording and transmitting clinical information, not a patchwork quilt of differing state and local standards. Fourth, insurance companies, health plans, pharmacy plans and other regional, national (and increasingly, international) health-related enterprises collect electronic records that may be useful as early warning systems for disease outbreaks. A national electronic system for receiving and routing this information would speed transmission and analysis. Finally, working from a common set of electronic disease information will greatly help state and national experts when local responders require their assistance.

Therefore, although the desired end is to put information into the hands of local responders, a national system for delivering and sharing this information is needed.

Decades of experience indicate that simply "mandating" more disease reporting by busy clinicians and labs will not actually produce better reporting. Instead, a reasonable goal is to enable electronic clinical information management systems to identify information of public health importance, transmit that information reliably to the appropriate authority, and cause that authority be alerted automatically of the receipt of time-critical

information. This is part of the vision of the Centers for Disease Control and Prevention's (CDC) Public Health Information Network. CDC, with partners like the eHealth Initiative, have in recent months completed several important steps, including selecting standards for recording and transmitting several types of clinical information, and establishing draft structures of directories and messaging systems to help such information find its way.

This complex and difficult work will help health care providers, public health agencies, and just as importantly, their information systems vendors, to assure their systems are interoperable for these functions. It has taken several years to get to this point and much critical work remains unfinished. This unfinished work leaves those who wish to move ahead rapidly on the design of interoperable systems in a degree of anxious hesitation. CDC and its partners need to provide confident guidance now to speed the initiation of critical surveillance information for which standards are complete, and to identify priority areas where standards and implementation guides are still lacking. In particular, the nation should have an aggressive yet realistic timeline for both of these tasks.

You asked how this process could be speeded. From my perspective (as a large city health officer external to CDC), it appears that CDC staff working on PHIN and a national surveillance system is frequently and necessarily diverted by one urgent situation after another (smallpox vaccination, BioSense and BioWatch, Severe Acute Respiratory Syndrome (SARS) surveillance). That is why I suggested to the Subcommittee that CDC would benefit from greater dedicated funding and staff for this work. I also suggested that CDC be funded to obtain sustained access to some of the most experienced minds in the area of developing industry consensus standards and linking complex, interoperable enterprise systems. Rep. Janklow asked me to submit names for these experts but that lies outside my experience. However, I sit on the board of the eHealth Initiative which has assembled many creative and experienced leaders in health care informatics and information technology. I believe they can help CDC access appropriate expertise on demand.

I do not believe, however, that this work would be better and faster performed outside the CDC. This work requires considerable medical, laboratory, epidemiological and public health expertise, and CDC is best poised to provide leadership to the project.

However, the real issue is not whether CDC has created an interoperable surveillance system, but rather, whether local providers and health officials are using it. What will propel the nation's health care providers, state health departments, and perhaps most importantly, local public health agencies, toward developing and using the capability to send, receive and apply such information electronically?

First, they must have a clearly defined minimum goal in sight. I suggest that CDC rapidly convene critical public health stakeholders to prioritize a first set of the most critical (and practical) information to be shared electronically using currently available standards. This would include a limited basic directory set for routing reports and alerts; a set of laboratory and clinical information for mandated (patient-identified) disease

reporting; and the set of top-priority syndromic information (not-patient-identified) for early detection or tracking of an outbreak like SARS or bioterrorism agent.

Once this first set of priority information and related standards and implementation guides are identified and disseminated, local, state and federal agencies can immediately and confidently begin determining how their systems must be upgraded to transmit and receive this information.

CDC and Congress should regularly assess the implementation of this information exchange at the local level across the nation. What proportion of laboratories can transmit and receive the information? What proportion of local health departments? What proportion of emergency rooms? This should be the true metric of our success. Otherwise, I fear, we could end up with a nice system with very little information moving around inside of it, because the information producers and end-users are not connected.

The ultimate goal must be for timely and accurate mission-critical public health information to reach *local* public health agencies so they can *act* on it. Each local health officer needs to be equipped to send, receive, analyze, and display this information. The information necessary for rapid follow-up and intervention (such as patient addresses, clinician phone numbers, the location of origin of environmental samples) should flow right to the fingertips of the public health nurses, epidemiologists, and sanitarians in the field. CDC can help create a socket from which this information will flow, but local public health agencies must develop locally-useful tools to plug into that socket. I suggest that Congress dedicate specific funding the local public health information infrastructure, and to the development of applications *by and for* local public health response agencies. Until information systems enable local personnel to improve local public health response, our work on national surveillance systems will have little overall impact.

Thank you for your attention to this critical issue. The National Association of County and City Health Officials will be happy to render any further assistance we can.

Sincerely,

Seth L. Foldy, MD
Commissioner of Health, Milwaukee, Wisconsin
and
Chair, NACCHO Information Technology Committee

Testimony of Shelley A. Hearne, DrPH
Executive Director
Trust for American's Health
Washington, DC

Regarding Homeland Security: Improving Public Health Surveillance

Submitted to the
Committee on Government Reform
Subcommittee on National Security, Emerging Threats, and International Relations
United States House of Representatives
May 5, 2003

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to submit testimony on the importance of improving public health surveillance as an essential step toward bolstering our homeland security. My name is Dr. Shelley Hearne, and I am the Executive Director of the Trust for America's Health (TFAH) and the Chair of the American Public Health Association (APHA) Executive Board. TFAH, a nonprofit, non-partisan advocacy group, is dedicated to protecting the health and safety of all communities from current and emerging health threats by strengthening the fundamentals of our public health defenses.

A strong public health defense begins with disease surveillance, which is why today's hearing is so important. Public health surveillance, also known as health tracking, not only helps us monitor and mitigate potential chemical and bioterrorist attacks, but also is crucial to unlocking the mysteries behind chronic and infectious diseases. Tracking disease is one of the most vital weapons public health officials have in the fight to prevent and control threats to the country's health.

Public health surveillance is defined as "the ongoing, systematic collection, analysis and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know."[1]

A comprehensive disease tracking system monitors the occurrence of disease and can inform the rapid identification of outbreaks or "clusters" of cases and analysis of geographic variations and temporal trends. With this information in hand, public health investigators can search for the sources and routes of exposure to determine why the outbreak occurred, how to prevent similar outbreaks in the future, and, if the outbreak is ongoing, how to prevent others from being exposed. Concurrently, action must be taken to control the spread of the disease and minimize further illness and death, even when clear cause and effect have not been fully identified.

[1] Thacker, S.B. and Berkelman, R.L. Public Health Surveillance in the United States. Epidemiology Review. 10: 164-190 (1988).

The public health community overwhelmingly agrees: health tracking works. Unfortunately, up until now, we have lacked the resources and national resolve to make effective, comprehensive health tracking a reality. The new threats of potential chemical and bioterrorism, combined with emerging health crises like severe acute respiratory syndrome (SARS) and West Nile Virus, mean that health tracking is even more essential. Now is the time for Congress to make it a national priority.

Even limited health tracking efforts have already helped us make advances toward improving the health of communities. For example, through health tracking information, we have been able to better understand how West Nile Virus is spread.

The good news is that as we are working to prevent these possible and emerging health dangers through public health surveillance, we can put this same tool to work to curb and control existing chronic disease epidemics, from cancer to asthma to diabetes. Seventy percent of Americans will die from a chronic disease. At the same time, according to the Centers for Disease Control and Prevention (CDC), approximately 70 percent of these illnesses are preventable through strong public health measures.

As we work to improve public health surveillance efforts, we must also realize that our entire public health system is in urgent need of revitalization and modernization. It is no secret: the current system is painfully under prepared to meet the public health threats that Americans face today.

In the past, the U.S. public health system served as the world leader in stamping out diseases like yellow fever, typhoid, influenza, and cholera. Just as the world is looking to our country for leadership in the war against terrorism and the worldwide SARS epidemic, the United States also should be at the forefront of the global war against modern disease.

Instead, we find our public health defense system ailing: the 2001 CDC report *Public Health Infrastructure* stated the current U.S. public health infrastructure "*is still structurally weak in nearly every area.*" The report calls for a system of "public health armaments," including a "skilled professional workforce, robust information and data systems and strong health departments and laboratories."

In a separate report, the General Accounting Office (GAO) found that "the 1999 West Nile virus outbreak, which was relatively small, taxed the federal, state and local laboratory resources to the point that officials told us that CDC would not have been able to respond to another outbreak had one occurred at the same time." According to the GAO report, coordination between state, local and federal authorities, communication systems, disease surveillance, staffing and laboratory capacity are areas that require immediate improvement.

In order to provide public health surveillance that bolsters homeland security, we must focus on: national authority and commitment to disease tracking standards and reporting systems; rapid communication links with all health agencies, hospitals, first responders and laboratories; modern and compatible equipment; and a trained workforce. Sadly, many of these elements are missing currently. Consider:

- The lack of national coordination -- mandated standards, support and enforcement. CDC does not have a command and control mentality with respect to surveillance. The most recent example is the agency's unwillingness to require that SARS be considered a reportable disease in every state. In fact, most of the nation's disease tracking systems

suffer from the lack of national standards and uniform structures, resulting in a patchwork approach to surveillance. Often, the CDC is in the unenviable position of having to cajole state health departments to provide important data about cancer, birth defects, and many other chronic diseases and conditions.

- The data collected may never be analyzed or disseminated. The 2001 Pew Environmental Health Commission's *Transition Report to the New Administration: Strengthening our Public Health Defense Against Environmental Threats* found that there is virtually no "synchronization in the collection, analysis and dissemination of information. In addition, much of the data that is collected is never analyzed or interpreted in a way that might identify targets for further action."[2]

- Inadequate resources. At a time when the public health system needs substantial investments and a 21st Century overhaul, the Administration had proposed over $100 million in cuts to the CDC budget for FY 2004. At the same time, state budget deficits are leading to massive cuts in chronic and infectious disease prevention, putting vital programs at risk and there is no way for the CDC to fill those gaps.

Together, these factors present a dangerous and, frankly, unacceptable way to watch guard the health of the nation. The result is that our public health and homeland security face serious risks.

Public health officials know how to reduce these risks: watchfulness, rapid response, research and action are the trademarks of an effective, responsive public health system. The response of the CDC to the global SARS epidemic is testament to why a coordinated public health game plan can and will save lives. At the same time however, it is important to note that SARS has barely touched U.S. shores, so the preparedness of the entire public health system --local and state health departments, hospitals, and laboratories--remains largely untested.

In fact, it is worth remembering that the anthrax attacks in Fall 2001 exposed and exacerbated the weakness in the public health infrastructure. Lack of a national response plan and deficiencies in our public health apparatus made a terrible situation even harder to manage.

While improvements are urgently needed in virtually every aspect of the U.S. public health infrastructure, Congress can and should take these immediate steps:

- Increase funding for the Nationwide Health Tracking Network to $100 million. We are encouraged that in the Administration's budget request to Congress calls health tracking a "major focus" of its environmental health program. We are equally encouraged that the Congress has taken the lead in providing initial funding for the Nationwide Health Tracking Network in Fiscal Years 2002 and 2003. It's time to take this critical surveillance tool to scale. A fuller description of a Nationwide Health Tracking Network is described in Attachment A.

- Substantially increase funding to enhance the information and communications systems related to public health surveillance. Specifically, provide full funding for the National Electronic Disease Surveillance System (NEDSS), which serves as CDC's architectural backbone of surveillance. As former CDC Director, Dr. Jeffery P. Koplan wrote in 2002,

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[2] Pew Environmental Health Commission. Transition Report to the New Administration: Strengthening our Public Health Defense Against Environmental Threats. Johns Hopkins School of Public Health. Baltimore: 26 (January 17, 2001).

"As the initiative [NEDSS] proceeds, it will reshape the way public health is practiced with unprecedented access to high-quality and timely surveillance data.[3]

- Chronic under-funding has led to a network of health agencies that have trouble communicating with each other, let alone with the public. As we have learned with SARS, communicating with a shaken public is key to alleviating natural fears that arise with an emerging illness. The Health Alert Network (HAN), a federally coordinated system between the CDC and state/local health departments, has the potential to fill this current communications gap. By using advanced technological tools, HAN will allow for real-time coordination in situations where even seconds matter. HAN plays a vital role in the nation's state of readiness and timetables to completion and activation must be accelerated and linked to state and major metropolitan health departments.

- Given the importance of CDC for protecting the public's health, restore at least FY 2003 funding levels to all programs at the CDC. The proposed cuts are unwise at a time of a global epidemic caused by "Mother Nature" and in light of potential biological and chemical terrorist attacks.

- Ask the Department of Health and Human Services to convene a national summit on the future of the American public health system and the resources needed to build a robust, integrated 21st Century infrastructure that can play a "double duty" role by enhancing preparedness for the full spectrum of health threats from chemical terrorism to cancer and from biological attacks to birth defects.

Mr. Chairman, the unimaginable happened on September 11, 2001 -- an act of intentional terrorism on American soil. The unimaginable struck again in the past few months with SARS outbreak -- this time an act of nature. An effective public health defense requires us to be prepared for the epidemics we already know and those we have yet to imagine. Health tracking and reviving our public health system are vital to our nation's security. The health of the American public deserves no less.

Thank you again for the opportunity to submit this testimony on behalf of Trust for America's Health.

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[3] Baker, Edward L. and Koplan, Jeffery P. "Strengthening the Nation's Public Health Infrastructure: Historic Challenge, Unprecedented Opportunity," Health Affairs, Volume 21, Number 6: 16 (November/December, 2002).

ATTACHMENT A:

Fundamentals of the Nationwide Health Tracking Network

1. *Establishing essential data collection systems for chronic diseases and conditions and potential links to environmental factors:* The network would build on existing health and environmental data collection systems for infectious diseases and ensure uniform coverage in all 50 states.

2. *Developing an Early Warming System:* A network would serve as an Early Warning System to alert communities immediately of health threats to the population. The same system used to alert officials in the event of a terrorist attack could also help in detecting possible disease clusters.

3. *Creating Rapid Response Teams:* Such teams able to deliver instant information are crucial to communities in crisis. The network would coordinate federal, state, and local health officials to quickly investigate situations of concern.

4. *Addressing Unique Local Health Problems:* The seventeen states and cities and three Centers of Excellence established through the 2001 health tracking funding serve as excellent models for a broader Nationwide Health Tracking Network. Local and state health departments are often the first line of defense in protecting the health of communities.

5. *Creating Community and Academic Partnerships:* Relationships with communities and academic centers will help ensure that data collected is accessible and useful on a local level. Collaborating with research groups will aid in training the local workforce, analyzing data, and developing links between tracking results and preventative measures.

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