

**A REVIEW OF FEDERAL BIOTERRORISM PRE-
PAREDNESS PROGRAMS: BUILDING AN EARLY
WARNING PUBLIC HEALTH SURVEILLANCE SYS-
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HEARING
BEFORE THE
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES

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A REVIEW OF FEDERAL BIOTERRORISM PREPAREDNESS PROGRAMS: BUILDING AN EARLY WARNING PUBLIC HEALTH SURVEILLANCE SYSTEM

THURSDAY, NOVEMBER 1, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:40 a.m., in room 2322, Rayburn House Office Building, Hon. James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood, Stearns, Burr, Whitfield, Bass, Tauzin (ex officio), Deutsch, Stupak, Strickland, DeGette, Rush, and Dingell (ex officio).

Also present: Representative Harman.

Staff present: Tom Dilenge, majority counsel; and Edith Holleman, minority counsel.

Mr. GREENWOOD. Good morning. This hearing of the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee will come to order, and the Chair recognizes himself for 5 minutes for an opening statement.

Three weeks ago, this subcommittee held a hearing to evaluate the effectiveness of Federal programs designed to bolster the preparedness of States and local communities to deal with bioterrorist attacks. At that time the second and third cases of anthrax infection in Florida had just been discovered.

Several hundred people who worked with those individuals were being tested and put on Cipro as a precautionary measure. It was still unclear at that time whether the Florida situation was an isolated incident or part of some broader criminal or terrorist enterprise.

Since that hearing the anthrax scare has spread and the death toll has increased. The numbers infected seem to increase daily, as do the number of locations with anthrax detected in them.

An anxious Nation is left to wonder if in Emerson's words, "Things are in the saddle and ride mankind." People are afraid and some with good reason. Unlike the 1930's, we have more to fear than fear itself. An unscrupulous enemy, with access to the most insidious means of human destruction, and a demonstrated willingness to use them, is in fact a fearful thing.

But what is truly worrying about the recent outbreak is the possibility that this is a prelude to a worse attack, and that this effort

was designed more to test our capabilities and probe our weaknesses than to cause sustained damage.

Surely there can be little doubt that this mail borne anthrax attack was well coordinated and is in fact this Nation's first real example of bioterrorism at work. All the more reason that this Nation must promptly improve its public health surveillance activities, which is the focus of today's hearing.

Sadly for thousands of Americans, the 1993 attack on the World Trade Center did not serve as a wakeup call on the need to better protect our critical physical infrastructure. We cannot afford to let this happen to our critical public health system.

In this new kind of war where terror is the enemy's chief aim, the most potent weapons may very well be biological agents, and increasingly the battlefield will not be in some far off land, but here at home. The anthrax outbreak is our fire bell in the night, and we may not get another warning.

And a very real fear we now confront is the one H.G. Wells wrote of in 1920 when he observed that human history becomes more and more a race between education and catastrophe.

This is a race that we cannot afford to lose, nor will we. America has always risen to meet the challenge, and our public health system, while in need of repair, has more than an adequate foundation to begin to wage a successful war at home against our enemies, and the diseases that they may seek to inflict on us.

But to do that more of our Nation's leadership, and the President, and Congress, must be galvanized by the dangers we face and must commit themselves to leading the effort to fight this new kind of war in a new kind of way.

This is about much more than appropriating new money, though money is needed. To be successful, we must harness the creative genius of the American people in the public sector, and in the private sector, and in academia.

Our traditional public health surveillance system, which in many parts of this country still relies on doctors mailing in post cards to their local public health departments is too limited with regard to what is reported, and too slow to be effective, to late in the patient evaluation process, and too incomplete to meet our country's emerging needs in this area.

It is the equivalent of relying on the pony express in the age of the worldwide web. Some bioterrorist attacks, like sending anthrax powder in the mail, tend to be readily apparent, at least to those who open the laced mail.

Other attacks, such as pumping bacteria or viruses through ventilation systems, are more covert, and may not be detected until exposed individuals get sick and go to their doctors or local hospitals.

The goal must be to detect these covert releases as soon as practicable. The successful early detection regime will enable us to identify the exposed population sooner, and get those individuals treatment faster.

Early detection will also allow us to contain the spread of disease, which while less important with non-contagious diseases, such as anthrax, will prove critical if a terrorist's agents were a highly contagious disease, such as smallpox.

And even after initial detection, a good surveillance system will enable our public health officials to more effectively manage such outbreaks and quickly intervene with appropriate care and guidance.

While astute and well-trained clinicians will always be the bedrock of our health care surveillance system, we need to ensure that recent advances in medical informatics and improved health care technology supplement our human intelligence system.

As we will learn in today's hearing, our public institutions and our private sector have already begun to make substantial progress in developing early warning systems to detect outbreaks of bioterrorism, and in developing rapid responses to outbreaks.

This is essential if we are going to protect our Nation and our people. We will also hear today about the Federal Government's promising, but so far quite limited, efforts to improve both the traditional surveillance system and to fund pilot projects at the State and local levels to develop and test more advanced, more proactive, and decidedly more unconventional surveillance systems.

I have been concerned, however, that our Federal health officials have done little to oversee and to better direct such activities. In particular, it seems like we lack a national strategic plan to test and evaluate these advanced systems, and are presently unable to provide clear guidance to State and local public health officials as to what we believe a good surveillance system would look like.

The Director of the Federal Centers for Disease Control and Prevention recently initiated a working group to review the potential of some of the new surveillance techniques that are being or already have been developed, and I welcome that initiative.

I look forward to the testimony of all of our witnesses today, and I will now recognize the ranking member, Mr. Deutsch, for 5 minutes for his opening statement.

Mr. DEUTSCH. Thank you, Mr. Chairman. Thank you for having this hearing. As I recall this was a hearing that was interestingly scheduled before the events of September 11, and the work of this subcommittee on this issue has been something within our jurisdiction literally from the creation of the CDC.

I think though since September 11, not has just the work of this committee changed, but obviously the work of the Congress, and obviously the work of the country has changed.

And my hope is that as we have talked outside of the hearing room, my hope is that we really broaden what we are doing, because I think that our jurisdiction is as critical as any jurisdiction in the Congress right now.

I mean, we have the legal responsibility to work on public health issues, and work on our jurisdiction regarding the CDC, and HHS has responsibility for public health, and I think we need to take that job very seriously as we are.

But I think some of the focus needs to be ongoing in real time, and the real time issues that I would focus on as we have discussed is right now the HHS is working on trying to develop 250 million additional smallpox vaccines.

That is an issue which I don't believe there is a more critical issue that the Federal Government is working on today. And I know that everyone involved at HHS is incredibly sincere and in-

credibly bright, and incredibly hardworking in the efforts to successfully complete that endeavor.

But I think it is critical that we engage our resources working with them toward the same goal of trying to acquire those vaccines in as quick a real time basis as possible. And we can talk, and we will have some testimony about the ability of preparing the systems, in terms of what they can do down the road, and what they might be able to more.

But I think there are some potentially cataclysmic events that I will work and help prevent, and I think that is really the focus, not just of the subcommittee, but I see the chairman of our full committee here as well, and I know that next week we have a briefing that both of our staffs are working on together toward that goal.

So I welcome the testimony that we are expecting to have today, but I urge us, and I am going to focus even some of those questions regarding some of the more immediate potentially relevant issues, and again not just smallpox, which I think is in fact the more relevant, but as they also relate to real time issues on anthrax, and real time potential issues on the plague. So I look forward to your testimony. Thank you.

Mr. GREENWOOD. The Chair thanks the gentlemen from Florida, and looks forward to his specific recommendations in those regards. The Chair recognizes the chairman of the full committee, Mr. Tauzin, for an opening statement.

Chairman TAUZIN. Thank you, Mr. Chairman, not only for today's hearing, but for having the foresight even before September 11 to schedule this hearing, and to continue the work of our committee in this important area of bioterrorism.

And I want to particularly thank you because today's hearing, as Mr. Deutsch points out, is just the beginning of a process, in which our full committee has been now recently charged by the leadership to produce a major terrorism/bioterrorism package for the U.S. Congress to consider before we leave here this November, perhaps December.

The Health Department has already sent to us a food safety package that we are now working with Mr. Dingell and his own version of food safety, to see if we can come up with a common ground document that will enhance dramatically the inspection of food at America's borders as part of our oncoming efforts, but nevertheless now an emergency need of this Congress and of this Nation.

It is contemplated that now with the events of this anthrax attack on American citizens, and we have just seen the fourth victim in New York die, that while human toll so far has been limited, the havoc brought by these attacks has been rather broad.

And the damage done to public confidence in the mail, and to the capacity of the CDC, and our health response systems to deal with these, is seriously in question. The bioterrorism package that we will design will hopefully answer those questions, and begin to move the CDC and the health department—and by the way, the EPA, which is now in charge of the cleanup of these buildings here in the Nation's capital—into a position where all of those agencies working in conjunction with State and local government agencies, including the National Guard, the Veterans Hospitals, and other

great institutions of that nature, will be more thoroughly coordinated.

Today we will focus on how technology can help us identify and react quickly to the evidence of an epidemic or bioterrorism attack, and in the process this committee will engage in next week, we will look at the CDC more precisely and at the Health Department's capacity to respond more precisely.

We will be looking at such questions as how much and how extensive should be our drug stockpile to react to attacks, or to the spread of infectious or biological diseases. We will be looking at how well we currently incentivize vaccine research, and whether or not we ought to do more to encourage not only the production, but the research and development of new vaccines to protect our country against these new forms of attack.

We will be looking at whether or not the infrastructure of the CDC is sound, or whether or not some of the systems of communications within the CDC are adequate. We know that one-third of all the labs and medical facilities in this country are not on the emergency alert system of the CDC. They need to be connected.

And every lab, and every medical facility, needs to be part of a medical alert when it goes out. We want to look at how well we are currently educating hospitals, doctors, and nurses, in the special needs of bioterrorism attacks and infectious disease spread.

We are going to look at whether we are doing a good enough job in public education to make sure that its citizens understand and can deal with some of these threats and understand the nature of these threats so that they don't have to be afraid. They can deal with them without fear.

We are going to be looking as I said at EPA and its authority to respond quickly and to clean up properly when buildings or systems like our mail systems become contaminated.

We were very blessed to have the Marine Corps response team available to us here in Washington when our own buildings were contaminated, but we need to make sure that all of that is organized and we have proper lines of authority, and proper funding for these agencies when they are called upon to act.

We know that we have four major medical response teams in this country established in the four district regions of our country. How well are they organized, and how well are they prepared to respond if in fact a medical alert goes out to our country.

We are going to be looking at all of that next week and through the next 8 to 10 days, and under the instructions of the leadership our Energy and Commerce Committee will be producing the major package on bioterrorism for the House to consider.

So, Mr. Chairman, the work that you do today examining how technology and how improved communications infrastructures can assist in our Nation dealing with these problems is a critical step.

And most importantly, I want to thank you for being awake at the switch when so many others were asleep, and working on this problem even before September 11. Our work now is urgent. Our work now is extraordinarily important and the responsibilities of our committee are deeply felt.

Mr. Deutsch, I want to assure you, and I see that Mr. Dingell has arrived, and all the members on the other side, that in the

next 8 or 10 days we are going to have to all be working in locked step, and we are going to work as we always do in a close bipartisan fashion for a good piece of legislation for the floor. This is the first step, Mr. Chairman, and I thank you for it.

Mr. GREENWOOD. The Chair thanks the chairman of the full committee, and notes the diligence with which he attends all of our hearings, as well as the other five; I don't know how you manage to do it. The Chair recognizes the ranking member of the full committee, the gentleman from Michigan, Mr. Dingell, for 5 minutes for an opening statement.

Mr. DINGELL. Mr. Chairman, thank you for your courtesy, and thank you for holding this very important and informative hearing. Effective disease surveillance is an essential part of the successful operation to protect the public health system at the local, State and national levels, whether we are talking about disease control or bioterrorism attacks.

The public health system, which has been functioning for more than a century in this country, is grounded in the skills and dedicated skills of medical personnel who identify unusual symptoms and diseases and then alert the public health departments of the Federal, State, and local units of government.

Their information allows the public health system to identify and deal with outbreaks of things like salmonella, E. coli, food poisoning, flu, HIV, hepatitis, and tuberculosis epidemics.

Just like politics, however, disease surveillance is local. Sick people go to doctors or an emergency room and not to the Centers for Disease Control and Prevention, or government contractors. Doctors go to their local health departments for help, and not the Federal Government.

And that is where the emphasis of our effort must be. Many people, especially those who stand to benefit from lucrative government projects, say this old system no longer works. A Florida State epidemiologist, who talked to our staff, but who was not able to be here, vehemently denies that position.

The traditional system has functioned exactly as it should have when anthrax appeared in Florida last month, and an alert doctor saw something in Mr. Stevens that looked like anthrax. He immediately alerted the State health department.

The State lab identified anthrax from a blood sample, and this became the indicator case that alerted the entire national public health system. Fancy syndromic surveillance systems would never have alerted the health department to anthrax because there was only one case there at that time.

Hospitals also do not need computers to tell them that something unusual is going on if a thousand people show up in the emergency room with plague-like symptoms. So we must be very careful about developing high-powered surveillance systems that provide daily reams of information that cannot be analyzed, are not useful, and in the words of one public health official, "wear people out."

They will likely cost much, and probably confer little benefit. A good public health disease surveillance system is not one that sits on the shelf spewing out endless reams of useless information while we wait for another bioterrorism attack.

It is one that is an integral part of a health department's day to day operations tracking communicable diseases and outbreaks of other diseases, and educating the medical establishment and the public as to health risks.

A good system puts most of the investment into State and local systems, and not into inside the Beltway projects that do not meet the needs or realities of existing structures.

That said, however, there are many improvements that can be made to our long-neglected public health system to make it more effective and timely. It needs quicker electronic reporting that link laboratories, hospitals, and medical providers to the Public Health Department.

It needs interactive systems so that alerts and treatment information can be sent from the health department back to the providers. It needs better trained medical providers and lab personnel, and it needs more epidemiologists.

It needs more staff so that the public health departments can be staffed 24 hours a day for a quick response. It needs money to upgrade laboratory facilities and to train lab personnel.

This morning, we will hear from public health officials who have taken relatively small amounts of money and are using them to establish electronic systems to speed up disease surveillance, to rebuild their labs, and to train medical personnel.

This is to be commended. Mr. Chairman, we in the Congress need to encourage these kinds of efforts and to fund them at a higher level than we do today. We can also no longer put off rebuilding our public health system. It has fallen into sad states of disarray because of neglect by the Congress and other agencies responsible for that kind of undertaking.

This is the first and best defense we could have against bioterrorism. I heard the comments of our Chairman just a minute or 2 ago, and I am pleased to hear his comments and to know that we on this side will be very happy to work with him and with the leadership to come up with a meaningful, effective, useful, and intelligent program, legislative in character, to deal with the problems of bioterrorism. I thank you for your courtesy, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes the gentleman from Florida, Mr. Stearns, for 5 minutes for his opening statement.

Mr. STEARNS. Good morning, and thank you, Mr. Chairman. Again, like my colleagues, we appreciate holding this hearing and the fact that you were going to have this hearing well before September 11 is a commendation to you and to your staff.

And I believe that while it is essential and worthwhile to hear from the public health department officials, it is also a great opportunity for all of us to hear from those in the private sector, in academic health, and in the Department of Energy contracted laboratories.

My colleagues, these witnesses have valuable real world experiences in disease surveillance, and now more than ever is the time to learn from them. I am particularly interested to hear how we might employ data base systems to report outbreaks, thereby injecting automation in a system that now is manual, voluntary, and not highly complied with.

As the chairman has mentioned there is a problem that the terribly low compliance rate with reporting some diseases. We have got to correct that. The system which relies on "passive surveillance" by doctors often has been criticized as too slow, and has been plagued by poor compliance from overworked health care personnel.

And as the chairman of our committee has mentioned, we need to correct that. I also read in the Washington Post this morning that Dr. Zelicoff, who is one of our witnesses, a senior scientist with the Center for National Security and Arms Control, Sandia National Laboratories, in Albuquerque, New Mexico, he said, Mr. Chairman, "Investigators need to begin to focus less on the microbiology than the physics which is impressive."

He goes on to say that "We didn't think that anybody could come up with the appropriate coatings for anthrax spores to make them float through the air with the greatest of ease. Exposing 28 people with a single opened envelope is no mean trick."

So I think he has pointed out and pointed to all of us a nuance of this debate that we have to understand as to how this could be accomplished. The tentacles of this anthrax menace are spreading from the Postal Service and locations in the Federal Government, to Indiana, Kansas City, Missouri, a hospital in Manhattan, and the British Embassy in Beijing, recently.

What more devastation might lurk from anthrax or other biological agents. Who knows. These are very chilling fears that Americans have. We must be prepared and so I think this hearing is crucial and timely.

And I would be anxious to hear from the other witnesses how we can get higher compliance and so we can improve the system so that it is faster and more automated, and more universal, and I thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman from Florida for his opening statement, and recognizes the gentleman from Michigan, Mr. Stupak, for his opening statement.

Mr. STUPAK. Thank you, Mr. Chairman, and thank you for holding this timely and important hearing on Federal bioterrorism. As we sit here today the reality of bioterrorism has hit home for many Americans and us here on Capitol Hill.

And the reality is that we are not prepared. Today's hearing focuses on how best to prepare our local communities to monitor and integrate a public health surveillance system.

The logistical elements of coordinating our efforts are staggering to say the least, but necessary because local monitoring is where the epidemics and major health problems first get noticed.

Effective communications, means establishing links among law enforcement, local health departments, clinics, and hospitals, so that the critical data in the emergency situation can identify, contain, and respond to an emergency efficiently.

However, we lack the personnel and the resources to do this. I remain highly interested in just how we aim to have a completely integrated public health system in this country. The systems that we will discuss today seem like good ideas, but again good ideas are not necessarily a mark of success.

We need a proactive health surveillance system, and not systems where data and information lie untouched. I look forward to the testimony of today's witnesses to see how we can best accomplish these goals without unnecessarily burdening the front lines of our health care system; that is, our providers and our doctors.

Thank you, Mr. Chairman, and I will yield back the balance of my time as I look forward to hearing from our witnesses.

Mr. GREENWOOD. The Chair thanks the gentleman, and recognizes the gentleman from Kentucky, Mr. Whitfield, for 5 minutes for his opening statement.

Mr. WHITFIELD. Mr. Chairman, thank you very much. This obviously is a timely hearing, and I am not going to make a long statement, except to say that I am looking forward to the testimony on the electronic surveillance information system.

I know that there have been pilot projects in some States with a desire to expand that, and I do look forward to that testimony, particularly on that issue as well as others.

Mr. GREENWOOD. The Chair thanks the gentleman, and recognizes the gentlelady from Colorado, Ms. DeGette, for her opening statement for 3 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman, and I would particularly like to welcome Dr. Davidson, who is with us here today, and who I only found out was appearing here last night.

And so I would particularly like to welcome him. I met with Dr. Davidson and a number of representatives of the Denver Health Departments team that is charged with some kind of early response to bioterrorism.

And I must say, and not to be a local bragger, but we have a fantastic program in Denver and Colorado designed to coordinate agency responses with physician responses, and I know that the committee will love hearing about it today.

I am very proud of it, but I also know that to have any kind of effective network that it has to be a national network, and I know that we are looking forward to hearing about that today.

We had a hearing on October 10 in this subcommittee about the threat of a biological or chemical attack, and at that time Americans feared that post-September 11 that a biological or chemical assault was imminent. Well, guess what. Here we are today.

At the time of October 10, bioterrorism experts pointed out the difficulties of pulling off such an attack. They said that the No. 1 obstacle is disseminating the agent, and pointed to the attempts and relative failures made by terrorists across the world as an illustration of the difficulty.

Unfortunately, what most Americans feared back then has now come to pass. The attack that we are in the midst of appears to be small in scale, but it is clear that we must be better prepared in the event of a larger, more widespread assault.

Issues surrounding biological weaponry, and how various agents can be spread, and their effect on the human anatomy, for example, need greater understanding and clarity. We had an exercise about a year ago.

Some of you have probably seen Dr. Davidson and Dr. Steve Cantrell from the Denver Health Department talking about Oper-

ation Top Off, where we actually had an exercise involving the plague.

And what was really disturbing in that exercise is how many thousands of people were affected by it, and equally disturbing is because of the movements in our society today, how almost immediately the plague in this exercise was spread throughout the United States and even around the world.

And so early response and coordination is clearly the key, and is what we need to work at. There are gaps at the State and local level because of a lack of coordination at the Federal level.

For example, the September 2001 General Accounting Office report on bioterrorism, Federal research and preparedness activities, points out that at the Federal level alone several agencies share responsibility for coordinating various functions, which limits accountability and hinders unity of effort.

What is even more amazing to me is some of these agencies that are dealing with emergency preparedness don't even have e-mail capability, and so they cannot coordinate with their fellow agencies.

I look forward to hearing from each of the panelists. I think that this is an urgent need that we need to address before we see widespread bioterrorism or chemical terrorism, and not after, and I know that everybody can contribute to this effort, and I yield back.

Mr. GREENWOOD. The Chair thanks the gentlelady, and with unanimous consent, would recognize the gentlelady, Ms. Harman, from California, who while not a member of this subcommittee, is a member of the full committee, and a very active participant as a member of the Intelligence Committee in all of these issues, and she is recognized for 3 minutes for an opening statement.

Ms. HARMAN. Thank you, Mr. Chairman, and I appreciate the opportunity to attend this meeting and participate even as an outsider in what I think are the most important issues that our country faces.

This hearing, as I understand it, will highlight the most important functions of our public health system in confronting and combating terrorism. Disease surveillance, and outbreak detection, as we are now learning are the greatest challenges of our terrorism response. This is the foundation of all other health consequence management actions by doctors and government officials.

Much of the language that we use in discussing health security is the same as in discussing national security. Syndromic surveillance, epidemiological intelligence. This link just highlights what more and more people are coming to realize—that our public health system is an essential part of our homeland defense strategy.

I am particularly glad that we will hear from infomatics experts on how to upgrade our surveillance system. I have long advocated the need to eliminate barriers of communication between our intelligence and defense agencies, and for upgrading our intelligence technologies for the digital era. In fact, I often say that we have analog capacity to confront a digital threat. Our public health system must have integrated, advanced, digital communications systems so it can respond quickly and effectively to the bioterrorist threat and disease outbreaks.

Only yesterday, Mr. Chairman, some of us who visited the Center for Disease Control last week introduced a bill to accelerate

\$300 million in infrastructure investments in a new infectious disease building at the CDC.

This new facility is critical to our surveillance effort, and I would hope that all members of the subcommittee, and in fact the full Commerce Committee, will get behind the Lender-Harman bill.

I also hope, Mr. Chairman, that as we develop the bioterrorism package that you and Chairman Tauzin talked about, we might consider this bill as part of the package. It may seem strange to think that a building is a critical part of a bioterrorism effort. But this building will conduct the critical cutting edge research and design the strategies to confront the threat, and as we think about moving forward as you say in real time to our ability to respond, I think it relies on three things.

One, talented people; two, technology that integrates all aspects of the response, starting with understanding what is going on out there, and who is coming to our hospitals; and, three, having the infrastructure to house the people in that technology in a safe and secure fashion.

So I thank you for letting me participate, and I am very eager to hear these witnesses. I yield back.

Mr. GREENWOOD. The Chair thanks the gentlelady, and notes or appreciates the reference with regard to the CDC infrastructure. In fact, if the schedule permits, some of the members of this committee will be flying to Atlanta tomorrow to visit the CDC.

Without objection, the opening statements of any other members not present will be entered into the record.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. MICHAEL BILIRAKIS, A REPRESENTATIVE IN
CONGRESS FROM THE STATE OF FLORIDA

Thank you, Chairman Greenwood, for holding this important hearing today. The Oversight and Investigation Subcommittee's hearings on bioterrorism have been instrumental in assessing the needs of our nation in the event of a bioterrorist attack. In particular, these hearings have informed the bipartisan process that Chairman Tauzin, Ranking Member Dingell, Representative Brown and myself have been engaged in to develop new comprehensive and appropriate legislative authorities that will protect us from a bioterrorist event.

Since the horrific events of September 11th, the United States has been engaged in a war on terrorists who threaten our way of life. Our thoughts and prayers are with those whose lives have been forever altered by the evilness of terrorism. Unfortunately, the weapons of terrorism are not limited to hijacked airplanes and bombs, but also biological agents. Through these hearings and our legislation the Energy and Commerce Committee is taking the lead to ensure that our nation can tackle this very difficult issue.

I share the concerns of many Americans who are worried about possible bioterrorism attacks such as anthrax exposure and outbreaks of smallpox. There recently have been several cases of anthrax exposure through the postal mail which have not only complicated the mail delivery process, but have caused all Americans to fear for the health and well-being of their families.

An outbreak of smallpox is another potential threat. The United States currently maintains national smallpox vaccine stocks sufficient to immunize 6 to 7 million people. Efforts are being undertaken to expand this reserve so that more Americans can be protected from the threat of smallpox.

Cases of anthrax exposure can be treated and infection can be prevented through antibiotics. Great quantities of antibiotics for anthrax and smallpox vaccines are being stockpiled by the Centers for Disease Control and Prevention (CDC) in the event of additional biological attacks. We must ensure that the United States has a sufficient stockpile of vaccines and antibiotics, and that these medications are securely protected. We must also make certain that our public health infrastructure can detect disease outbreaks that may represent a bioterrorism attack.

This is a time for all of us to pull together as Americans. I personally thank and honor those who are on the front lines fighting this war. The United States is a great country, and we are all blessed to enjoy our freedoms.

Again, thank you Chairman for holding this important hearing.

Mr. GREENWOOD. And with that, the Chair welcomes the first panel of witnesses. And they are Dr. Claire Broome, who is the Senior Advisor of Integrated Health Information Systems, Office of the Director, Centers for Disease Control and Prevention, in Atlanta.

And Dr. Anita Barry, Director, Communicable Disease Control, of the Boston Public Health Service; and Dr. Arthur J. Davidson, Director, Public Health Informatics, Denver Public Health Department.

I assume that each of you have been advised that this is an investigative hearing and it is the practice of this committee to take testimony under oath. And so I should ask if any of you have any objections to offering your testimony under oath.

[No response.]

Mr. GREENWOOD. Seeing no such objections, I would advise you that under the rules of the House and the rules of the committee that you are entitled to be advised by counsel. Do any of you care to be advised by counsel today?

[No response.]

Mr. GREENWOOD. In that case, if you would please rise and raise your right hand, I will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. You are now under oath, and we will turn to Dr. Broome first, and you are recognized for 5 minutes for your testimony. Thank you for being with us.

TESTIMONY OF CLAIRE BROOME, SENIOR ADVISOR, INTEGRATED HEALTH INFORMATION SYSTEMS, OFFICE OF THE DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; ANITA BARRY, DIRECTOR, COMMUNICABLE DISEASE CONTROL, BOSTON PUBLIC HEALTH SERVICE; AND ARTHUR J. DAVIDSON, DIRECTOR, PUBLIC HEALTH INFORMATICS, DENVER PUBLIC HEALTH DEPARTMENT

Ms. BROOME. Good morning, Mr. Chairman, and members of the subcommittee. Thank you for the invitation to discuss CDC's public health surveillance activities. As the events of the last month have shown, and as the subcommittee has so eloquently described, public health surveillance is a crucial monitoring function for CDC, its partners, and the country.

Ongoing data collection activities help us detect threats to the health of the public in time to prevent the further spread of disease. Usually the original source of information is the health care provider.

For example, the Florida physician's ability to recognize a suspected case of anthrax and his role in rapidly reporting it to the local health department, was critical to our original recognition of the current bioterrorist events.

There is no substitute for this heightened awareness for diagnosis of conditions of public health importance by doctors. They are the front lines, and they need to be aware, and they need to know

who to notify in the local health department, the State health department, and the CDC.

We work with our public health partners to define conditions that should be reported to public health departments. Health Departments then work with their local partners in the health care system to be sure that they have the information needed.

You have received copies of an October 19, 2001 issue of our MMWR, recognition of illness associated with the intentional release of a biologic agent. I think this is a concrete example of the kind of information that we are constantly distributing to our partners to ensure that they have the latest information.

Of course, this information also goes out electronically. If a case of illness is particularly unusual or severe, such as a case of anthrax or rabies, the provider will call the local health department immediately.

However, routine public health surveillance, the reporting is still done largely by paper or fax. This largely paper based system is burdensome both to providers and health departments, and therefore reports are often incomplete and not timely.

I have discussed the role that surveillance plays in early detection, but surveillance data are also crucial for the public health response. Surveillance data helps us to determine where cases are occurring, and where they are not occurring, so we can target the response appropriately.

It tells us when cases are occurring. Are they increasing, or are they decreasing. It also helps us to take our laboratory test results and match them with the case information so that we can track down the source and define areas at risk.

Such information is vital to directing our investigation and control efforts, but it requires a well designed system to rapidly input and analyze the voluminous data required, such as the thousands of swabs tested for anthrax in the current investigations.

We also recognize the need to take advantage of recent information technology advances to bring our surveillance systems into the 21st century, and I would like to describe a little bit about our new system that has been developed based on informatics principles.

Several years ago we initiated the development of the national electronic disease surveillance system, NEDSS, a web-based surveillance system for use at State and local levels. The goal of NEDSS is electronic real time reporting of information for public health action.

NEDSS includes direct electronic linkages with the health care system. For example, information about relevant diagnostic tests can be shared electronically with public health as soon as a clinical laboratory receives a specimen.

For example, requesting testing for anthrax.

NEDSS emphasizes national standards, and using national standards for data content, security, and information technology architecture. As we build NEDSS, we are ensuring that the data standards we use are compatible with the leading standards for health care systems, so the public health can receive data electronically from the health care delivery systems with less burden on data providers.

The reliance on de facto industry standards for information technology means that NEDSS can incorporate sophisticated commercial products for security, for analysis, for mapping. This is particularly critical for guiding the public health response to an epidemic.

Standards also mean that systems can inter-operate between States so we can detect problems occurring in multiple locations. The CDC has worked with our State and local partners on the development of NEDSS. We have provided funding and support to all 50 States for activities related to NEDSS planning and development.

A NEDSS based system that incorporates the standards and functions mentioned will be deployed in at least 20 States during 2002. This project is critical for ensuring our ability to capture data efficiently, electronically, and to use it effectively for public health response.

And a public health surveillance system that spans the Nation will be essential to detect threats to the public, wherever they might occur and whatever they might be. Recognizing the need for immediately increased capacity while NEDSS is implemented, CDC and its public health partners initiated various activities to improve their ability to detect events of importance.

For example, with the first CDC funding for countering bioterrorist activities, many State health departments were able to purchase the most advanced pattern recognition analytic capacity available today, a trained human being.

We funded States to hire epidemiologists, whose duties included coordinating bioterrorism surveillance, informing health care providers of what to look for, and who to contact if something suspicious turned up.

CDC also funded eight States for special surveillance projects, and projects looked at the utility of possible early warning systems, such as emergency medical systems, 911 calls, hospital admissions, emergency department visits, absenteeism rates, pharmacy data.

After September 11, these systems were explicitly called on to provide heightened surveillance information. CDC is undertaking a critical review of these activities to identify the most useful and practical approaches that may be implemented on a national basis.

Key questions to address include how rapidly are data available for analysis; can the systems identify true outbreaks in the noise of ongoing illness; what effort to enter data is required from already busy health providers; can the systems be used in geographic areas beyond those where they were developed.

In addition, CDC has established networks of clinicians, infectious disease specialists, travel medicine specialists, 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 practice of their members.

In conclusion, 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 infectious diseases.

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. These cross-cutting efforts to build the surveil-

lance infrastructure will be useful to detect any problem, and not just potential bioterrorist events.

The ongoing use of this surveillance capacity will assure 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. Thank you very much for your attention. I will be happy to answer any questions you may have.

[The prepared statement of Claire Broome follows:]

PREPARED STATEMENT OF CLAIRE BROOME, SENIOR ADVISOR TO THE DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning, Mr. Chairman and Members of the Subcommittee. I am Dr. Claire Broome, Senior Advisor to the Director for Integrated Health Information Systems at the Centers for Disease Control and Prevention (CDC). Thank you for the invitation 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 the National Electronic Disease Surveillance System.

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 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.

Much has been in the news lately about the disease detective function of CDC and its epidemiologists, including Epidemic Intelligence Service Officers. What has not been often emphasized is the need for continued watchfulness to first detect problems that our disease detectives then investigate. We refer to this function—this constant state of alert—as public health surveillance.

Public health surveillance is a crucial monitoring function for CDC and its partners. It is these ongoing data collection activities that 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 have underscored this essential role of public health surveillance, as well as the integral role of health care providers in the overall public health system. For most of our surveillance data, the original source of information is the health care provider; the Florida physician's ability to recognize a suspected case of anthrax and his awareness of his role in reporting it to the local health department was critical to our initial recognition of the current bioterrorist events. Indeed, identification of subsequent anthrax cases has also relied on heightened awareness among health care professionals that the wounds and respiratory syndromes they were seeing were actually cutaneous and inhalation anthrax, not merely spider bites and pneumonia.

CURRENT SURVEILLANCE SYSTEMS

The best initial defense against any threats to the health of the public, whether naturally occurring or deliberately caused, continues to be accurate, timely recognition of a problem. Key elements of our current surveillance systems include awareness and diagnosis of a condition of public health importance, whether by a clinician or laboratory, with subsequent notification of the local health department, which in turn reports to the state health department, which shares information with CDC. We work 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. A timely example of such guidelines was included in the October 19, 2001, issue of the *Morbidity and Mortality Weekly Report (MMWR)*, in the report that dealt with "Recognition of Illness Associated with the Intentional Release of a Biologic Agent." Copies of the MMWR have been provided to the Subcommittee.

The traditional operation of our surveillance systems generally consists of paper or facsimile reporting by providers to health departments. If a case of illness is particularly unusual or severe (such as a case of anthrax or rabies), the provider will

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. It was another alert clinician in 1993, a pediatric gastroenterologist, who provided the early warning about a potential diarrheal disease outbreak to the Washington State Department of Health. Within one week, the Health Department identified hamburgers from Jack-in-the-Box as the cause of the outbreak, and the fast-food chain voluntarily recalled all hamburger meat from their restaurants in the state. However, for routine public health surveillance, this largely paper-based system is burdensome both to providers and health departments, and therefore reports are often incomplete and not 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.

Given the crucial function of public health surveillance, we have recognized the need to take advantage of recent 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 the aftermath of September 11, as described in the MMWR report mentioned previously.

INTEGRATED, ELECTRONIC SURVEILLANCE INFORMATION SYSTEMS

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 computer-based vital statistics system 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 emphasizes a standards-based approach, relying on the use of standards for data, information architecture, security, and information technology (de facto industry standards). This reliance on 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. As we build NEDSS we are ensuring that the data standards we use are compatible with those used in health care systems, so that we can make sense of health-related data and therefore detect potentially related cases across the country. In addition, a standard information architecture and appropriate, high level security 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 de facto industry 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 has worked with our state and local partners on the development of NEDSS. We have provided funding and support to all 50 states for activities related to NEDSS planning and development. NEDSS is an ambitious project; defining appropriate standards and ensuring appropriate data sharing among the myriad health care systems, over 2000 local health departments, 50 state health departments, and numerous federal public health agencies is a complex process. As a start, a NEDSS

Base System that incorporates the standards and functions mentioned will be deployed in at least 20 states during 2002. This project will ensure our ability to capture data efficiently, electronically, and to use it effectively for public health response. And a public health surveillance system that spans the nation will help detect threats to the public, wherever they might occur.

Indeed, 2 related projects also provide a key part of the effort to ensure the development of the public health communications infrastructure. Health Alert Network (HAN) is a nationwide program, the goals of which include provision of Internet connectivity and rapid communications capability among local and state health departments, which will also facilitate linkage of local health departments and health care providers. This connectivity will be crucial for rapid sharing of surveillance data among public health agencies. In addition, the Epidemic Information Exchange, or *Epi-X*, provides secure, high-speed, Web-based communication about outbreaks and other acute or emerging health events among public health officials from CDC, state and local health departments and the military. One of the unique features of *Epi-X* is the ability to provide a forum for secure communications for state epidemiologists to post information on surveillance and response activities for approximately 500 public health officials around the country, including the U.S. military. Another unique feature of *Epi-X* is emergency notification by telephone and/or pager to defined groups of public health officials.

Support to date for these important national projects has strengthened our public health infrastructure for detection of events of concern and subsequent communication to ensure appropriate public health response.

NEAR TERM SURVEILLANCE EFFORTS

Recognizing the need for near term increased capacity while NEDSS is implemented, CDC and its public health partners initiated various activities to improve their ability to detect events of importance to the health of the public. For example, with the first CDC funding for countering bioterrorist activities, in Fiscal Year 1999, many state health departments were able to purchase the most advanced pattern recognition analytic capacity available today—a trained human being: an epidemiologist whose duties included coordinating bioterrorism surveillance and rapid response activities. The activities range from enhancing communications (between state and local health departments and between public health agencies and health-care providers) to conducting special surveillance projects. These special projects have included active surveillance for changes in the number of emergency medical system/911 calls, hospital admissions, emergency department visits, and occurrence of specific syndromes. After September 11, these systems were explicitly called on to provide heightened surveillance information. CDC is undertaking a critical review of these activities to identify the most useful and practical approaches that may be implemented on a national basis. One key question to address is the feasibility of capturing medically relevant data in a timely and appropriately representative fashion, since we do not know when or where the next event might occur. Furthermore, what effort do proposed systems require from health care providers to report, or enter data in the systems? Can the systems be used in geographic areas beyond those where they were developed? In addition, given the substantial burden of investigating potentially concerning events, we are evaluating mechanisms for minimizing the proportion of alerts generated by the system that are false alarms.

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, and often involve partnerships among public health agencies and academic medical centers. 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. The guidance provided in the October 19 MMWR is intended to heighten awareness among these clinical partners about what to watch for, and what to report to public health. 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 local health department is the front-line of defense for the public health system. Many other projects and proposals for rapid surveillance omit the vital connection to public health, especially the local public health agency, which is responsible for the initial public health response.

CONCLUSION

In conclusion, CDC is committed to working with other federal agencies and partners as well as state and local public health departments to ensure the health and medical care of our citizens. The best public health strategy to protect the health of civilians against illness, regardless of cause, is the development, organization, and enhancement of public health prevention 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 infectious diseases. 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 as special 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 in coming weeks. We are implementing the National Electronic Disease Surveillance System, which will provide direct linkages with the health care system in 2002, 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 assure 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.

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

Mr. GREENWOOD. Thank you, Dr. Broome. I appreciate your testimony.

Dr. Barry, you are recognized for 5 minutes for your testimony.

TESTIMONY OF ANITA BARRY

Ms. BARRY. Chairman Greenwood and honorable committee members, thank you for inviting me here to speak with you today about public health surveillance. My name is Dr. Anita Barry, and I am the Director of Communicable Disease Control for the Boston Public Health Commission, which is the local health authority for the city of Boston under the leadership of our mayor, Tom Menino.

In 1999, the Boston Public Health Commission participated in a city-wide disaster tabletop exercise that simulated an outbreak of pneumonic plague. Through this exercise, we realized that in a medical or public health crisis, health care providers must have timely and accurate information, including clinical guidelines.

Boston's disease monitoring system at that time relied primarily upon local hospitals, health care providers, or laboratories, to call when they diagnosed a reportable disease or identified a cluster of unusual illness.

Unfortunately, this method often provides late and incomplete information, especially in an emergency. It became clear that we needed an active system to let us know about problems early on.

Thanks to the Federal Centers for Disease Control and Prevention, Boston received a grant for \$1 million over 5 years to develop and implement an early warning system to detect bioterrorism or any other infectious disease mass casualty event.

For the last 2 years, we designed and set up this system, which has now been operational for 6 months. Additional components of the system, including daily information from the Poison Control Center located in Boston, Boston Emergency Medical Services, and death certificates, will be on-line in the next few months to supplement the already incoming health care site data.

One of the first things we did to create our surveillance system was to convene a task force of key stakeholders to develop a workable system. We invited representatives from emergency departments, acute care sites, infectious disease departments, the State Health Department, and our local zoo, among others, to help us develop this system.

As a group, we designed the Boston system to minimize the effort on the part of emergency department personnel and other hospital based personnel. We heard very clearly from the emergency department directors that drop in surveillance systems, in which a separate additional sheet of information for each patient is required to be filled out by their personnel, is completely unworkable.

The Boston system works as follows. Each night the medical information system at each facility automatically sends our secure web-based server the number of persons seen in that emergency department or other acute care site.

This figure is automatically compared to the expected number of visits for that site, adjusted for season of the year and day of the week. If it is higher than expected, a one page follow-up form is automatically sent to a pre-identified contact at that hospital.

This form asks more detailed questions about the nature of cases seen in the acute care site to determine if anything unusual is going on. This follow-up information determines whether or not further investigation is required.

Hospital staff appreciate the fact that they are asked to take time to provide detailed information only when the system indicates that something may be going on. While this volume based system will not identify an isolated case like the anthrax cases in other cities, the constant reminders that we send to health care providers through this system increases the chances of timely reporting.

Our experience in the past 6 weeks has also highlighted how this system provides important public health data, whether or not there is a mass incident. Although we have had no bioterrorist events in Boston, during the first week of reports of anthrax cases, we observed a surge in patient volume at several hospital sites.

Follow-up investigation revealed that this was not due to any unusual clusters of symptoms, but rather to an influx of frightened people requesting nasal swabs and cipro prescriptions, despite the absence of any confirmed or suspected anthrax exposures in Massachusetts.

At the local health department, we used this information as an indicator of the need for increased public education and increased public timely information release. One of the most important purposes of the system is to create a flow of information between that local health department and local health care providers.

The Boston Public Health Commission, with our surveillance task force, also developed a provider education initiative on bioterrorism. This program, which began about 1½ years ago, uses a train-the-trainer model to teach physicians and nurses to educate their peers.

This training has been much in demand of late. Additionally, we use this electronic surveillance system to post and send regular clinical advisories and updates out to the surveillance task force

members and others, including the city's 25 community health centers, the college health centers, Boston Emergency Medical Services, and others.

These guidelines have served as the foundation for protocols developed by local hospitals regarding the medical management of people being seen with possible anthrax exposure.

I believe that the Boston system is replicable with modifications in other cities and regions, as well as on state-wide levels. Our experience has also implications regarding what is needed for local health departments to maintain an effective early warning system, as well as the ability to respond to public health events detected by these systems.

First, key stakeholders must be at the table to design the system. Second, the system should serve as a communication network, as well as a surveillance system. Third, the system should be simple and as automated as possible so it is doable by busy health care systems.

And finally at the same time, it should account for the human factor, which is essential both to maintain the system, and to obtain the data if the electronic system is delayed or temporarily not functioning.

I also would like to share some thoughts about the broader implications of Boston's experience. Last week, Boston Mayor Menino and City Public Health and Safety Officials joined mayors from across the country at the U.S. Conference of Mayors' Emergency, Safety, and Security Summit.

The following suggestions combined public health action steps recommended by the Boston Public Health Commission, and the U.S. Conference of Mayors. First, the technical capabilities in communication infrastructure of local health departments must be improved.

Our ability to create this surveillance system was the result of a CDC grant. Without Federal funding, we could never have designed this system. Second, all local health departments should have direct access to communications systems like CEC's Epi-X to receive ongoing timely updates.

Such a system is key to having accurate and timely information from local public health officials, and so we strongly support full funding and expansion of the health alert network.

Third, we need to think regionally about surveillance and communications systems, and we need Federal support to implement such regional systems. Boston is currently in discussion with surrounding communities about sharing and expanding our surveillance system, because the impact of an infectious disease or bioterrorist events will not end at the Boston city borders.

Fourth, Federal Agencies should direct more funding directly to local communities. National public health organizations recommend that at least \$835 million of the Emergency Bioterrorism Funding Request go directly to local and State health departments.

Local communities must receive a significant portion of that funding. Too often local health departments are left out of the equation, and we bear the major burden of the day to day response.

For example, in Boston alone, the health department anticipates spending \$700,000 by the end of this fiscal year on bioterrorism-

related emergency medical service response, and a surveillance, epidemiology, communication, and coordination of activities within the communicable disease control program.

Federal funding should be flexible. We need to track and respond to a range of public health concerns, including not only bioterrorist agents, but also influenza and other emerging problems.

And finally local public health departments should be represented at the table in national emergency planning. A permanent commission, including mayors, local public health officials, and local public safety officials, should immediately be established by the Director of Homeland Security.

Local officials are on the front lines of homeland security, and it is essential to forge direct lines of communication among the Office of Homeland Security, Federal Agencies, and local governments.

In closing, I thank Chairman Greenwood and the committee for inviting me to speak today on behalf of local health departments, and I would be pleased to provide any further information you would like.

[The prepared statement of Anita Barry follows:]

PREPARED STATEMENT OF ANITA BARRY, DIRECTOR, COMMUNICABLE DISEASE CONTROL, THE BOSTON PUBLIC HEALTH COMMISSION

Chairman Greenwood, Honorable Committee Members, thank you for inviting me here to speak to you today about public health surveillance. My name is Dr. Anita Barry. I am the Director of Communicable Disease Control for the Boston Public Health Commission, the health department for the City of Boston, under the leadership of Mayor Thomas Menino.

In 1999, the Boston Public Health Commission participated in a citywide disaster tabletop exercise that simulated an outbreak of pneumonic plague. Among the participants were representatives from all the major Boston hospitals. Through this exercise, we realized that in a medical or public health crisis, health care providers must have timely and accurate information, including clinical guidelines. At that time, Boston had only what most local health departments have: a passive surveillance system. We waited for local hospitals, health care providers, or laboratories to call us when they diagnosed a reportable disease or identified an unusual cluster of illness. Unfortunately, this method can provide late and incomplete information, especially in an emergency. For example, influenza—one of the diseases we are most interested in identifying early—is not required to be reported in Massachusetts. Influenza outbreaks tended to be reported late—or not at all, making it impossible to introduce timely measures to contain the spread of disease. It became clear that we needed a system to let us know about problems early on.

Thanks to the federal Centers for Disease Control and Prevention, Boston received a \$1 million five-year grant to develop and implement an early warning system to detect a bioterrorist or other infectious disease mass casualty event. We were one of about seven localities in the country to be awarded such a grant, and the only city to monitor volume in emergency room and acute care facilities through an automated, electronic, real time system.

For the last two years, we designed and set up the system, which has now been operational for about six months. Additional system components, including daily information from the Poison Control Center in Boston, Boston Emergency Medical Service, and death certificates will be on line in the next few months to supplement the health care site data. I will give you a brief overview of how the hospital-based system works and then share what we have learned that is relevant to other localities, as well as federal bioterrorism preparedness planning and funding.

One of the first things we did to create our surveillance system was to convene a task force of key stakeholders to help develop a workable system. We invited representatives from emergency departments, acute care sites, hospital infectious disease specialists, state health department infectious disease specialists, representatives from Zoo New England, Emergency Medical Services, the Poison Control Center, the Chief Medical Examiner, and others.

As a group, we designed the Boston system to minimize the effort on the part of emergency department and other hospital-based personnel. We heard very clearly

from emergency department directors that drop-in surveillance systems in which a separate additional sheet of information on each patient is required to be filled out by ED personnel are unworkable. The system works as follows. Each night the Medical Information Systems at each facility send to our secure web-based server by FTP the number of persons seen in their Emergency Department or other acute care site. This figure is automatically compared to the expected number of visits for that site, adjusted for season of the year and day of the week. If it is higher than expected, a one page follow-up form is automatically sent to a pre-identified contact at the hospital.

This form asks more detailed questions about the nature of the cases seen in the acute care site to determine if anything unusual is going on. We usually receive these completed forms back from hospitals within 1-2 hours. If a form is not returned from a site, the system automatically pages a contact at that site to obtain further information. This follow-up information determines whether or not further investigation is required. Hospital staff appreciate the fact that they are asked to take the time to provide detailed information only when the system indicates that something may be going on.

In order to determine the normal volume thresholds as well as what is a statistically significant increase in volume for each site, we obtained retrospective data from all of the sites and analyzed it. To validate the system's ability to detect clusters of illness, we retrospectively compared volume spikes above threshold at sites with the first confirmed presence of influenza in Boston in 1999. Changes in volume detected using the system correlated well with the first laboratory confirmed case of influenza. We believe the system will give us early warning of other public health concerns, including a range of infectious diseases.

While this volume-based system will not identify an isolated case, like the anthrax cases in other cities, the constant reminders that the system allows us to send health care providers increases the chances of timely reporting.

Our experience in the last 6 weeks has also highlighted how this system provides important public health data. Although we have had no bioterrorist events in Boston, during the first week of reports of anthrax cases, we observed a surge in patient volume at several hospital sites. Follow-up investigation revealed that this was not due to any unusual clusters of symptoms, but rather to an influx of frightened people requesting nasal swabs and Cipro prescriptions, despite the absence of any confirmed or suspected anthrax exposure in Massachusetts. At the local health department, we used this information as an indicator of the need for increased public education and increased public information efforts.

Because one of the most important purposes of the system is to create a flow of information between the health department and local health care providers, the Boston Public Health Commission, with the Surveillance Task Force, also developed a curriculum on bioterrorism for physicians and nurses. This educational initiative which began about a year and a half ago, uses a "train the trainer" model. The health department provides a CD containing slides as well as handouts to these trainers, who are physicians and nurses, to educate their peers. This training has been much in demand of late.

Additionally, we use our electronic surveillance system to post and send regular clinical advisories and updates out to surveillance task force members and others, such as community health centers, college health centers, and Boston Emergency Medical Services. These guidelines have served as the foundation for protocols developed by local hospitals regarding medical management of patients with possible anthrax exposure.

I believe Boston's system is replicable, with modifications, in other cities and regions, as well as on a statewide level. Our experience also has implications regarding what is needed for local health departments to maintain effective early warning systems as well as the ability to respond to public health events detected by surveillance systems.

1. Key stakeholders must be at the table to design the system.
2. The system should serve as a communication network as well as a surveillance system.
3. The system should be simple, and as automatic as possible, so it is "doable" for busy health care systems.
4. At the same time, it should account for the "human factor," which is essential both to maintain the system and to obtain the data if the electronic system is delayed or temporarily not functioning.

I'd also like to share some thoughts about the broader implications of Boston's experience. Last week, Boston Mayor Menino and City public health and safety officials joined mayors from across the country at the U.S. Conference of Mayors Emergency, Safety, and Security Summit. The following suggestions combine public

health recommendations from the Boston Public Health Commission and the U.S. Conference of Mayors National Action Plan for Safety and Security in America's Cities:

- The technical capabilities and communication infrastructure of local health departments need to be improved. Our ability to create this surveillance system was the result of a CDC grant. Without federal funding, we could not have designed this system.
- All local health departments should have access to communications systems like Epi-X to receive ongoing timely updates. Such a system is key to having accurate and timely information from local public health officials, so we strongly support full funding and expansion of the Health Alert Network.
- We need to think regionally about surveillance and communication systems, and we need federal support to implement such regional systems. Boston is currently in discussion with surrounding communities about sharing and expanding our surveillance system because the impact of an infectious disease or bioterrorist incident will not end at city borders.
- Federal agencies should direct more funding to local communities. National public health organizations recommend that at least \$835 million of the emergency bioterrorism funding request go directly to local and state health departments. Local communities must receive a significant portion of that funding. Too often, local health departments are left out of the equation, and we bear the major burden of day-to-day response. For example, in Boston alone, the health department anticipates spending \$700,000 by the end of this fiscal year on bioterrorism-related emergency medical service response and the surveillance, epidemiology, communication, and coordination activities of the communicable disease program.
- Federal funding should be flexible—we need to track and respond to a range of public health concerns, including bioterrorist agents as well as influenza and other emerging problems.
- And local public health departments should be represented at the table in national emergency planning. A permanent commission including mayors, local public health officials, and local public safety officials should be immediately established by the Director of Homeland Security. Local officials are on the frontlines of homeland security, and it is essential to forge direct lines of communication among the Office of Homeland Security, federal agencies, and local governments.

In closing, I again thank Chairman Greenwood and the Committee for inviting me to speak on behalf of local health departments, and I would be pleased to provide any further information in the future.

Mr. GREENWOOD. Thank you, Dr. Barry. I appreciate your testimony as well, and coming here, and Dr. Davidson, you are recognized for 5 minutes for your testimony. Thank you for being with us as well.

TESTIMONY OF ARTHUR J. DAVIDSON

Mr. DAVIDSON. Thank you. Mr. Chairman, and members of the committee, I am Arthur J. Davidson, a family physician, epidemiologist, and the Director of the Denver Public Health Informatics at Denver Health.

I consider it a privilege to testify before the committee, providing a local perspective about our public health surveillance system. I guide Denver's public health surveillance activities, and am the principal investigator of the Denver Center for Public Health Preparedness, where I have been involved in the preparation and training from weapons of mass destruction over the past 2 years, including the planning and execution of Operation Top-Off.

What I would like to do today is describe Denver Health as an example of how an integrated safety net system may play a role in public health surveillance, and then discuss linkages and potential barriers with other critical health care entities, including State and Federal systems.

Denver Health is a highly integrated safety net institution, serving a quarter of Denver's half-million residents. Some of its components include Denver's emergency response system, an acute care hospital, neighborhood and school based health clinics, the public health department, and a regional poisonous center.

Each of these entry points has capacity to contribute to surveillance activities. Linked by a unique patient identifier, an integrated electronic medical record includes patient demographics, image medical records, laboratory, radiology, pharmacy, and ancillary systems.

Denver Health information technology investments have exceeded \$100 million in the past 5 years. From an infomatics perspective, data achieves value through conversion to information that guides action.

Examples of such action within Denver Health include electronic reporting of laboratory data to nurse epidemiologists for communicable disease surveillance and control; or patient-specific pharmacy adherence measures for tailored HIV outreach worker interventions.

While these customized applications have value, our vision is to achieve even greater yield through building around industry standards. Denver Health, in collaboration with the Agency for Health Care Research and Quality, our information systems vendor, Siemens, and the CDC, are developing a real time method to identify patients at risk for tuberculosis, and then alert providers of screening guidelines using a standardized rules language.

These partnerships seek to use our information infrastructure to enhance our return on investment by industry standard messaging. The ultimate goal is appropriate and timely surveillance data with less expended effort.

Physician identification of disease remains a critical component of surveillance. Physicians must be informed to fill this role. CDC's health alert network, HAN, has been a wise investment, rapidly bringing the latest anthrax information to 3,000 local health departments and beyond.

In Denver, I personally disseminate these alerts to all health care providers, enabling heightened awareness. While disease surveillance is a time honored public health skill, the concept of syndromic surveillance is new.

In Denver, we are testing this concept using an existing emergency department electronic data base, and with asthma as a disease model, we found symptoms surveillance to be less sensitive than diagnosis surveillance, but then more timely.

While we found spikes and seasonal patterns, thresholds still need to be established to assist in interpretation. I believe the jury is still out on this one. Although an integrated health care delivery system with advanced information technology has much potential, these data must be integrated with other local, State, and Federal health care institutions for a truly robust surveillance system.

Through preliminary discussions with local health maintenance organizations regarding electronic sharing of symptom and diagnosis data, issues of patient confidentiality have arisen to detect disease and guide local response to intentional biologic releases.

We need laws that protect individual confidentiality, but do not inhibit information flow to protect the larger population. Your committee may wish to review HIPAA legislation toward modifying laws that excessively regulate information sharing for public health surveillance activities.

Regarding Federal and State data linkages, CDC's national electronic disease surveillance system, NEDSS, provides a coordinated surveillance framework, developing standards and conceptual models that maximize information technology.

Accepting health information industry standards will enhance electronic information transfer and capacity for automated electronic surveillance. In Colorado, NEDSS, HAN, and our center's preparedness funds, are coordinated to help build an integrated data repository, support direct laboratory transfer of data to the Colorado Electronic Disease Reporting System, or CEDRS, develop hand-held devices as surveillance tools, establish secure wireless CEDRS access, add geographic information functionality, and assure an informed Colorado public health work force.

These are new and exciting challenges for a public health infrastructure that has been significantly under-funded in information technology for so long. While an effective early warning surveillance system is desirable, a major preparedness concern persists, insufficient surge capacity within the entire public health core system.

Today, in the absence of a bioterrorist event, most Denver hospitals are at capacity, and often cannot receive ambulances. Denver Health typifies safety net health care systems with extremely tight financial status and no additional support to build capacity to respond after a terrorist attack.

Given these comments, I want to thank Congress and the leadership of this committee for the efforts already accomplished. Exercises such as Operation Top-Off have proven invaluable to stimulate interest and planning for the unthinkable.

CDC's efforts to build and utilize HAN, develop and disseminate NEDSS, and focus on work force development, are bright spots with real potential to improve operational readiness and surveillance capacity.

However, as shown in numerous other industries information can drive feedback, quality control, and triggers for intervention. Such an integrated health data environment, with proper protection of individual confidentiality, should accelerate outbreak investigation, enhancing our public health response.

Your committee has the opportunity to promote and encourage this data integration. You should build on these initial positive steps and expand capacity to achieve early warning systems in every community.

In closing, I want to thank you, Mr. Chairman, and the committee, for this opportunity to discuss some issues of concern regarding early decisions detection and response to terrorist events at the local level.

Mr. Chairman, this concludes my testimony, and I am pleased to answer any questions that you or the committee might have.

[The prepared statement of Arthur J. Davidson follows:]

PREPARED STATEMENT OF ARTHUR J. DAVIDSON, DIRECTOR, PUBLIC HEALTH
INFORMATICS, DENVER PUBLIC HEALTH DEPARTMENT

Mr. Chairman and members of the Committee, I am Arthur J. Davidson, a family physician, epidemiologist and Director of Public Health Informatics at Denver Health. I consider it a privilege to testify today before the Committee to provide a local perspective and concern about our public health system surveillance system and its role in our preparedness for bioterrorism. One of my roles is to guide Denver's public health surveillance activities and I am the principal investigator for one of three CDC-funded local health department projects, the Denver Center for Public Health Preparedness. For the last two years, I have been involved in the local preparation and training for weapons of mass destruction and was a participant in the planning and execution of Operation TopOff.

What I would like to do is describe Denver Health's system as an example of how an integrated safety net system may play a role in public health surveillance, discuss linkages with other critical health care entities, the state and federal systems, and the barriers existing at each of these levels.

Denver Health is a highly integrated safety net institution serving Denver, the state of Colorado and the Rocky Mountain Region. Some of its components (see attachment 1), which are relevant to today's discussion, include the 911 medical response system for the City and County, an acute care hospital with a regional trauma center, 10 neighborhood health clinics, 13 school based clinics, the public health department and a regional poison center. This system has multiple entry points, each with capacity to contribute to surveillance initiatives. In addition, the system served more than one in four people in Denver last year and thus provides an ability to sample a large segment of the population at any given time. Care is provided by one group of employed academic physicians, enabling standardized approaches to monitoring, reporting and care. The system is linked by a single patient identifier and an electronic integrated medical record. The electronic record includes patient demographics, imaged medical records, laboratory data, radiology, pharmacy and ancillary systems. A picture of the information system is include with my remarks (see attachment 2). Denver Health's information technology investments have exceeded \$100 million dollars in the last 5 years.

We have begun to use and assess the ability of this system to serve as a public health and disease surveillance system and to improve health care delivery. From an informatics perspective, the true value of data can only be achieved through conversion to information that guides action. A few examples of such action within Denver Health include electronic reporting of laboratory data to Denver Public Health nurse epidemiologists for use in communicable disease surveillance and control. Patient-specific pharmacy adherence measures for prophylaxis and treatment regimens, are provided to HIV outreach workers to target interventions. Feedback to providers, using an immunization registry and administrative data, enhance efforts to keep children up to date with immunizations. While these customized applications have value, our vision is to achieve even greater yield through building around industry standards.

In that regard, Denver Health has a task order from the Agency for Health Research and Quality to work with our information systems vendor, Siemens and the CDC to develop a methodology to identify patients at risk for tuberculosis and alert the providers of the need for tuberculosis screening. Preliminary data suggest that we may have as many as 12,000 at risk patients in our system. We are collaboratively developing a real-time system to alert care providers of needed action for tuberculosis screening using a standardized rules language. Appropriately applied rules can be powerful tools to change provider behavior or improve surveillance efforts. This rules-based surveillance approach has the potential to dramatically reduce the incidence of this important infectious disease. Our goal, and that of Siemens and CDC, is to seek ways to take advantage of our information infrastructure capabilities and enhance our return on investment. These partnerships can improve electronic communication and provide models for using industry standard Health Level 7 messaging and extensible markup language. The ultimate goal is appropriate and timely surveillance data with less expended effort.

Currently and into the foreseeable future, physician identification of disease remains a critical component of surveillance. The two most recent nationally recognized emerging infections, West Nile Fever and anthrax were identified by astute clinicians. But physicians must be informed to fulfill this role. The Health Alert Network (HAN) exemplifies how we can wisely invest in infrastructure to quickly bring the latest information to the front lines. Now in it's third and final year, CDC continues to use the HAN daily, to inform and advise nearly 3000 local health departments of the latest and rapidly changing developments since identifying an-

thrax released through the mail. In Denver, I personally disseminate these alerts to all health care providers enabling heightened awareness.

While disease surveillance is a time-honored public health skill, the concept of syndromic surveillance is new and one worth a few specific comments. As part of our CDC-funded Center for Public Health Preparedness, we are still early in testing this concept. The goal would be to identify patterns of patient symptoms to alert public health care providers of potential illness. Using the chief complaint, recorded in an existing emergency department electronic database, we tested asthma as a model disease for our syndromic surveillance. We found symptom surveillance to be less sensitive than diagnosis surveillance but more timely. While we found spikes and seasonal patterns in asthma diagnosis, we need to establish thresholds to appropriately interpret the output from any symptom-based surveillance systems. Symptom data were easily collected as part of routine patient care in our integrated information systems, but a more structured format (rather than free text fields) would improve their surveillance utility. To date, we are just entering the evaluation stage. The jury is still out on this one.

Although this integrated health care delivery system and its linked information technology has much potential, data from such a system must be integrated with that of other local, state and federal health care institutions for a truly robust surveillance system. A local public health system needs to share information across all local health care institutions for early recognition and ongoing monitoring of an epidemic. We have had preliminary discussions with some local health maintenance organizations regarding electronic sharing of symptom and diagnosis data. There no doubt will be hurdles regarding confidentiality before this is achieved. To detect disease, assess threat and guide local response to intentional biologic releases, we need laws that protect individual confidentiality but do not inhibit information flow to protect the larger population. Since September 11th, with our national emergency, Congress and the President have modified laws that determine how information is shared between financial institutions and law enforcement and even diminished some civil liberties for the purpose of surveillance and national security. Given our recent tragedies, this seems reasonable and prudent. Similarly, your committee may wish to review HIPAA legislation toward modifying laws that excessively regulate information sharing for public health surveillance activities.

Regarding federal and state data linkages, CDC is in the early phases of building the National Electronic Disease Surveillance System (NEDSS) to provide a coordinated surveillance framework. Bringing local, state and national health departments to the table, NEDSS has worked to acknowledge and accommodate our unique data needs while developing standards and conceptual models that maximize information technology. Defining common information system architectures improves our return on investment with decreased maintenance costs. Accepting standards, like those within the health information industry, enhances our capacity for electronic information transfer, whether that be laboratory data or other health-related data such as symptoms or diagnoses. If public health surveillance ascribes to these industry standards, health care information systems may be better interfaced for automated, electronic surveillance seeking syndrome patterns and/or diagnostic trends for earlier alerts of potential biologic or chemical releases.

NEDSS within Colorado has permitted us to define a statewide, integrated data repository that becomes the hub for information organization. Our goal of direct laboratory transfer of data to the Colorado Electronic Disease Reporting Systems (CEDRS) is anticipated during this NEDSS funding cycle ending June 30, 2002. Direct laboratory reporting would improve surveillance completeness as busy clinicians are less likely to contact their local or state health department for a reportable disease. This should enhance early warning systems given improved reporting accuracy. However, laboratory reporting does not solve all surveillance needs as some demographic information (e.g., address of patient) would not be provided. With combined NEDSS/HAN funds, we are developing CEDRS geographic information system capacity to report visually based on space and time. Before achieving visual presentations of laboratory data, linkage with administrative databases for patient address would be necessary. This is a non-trivial task given issues of patient confidentiality.

To improve the timeliness of reporting, we are working to develop and test alternative data entry mechanisms. Using Health Alert Network and Denver Center for Public Health Preparedness funds, efforts are under way to build applications on hand-held devices as surveillance data collection tools. Training and testing public health employee skills in adapting to these devices is in progress. We have plans to develop secure wireless access for rapid data entry into CEDRS from multiple surveillance sites (e.g., hospitals). The pilot projects, using readily available technology already incorporated in other industries are new and exciting challenges for

a public health infrastructure that has been significantly under funded in information technology for so long.

Making sure that the personal and public health care workforces are adequately informed and trained in these new technologies is essential. In many rural and smaller urban communities in my state, public health workers need training on how to best use the surveillance measures that they collect or receive. Even if we had perfect information systems, the poorly skilled public health worker may lack the knowledge to put that information to good use. Similarly, medical and public health sectors that address medical aspects of a biological or chemical terrorist attack, sorely lack knowledge and planning to deal with such an incident. Enhancement of CDC- and HRSA-funded programs to create a knowledgeable and prepared public health system workforce is now of central importance to our national security. Coordinated public health systems will require additional funding to support planning, readiness training and an equipped infrastructure to deal with medical consequences of weapons of mass destruction.

While an effective early warning surveillance system is desirable, there remains a major preparedness concern regarding adequate resources or "surge capacity" within the entire public health core system. From Operation TopOff, our local hospital system quickly overloaded with patients infected with pneumonic plague. In Denver, over the last decade, cost-reduction and a competitive health care market have resulted in the loss of over 1000 hospital beds. Thus, at baseline even without a bioterrorist event, most Denver hospitals are at capacity and cannot receive ambulances on a normal day. Given recent events, we work to enhance our local readiness but Denver Health typifies safety-net health care systems with extremely tight financial status. Without additional support, public safety net hospitals, needed in a terrorist attack, will not have the necessary capacity to respond.

Given these comments, I want to thank Congress and the leadership of this committee for the efforts already accomplished. The federal government's investment in local training and planning for a potential WMD event have in my opinion made significant strides in our awareness and preparedness. Exercises such as Operation TopOff have proven invaluable to stimulate interest and planning for the unthinkable. Efforts to build and utilize the Health Alert Network and disseminate National Electronic Disease Surveillance System plans from the CDC as well as workforce development by CDC and HRSA are bright spots with real potential to improve our operational readiness and surveillance capacity. Public health surveillance however can benefit even more from information technology. As has been shown in numerous other industries, information can drive feedback, quality control and triggers for intervention. That same technology, in an integrated health data environment, with proper protection of individual confidentiality, should accelerate outbreak identification enhancing our public health response. Your committee has the opportunity to promote and encourage that data integration. We should build on these initial positive steps and expand capacity to achieve early warning surveillance systems in every community.

In closing, I would like to thank you, Mr. Chairman, and the Committee, for this opportunity to discuss some issues of concern to medical and public health communities in our preparedness for early detection and response to terrorist events at the local level. Mr. Chairman, this concludes my testimony. I am pleased to address any questions that you or the Committee might have.

Mr. GREENWOOD. Thank you for your testimony, Doctor Davidson, and the Chair recognizes himself for 5 minutes for inquiry. Dr. Davidson, in your testimony, you said that while disease surveillance is a time honored public health skill, the concept of syndromic surveillance is new.

The hypothesis that I think this hearing is meant to test is this one. It is that by it is possible to create, using state-of-the-art information systems, a nationwide early surveillance system that would by means of identifying spikes in early symptomatology for diseases that would result from a bioterrorist event, to get a head start and to move more quickly to deploy into that geographical location, or those geographical locations, and thereby diminish the infectious—the rate of infection and save lives.

And so that is the question that we are asking here, Dr. Davidson, and you also talked about a truly robust surveillance system, and I think that is what we are thinking about.

So the question that I would like to pose to each of you is do you believe that that hypothesis is a valid one, and therefore would you in fact recommend to the Congress that what we do is as quickly as is practicable, without throwing money at the wall, but to do it as quickly as it is possible, build such an early surveillance system nationwide that would obviously have great value for health care in general, and for such diseases in general, but would be of particularly acute value in protecting our country from a bioterrorist event, and I will start with Dr. Broome.

Mr. DAVIDSON. Thank you, Mr. Chairman. I think your question is an excellent one, but I think the answer is not either/or. I do not think there is a single magic bullet which will address all surveillance issues.

I think the critical issue is to be prepared to detect and respond to whatever may come along. If it is isolated single cases, as I have indicated, physician awareness, health care provider awareness, and contact with a strengthened local health department, and a public health infrastructure, is critical.

If it is routine—for example, a low level contamination across a commercial food product—and let's go away from bioterrorism for a minute and just consider something that does happen, the kind of systematic information about specific cases—you are looking for the proverbial needle in a haystack, and the best way to do that is to be able to define the needle.

It may not cause a big bump in disease. It may just cause a bump in a particular organism, and then finally you have the—and that is the kind of effort that NEDSS is designed to address, among others.

Then finally you have the potential that some of these supplementary surveillance systems might provide early warning information that would be more timely. But I agree with the other panelists that we need to look critically at what kinds of supplementary information would actually improve our ability to detect certain kinds of scenarios.

Mr. GREENWOOD. Let me see if I understand what you said. I gather from what you are saying that it may—would I be paraphrasing you correctly if you said that it is necessary, but not a sufficient response?

In other words, that it is worth doing this as long as we don't consider it to be sufficient, but rather a part of a broader approach to surveillance?

Mr. DAVIDSON. I think the critical elements of a surveillance system we know, and those are the first two points that I made; that we need to have educated capacity and information communication.

And then second, we need to have a systematic collection of what you might call traditional surveillance information, but in a far more timely, less burdensome, and more precise, way.

Then the final or third leg of the stool if you will is are there additional tools out there where we can benefit from syndrome surveillance technology and innovative approaches, and we are very interested in looking at those. But we think they need critical evaluation.

Mr. GREENWOOD. Okay. Dr. Broome, would you respond to the same question, please?

Ms. BROOME. Yes. I think the timely identification of clusters of infectious disease is critical, and I think it is possible. The way our system works, all our 11 sites close their books at midnight essentially, and their MIS system beams one number to ours at the health department.

We know by 1 a.m. if a site is over-threshold, and frankly, we can automatically page out to our onsite contact, but they would stop working with us if we made their beepers go off at 1 a.m. all the time.

So, typically at about 8 a.m., if a site has exceeded, they get a one page telling us so they can report to us if they have seen any type of syndromes. So I think it is helpful for us to identify changes in uses of health care very, very quickly in the city of Boston.

And as I mentioned, we did pick that up with the influx of people looking for cipro and nasal swabs. One thing that you should be aware of is that once we believe there is a cluster, the story doesn't stop there.

So we send out a one pager and Mass General, or whomever, reports back to us that we are seeing a cluster of febrile respiratory illness. That is one of our boxes that they could check on the one pager. I then need to have a public health nurse from the local health department then do more investigation.

We think that something is going on now, and she or he needs to get a line listing on those cases, and find out what was common about those cases so we can start to take appropriate control measures and move along with diagnostics.

I agree that the individual provider reporting is key in surveillance. You can't ever lose that. You have to have those providers. But I think that the cluster based systems, at least in my experience, can also do that.

We are constantly on the incoming side hearing about exceedences and threshold, and we also are feeding back to people: here are the symptoms of cutaneous anthrax, folks—post it in your emergency department, and here is who you call if you think that is what you have.

So I think that we need to merge many of these components. Our system has been validated to date and we clearly need to more work in this area. But we have looked at patterns of influenza ill-

ness in the city of Boston using retrospective data from our surveillance system.

And it turns out that what our system detected very well correlated with the first isolates of influenza in the city of Boston in 1999. I think that there needs to be much more emphasis on data mining.

You know, health care providers aren't going to fill out that extra sheet in the ED. We need to figure out how to suck out pieces from the medical record and have that make sense.

And some of the folks in Boston have tried to do that or we are currently doing it. One instance is that one of the fellows at a major hospital tried to electronically pull out RESP, standing for respiratory illness, electronically from records to see if that would help give us more information.

And I think a lot more work in that area will provide us very useful information. We are also looking in some of our sites at the use of laboratory data, because hospital labs can tell you in a matter of hours how many of certain lab tests are being requested.

So we are analyzing data from a few sites to say, well, they have ordered a lot more complete blood counts, and what is that telling us. So we think that the base for one of these systems, I feel pretty comfortable with what we have built, and if our funding doesn't drop out after these few years, I think we can use it to mine a lot more information.

Mr. GREENWOOD. Thank you, Dr. Davidson.

Mr. DAVIDSON. Yes. I think I agree with the other panelists that our current systems for disease surveillance, where we are dependent on physicians, have been serving us fairly well throughout the—at least in the last years, the incident of anthrax was identified by an astute physician.

And West Nile fever as well by astute physicians, and who have provided that front line for us.

I have reservations still about the value of a syndromic surveillance system only because we have not tested it enough. We know that the systems that have been available for a long time are a way that our society has dealt with diseases for centuries.

But for us to say that mining the data at this point has Dr. Barry mentions will definitely yield a benefit? I am uncertain. I think we still need to study this. I think that living in Denver, and working in a busy public care health system, physicians are overburdened with paperwork and activities just to get through their day.

And to put another computer that will be collecting additional information in an emergency room is just untenable to my colleagues; to Dr. Cantrell, who Ms. DeGette mentioned earlier.

I think that in terms of syndromic surveillance that we need to work to identify what are thresholds. Can we even establish a threshold. As we enter the influenza season, how does that threshold change if we are trying to look for symptoms consistent with inhalational anthrax.

How will we respond. At present, Dr. Barry mentions using her system to inform and have the nurse epidemiologist conduct some surveillance activity. I wonder how that may change as we get further into the influenza epidemic.

What will happen. How will the worried well be appearing and how will that impact on our need to act on syndromic surveillance monitoring.

Mr. GREENWOOD. Thank you, Dr. Davidson. Dr. Broome, if you can be very brief, we have a vote on, and so we are going to try and work the time out here.

Ms. BROOME. Just very briefly. I was trying to also reframe it not as syndromic surveillance versus routine. You have to define what you are trying to find. We have a very interesting system which has automatically detected outbreaks, but it is based on detailed information about salmonella, a food borne disease.

We picked up an outbreak in 13 States that nobody was aware of, but we needed to have not syndromic information, but detailed information about the pattern of isolation of that kind of salmonella. So it is complicated.

Mr. GREENWOOD. Thank you. The Chair recognizes the gentleman from Florida, Mr. Deutsch, for 5 minutes for questions.

Mr. DEUTSCH. Thank you. Dr. Broome, just to follow up, but I guess in a different capacity, what would you need to implement the national electronic disease surveillance system across all 50 States today?

Ms. BROOME. The implementation of this across all 50 States is partly a matter of the resources. That includes trained personnel and it includes being sure that information security is at a level that can handle this sensitive information.

So there is certainly a monetary figure, but there is also a huge active role for our State and local partners in either working with the NEDSS bay system that I described, which is an option that the States can choose, or some States have developed their own solutions using the standards.

Mr. DEUTSCH. So at this point, you are really just saying that it is a resource decision for us to make really. The bottom line is that based upon the positive effect you have seen in your test sites, it would appear as if there is almost no reason not to fully implement this system?

Ms. BROOME. We feel that this is a critical part of the public health infrastructure that it will support our local and State partners in detecting and responding to disease.

Mr. DEUTSCH. Let me jump to some of the issues that I mentioned in my introduction, and really ask very specifically if there were cases of smallpox in American today, I that all of us understand at this point that if someone had a full case of smallpox that they would look very obvious, assuming they didn't wear makeup of some sort.

Would it be possible to pick up a precursory of that a week before, 10 days before, 5 days before, because of a respiratory increase in hospitals in a certain location in America?

Ms. BROOME. As you are indicating, we have to be prepared for whatever might appear, and smallpox is very high on the list of syndromes. In the information that I mentioned, we do include information about early diagnosis of smallpox to our partners and to help care providers.

The most—really, the only way to identify that smallpox is occurring is to pick up the very earliest stages of the rash.

Mr. DEUTSCH. So the actual rash, as opposed to any other symptoms, would be the indicator?

Ms. BROOME. Essentially, yes.

Mr. DEUTSCH. All right. So, Dr. Barry, you are shaking your head, and so basically the system doesn't really help with smallpox because we are back to a clinician basically picking up a phone and saying that I have got a patient with smallpox?

Ms. BARRY. Well, I think I have a patient with smallpox. I guess the point that I was trying to make earlier is that there are a lot of different scenarios for different diseases, and it is not going to be a one size fits all.

Mr. DEUTSCH. And actually, Dr. Barry, do you want to respond to that, specifically the smallpox?

Ms. BARRY. Sure. I think it depends on how the smallpox exposure occurred. I think if someone did widespread dissemination of smallpox, you are going to have a whole cluster of people coming in to hospitals, and it is going to set off our threshold.

But more importantly, I think because of the system, because of the surveillance system feeding back and forth to these health care providers, they are going to know who to call and say I have all these adults with what looks like chicken pox, but you know what, and that is how we are going to pick that up. So it could be an isolated case, but it could be quite a number of cases.

Mr. DEUTSCH. Right. But I guess that the value of the system, in terms of basically bioterrorism, and it is not an unlimited number of agents that we are talking about, but for those particular agents I am trying to get a sense of—and as we are sort of in a funding mode, and let's just talk about bioterrorism.

And not to say that the work that we are doing in all these other areas are not very significant; such as with influenza, and in terms of food poisoning, et cetera, but I am trying to get a sense of the value added in any of these other types of—well, the plague.

If there was an instance of plague in America, would we pick that up through this system. And related to that, I guess it is sort of a contrast between just a traditional clinical approach.

I mean, one of the questions that I have, which is sort of a related question, is how much are we doing that on the public health side, and there are no physicians in America, I assume, who have seen the plague, because it has not existed, although we know that it exists in a sort of—in a bioterrorist world, but not in terms of the clinical world.

Now, I assume that there is probably still some clinicians out there who have seen smallpox, but the percentage has to be extraordinarily low at this point in time. So I am trying to get a sense from the system that we have in place how does it help us from a bioterrorism perspective?

Ms. BROOME. But I think even though not all physicians have seen it personally, the whole point of some of the training materials is to make available, for example, descriptions of the rash form smallpox, and descriptions of typical x-rays for anthrax, and making physicians aware to look for hemostasis with plague.

There are both pictorial and teaching aids which help us get from line physicians up to speed in both considering the diagnosis and then in being comfortable in making it. So that is a very explicit

part of the material that has been developed with the support for bioterrorism preparedness.

Mr. DEUTSCH. Dr. Davidson or Dr. Barry, did either one of you want to add to that? I know that my time is up as well, and this will be my last question.

Mr. DAVIDSON. In Denver, we are trying to inform our physicians, and we are working based on the CDC advice that we receive almost daily on the health alert network to build an algorithm that is useful within our own environment.

Something that tells people exactly what to do, and who to call, and how do you evaluate if someone had a known exposure to anthrax spores, versus someone who is not. One of the clinical signs and symptoms that we would expect on how to evaluate a patient who comes in with concern, and whether they are symptomatic or not, and whether they need to get prophylactics or not.

I think all of this information, even though I have not seen a case of anthrax, and I doubt that my colleagues have seen a case of anthrax, we now know how to deal with this. We are distributing that information. That sort of information provided to the front line is key.

And that comes from a disease surveillance system that says we found cases, and now we need to act and give the information to our front lines.

Ms. BARRY. One thing that I wanted to add is that with our current surveillance system that we have a secure website, and so if Hospital A thinks they have seen a case of bubonic plague, I post an alert that says Hospital A has a 45 year old man who they suspect has plague, and do any of the other nine acute care hospitals in the city of Boston seen anything like this, and that goes up right away on our website.

Mr. GREENWOOD. Thank you. The gentleman, Mr. Whitfield, is recognized for 5 minutes of inquiry.

Mr. WHITFIELD. Mr. Chairman, I know that we have a vote pending, and so I won't take too long, but it is my understanding, of course, that smallpox is quite contagious, and would spread rapidly. And I suppose that the bubonic plague would be the same.

And on the anthrax, it is my understanding that there is an abundant supply of drugs to deal with anthrax, but it is my understanding that there is a significant shortage to deal with smallpox; is that correct, if there was a mass outbreak of smallpox?

Ms. BROOME. For smallpox, the issue is the availability of vaccine.

Mr. WHITFIELD. Right.

Ms. BROOME. And it is very complex assessing what the likely scenario is and using the available vaccine effectively, and being sure that we have sufficient quantities being produced.

Mr. WHITFIELD. And we are making efforts to do that at this time?

Ms. BROOME. Yes.

Mr. WHITFIELD. Okay. How would you compare our reporting system with, say, the reporting system in Europe?

Ms. BROOME. Well, maybe I am—well, anyway, I think the U.S. actually has invested in a reporting system which in many ways is a leader in terms of approaches from the public health side.

I do think—and this was alluded to by Dr. Davidson—our ability to work with our health care colleagues to get information is a critical part of that. So we train providers, but to the extent that our health care information systems are more difficult to interface with, that does make life more difficult. So certain countries in Europe may have an easier time of getting that information.

Mr. WHITFIELD. Dr. Davidson, you had touched on briefly the patient's right of privacy, versus the right to dispense information necessary to protect the public health. Do you consider there to be a significant problem in that area?

Mr. DAVIDSON. Well, as I mentioned, the local health maintenance organizations with whom we would like to collaborate on collecting symptom information and diagnosis information, they want to collaborate with us, but they are concerned about the HIPAA regulations.

Mr. WHITFIELD. And do you feel that way, too, Dr. Barry and Dr. Broome?

Ms. BARRY. Well, our system to identify clusters, which the hospital MIS system, and not a health care provider, has to push to us is a number. It does not include names.

We only get into looking for names once we have reason to believe that there is an outbreak, and then as we would do with an outbreak of anything, we have access to names as needed.

Ms. BROOME. I think also one of the things that the CDC is trying to do is be sure that people have accurate information about the HIPAA privacy regulation. In fact, the regulation permits the continued sharing of identifiable information needed for public health activities.

There is certainly a level of concern and need for information in clarifying how that applies with some of these novel systems. So it is a very important issue, but the reg, per se, does permit legally authorized public health authorities to collect individually identifiable health information.

Mr. WHITFIELD. So it is not a major concern from your perspective?

Mr. DAVIDSON. Let me just explain a little bit more because this gets back to the issue of syndromic surveillance. I agree with Dr. Broome that we can collect that information for reportable communicable diseases. There is no question about that. We have the right to do that.

The question is around these syndromes or symptoms that we are looking for. Those are not required reportable diseases. How we use that when we want to figure out how many people does this really represent, and did someone call the nurse advice line more than once for the same patient.

Did the person who presented to the nurse advice line then go to the emergency room and that is still the same patient. So we are looking for unduplicated counts, and not just numbers of people who may be in duplicate when we use multiple different surveillance pathways to collect and create this picture of syndromes or symptoms in the population. That is my concern.

Ms. BARRY. Just one thing. I think that the reporting requirements and the ability to follow up probably vary by State, and

Massachusetts clusters, even without an identified agent or outbreaks, are reportable to the local health department.

And we have the authority to follow up, even if there is not a specific agent, and even if there is just a cluster or outbreak of disease.

Mr. WHITFIELD. Thank you very much. I see that my time has expired.

Mr. BURR [presiding]. The gentleman's time has expired, and the Chair would recognize, if the gentlelady is ready.

Ms. DEGETTE. One moment, please.

Mr. BURR. I would be happy to go and let the gentlelady take a few minutes.

Ms. DEGETTE. Okay. Well, that is what happens when you do tag-team questioning, you miss the answers.

Mr. BURR. The gentlelady is recognized.

Ms. DEGETTE. So I apologize if I re-ask some of the questions that have just been asked, but I am getting the sense, particularly from Dr. Barry and Dr. Davidson, that these syndromic surveillance systems are not really what you think is needed right now in local health departments.

And I am wondering if you can talk specifically about why you think that might be the case. Dr. Barry.

Ms. BARRY. Well, I think that syndromic surveillance gives us an opportunity to identify many problems early on. However, in some sites, syndromic surveillance has been carried out by having people in the emergency department fill out a separate sheet on every patient that comes in and that is never going to fly, and certainly not in Boston.

Ms. DEGETTE. Do you think it gives you any better diagnostic tools than the coordinated approach that you are using now, which by the way sounds very similar to what we are doing in Denver.

Ms. BARRY. I don't think it gives us enough of an advantage to try to put the burden on health care providers. I believe that the future here lies in mining data in already existing records that are coming in, and not in current syndromic surveillance.

Ms. DEGETTE. Dr. Davidson. I would agree with Dr. Barry that we need to find systems that use already existing datasets to identify these clusters or symptom patterns. A concern of ours is that the infrastructure for routine disease surveillance using systems such as NEDSS needs to be expanded.

We need to make sure that that is solid, and the syndromic surveillance system may assist, and I can't say whether it will or will not, but at this point I want to be sure that the fundamental surveillance systems that we have used for decades are improved and move into this 21st Century.

Ms. DEGETTE. Well, I know that we have two of the shining stars here with Boston and Denver. Do you know—and perhaps, Dr. Broome, you can speak to this, but are there other health systems whose traditional methods of surveillance could be improved as Dr. Davidson suggests?

Ms. BROOME. Well, to me, I think it is extremely valuable to hear what is happening in Boston and in Denver, and to me this shows what can be done with resources and smart people, and a commitment.

I wish that were true of every local health department in the country, and I hope that it will be true.

Ms. DEGETTE. But do you think that the way to go to improve the coordinated responses in these other communities is through the techniques that Dr. Barry and Dr. Davidson talked about, or this syndromic surveillance system, or some other method?

Ms. BROOME. I think the two critical pieces are that there are resources to hire trained staff. The trained recognition capacity of a human being is still what I am counting on.

Ms. DEGETTE. That is how we found the anthrax in Florida.

Ms. BROOME. The second is the kind of system that NEDSS represents is an automation, and it does have the electronic—what Dr. Barry is calling data mining capacity built in, but it goes way beyond detecting flu like illness. It lets you find out if there is an increase in lab tests submitted for Anthrax testing.

Ms. DEGETTE. Right.

Ms. BROOME. So it does have some of those capabilities, but in addition it supports the standard surveillance functions.

Ms. DEGETTE. So it would seem to me that that would be a place where we should put our resources to helping the other municipal systems like that.

Ms. BROOME. We think that this will make a huge difference in capacity.

Ms. DEGETTE. Okay. Thank you. Dr. Davidson—oh, you wanted to add something?

Mr. DAVIDSON. So that I think if we had a perfect robust information system is not enough. We need to have trained individuals who are able to use the data that come out of those systems or to look at those systems and say here is a pattern. I think we need to underscore training here, because in all of the health departments of the country there are insufficiently trained staff.

We know that from within my own State that we have people for whom I can give information about surveillance activities that we have conducted, and they look at it as if it doesn't make sense. I think that is something that we need to focus on as well.

Ms. DEGETTE. Thank you. Just one last question, although it is kind of a big question. Dr. Davidson, as I mentioned in my opening statement, when I visited—and I guess it was just last week, and it seems like about a month ago—with you and the rest of your crew over at Denver Health, what struck me was the highly integrated public health system you have put into place with your closed electronic system.

And as a result the reporting of data is made easier. I wonder if you can let me know what challenges Denver Health encountered in establishing that system, and what lessons other systems who are less integrated can learn. If you can—I know that I spent 1½ hours, and maybe you can tell me just in a brief moment.

Mr. DAVIDSON. There are 50 years of history in making Denver Health what it is today. It started back in the late 1940's when Florence Hayden decided to put the public health department inside of a personal health care agency, and we spanned from personal health care all the way to population bays for public health.

The coming of the community health clinics in the 1960's then contributed an outpatient focus. I don't think that there is another

institution in the country similar to Denver Health. I feel privileged to work there in an integrated system like that, but I think there is some lessons that can be learned.

Keeping turfs separate makes for less integration. Finding standards to make better integration is very, very important. Making each information system adhere and ascribe to those standards is essential if we are ever going to be able to mine the data from each of these separate turfs that exist in most other cities.

Ms. DEGETTE. And just for one example, the 911 reporting system goes into Denver Health, and not into the fire departments?

Mr. DAVIDSON. That's correct.

Ms. DEGETTE. And so that helps you find early reporting on issues like this.

Mr. DAVIDSON. That's correct.

Ms. DEGETTE. Thank you. Thank you very much for your indulgence, Mr. Chairman.

Mr. BURR. The gentlelady's time has expired. The Chair would recognize himself for questions. Let me take this opportunity to welcome this panel since I chose to forego an opening statement so that we could get into the questions. So, Dr. Broome, welcome, and like Ms. Harman, we had an opportunity several weeks ago to visit you at the CDC in Atlanta from another committee.

You mentioned the Florida detection, and how it was important it was that a health provider identified the problem and that that was certainly a key. If you will comment very briefly on the inability in Washington, DC, though health care providers treated two individuals, one of which I think has passed away, and tell us where the breakdown was there.

Ms. BROOME. I am afraid that the current events are under intense investigation, and it really would not be appropriate for me to comment on the details.

Mr. BURR. Well, let me ask it in a different fashion if I can. Was there a city in America where more education was done on the risk that existed, and the symptoms that went along, the profile of where one worked, that we would have felt confident that every health provider would have seen this matrix that we were looking at, and if anybody was close to the line would have said this is one that we need to look at. Clearly that was not done.

Ms. BROOME. It is an ongoing challenge. I mean, education is not something that happens once, and people are perfectly informed and clearly we are trying to reach every deliverer of health care in the country. That is an enormous task that we are continually trying to look at better ways to do.

I think that it is also important to point out that the kind of initial symptoms can be non-specific and can vary. So we do not minimize the challenge of doing this. I have enormous respect for the folks who are on the front lines and who are trying to do an incredibly difficult job.

Mr. BURR. As I do, and this is not a shot at any attending physician that saw these individuals, but I think you made my point for me, is that we can't rely just on the provider network to identify something that we feel we have successfully communicated to a health delivery network.

And if it just happens to be a bad day and somebody misses something, or there was an individual that was not included in the dissemination of the information that you distributed or that the public health distributed, then we have a potential problem.

And were this a contagious pathogen that we dealt with, that problem would be magnified greatly. Therefore, there are a lot of tools out there that we not only can use, we should use, and we should find a fast way to incorporate them.

I am a little curious on NEDSS, because this is a program that the CDC has been focused on since 1999, I think, when it was first talked about or initiated, and our goal was 20 States. I think everybody's goal is probably 50 States now, or I hope it is.

Ms. BROOME. Well, we received Congressional funding in 2000 to move ahead with NEDSS, and we actually have funded all 50 States, six cities, and one territory, for at least planning functions.

Mr. BURR. But the connectivity of these States is the crucial thing. I mean, we still have a third of public health in America not technologically connected to CDC. So, two-thirds are covered and for a third, we have to rely on another means other than your internal tools to disseminate information or warnings.

Ms. BROOME. Well, I think it is important to also focus on the systems that Dr. Davidson and Dr. Barry have mentioned, in terms of the urgent communications, and building the connectivity with the local health departments.

The health alert network support from Congress, and the Epi-X secure communications systems, are also critical parts of getting this information out.

NEDSS is—and forgive me if I get too much into the jargon, but NEDSS is a tougher job. It is basically using standards to actually collect the raw data that will help inform the decisions, and that will give us what we want to communicate to our partners.

Mr. BURR. The real capabilities that we have is data. I mean, that really is a key to our ability to understand what is going on isn't it?

Ms. BROOME. Well, I think it is, because it also can take information, and not just from providers, but it also can take information from laboratories, and it can take information about what is going on.

So we do see this as a critical part, but it takes more time to get that kind of complex system to functionality.

Mr. BURR. HHS has received \$1.5 billion out of the \$20 billion emergency bioterrorism money. Of that, my understanding is that \$40 million by CDC is directed toward preparedness, NEDSS, health alert network, and other things.

Now, of the money that is left over after the stockpile, which is \$1.1 billion, there is \$400 million. So, less than 10 percent of the bioterrorism emergency money is directed to the thing that all of you, and I think all of us, would agree is the most crucial challenge that we have today to put in place.

Why only 10 percent of over and above the stockpile money is devoted to this crucial effort?

Ms. BROOME. I think that is a good question.

Mr. BURR. And I don't want to put you on the spot if the question is something that needs to be answered by somebody else, and I

assure you that the Secretary will be in next week, and I am sure that he will get this question.

But if it is important that 50 States be connected, and we see that as a first step to our ability to rebuild our public health infrastructure, and to make sure that the dissemination of information about potential biologic attacks in fact is transmitted, then it seems like the single greatest thing that this Congress and the CDC can do is to take enough money and devote it to connectivity of public health with our Federal entities.

And to make sure that at least we can get this information, or in the reverse, at least they can access the data that they need to successfully monitor public health in their communities and localities that they live in.

So I am a little bit troubled in the fact that maybe in your testimony or in CDC's public statements you should be out there demanding to extend this to 50 States today. You can take that back in whatever form you would like to Jeff, and to the rest of them, and I will certainly take it to the Secretary.

My time has expired, and the Chair would recognize Mr. Stupak for questions.

Mr. STUPAK. Thank you. You know, as I sat here and listened to the testimony, and looked forward to the testimony, especially from Dr. Barry and Dr. Davidson, I got the impression that we don't really need NEDSS.

And that there is a system in place now that works that the money should really go toward providing stuff at the local level, and not another federally developed system, and with it, Federal regulations, and with it more reporting on doctors and health care professionals.

And, of course, the money never really gets back to the local people. Is that a fair summation?

Mr. DAVIDSON. I would say not. I think from a local public health perspective as a Director of Public Health Informatics, NEDSS is my hope for the future. The current systems that we have are probably—I think a dozen, that are CDC developed systems that require intensive maintenance on a daily basis in a local health department.

Having 12 systems built with different standards and in different languages is very labor intensive at a local health department. Having a system that is common across all the surveillance activities that we do is important for us not to expend effort when we don't need to.

Making everything come together with a standard language on operating assumptions, and all the necessary requirements for a information system is important at a local level.

So from my perspective, NEDSS brings an integration. It reduces the burden locally, and I feel that while we certainly do need local public health infrastructure support, we need guidance to make that happen not only in a local area, but with our State partner and our Federal partners as well.

Mr. STUPAK. Dr. Barry, did you want to comment?

Ms. BARRY. I certainly am in favor of data consistency among systems, and from my perspective I really haven't as a local health department been involved in NEDSS at all, and what I think what

we need right now in the city of Boston is the ability to expand and keep building our local surveillance system, which I would be very happy to connect to NEDSS, or whatever other consistent system will provide the most data for us nationally.

Mr. STUPAK. I went back before the hearing and checked with my local folks, and I have got a very rural area. My biggest city is 20,000 and I am rural. They just saw this as another Federal program that would do nothing for them.

They need quarantine rooms, and they need supplies, and they need things like that at the local level so that if an epidemic does start, there is something there. We had testimony here about 3 weeks ago from an expert who testified before us, a Dr. Smithson, and basically they said, look, last year you appropriated \$8.7 billion in your terrorism appropriations, but only 300 ever made it past the Beltway in Washington, \$300 million out of \$8.7 billion.

So, \$8.4 billion stayed here in Washington, and I am real skeptical. Are we building another system where all the money is going to go to a few places, and cost us hundreds of millions of dollars, and nothing gets to local people where they really need it.

Ms. BROOME. We also think that local health departments are where the action is, and 75 percent of NEDSS funding has gone to State and local partners because we think they are the folks who need systems.

Some of those State health departments are building their own systems, but as Dr. Davidson has pointed out, NEDSS provides standards for them to use in building those systems so that they can connect with the health care sector, and so they can do the data mining that Dr. Barry was mentioning.

However, some States don't feel that they have the resources or the capacity to build their own systems. So they explicitly asked CDC to create an option that they could use. But I think it is very important that this is not building another Federal stove pipe of the kind that Dr. Davidson described.

That is sort of past history of these categorical systems. It is based on modern infomatics standards, and it uses state-of-the-art commercial software packages. You can drop in the leading mapping software so that that local health department will be able to take the data and actually use it to see where things are occurring in their district.

And that also lets them hire people and use them for intelligent activities rather than data entry.

Mr. STUPAK. So that 75 percent you said that went to locals, was that just to set up the system, or are you paying the salary of these local people? And Dr. Davidson said this would be very labor intensive, and you need people there.

In small areas like mine, if you want to hire one person and dedicate it to it, that is something out of our budget.

Ms. BROOME. Well, in fact, the NEDSS' awards include funding for skilled information technology personnel, because that capacity has not been available at State health departments in a number of the smaller States.

Mr. STUPAK. And how long is that for, just to set up the program?

Ms. BROOME. Pardon?

Mr. STUPAK. How long is that for, that contracting of personnel?

Ms. BROOME. It is built into the NEDSS awards, and it will depend on the duration of Congressional support. But we also see in many settings as people realize the value of these information systems very—it has made a change in local and State investment in this infrastructure.

So, for example, the State of Missouri has invested major State funding in their information system because they see the value of it. So I see the Federal funds as providing real benefit, but also providing and leveraging additional resources for this critical function.

Mr. GREENWOOD. The gentleman's time has expired, and the Chair recognizes the gentleman from Florida, for 5 minutes of inquiry.

Mr. STEARNS. Mr. Chairman, thank you. Dr. Broome, the initial version of NEDSS that will be implemented next year in 20 States as I understand it will not contain what you described as aberration software, which is the ability to automatically sort and review the data for unusual activity, considering where we are at, why not? As I understand it this software is commercially available, and is already in use in some parts of this country.

Ms. BROOME. I would like to clarify that the 20 States are the States that have requested and have been funded for the NEDSS base system, which is this NEDSS compatible platform that we are developing. An additional 16 States have received funding to develop NEDSS compatible systems or to modify existing systems.

So there are actually 36 States in the development phase. I am sorry that was not clear. In terms of the aberration detection software, this is a target for inclusion in NEDSS, and we will be looking at a range of commercially available tools, tools developed by a range of entities, such as the Department of Defense, to see which ones are appropriate.

Because of the standards based approach to developing NEDSS, it is very feasible to drop in software which has been developed according to industry standards for interoperability. Now, your question is, okay, why isn't it done now, and that is—

Mr. STEARNS. Well, just a sense of urgency in when are you going to do this. I mean, you can drop it in, but the question is when is this going to occur.

Ms. BROOME. We do think that the first absolute priority is getting basic capacity out to all 50 States. At the same time, we—

Mr. STEARNS. And when would that be, that all 50 States would have the basic capacity?

Ms. BROOME. Well, with the resources that we have, we will be deploying in 20 States in 2002. We would certainly—we have certainly proposed ways to accelerate that.

Mr. STEARNS. And so you are saying today that you will accelerate it?

Ms. BROOME. With the resources, yes, we will accelerate it.

Mr. STEARNS. Dr. Broome, NEDSS, even when implemented, will only be as good as the data input into it by local health care practitioners and health departments. In this vein, you discuss CDC's funding of special surveillance systems at the State and local level,

and how these systems have actually been put into place since September 11.

Can you discuss in more detail what the benefits and shortcomings of these systems have been in this real world test, and what advantages they offer beyond NEDSS? And I would like the other witnesses to respond as well.

Ms. BROOME. First of all, I would like to clarify. NEDSS does permit inputting by practitioners over the web, but it also permits electronic input. Data from a clinical laboratory can be sent electronically without having to have a person think, oh, here is a reportable disease.

We can automatically get all appropriate information about specimens or conditions. So it actually represents a real step forward in one of the big problems—

Mr. STEARNS. So a clinical laboratory could input it through the web?

Ms. BROOME. No, they don't have to do anything.

Mr. STEARNS. They just are going to do it through the telephone?

Ms. BROOME. No, no. This is basically—well, we are working with the multi-jurisdictional laboratories which cover basically all the States, and for them to send out an automatic electronic message over the Internet, appropriately encrypted and secure, that would be routed to the State health departments basically as soon as that laboratory result, or even a specimen, is submitted.

So this means that it is just a huge step forward in the speed and completeness, and accuracy, and the ease with which relevant information can get to the people who need it at State and local health departments.

So there is a real difference. It's not just counting on that overburdened physician to actually report a case. Your question then was what about NEDSS and what about these other alternate approaches to surveillance.

Mr. STEARNS. Particularly in light of what happened in September.

Ms. BROOME. First of all, we did support these pilots with the very first bioterrorism—with these surveillance grants. So those have been undertaken by States since late 1999/2000. There has been a range of sources looked at, and I think the kind of experience that you are hearing from Dr. Barry is really very useful in looking at how they might be useful.

We have had other folks discover that some of the information that they were getting from their heightened surveillance was not timely. Some of the sources they thought might be promising either were not feasible or not timely.

What we are doing is collecting systematic information on these pilots to try to provide some broader guidance about what worked and what didn't work.

Mr. STEARNS. Dr. Barry.

Ms. BARRY. Yes. I would like to comment that we were one of those special surveillance sites that was funded with the initial CDC funding in 1999, and have really tried to look locally in very creative ways to build a system that is not going to burden people.

In our current system the ED people don't have to do anything. The MIS just sends us that data. So there are some aspects of the system that I think might be useful to other localities.

Mr. STEARNS. Dr. Davidson.

Mr. DAVIDSON. Since September 11, there have been relatively few changes in terms of NEDSS activities within the State. We still are targeting completion of laboratory reporting from the State labs into our version of NEDSS, called Colorado Electronic Disease Reporting System, by the end of this fiscal year, and that would be June 30, 2002.

So our goal is still to achieve that, but we have not been able to accelerate that in the last 6 weeks. That is a difficult project. It is not easy to make these systems talk to one another.

Mr. GREENWOOD. The gentleman from Florida's time has expired, and the Chair recognizes the gentleman from Illinois, Mr. Rush, for 5 minutes of inquiry.

Mr. RUSH. Thank you, Mr. Chairman. I want to commend not only you, but also the witnesses, for this hearing and for the testimony that they have provided so far. I have a couple of questions that I would like to ask both Dr. Davidson and Dr. Barry.

You have stated, and I guess everyone can agree, that the ability to identify a bioterrorist attack depends on the ability to diagnose medical conditions. And we have also further agreed that this requires a laboratory test at the local level spanning the entire Nation.

My question is do local health departments have access to the modern up-to-date labs, and if they don't, what resources do the local health departments need in order to make sure that they are up to speed, and that they can provide the most accurate and up-to-date laboratory tests that is possible?

Ms. BARRY. I think for many conditions a laboratory diagnosis is not going to be the most important feature. It is going to be the number of people with a clinical syndrome. But with regard to laboratory—

Mr. RUSH. A clinical syndrome?

Ms. BARRY. A clinical syndrome. So, even if we don't know what is causing all those people to have fever and pneumonia, we realize that we have a problem. With regard to laboratories, we are very fortunate to have the Massachusetts State Laboratory Institute, which has also received funding from CDC, to be in the network to be able to identify for us very quickly agents of concern for bioterrorism. It works very well, that system.

Mr. DAVIDSON. Within Colorado, we have an excellent laboratory as well, and the State lab has been the recipient of Federal funds. The epidemiologic laboratory capacity program, I think it is, that you have supported in the past, and currently through the larger bioterrorism preparedness grant, there is support for the laboratory as well.

We are using NEDSS funds to support development of a laboratory information system. I think that the capacity to do the diagnostic testing is there, at least in Colorado.

Mr. RUSH. Dr. Broome.

Ms. BROOME. I am really delighted that you asked this question, because the laboratory really is a critical partner in this. I agree

with Dr. Barry that sometimes you would love to do it before the laboratory makes the diagnosis, but that is the backup, and it also gives you specific information.

So I consider it a critical part of the system, and it is one which requires particular attention. In addition to the funding and programs that Dr. Davidson mentioned, we also have made available on the web information that laboratories can use about what procedures to use.

They can order reagents so that they can diagnose these conditions, and there is a network set up so that there is a way for a State to decide how they want to organize their laboratory system and get the information, and testing materials that they need.

And then finally this information is most valuable if it can get into the surveillance information systems that we are talking about. So again this is a place where we need to be integrated, and where we have to be able to take the results of testing and be sure it gets to the people who need to use those results.

Mr. RUSH. And can we assume that if we have an adequate lab system that we can assume that there would be an adequate number of trained lab technicians, or is that too much of an assumption?

Ms. BROOME. I think as with all of these that you have areas that are very well equipped and staffed. But we are talking about the country, and a country-wide system, and that is where you really have to be thoughtful about the resources that are needed so that there are the trained personnel, and so that they have the laboratories, and they have the biosafety capacity, and they have the information systems to participate in a national network.

Mr. RUSH. If one thing that has come out of our tragedy of September 11, or one good thing, is the focus on the local public health system. And I think that we need to take this opportunity to strengthen our public health system for the long term.

And I wanted to ask you what long term changes should we make to our surveillance system, particularly at the local level, but also where they want us to focus on, and the two-tiered health system in this country.

And whereby—and maybe you could tell me the impact, the possible impact that you can envision, because there is a significant population segment in our Nation that is not really adequately tuned into the public health system or to the private health system.

And I will just give you an example. Maybe it is not congruent, but about 6 years ago in my city, there was a heat epidemic. And 700 people died from heat stroke. I mean, something that could be readily identifiable, but yet still it took my city at least—well, longer than necessary—a week or 2 weeks, to really get in front of the issue and respond.

And I am trying—I believe that this kind of example will be duplicated many times if in fact a bioterrorist attack or a natural tragedy will occur. And I just want you to respond to what can we do to buttress the public health system in order to make it touch as many Americans, or more Americans than it currently touches?

Ms. BARRY. Well, I think you have touched on a critical characteristic of the public health system, and that is that it has to

cover the whole population. It has to be able to detect health problems wherever they may occur, and it has to be able to respond to protect the health of the entire population.

I do think that there are ways in which the kind of information systems that we have been talking about, and the kind of response systems, are truly population based. The challenge really is to be sure that all local health departments and that the medical care delivery system is there to participate.

Mr. RUSH. Dr. Broome, would you care to respond?

Ms. BROOME. Yes. What I would say is please give us some funding at the local level so that we can hire nurses, so we can hire outreach workers. You know, if we have an event in the city of Boston, we have a very large Haitian community.

Somebody has got to be able to speak to that community, and go out to that neighborhood, and speak to those folks, and help them out. Right now I am the only infectious disease physician in the City Health Department in Boston.

And it is a resource issue. We need direct funding to the local health department to take care of those very people that you are talking about.

Mr. RUSH. Dr. Davidson.

Mr. DAVIDSON. I agree with my colleagues. We definitely need more support at the local health department level, but I think to answer some of the questions that you asked earlier, you need to support the safety net institutions.

You can't expect people to show up at an emergency room and wait a dozen hours, and then say, well, you have to wait another 10 hours because there is just too many people in front of me.

I think we need to have institutions that can be responsive to those patients who were suffering from heat stroke, and I am sure that the emergency rooms were overwhelmed, and the community health centers were overwhelmed, and the hospitals had insufficient beds.

So if we are talking about dealing with a large issue in the public health infrastructure, it spans all the way from the local health department as Dr. Barry just mentioned, all the way to those safety net institutions.

Mr. GREENWOOD. The gentleman's time has expired, and all the questioning for this panel has expired. So we thank you again, each of you, for coming, and for helping us to understand this complex issue, and you are excused.

We will now call up the second panel, and it will take a couple of minutes for the second panel to set up some of their equipment for demonstrations.

[Brief recess.]

Mr. GREENWOOD. While we are waiting for Dr. Wagner to arrive, I will introduce the witnesses for our second panel. They are Dr. Alan P. Zelicoff, who is the senior scientist at the Center for National Security and Arms Control, at Sandia National Laboratories.

And, Mr. Zelicoff, let me tell you that Congresswoman Heather Wilson had hoped to be here to introduce you, and have some questions for you, but she is tied up at the White House.

Also, we are pleased to have Dr. Michael Wagner, Director of the RODS Laboratory, Center for Biomedical Informatics, from the

University of Pittsburgh; and Mr. John S. Russell, Executive Vice President and General Counsel of Quintiles Transnational, which is from North Carolina.

And we thank each of you for coming. I think that you have been informed that this is an investigative hearing, and it is our custom to hold to ask the witnesses to provide their testimony under oath. Do any of you have an objection to offering your testimony under oath?

[No response.]

Mr. GREENWOOD. You should then be advised that under the rules of this committee and the rules of the House, you have the right to be represented by counsel. Do any of you choose to be represented by counsel?

[No response.]

Mr. GREENWOOD. Seeing no such desire, then I would ask you to rise and I will administer the oath.

[Witnesses sworn.]

Mr. GREENWOOD. Okay. So saying, you are now under oath, and you may give your testimony, and I will start with you, Dr. Wagner. You are recognized for 5 minutes for your testimony. Thank you for being here.

TESTIMONY OF MICHAEL M. WAGNER, DIRECTOR, RODS LABORATORY, CENTER FOR BIOMEDICAL INFORMATICS, UNIVERSITY OF PITTSBURGH; ALAN P. ZELICOFF, SENIOR SCIENTIST, CENTER FOR NATIONAL SECURITY AND ARMS CONTROL, SANDIA NATIONAL LABORATORIES; AND JOHN S. RUSSELL, EXECUTIVE VICE PRESIDENT AND GENERAL COUNSEL, QUINTILES TRANSNATIONAL

Mr. WAGNER. Good morning, Mr. Chairman, and members of the subcommittee. My name is Michael Wagner, and I am a Physician and Assistant Professor of Medicine at the University of Pittsburgh.

My training is in the fields of internal medicine and medical informatics and artificial intelligence, and for the 2 years my research has been focused exclusively on the building of an early warning system for detection of outbreaks of disease.

I wish to thank the subcommittee for this opportunity to share information with you. The research that I am going to describe has been funded by the National Laboratory of Medicine, and the Agency for Health Care Research and Quality, and the Centers for Disease Control and Prevention, and the Defense Advanced Research Projects Agency.

Please note that the views that I express today are my own, and not necessarily those of the agencies. In our research on early warning systems, we have been concerned about early detection of disease outbreaks caused by medium-to-large scale bioaerosol releases of anthrax, smallpox, plague, or any other aerosolizable agent.

With this type of outbreak, early notice of detection is of paramount importance, and our improvement in early notice can translate into scores of lives saved. A product of this research is a system named RODS, which stands for real time outbreak and disease

surveillance. It is an early warning system that has been deployed in Western Pennsylvania for 2 years.

The key feature of RODS is that it receives data directly and without delay from computers in emergency departments and hospitals. This anonymous data includes patient's symptoms, age, gender, address information, and results of tests.

The data are transferred directly computer to computer, which means that seconds after a patient registers in an emergency department complaining of a cough, this fact is pooled with data from other patients in the region at a central location, and is available for automatic analysis.

At present, RODS emphasizes data collection from emergency rooms and hospitals monitoring 800 visits per day for like symptoms of diarrhea, rash, and other key symptoms, and all the approach is general, and it can include data collection from other computer sources, such as direct entry of case reports by clinicians.

The earliest of detections approach is achieved first by identifying as many people in the region as early as possible in their disease process while they have non-specific symptoms, such as cough or diarrhea, and then by using brute force computer power to find any interesting patterns among the sick individuals that would suggest an unusual outbreak is occurring.

An interesting pattern, for example, might be an unusually high number of sick people in the past 24 hours who happen to live in the same zip code area. Our design for the RODS system was heavily influenced by prior work in the field of medical informatics.

From this experience, we knew that the most important ingredient for success would be obtaining the right data electronically in real time and without asking doctors to fill out forms or enter data into computers.

We knew that computers in emergency rooms and hospitals would be able to provide useful data through standard computer-to-computer interfaces. We also knew the importance of standards in building early warning systems, especially those having regional, State, and national coverage.

We ascribe to the standards now recommended by the National Electronic Disease Surveillance System project, and we think that those standards are excellent. One new lesson that we have learned from the research is that health departments may have limited resources to do this kind of work due to their front line responsibilities.

And that this problem in our case can be addressed by the creation of a trusted broker, which is an administrative entity created by a memorandum of understanding with the health department that allows pooling of data regionally for mutual defense.

Another lesson from the research is the central importance of obtaining data about patient's symptoms even earlier than at present, even before they seek emergency care.

Other lessons include the importance of large interdisciplinary research groups with experience in medical informatics, public health, computer science, statistics, emergency response, and to conduct the research in as big a region as possible so that there is sufficient data available about naturally occurring outbreaks for system validation.

So as a result of my basic and implied research on early warning systems for public health surveillance, I would like to offer the following recommendations to the subcommittee.

First, Congress should provide funding directly to ongoing regional efforts to build early warning systems, and not necessarily limit it to those that are affiliated with health departments, and not necessarily funding all the money through State and local health departments, although that basically is a very sound approach.

And stipulate that every funded project adhere to the National Electronic Disease Surveillance System standards. The rationale for this recommendation is that the regional efforts will be most effective in obtaining access to the data needed for early detection.

And additionally the reality is that right now that many of these research projects are being called on to rapidly deploy and provide reliable 7-by-24 services in defense of the community without sufficient resources to take on the task.

My second recommendation is that in the near term the greatest improvement in capability will depend on obtaining information from or about sick individuals as early as possible in their illness.

There are many potential ways to do this, and therefore the Nation's health systems need to conduct research to find workable solutions. The Congress should fund centers of excellence to do this research, and these centers need to be interdisciplinary and need to have multiple year funding.

And Congress may need to prove incentives for specific industries with needed data to construct real time privacy protected data feeds. Congress may need to also enact legislation to facilitate data collection that balances the needs of the community for defense, with the rights of individuals to confidentiality.

My last recommendation is that Congress should encourage through Federal funding several regions to participate in an intensive level in early warning research. The reason is that the field of bio-defense is a lot like the field of particle physics, by which I mean that a large particle accelerator is necessary to answer certain questions in particle physics and in the field of bio-defense, a very large region with rich, multi-year datasets, are needed to persist in validation and hypothesis testing.

In closing, I would suggest that Congress note that developing very early detection of major public health threats is an ambitious scientific undertaking that resembles in both urgency and technological breathe the space race in the 1960's and the Manhattan Project in the 1940's.

And that there are lessons to be learned from those projects, such as the value of having clear goal statements, such as short term objectives to reduce detection time by 2 days over current levels, and stretch goals of being able to reduce detection time within 1 day of release for any biological agent that threatens the health of our citizens.

And I thank you very much for the opportunity to speak here today.

[The prepared statement of Michael M. Wagner follows:]

PREPARED STATEMENT OF MICHAEL M. WAGNER, ASSISTANT PROFESSOR OF MEDICINE
AND INTELLIGENT SYSTEMS, UNIVERSITY OF PITTSBURGH

Good afternoon, Mr. Chairman and Members of the Oversight and Investigations Subcommittee. My name is Dr. Michael Wagner. I am a physician and an assistant professor of Medicine and Intelligent Systems at the University of Pittsburgh. I am also co-scientific director of an institute in Pittsburgh that focuses on bioterrorism research.

My training is in the fields of biology, internal medicine, medical informatics, and more recently I received a PhD in artificial intelligence. Over the past decade, I have been building computer systems that detect cases of disease and potential medical errors. For the past two years, my work has been focused exclusively on the building of early warning systems for outbreaks of disease.

I wish to thank the Subcommittee for this opportunity to share information with you about this research and to offer my observations and recommendations to the Subcommittee in its deliberations on public health early warning systems.

My research has been funded by four federal agencies—the National Library of Medicine, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, and the Defense Advanced Research Projects Agency, but the views I express today are my own and not necessarily those of the agencies.

THE REAL-TIME OUTBREAK AND DISEASE SURVEILLANCE (RODS) SYSTEM

Why are we doing the research?

A scenario we have been most concerned about is early detection of disease outbreaks caused by large-scale aerosol release of Anthrax. Without very early detection of this type of outbreak, it has been estimated that there will be mortality rates of hundreds per hour within 4 or 5 days of release. In this kind of outbreak, hours count, and detection needs to occur very early to allow time for response and treatment to occur.

What is RODS?

A product of this research is RODS, an early warning system that has been deployed in Western Pennsylvania for two years. The acronym RODS stands for Real-time Outbreak and Disease Surveillance. The purpose of RODS is to provide early warning of infectious disease outbreaks, possibly caused by acts of terrorism using biological weapons, so that treatment and control measures can be begun, to protect and save larger numbers of people.

A key feature of RODS is that it receives data directly and without delay from computers in emergency departments and hospitals. The data include patient symptoms, age, gender, address, and results of tests. The data are transferred directly computer-to-computer and without delay, which means that seconds after a patient registers in an emergency department complaining of cough, this fact is pooled with data from other patients in the region at a central location and is available for automatic analysis. At present, RODS emphasizes data collection from emergency rooms and hospitals—monitoring 800 visits per day for flu-like symptoms, diarrhea, rash and other key symptoms—although our approach is general and includes data collection from other computer sources as well as direct entry of case reports by clinicians.

How is early detection achieved?

Early detection is achieved in this approach by identifying as many patients as possible early in the disease process when they have nonspecific symptoms such as cough or diarrhea, and then using brute-force computer power to find any interesting patterns among the sick individuals that would suggest that an unusual outbreak is occurring. An interesting pattern, for example, might be an unusually high number of sick people showing up at emergency departments in the past 24 hours who happen to live in the same zip code area.

Why did we take this approach, and what have we learned?

Our design for RODS was heavily influenced by prior work in the field of medical informatics. From this experience, we knew that the most important ingredient for success would be obtaining the right data electronically, in real time, and without asking doctors to fill out forms or to enter data into computers; so, we spent a great deal of time being clever about this. The approach builds on electronic medical records and other existing computer systems. These elements are widely available in the country and represent an enormous resource. We knew that computers in hospitals and emergency departments contained relevant data, and we knew that they would be able to provide the data through standard computer-to-computer

interfaces, in fact, from the beginning we used many of the standards now being recommended by the National Electronic Disease Surveillance System (NEDSS) project, and we think those standards are excellent.

We have learned that health departments have limited resources for any kind of participation in this kind of project due to their front-line responsibilities. Therefore, we developed the concept of a *trusted broker*, which is an administrative entity that allows pooling of data. The trusted broker is created by formal memoranda of understanding between the health department, data providers, and an outside technical group. This organizational model has proven effective, especially with the facilitation of a highly respected local foundation with contacts in the community.

We also understand that although the approach taken in RODS can significantly reduce the time delay to detection, it is not a complete solution to the country's needs. As you know, the earliest possible detection will eventually be accomplished by biosensors that detect bacteria and viruses when they first appear in our environment, but before they infect us. However, such technology is a ways off especially in a sufficiently cheap form that every person can carry a personal monitor, or every building and open space can be monitored continuously. In the meantime, early detection of a surreptitious release will depend on monitoring people and animals for the early effects of that release, and through detailed analysis of the epidemiological characteristics of sick individuals.

From the research, we know that the earliness of detection in RODS can be improved further if we can obtain data about patient symptoms even earlier than at present, even before they seek emergency care. This latter point is the subject of a specific recommendation.

RECOMMENDATIONS

I would like to use the remaining time available to me to offer my recommendations to the subcommittee for rapid improvement in detection capabilities.

1. Congress should provide funding directly to all ongoing metropolitan and regional efforts to build early warning capability, provided they adhere to National Electronic Disease Surveillance System standards. Early warning can be implemented most quickly by regional efforts, with federal coordination. Some of these efforts are research projects that are becoming regional or national resources for early warning, and they are not currently staffed or funded for rapid deployment or for the provision of 7x24 services.

2. The earliness of outbreak detection depends fundamentally on obtaining data about early symptoms of disease. In the near-term, the greatest improvements in capability will depend on improving the earliness with which such data—and epidemiologically relevant information such as work location—are collected. There are many potential ways to do this, and the nation and its health systems need to find workable solutions. This goal may require legislation to facilitate such data collection. Congress may need to provide incentives to specific industries that have needed data to develop real-time, privacy-protected data feeds for public health early warning systems.

3. There is a need for basic and applied research in early warning systems for biological threats. Congress should provide funding through the National Library of Medicine and the Agency for Healthcare Research and Quality to support several interdisciplinary Centers of Excellence. *The National Library of Medicine is the principal federal funding source for research and training in the field of medical informatics, a field that has and can continue to provide tools and expertise needed to accomplish these objectives. The Agency for Healthcare Research and Quality has extensive experience in medical process improvement and change management. The centers of excellent must be large and interdisciplinary, comprising teams of public health physicians, epidemiologists, contractors, medical informatics researchers, mathematicians, and computer scientists, and they need to have multi-year funding to attract and maintain highly qualified individuals.*

4. Congress should encourage, through federal funding, several cities and regions to participate in early warning research. The field of biodefense is like the field of particle physics: a large particle accelerator is necessary to answer certain questions, and in general the bigger the accelerator the better. In the field of biodefense, the equivalent of a large particle accelerator is a large geographic region for which rich, multiple-year data sets are available for research and system validation.

In closing, I would suggest that the Congress note that early detection of major public health threats is an ambitious undertaking that resembles in both urgency and technological breadth the Space Race in the 60's and the Manhattan Project in the 40's. Those projects had clear goal statements that facilitated the work of multiple teams located in different regions of the country that were necessary to accom-

plish the mission. The DARPA Biosurveillance Program is an example of a program with a clear short-term objective to reduce detection time by two days over current levels and a stretch goal of being able to detect within a day of release, biological or toxicological agents that threatens the health of its citizens.

Thank you very much for the opportunity to speak here today.

INFORMATION ABOUT FEDERALLY FUNDED RESEARCH

National Library of Medicine

The initial funding for this research into early warning systems began in fall 1999, and came from the National Library of Medicine. The agency approved a request to redirect an ongoing project (to develop capability to detect rare health events automatically using health system data) to the problem of early detection of bioterrorism. In the ensuing two years, NLM has provided direct grant support of \$200,000.

The National Library of Medicine has also supported this work by funding trainees in medical informatics and infrastructure development under grants for training in Medical Informatics and the Integrated Academic Information Management Systems program.

Agency for Healthcare Research and Quality

In September 2000, the Biomedical Security Institute received a \$1,020,000, 1.5-year contract from the Agency for Healthcare Research and Quality (AHRQ) to study basic questions including (1) What is the capacity of existing information systems to detect outbreaks of disease? (2) How can existing systems be adapted to enhance early detection of a bioterrorist release? (3) What data elements are needed for early detection of a bioterrorist event? (4) What are the performance characteristics (including sensitivity, specificity, and timeliness) of different approaches to early detection of a bioterrorist threat? And (5) How can computerized clinical decision support be linked to early detection strategies?

Results of the AHRQ contract are described in two reports. The first is entitled *The Nation's Current Capacity for the Early Detection of Public Health Threats including Bioterrorism*, and the second is a report due in late November entitled *The Availability and Comparative Value of Data Elements Required for an Effective Bioterrorism Detection System*. We have published additional results in papers titled *Modeling the Effects of Epidemics on Routinely Collected Data*, and *The Emerging Science of Very Early Detection of Disease Outbreaks*. The references are listed for your convenient use in the next section.

Centers for Disease Control and Prevention

Also in September 2000, the Biomedical Security Institute entered into a cooperative agreement with the Centers for Disease Control and Prevention. In the first year of this agreement ('01), approximately \$540,000 (of \$920,000) was provided for research on early detection. The results of this research are described in five technical papers that are also listed in Appendix II. The papers describe data modeling for the National Electronic Disease Surveillance System, evaluation of an electronic laboratory reporting system for notifiable diseases, the use of routinely collected emergency department data for early detection of respiratory outbreaks, and the use over-the-counter sales of cough syrup and other products for early detection.

In the current fiscal year ('02), the Centers for Disease Control and Prevention is providing an additional \$400,000 (of \$720,000) for a number of projects including development of a health-system-resident component for RODS, development of a trusted broker, analysis of how a "zebra chip" could optimally be deployed in a detection scheme, and further support of ongoing work in natural language processing of chest radiographs to identify patients with inhalational anthrax.

Defense Advanced Research Projects Agency (DARPA) Biosurveillance Program

Recently (August 2001), we were awarded a contract by the Air Force providing \$1.6 M over 1.5-years to participate in the Defense Advanced Research Projects Agency (DARPA) Biosurveillance Program. The program's goal is to develop and validate city-scale prototypes of early warning systems. The emphasis of the program is on the use of nontraditional data. Our specific tasks include development of automatic detection algorithms, computer-based simulations of epidemics for "what-if" analyses, and computer models of early response decision-making under uncertainty.

Mr. GREENWOOD. Well, we thank you, Dr. Wagner, and thank you for joining us this afternoon. I believe we are going to go to

Dr. Zelicoff next. You are recognized for 5 minutes for your testimony.

TESTIMONY OF ALAN P. ZELICOFF

Mr. ZELICOFF. Thank you, Mr. Chairman. I am going to be departing from my prepared remarks. I would ask that if it is possible and proper that my prepared remarks be entered into the record.

Mr. GREENWOOD. Without objection, your remarks will be part of the record.

Mr. ZELICOFF. I will spend just a few moments introducing myself. My name is Al Zelicoff, and as you heard, I am a senior scientist at the Center for National Security and Arms Control at Sandia National Laboratories, which is a Department of Energy government owned laboratory.

I am a physician and physicist, and our center develops technologies for counter-proliferation of weapons of mass destruction, and for verification of the entire panoply of arms control agreements of which the United States is a party.

I was in medical practice for about a decade, but my area of interest since joining Sandia has been in non-proliferation of biological weapons, and specifically in coming up with clinical tools that could be of use for people who are actually at the front lines of medicine.

There were a number of things that my colleagues in the previous panel testified to with which I agree, and there were a number with which I profoundly disagree, and I hope that I will have a chance to flush some of those out in the question period.

But let me tell you where I certainly do agree with some of the generic and not so generic statements that were made previously. Any system that we use for early surveillance has to have a couple of characteristics that are pretty obvious.

You can't wear people out, and it should be local, and I will be coming back to that point in a moment. It has to maintain patient confidentiality. Obviously, the key stakeholders who will be using the system should be involved in its design.

It has got to be simple, and it has to serve as a communication tool between physicians and public health officials. I think all of those things are very obvious. Let me lay a couple of other items on the table and then show you at Sandia how we believe we have achieved at least an 80 percent solution for all of those exacting requirements.

The information has to be accessible to other agencies and decisionmakers on a need to know basis and that will vary from agency to agency. The system has to be cheap, fast, and most importantly of all, it has to be sustainable on its own merits.

If the system doesn't work because it helps physicians in their daily practice, it is not going to survive, no matter what. It does no good to send CDC officials, however well trained they are, to sit in emergency rooms around the country when we all know that there aren't nearly enough CDC officials to go around. It is far too expensive, and therefore, not sustainable.

Remember that we have a private health care system in this country, and I don't know if that is going to change in the future,

but for the foreseeable future I expect it is going to be private and it is fractionated.

Now, if I can call your attention to the screen, and if I could ask that some of the lights go out. Let me tell you a little bit about the Rapid Syndrome Validation Projection, or RSVP for short.

This is a syndrome-based disease surveillance system that has been developed with the help of the New Mexico Department of Health in Albuquerque, and in my view some of the best disease sleuths that the country has to offer.

As has been indicated earlier, we have broken all of the rules of epidemiology. We are not using disease based or laboratory based diagnosis. We are looking at syndromes which are listed here, and I will have more to say about those in a moment.

We do, however, permit the physician to enter reportable diseases, and just to show you how awful that is in the real world, let me indicate to you that the reportable diseases that physicians are actually supposed to be aware of in the community.

And let me tell you that the rapid syndrome validation project is designed to be used by primary care physicians in their offices and clinics, and the human in the loop is the local public health official, the local epidemiologist who unquestionably is the most knowledgeable person in the community about diseases.

And the reason that I emphasized local a little bit earlier is that disease patterns in communities vary from place to place, and here is no one who knows the disease patterns in their community or to borrow a phrase I think from Dr. Barry earlier, who has the highly trained sophisticated genetically engineered neuro network algorithm called the Mark One Eyeball that can recognize disease patterns as they come and go through a community, and determine simply by extent of experience what is normal and what simply is not normal.

So, if you will give me 1 more minute, I will bring up the software again. By the way this is not a canned presentation. This is actually on-line and is precisely what physicians see when they are using it in the community. And we have had this on-line now for about 9 months in New Mexico.

And you will see in a moment that the only software that is required for the person to use it is any available web browser, which are all free, and so the barriers to entry here are extremely small, and I believe that the cost, which I can provide to you in some detail if you would like during the questioning period, are also very small as well.

All right. So the physician logs in by choosing their user name, and what we have put in in the local emergency rooms and primary care clinics is a touch screen, because it is much, much faster than using a mouse.

We were after about 45 seconds of the physician's time, which most of you will recognize is about the attention span of the average clinical physician today. Demographics are the first part of epidemiology, and it answers three questions; what, where, and when.

In the early disease investigation what you are trying to determine if you are a local public health official is whether or not to worry, and then begin a disease investigation as I think has been indicated earlier.

So I will enter a zip code of work, and notice that the system asks for additional information if you happen to hit yes on travel, for example, and it asks if you traveled internationally.

We have certain high risk occupations, like a postal worker, for example; and I am going to pick one of the syndromes, which is influenza like and that is the one that you hear so much about.

This is a term of art in medicine. It is not a head cold. It is severe illness, with fever, myalgia, muscle aches and headache, generally accompanied by respiratory symptoms.

What we are after here to try to get the noise down and get the information content up is the clinical judgment of the physician. And I disagree with one of the previous testifiers who stated that physicians aren't going to welcome one more computer screen into their clinic.

Indeed, I have many people asking me for this system, simply because as you will see, it gives something back to the physician, as well as giving something to the epidemiologist.

All the other screens look pretty much the same, and symptoms are at the top, and so I am going to enter somebody who has a productive cough here, with severe muscle aches, and I am going to allow this physician to say that they got a chest x-ray and it was abnormal.

And the system actually prompts the doctor to look for certain signs and symptoms that are actually classically associated with terrorism diseases or diseases of public health importance.

Not that the average doctor would know that. They don't. But the system does. So in this case wide media stannum is a particular finding on the chest x-ray, and almost always associated with anthrax in the setting of an acute respiratory illness.

In fact, it is anthrax until proven otherwise, although the vast majority of physicians won't recognize that. We are done. In practice, that takes about 30 seconds for the average physician to do, and when we are done, three things happen.

The data goes off to the local server, which is sitting in the local public health department. Second, that data that I just entered got screened for combinations of signs and symptoms that the local public health authority once again, and besides local, are strongly correlated either with diseases of public health importance—measles, for example—or are associated with bioterrorism related illnesses.

If that combination of signs and symptoms happens to be picked, the system automatically e-mails, faxes, and pages the local epidemiologist who is on-call—there is almost always one in every jurisdiction in the country—with all of the information that I just entered, including the name of the physician who logged in and their phone number.

That happens within 30 seconds, and so the State epidemiologist, and in our case in New Mexico, can get on the phone and call Dr. Zelicoff at UM Hospital, and remind him that he might be seeing a case of anthrax, and would you please hold that patient there.

And we will start the case investigation 2 days before that person pops into the hospital, or at worst, 3 days when they are having their autopsy done. But the most important thing of all is what comes back to the physicians.

In all cases, this screen comes back and in the lower left-hand corner what you see is the results of all culture data, of all major respiratory passages, and it varies from syndrome to syndrome.

And from the entire State, going all the way back to March, and it would be foolish for a physician in October in New Mexico to make a diagnosis of flu, for example, because there is no flu in the communities at that time.

There is a temporal plot that shows similar cases, and most important of all, there is an advisory message which is controlled by the local public health authority that I like to refer to as medical intelligence.

I think one of the committee members referred to the links between epidemiology and intelligence, and indeed the advisory message is the sum total knowledge of all information of local public health officials have with reference to that particular State, and it varies from syndrome to syndrome.

And finally the physician also gets a map, and this map is zoomable to any portion of the United States, down to zip code level, and it shows you that the epi-center right now of respiratory disease in the Albuquerque area is in fact in Albuquerque and it is coded.

And then it is color coded and then indeed other maps can be laid on top of that for analysis. I will wrap up now, Mr. Chairman, by making one final point. I served for 9 years on the U.S. Delegation to the Biological Weapons Convention. It is the only treaty that regulates or in fact bans the ownership of biological weapons.

As a participant in that process, I believe that the current administration was correct to reject the protocol to straighten the biological weapons convention. I believe that that protocol was not nearly worthless, but was actually quite a bit worse than that.

In fact, it was worse than worthless. This is not merely an opinion. My conclusions are backed up by the only scientifically cogent, technically meaningful, mock inspections done by any of the State's parties to the convention, which were done here in the United States, yet actively ignored by the decisionmakers during the time of the negotiation.

Let me be clear that the failure of that protocol lies squarely at the feet of the previous Administration. The delegation and the inter-agency working group suffered enormously from a near total lack of leadership and a complete absence of vision, which is a great tragedy.

Despite protestations to the contrary, there was no thoughtful senior level involvement in the U.S. negotiating strategy beyond a single tired phrase that appeared yearly in the State of the Union address.

Because of the events of the last several weeks, I am very sympathetic to the argument that for the short term and at the moment, there is little time for policymakers to rethink our approach to future protocol negotiations.

But when management of the current price no longer dominates all the attention of the decisionmakers, I would urge the U.S. Government to appoint a seasoned negotiator with one key goal in mind; to establish an international system of disease monitoring

that is electronically based and a value to clinicians, veterinarians, and their patients.

So in summary I believe we have identified a set of electronic tools for both epidemiologists and clinicians in New Mexico that meet the very exacting requirements that you heard about from the previous speakers, and I would be very, very grateful if you will take time to ask me more questions about it, and I will be happy to entertain any other questions the committee might have.

[The prepared statement of Alan P. Zelicoff follows:]

PREPARED STATEMENT OF ALAN P. ZELICOFF, SENIOR SCIENTIST, SANDIA NATIONAL LABORATORIES

Mr. Chairman and distinguished members of the Committee, thank you for the opportunity to testify today. My name is Alan Zelicoff, and I am a senior scientist at Sandia National Laboratories in Albuquerque, New Mexico. Sandia is a multiprogram laboratory of the National Nuclear Security Administration (NNSA) of the United States Department of Energy.

I am a physician and physicist at Sandia's Center for National Security and Arms Control. Our center develops technologies for counter-proliferation of weapons of mass destruction, and for verification of the entire spectrum of arms control treaties to which the United States is a party. I practiced internal medicine for about a decade. My area of interest since joining Sandia twelve years ago has been in biological weapons nonproliferation. I have pursued technical work in the laboratory, as well as in my capacity as an Advisor for nine years on the U.S. Delegation to the Biological Weapons Convention.

These activities have repeatedly demonstrated to me that we, as a country, have not taken the biological weapons proliferation problem seriously, and we have squandered important opportunities in the international arena to strengthen norms against the acquisition and use of biological materials as weapons. But more important, Mr. Chairman, is that our public health systems and traditional medical care delivery systems are minimally prepared to detect the early manifestations of disease that is intentionally introduced into a community.

In any biological weapons attack, large or small, hours matter. I hope to make this particularly important point vivid for the Committee, and to make a suggestion for a simple measure that we can implement immediately, not merely to plug the obvious gaps, but as a step toward a systematic solution that will be of day-to-day benefit in the diagnosis and treatment of all infectious diseases of public health importance.

There are many dirty little secrets in medicine. One of them is this: Practicing physicians don't report unusual diseases to local public health officials (including signs and symptoms that could be due to bioterrorism), and public health officials don't have the ability to provide timely disease information to physicians working in clinics and hospitals. In my ten years of medical practice, I never—not once—saw a physician or physician assistant pick up the phone to report a so-called "reportable" disease. Even in areas of the country where reporting of a small set of key infectious diseases is a legal requirement, physicians rarely comply. Why? The process is burdensome, inefficient, and most importantly, almost never gives anything back to the physician that is of relevance to the patient she is caring for.

The reporting network—and I use this term loosely—relies on physicians first to recognize that they are dealing with an unusual disease; second, to know the phone number of whom to call; third, to be willing to wait for a public health officer to be available; and fourth, to field follow-up phone calls and answer what seems to be a never ending stream of questions. The first three are unlikely to come to pass, and the fourth is a powerful disincentive against accomplishing the first three.

Busy doctors—and they are busier, though not necessarily more productive, than ever before—don't have time for this. Yet, they are desperately in need of information about even *common* diseases circulating in the community. As but one example, we know that 60 percent—yes, 60 percent—of antibiotics prescribed in the primary care setting are unnecessary or inappropriate. During flu season when *viruses* are causing disease, physicians routinely reach for the prescription pad and write orders for *antibacterial* antibiotics. Part of this is due to ignorance, and the other part is due to pressure from patients who are themselves ill informed about the diseases that are prevalent in their community. A system that provided physicians with this knowledge alone, and the means with which to show their patients what is going on in the disease mix at any given time would, in and of itself, greatly improve the

quality of medical care in the United States and substantially reduce costs and the emergence of antibiotic resistance.

You may be surprised to learn that the repository of knowledge regarding infectious diseases resides not with the primary care physician but in local (and I emphasize *local*) public health officials. These highly trained specialists—physicians with specialties in disease outbreak investigation (epidemiologists), veterinarians, and nurses—know by dint of their long experience, the pattern diseases in their area—which viruses are normal, what microbes are unusual, what seasonal course diseases take, all of which varies tremendously from place to place in the United States. Further, while public health officials rarely see patients in the clinical setting, they are well bearded in the truly novel diseases that primary care physicians and community veterinarians see once in a lifetime if at all: plague, anthrax, foot-and-mouth disease, and other potential bioterrorism related diseases. It is perhaps best to think of epidemiologists as disease hunters with the wits and senses of fine detectives, reinforced by strong backgrounds in medicine and statistics. They are much more than the usual doctor or veterinarian.

What is required immediately (actually, it has been required for a long time) is an inexpensive tool that will establish and maintain communication between overworked clinicians and out-of-reach public health officers. The tool must be easy and intuitive to use, ubiquitous, very fast, and sustainable on its own merits. It does little, if any, longterm good to assign CDC epidemiologists to a few hospitals in New York City only during a crisis, when we all know that the costs involved are prohibitive and that there are far too few CDC personnel to be in even the fifty largest metropolitan areas, let alone everywhere.

But physicians and patients *are* everywhere; so are veterinarians and the animals they care for. The challenge I have faced in my work is figuring out a way to help these earliest-possible “sensors” of disease report accurately to public health officials and meet all of the demanding requirements I have just outlined. I think we have a solution. It is not a “complete” solution, but it is an essential part of a *systematic* solution. At Sandia, we have developed an Internet-based, secure, inexpensive, simple reporting system that we call the Rapid Syndrome Validation Project (RSVP). The Department of Energy’s Chemical and Biological Non-Proliferation Program—a small, forward-looking, and creative bunch of planners—has funded this work.

What they realized about two years ago is that good health surveillance (of animals and humans) is also good counter-terrorism against biological weapons. Automated sensors are still a little way off, and more to the point, will *never* be as ubiquitous as people. But with some straightforward modeling, we at Sandia were able to show that if public health authorities can be apprised of the earliest cluster of illness that occurs a few days after a large scale bioterror attack (rather than at the time of first death or even the time of first positive laboratory test result), the vast majority of people exposed—even to anthrax and smallpox—can be saved. This is because, by definition, there will always be a few percent of the exposed population who will show symptoms first. This will occur because some people receive a larger dose of the biological agent, or because some people are more susceptible to disease, biological variability being what it is.

Equally important—and I can not emphasize this enough in light of our recent experience in Florida and in the Washington area—is that the system can show whether there is *widespread* exposure, or instead, that it is likely to have been more localized. This is critical information for decision makers. It goes directly to the question of how many people need to be tested, how many people need prophylaxis, and how many people should be followed-up. Mark Twain had it about right when he said, “It ain’t so much knowing about that what is, but not knowing about that what ain’t.” Reassuring the public with substantive knowledge of the limits of exposure will make all the difference in the use of resources should there be a large scale dissemination, and all the difference in degree of disruption of our lives should the use of decidedly low-tech but nonetheless terror-inducing dissemination of anthrax by mail be repeated in other cities.

Let me show you briefly, how the system works.

I don’t purport that syndrome-based surveillance is the complete answer to our bioterrorism problem, nor that it is the salvation of the decaying public health infrastructure in the United States. What it *does* do, however, is provide an easy, inexpensive way to get the real experts (public health officials) the data they need to decide whether or not a disease outbreak investigation is warranted, at the earliest possible time, well before our laboratory-based surveillance system would alert them to serious disease in the community. It also gives back to physicians something useful in the bargain.

We need a decision at the highest levels to *begin* with a system like RSVP that is built with a view toward add-ons and augmentation for various potential users,

from local authorities (such as public health officials and local governments) to national-level decision makers and those who allocate precious remedial resources (such as FEMA and the CDC).

One final thought: for the past nine years or so, the United States has participated in negotiations in Geneva to implement measures to strengthen compliance with the Biological Weapons Convention. As a participant in Geneva and in the interagency work in Washington, I believe that the current Administration was correct to reject the draft Protocol. As I have testified and written previously, the Protocol is not merely worthless; it is worse than worthless, as it would provide easy refuge for cheaters and place unacceptable burdens on U.S. industrial and military facilities. This is not merely an opinion. My conclusion is backed up by the only scientifically cogent, technically meaningful mock inspections conducted by any States Party to the Convention—done here in the United States and actively ignored by the low-level staffers who pretended or presumed to direct the formation of our policy on the Protocol at the time. Let me be clear: The failure of the Protocol lies, in my view, at the feet of the previous Administration. The delegation and interagency working group suffered enormously from a near total lack of leadership and a complete absence of vision. Despite protestations to the contrary, there was no thoughtful senior level involvement in the U.S. negotiating strategy beyond a single tired phrase repeated yearly in the State of the Union address.

Because of the events of the last several weeks, I am sympathetic to the argument that for the short term, and at the moment, there is little time for policy makers to re-think our approach to future Protocol negotiations. But when the management of the current crisis no longer dominates all of the attention of decision makers, I would urge the United States government to appoint a seasoned negotiator with one key goal in mind: to establish an international system of disease monitoring that is electronically based and of value to clinicians and veterinarians and their patients.

Ladies and gentlemen of the Committee, we have dawdled far too long in addressing the collapse of the public health system. We have always had, and will continue to have, a mostly non-government, private health care system. Yet, the expertise for population health lies not in individual practitioners but with the oft-forgotten state and county public health epidemiologists who work with a dearth of data but a plethora of expectation. We can and must do better than this. A simple, Internet-based, *syndrome*-based reporting system is the key component of a renewed, effective surveillance network that will serve us during this critical hour, as well as *after* we have resolved this most acute crisis, as we surely will. The questions are: How many lives will be lost in the process, and how quickly can we restore a sense of confidence to the American people? With inexpensive, readily available tools, the medical and public health communities will be among your chief agents and allies in relieving uncertainty and restoring faith, which are so essential to getting people back to living their lives and fulfilling their hopes.

Thank you Mr. Chairman.

Mr. GREENWOOD. Thank you, Dr. Zelicoff, and we certainly will ask you questions. Mr. Russell, you are recognized for 5 minutes to provide your testimony, please.

TESTIMONY OF JOHN S. RUSSELL

Mr. RUSSELL. Thank you, Mr. Chairman. Perhaps I should pause and see if I am hooked up here to the system.

Mr. BURR. Mr. Chairman, while he is hooking up to that, could I just take the opportunity to introduce John.

Mr. GREENWOOD. I wish you would, please.

Mr. BURR. He is from North Carolina, and he is the Executive Vice President and General Counsel of Quintiles. Quintiles is one of the largest data warehouses of medical data in the United States, and it collects identified data from hundreds of insurance companies, pharmacy benefit managers, hospitals, and physicians.

They also conduct numerous clinical trials. Quintiles has over 18,000 employees located in 38 countries, and they have some of the most state-of-the-art de-identification software in the private or public sector.

John, let me take this opportunity to welcome you since I didn't earlier, and I certainly encourage my colleagues to pay special attention to the resources that they have at their fingertips today, and how that might be able to help us.

Mr. RUSSELL. Thank you very much, Congressman Burr, for that gracious introduction. Chairman Greenwood, Congressman Deutsch, members of the subcommittee, my name is John Russell, and I am the Executive Vice President of Quintiles Transnational, which is the world's largest manager of clinical trials for the pharmaceutical and bio-tech industries.

And, Mr. Chairman, while my comments will be brief, I ask that my written statement be made part of the record.

Mr. GREENWOOD. And it will.

Mr. RUSSELL. Thank you, sir.

What I want to speak to you this morning about is one of our areas of expertise, which is health care and infomatics. We have developed for commercial purposes a national system to register on a daily basis prescription use and diagnostic trends.

This system draws on a de-identified data base that consists of pharmacy claims and medical claims posted for insurance payment. The data base contains currently over 2.4 billion transactions, and is refreshed by 3 million claims per day, representing health care experiences for more than 100 million anonymous persons in the United States.

It is also longitudinal. It has a 3-year life to it. Through matching these medical claims with pharmacy prescriptions, we can track disease trends and patterns. For example, we can track the prescription of a certain drug in any city of the United States.

In fact, in any zip code, and for the country as a whole. We can by matching the prescriptions to the medical claims see a disease pattern as it develops nationally overnight. The system is automatic. It is fast, with reports that can be delivered daily.

It is based on a pioneer technology that we developed in the late 1990's. The technology is proven and in use. Now, let me say why I think briefly how this system can begin to be part of the solution.

We believe that this system can provide a complimentary solution to a problem that we are all addressing today. It is not—this system does not in any way substitute for the absolutely indispensable work of local intelligence.

The problem as we see it is that the detection of a disease outbreak is episodic, relying primarily on reports from the field. If I may use a battlefield analogy, I would call this—and I believe the chairman himself used this term, but I would call this human intelligence.

It is indispensable, but incomplete. What is also needed is an electronic national early warning system that we would characterize as satellite intelligence to compliment this human intelligence.

I am reminded of how perhaps we follow a storm, even on the nightly news. I mean, we have a weatherman or a weatherwoman who just reports from the field. And then we have a weather satellite that tells us how the storm is approaching, and what the speed and direction of it is.

And with these two things put together, we are better informed, and I think we can have that system. Now, how does our system work? The system as I said matches medical and pharmacy claims to anonymous patients over the whole country.

It is both historical and current. That is, it tells a story now and over time, and has the ability to benchmark normal trends and spot the unusual, which is key to this exercise; benchmarking and spotting anomalies.

It can be in its current state readily adapted with disease markers, and what we would call sentinels. Also, intelligence software in the form of neural networks that would actually spot these anomalies and also throw out false positive indicators.

And also with a communications capability that we have already developed which would make this system send messages out through E-mail and voice mail either to public health officials or to doctors in the field, or to both, because it would be adaptable in that way to both a national and a local form of communication.

So equipped, let me give you an example of how it might work and what it might do. Imagine five cities in five different States, all located on a different reservoir. Suppose in an overnight reading we saw that each of those cities showed an increase against a benchmark of gastrointestinal symptoms which we had previously marked for surveillance.

Our system would light up like a Christmas tree. It would signal out to the health authorities. It would allow perhaps precious hours, and maybe even a day, so that these symptoms could be readily diagnosed by the expert doctors in the field.

Now, perhaps I could pause and show you some real examples of how our current data base works. Let me refer you up to the screen. This is a slide that represents a study that we initiated immediately after the September 11 attacks, where we decided to follow cipro use in New York City.

This is from our prescription data base. You see interestingly an uptick on the actual day of September 11. That might be because of the anticipation of casualties, because cipro has many uses other than for anthrax.

Or also it could be for some preliminary stockpiling. But then you see actually interestingly a large spike up, reaching its apogee at October 12 when we had begun to hear warnings of bioterrorist attacks, indeed first reports.

Now if I could show you this slide. As my diagnoses increase in New York City after the terrorist attack, this is from the medical side of the data base, also matched against prescription claims.

And what we can infer is that after the September 11 attacks there is something of an uptick that you can notice in asthma and upper-respiratory type ailments along the ICD-9 or medical diagnosis patterns that we would see.

This could be because of air quality or because of stress. It is an interesting piece of data, and it can be produced on an overnight basis. Let me go to something else which shows you a bit of benchmarking.

This is a lime disease study, and this was provided to CDC as a means of tracking lyme disease in the year 2000. What you see is that our automatic reporting system picked up over 27,000 cases

to follow, and you can see that the spread of those cases is somewhat beyond the traditional northeastern United States locations.

Now, this is what the CDC reported, a little over 13,000 cases through the voluntary system. If you recall the slide before, the spread is greater, and the concentration is very similar, but again an interesting piece of complimentary data to the local reporting system, that we would refer for further analysis.

Now, to stress the point that this is both local and national, I showed you a New York City slide about cipro use. Now, this is the same slide on a national basis which actually does show if you recall the New York City slide the bump up on the week of October 12.

But that would be normalized on a national trend, and so both local and national. Mr. Chairman, let me sum up by saying that there are many things that I could say in summary, but let me leave you with these thoughts.

The system in the data base necessary for real time bioterrorism surveillance system exists today. It works nationally and locally. It is a proven technology and it operates on agreed reporting standards. This automated surveillance system will operate without any additional reporting by health professionals.

All the reporting is already done in order to affect payment through the national payment system that you in your wisdom so regularized through the HIPAA legislation and its attendant regulations.

This system can be quickly adapted to use as a national electronic early warning system to provide that satellite intelligence that I was talking about. Mr. Chairman, with a system like this, we can deliver more information faster. We can inform those doctors in the field so that they can make those ready diagnoses that we all talked about today.

We can get ahead of the threats that lie before us, and we can play offense rather than defense. I thank the committee for hearing our presentation today, and I would be glad to answer any questions that you may have.

[The prepared statement of John S. Russell follows:]

PREPARED STATEMENT OF JOHN RUSSELL, EXECUTIVE VICE PRESIDENT, QUINTILES
TRANSNATIONAL CORP.

Introduction

Chairman Greenwood, Congressman Deutsch, members of the Subcommittee: My name is John Russell. I am Executive Vice President of Quintiles Transnational Corp., the world's largest clinical research organization and also the leader in monitoring medical and pharmaceutical data to improve drug development and healthcare.

Thank you for the opportunity to participate in this critical discussion about improving our nation's ability to detect and respond to bioterrorism.

The Challenge

The key to our preparedness for biological attack is rapid detection, determination of the source, and response. Every minute that we can speed up that process can reduce the number of individuals infected, and provide better odds for recovery for those who are. The intentional release of a biological agent may not be recognized for several days or more, during which time a biological agent can spread to others who were not initially exposed. Some biological agents produce symptoms that can be easily confused with influenza or other, less virulent illnesses, leading to a delay in diagnosis or identification.

Over the past few weeks, we have seen how our nation's current disease surveillance system works. It relies primarily on reports from the field. Health care professionals contact local, state or national public health officials to report unusual diagnoses, reportable diseases, or odd disease patterns, often prompted by specific alerts. Analysis and response follows from this survey process.

This process is rightfully being improved to real-time standards; but bringing an electronic environment to this network is deliberate and fragmented work. Even as improvements take hold, for the foreseeable future large segments of the public health surveillance system will remain local, voluntary and people-intensive. While it compiles critical information and provides definitive analysis of confounding events, this "human intelligence" system—if I may borrow a military term—should not stand alone in the current crisis.

The fact is that the technology exists today to deploy a parallel system—a national early warning system—that could quickly signal bioterrorist events directly to CDC and to any state and local public health office online. The system works by collecting pharmacy and medical data and relating it to de-identified patients to create inferences of disease patterns. It is built on the national health insurance payment system that exists now. This system would not replace current reporting; rather, it would augment and complement local level data with a near real-time national picture. In effect, it would give local, state and national public health authorities a big-picture perspective, a kind of "satellite intelligence"—if I may continue the military analogy—that complements "human intelligence."

The effect of running these systems in parallel is to permit public health officials to react quickly to the truly surprising fact—flu-like symptoms in West Coast port cities or gastrointestinal symptoms near five scattered reservoirs—which can give the opportunity to respond proactively. The advantages of this approach can be stated succinctly. This electronic system is automatic, not voluntary. It never gets tired. It covers the whole country, or any part, down to a zip code. It operates daily. It is a proven technology. With a national early warning system built on this foundation at their disposal, public health officials at all levels could be deployed in advance, to play offense rather than defense.

National Early Warning System: How It Works

The electronic early warning system we will describe will be built on a system we currently use to generate weekly statistical analyses of disease trends and treatment patterns across hundreds of conditions and over 8,000 prescription drugs, which can be enhanced as needed. In effect, this national early warning system could produce a virtual, daily snapshot of disease trends and treatment patterns across the United States. Its reach is both broad and specific in that it can survey the whole country, or any Metropolitan Statistical Area (MSA), or even any zip code. The data driving this system is de-identified health data. Over 100 million patients are assigned a unique code that attracts diagnostic and prescription events from insurance claims. The results are both rapid and historical; in other words the story is told in near real time and longitudinally over time.

Our health monitoring system analyzes the largest, integrated warehouse of current medical and pharmaceutical data in the world—a database that contains information derived from more than 2.4 billion de-identified hospital, medical and pharmaceutical transactions. The system is refreshed with about 3-million new transactions per day. These include claims from thousands of pharmacies, hospitals and physicians, and more than 680,000 total providers of pharmacy, medical and dental services. [See Exhibit 1] This longitudinal data, linked for each patient through a unique encryption engine, can provide, with adaptation, a powerful tool for our national security.

To support this national early warning system, we will install neural networks—software programs that "learn" and become increasingly accurate over time in pattern identification and trend prediction, that can distinguish, for example, between seasonal variations in flu cases and real anomalies.

To give you an example of what this electronic early warning system captures, if there is an outbreak of flu-like symptoms, the trend can show up locally in our database as early reports begin to come into the CDC and other public health authorities, often within a day. Similarly, if there is a significant increase in antibiotic use, asthma diagnoses, or anxiety disorders—all of which we have recorded in the New York area since September 11 [Exhibits 2, 3, and 4]—the system can track the progression of those events through the health system in something close to real time, and we can analyze the data by age group, or zip code, or date. To illustrate the sensitivity of the current data sample, in the year 2000 we recorded a little more than 27,000 cases of Lyme disease in the United States [Exhibit 8], while the CDC case count projected about 13,000 cases. [Exhibit 9]

This system could be used to scan millions of patient medical and pharmacy encounters *per day*, and—with the application of appropriate analytics—provide U.S. public health officials with a near real-time picture of disease patterns and treatment trends.

Let me stress further that deploying this system to monitor indicators of potential bioterrorist events will not require any new reporting mechanisms; that is, we don't need to ask doctors or hospitals or pharmacies to do anything they don't already do today. As suggested by our Lyme disease findings, the electronic claims payment system—the mechanisms by which health care providers get compensated for providing services—is likely to capture more and broader data than a voluntary or special reporting system. Today, most pharmacy claims and payments are submitted electronically and paid before the patient leaves the store. Similarly, many hospitals and large provider groups electronically transmit key health care data—the diagnosis and the care rendered—daily. Certainly, while we wish to see more data—such as claims from small general medical practices—submitted just as quickly, a critical mass of health care encounter information flows electronically today, and a national model that can take immediate advantage of this fact can be built rapidly.

This system would allow for significantly faster and more accurate detection of possible bioterrorist events than currently possible. In a matter of weeks, we can demonstrate a prototype system to provide critical bioterrorism tracking data to designated public health officials at the local, state and national level. Moreover, the system can be programmed to trigger electronic or voice-mail alerts to designated federal and state government officials when anything out of the ordinary is detected. This could provide significant benefits in mitigating injuries or deaths from bioterrorism and tracking points of origin of bioterrorist events, and for ongoing use in improving effectiveness and efficiency of public health delivery by physicians on the front line.

Prior Public Health Uses

Using this patient-level database and Web-based analytical tools, we have performed several discrete projects in health care monitoring and analysis, including vaccination monitoring (e.g., hepatitis), public health screening (e.g., peptic ulcer disease), disease prevalence trends (e.g., respiratory conditions), preventive health (e.g., hormone replacement therapy), safety surveillance and risk monitoring of drugs, and medical treatment patterns (e.g., surgical techniques). The results of some of these projects have been provided to federal agencies such as CDC and FDA. Indeed, CDC, while it had the funding, used our database as part of a pilot project on anti-bioterrorism. Speaking of our system, a former CDC official stated, “In addition to their public health role, . . . information products . . . promote an important national security interest—the detection and prevention of biological terrorism . . . the breadth, reliability and timeliness of . . . healthcare data are critical to this effort . . . CDC can use this data for early detection of unusual prescription patterns that could be evidence of an intentionally introduced disease . . . such as smallpox . . . [which] would be a national and global calamity if the earliest possible detection of the first wave of ill person is delayed . . . [T]he saving of even a single day in detection and response time can translate into the saving of hundreds or thousands of lives and the prevention of a global pandemic.”—*Sworn testimony of Joel Greenspan, M.D., M.P.H., former CDC commissioned officer and medical epidemiologist.*

This capability is the result of developments in the commercial sector and government regulations during the 1990s. By mid-decade the private health insurance industry introduced a nationwide electronic data interchange—or EDI—network that processed in real-time pharmaceutical and medical insurance claims that were in electronic form. The purpose was to route claims immediately from providers for the proper payment sources for reimbursement. Congress encouraged this development through the passage of the Health Insurance Portability and Accountability Act (HIPAA) in 1996, and the Department of Health and Human Services issued a series of regulations to provide oversight to this national EDI system.

As this payment system developed, the aggregation of data from these claims for analytical purposes to improve public health became a possibility. By late decade, longitudinal databases were in use, and the marriage of developing technology to healthcare improvement began to show results. The latest HIPAA regulations generally encourage the use of aggregated healthcare data, explicitly recognizing the benefits of these data sets in improving healthcare quality and efficiency.

The pharmaceutical industry has been an initial user of the system's capabilities. Now the national public health surveillance system stands to benefit greatly.

Technological and Regulatory Origins of the System

The current monitoring system was created for commercial purposes, following the confidentiality standards established by the HIPAA privacy rule, and, consequently, registers particularity of zip codes to the two or three-digit level. *See, e.g.*, 45 CFR § 164.514. However, I would note that several exceptions to the HIPAA privacy rule are permitted for activities in the public interest, such as: for public health activities (e.g., CDC), for health oversight activities (e.g., FDA), for law enforcement, to avert serious threat to health or safety, for national security and intelligence activities, and for protective services for the President and others. *See, e.g.*, 45 CFR § 164.512. Therefore, in accordance with HIPAA provisions and the government's specifications, the database could be enhanced to include additional data fields and zip-code particularity to refine and augment the accurate tracking and location of infectious disease patterns of bioterrorism agents, such as smallpox and anthrax.

Benefits to Entire Public Health System

The usefulness of this system would extend considerably beyond detection of possible bioterrorist events. Once in place, it could be used by federal and state public health officials to analyze disease patterns and treatment trends, aid vaccination monitoring and public health screening, conduct cost-benefit analyses of alternative treatments, enhance safety and risk monitoring of drugs, and improve allocation of disease prevention resources.

To demonstrate the current effectiveness of this system, we have attached several exhibits of particular research projects, some of which we alluded to briefly above.

Exhibits 2, 5, 6, and 7 demonstrates the use of Cipro—the powerful antibiotic typically prescribed for treatment (or prevention) of serious bacterial infections, including gastrointestinal ailments, pneumonia, bronchitis, and for conditions resulting from burns and compound fractures, but also for anthrax—before and after the tragic day of September 11—normalized for the day of the week and seasonal variations. On September 12, our prescription database detected [Exhibit 2] a small (~35%), though significant, increase in Cipro use in New York City on September 11. This may be attributed to prophylactic treatment against infections of the victims of the terrorist attack and possibly some early stockpiling of Cipro. Then, there was a rapid decrease, which was followed by a gradual, then dramatic ~500% increase on October 12th in Cipro prescriptions in a 60 mile-radius of the World Trade Centers. This increase is likely due to stockpiling of the drug from fears of bioterrorism attack with anthrax. For the same time period, Exhibits 3 and 4 demonstrate an increase in New York City of asthma symptoms and anti-anxiety drug prescription, respectively, after September 11. These findings have been provided to the CDC.

In a 60-mile radius of the Pentagon, Cipro use increased by ~100% immediately following President Bush's warning on October 12th of increased risk of terrorist attacks. [Exhibit 5] Moreover, our system shows that Cipro utilization increased by more than ~200% in Miami-Dade County on October 9th, which aligns with the first reported anthrax case in that area. [Exhibit 6] Note, too, that on a national level, Cipro use also increased after October 12th, but to a lesser extent (~50%). [Exhibit 7]

In Exhibit 8, we showed to the CDC tracking of the spread of Lyme disease in the year 2000 from actual cases reported in our system. Compare this to the data shown in Exhibit 9 of the accumulated cases of Lyme disease reported to CDC from State Health Departments. Note that the claim-based database detected approximately twice as many Lyme disease cases than did the physician-reporting system for the same period. The spread of cases is also greater in the claims-based data, although the areas of highest concentration remain constant.

In Exhibit 10, using the medical diagnosis database, we presented to the CDC the detection of an *E.coli* outbreak in a county fair in Washington County in New York State in 1999. Note the concomitant increase in diagnosis of *E.coli* in fair attendees from the surrounding counties.

Hard-to-find patients diagnosed with rare diseases also can be tracked with this system. Exhibit 11 demonstrates the detection of 85 Brucellosis patients nationally in the year 2000 compared with 63 cases reported to the CDC for the same period. We provided our results to the CDC. Note that Brucellosis has been identified as a possible biological agent for bioterrorism.

Summary

We urge the government to deploy an electronic national early warning system as a 21st century tool in its defense arsenal against 21st century warfare—bioterrorism.

The database, infrastructure and statistical tools needed to build and operate a national early warning system are already in place. Upon commencing the project, experienced statisticians and healthcare analysts could be turned to the bioterrorism challenge. In a matter of weeks, modifications could be made to the basic infrastructure to create a prototype system that detects a range of events and enhances public health response.

First, we should determine, in consultation with public health authorities, the “marker” or “sentinel” symptoms of a possible bioterrorist event, such as flu-like symptoms and upper respiratory and gastrointestinal distress, which are likely to be seen in hospital emergency rooms and pharmacies, and which should be screened for continuously.

Additionally, with neural network enhancements, we can deploy increasingly sensitive modeling; that is, truly intelligent software that can detect spikes such as those detected in Florida, or unusual patterns in the data in order to alert public health officials, and at the same time minimize false alarms. Our neural networks can “learn” and become increasingly accurate over time—distinguishing, for instance, between seasonal variations in disease reports and real anomalies. Finally, we can increase cooperation with local and state public health networks that are striving themselves to migrate to near real-time electronic data interchange. For public health purposes, the government can encourage the use of patient health information reported through Medicare, Medicaid, public hospitals, and U.S. Public Health Service facilities to enhance the de-identified patient database.

Our existing electronic system can be configured to allow queries by local, state or national public health officials who want information specific to a given geographic area or a particular symptom cluster, and it can be pre-set to send out e-mail or voice mail alerts to those officials when certain patterns are recognized. Future modifications could add even more communication capability for public health officials across the national system.

Conclusion

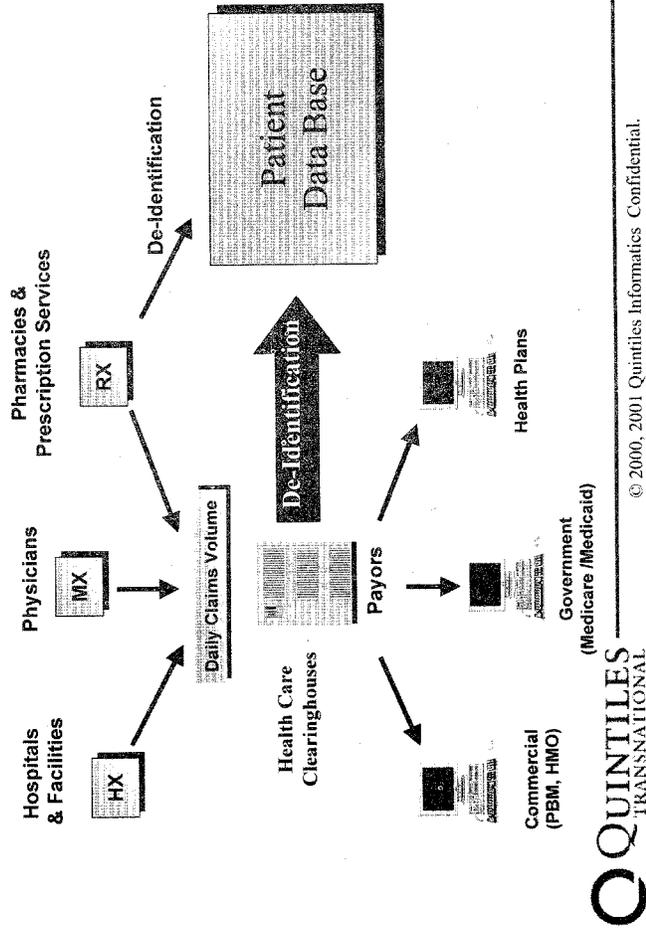
History offers us many examples in which seemingly disparate, and sometimes tragic, events converge to produce profound change for the good. I believe we are at one of those moments in history.

This body had the foresight in 1996 to pass legislation regulating healthcare electronic data interchange processes and technology. This technology—created at first to improve the efficiency and speed of medical and pharmacy reimbursements—now offers us a platform for a greater good. Good intelligence from several sources and levels is absolutely key to our fight against terrorism. This especially applies to our fight against bioterrorism. We have already seen the sad results of bioterrorism in our country. We need to bring every tool to bear for the challenges ahead. We have an excellent system of human intelligence that is even now improving. We need to complement this system with healthcare’s version of an electronic national early warning system.

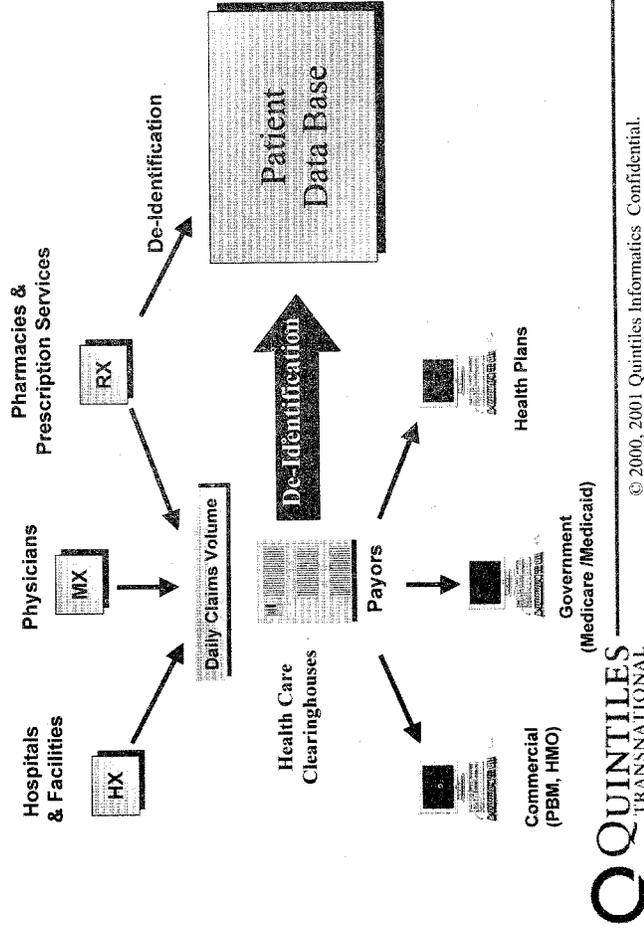
Technology and the public health can be joined at this historic moment. The result could be, and I believe it should be, a national early warning system that can be employed in the fight against bioterrorism—and used every day by public health officials seeking to halt the spread of disease and save lives.

Thank you.

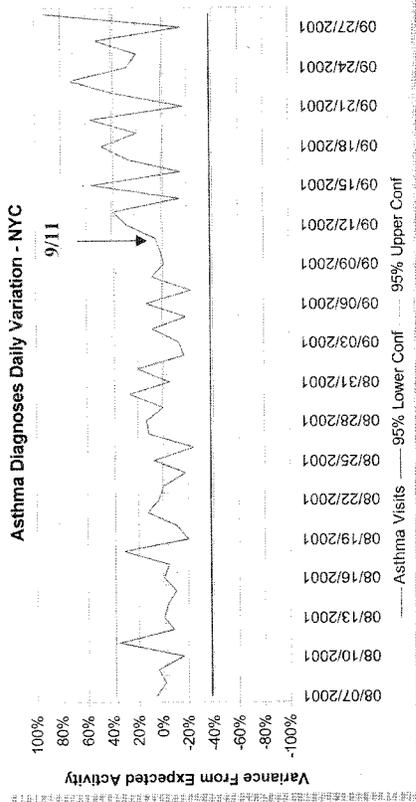
Where Does De-Identified Health Data Come From?



Where Does De-Identified Health Data Come From?

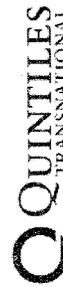


Asthma Diagnoses Increase in NYC After Terrorist Attack



70

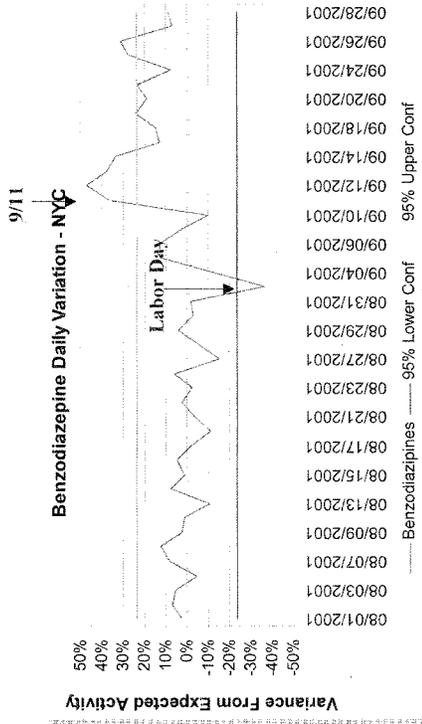
Source: Quintiles Informatics Mx Database



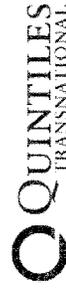
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3

Terrorist Attack Related Anxiety: Anxiety Drug Use in NYC



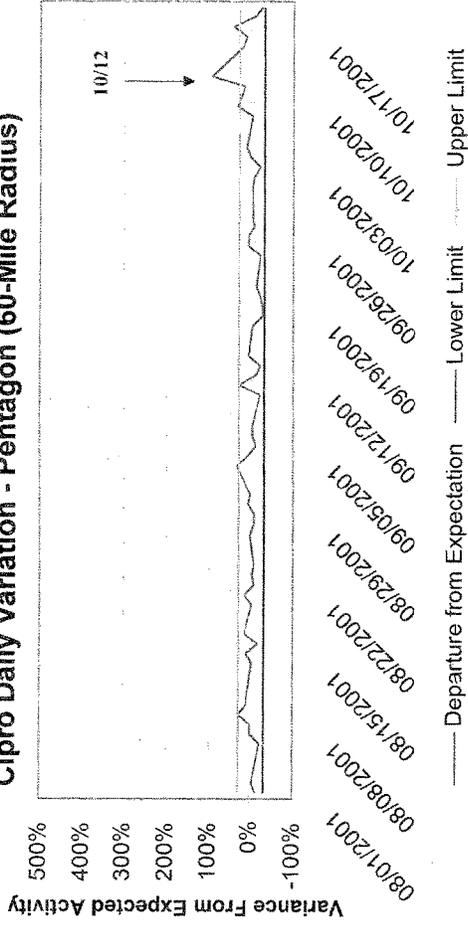
Source: Quintiles Informatics Rx Database



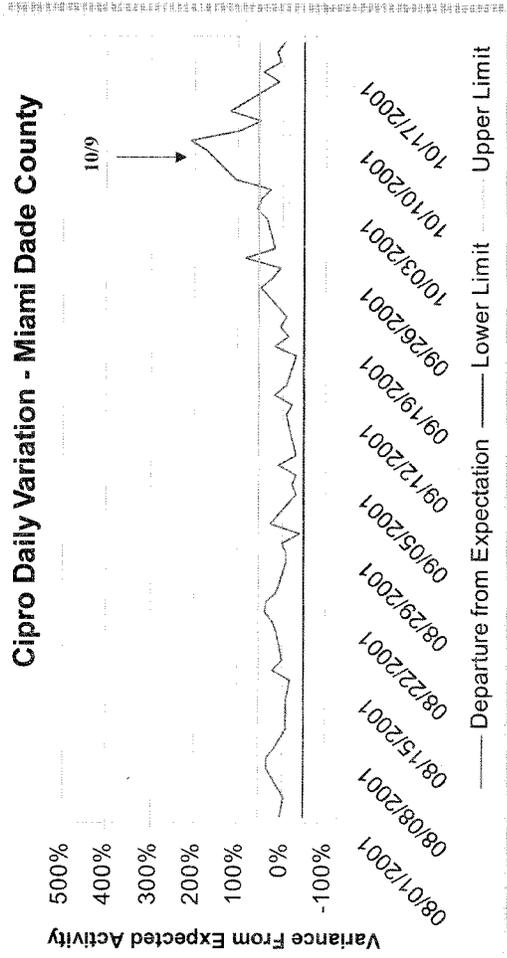
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Washington DC Cipro Utilization

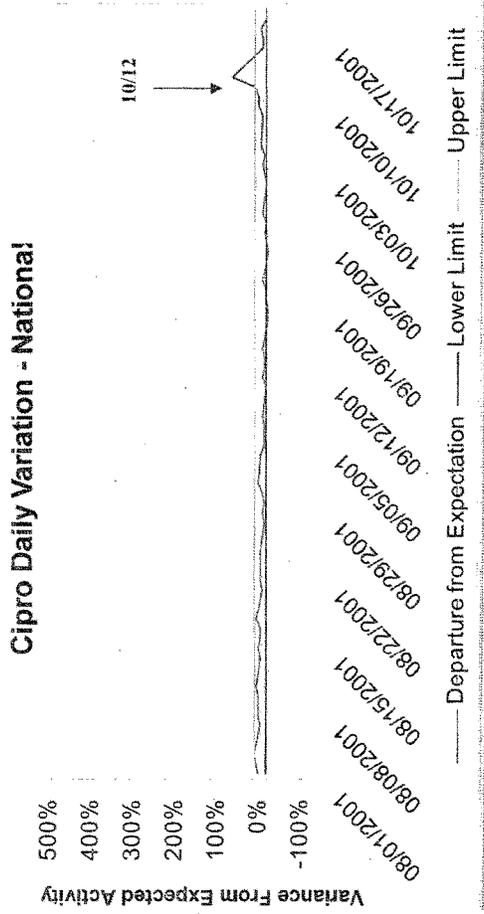
Cipro Daily Variation - Pentagon (60-Mile Radius)



Miami-Dade County Cipro Utilization



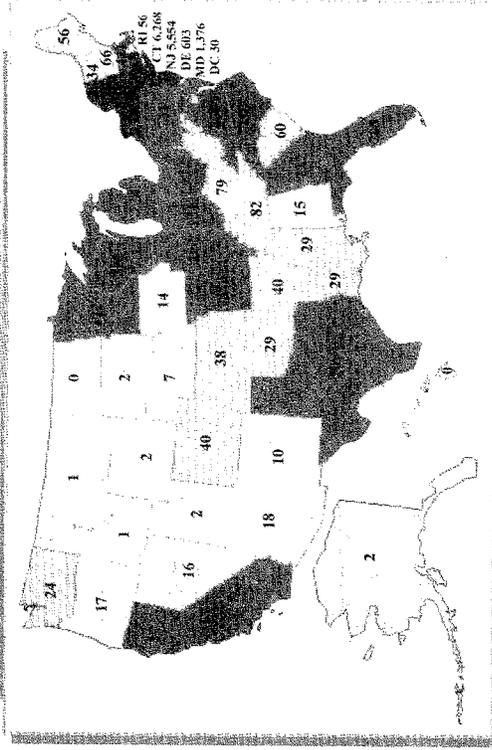
National Cipro Utilization



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Lyme Disease Outbreak as Tracked by Quintiles Informatics

Cumulative Cases Reported in Quintiles Informatics Data: 2000



Quintiles Informatics case count: n = 27,184

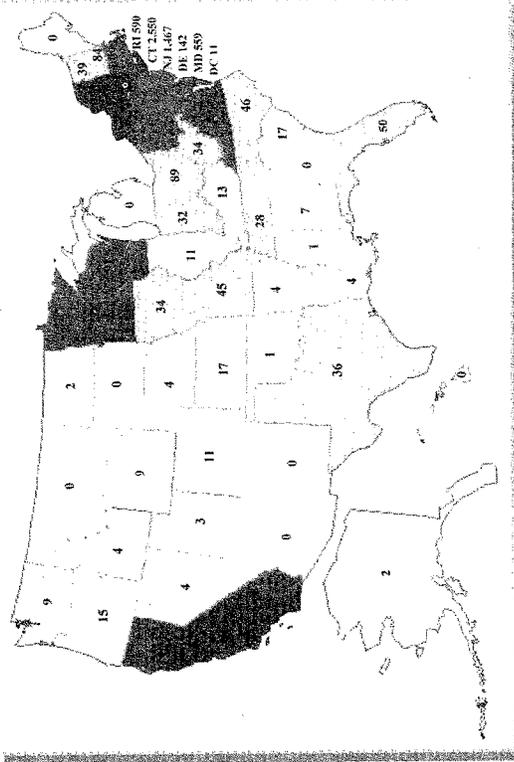
CDC preliminary case count: n = 13,309 (MMWR Volume 49 [52])

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... And as Tracked by CDC

Cumulative Cases Reported to CDC from State Health Departments: 2000



Color Code Key:
 # of Cases: Color
 3000+
 100-2999
 20-99
 1-19
 No Cases

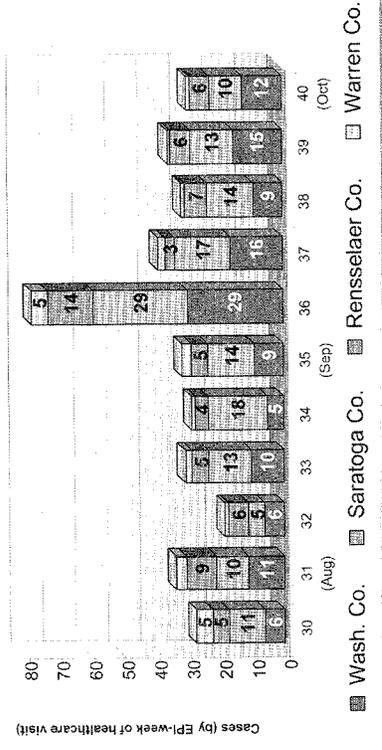
Leish Disease
 ICD-9-CM: 088.81

Quintiles Informatics case counts: n = 27,184
 CDC preliminary case counts: n = 13,309 (ANAVR, Volume 49 [23])
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Consumption: E. Coli Outbreak

County Fair E.coli 0157:H7 Outbreak*, NY State, 1999
Using the Quintiles Informatics Mx Data Base

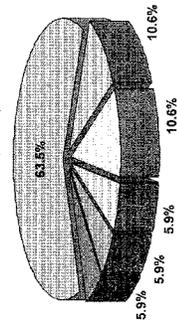


Ref: Outbreak of *Escherichia coli* O157:H7 and *Campylobacter* among attendees of the Washington County Fair - New York, 1999 (MMWR Volume 48(36): 803)

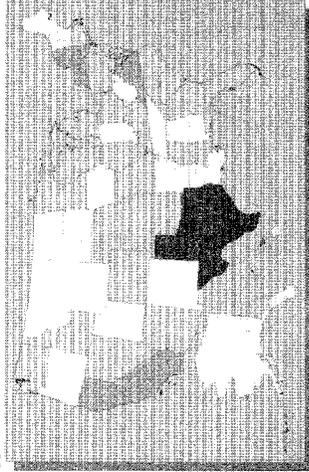
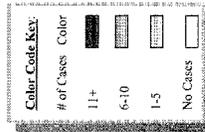
*Based on ICD-9-CM codes: 008.00, 008.04, 008.43, 009, 283.11, 787.91 [Values are raw and unadjusted]

Hard to find Patients: Brucellosis

ICD-9-CM Diagnosis Distribution for Brucellosis Patients:
2000: (n = 85)



- BRUCELLOSIS UNSP
- BRUCELLOSIS OTH
- BRUCELLA ABORTUS
- BRUCELLA MELITENSIS
- BRUCELLA SUI

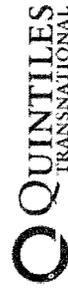


*Based on ICD-9-CM: 023.XX

Primary CDC Brucellosis case count for 2000 = 63 (MMWR Volume 44[52])

Patients can be segmented into any age grouping. [Values are raw and unadjusted.]

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Mr. GREENWOOD. Thank you, Mr. Russell. I appreciate your testimony as well. The Chair recognizes himself for 5 minutes for inquiry. Let me pose to each of you the question that I posed to the first panel, and that is this.

This hearing is really designed to test a hypothesis, and the hypothesis is that using the state-of-the-art information technology, some of which we have just seen displayed, we could in fact build a national and robust system that—and I will add a little bit to the question, that does in fact not intrude unnecessarily into the health care profession, but that can by identifying abnormal increases in symptomatology anywhere in the country give us the opportunity not only to do a better job with infectious diseases in general, but to get a head start on a potential outbreak caused by a bioterrorist attack.

And let me add to that, that if you believe that that is the case, I would like to know your opinion as to what it might take us in order to have that system ready as soon as possible. We will start with you, Dr. Wagner.

Mr. WAGNER. Well, the direct answer to your question is that I believe that the hypothesis has already been partly tested. We do know, for example, that epidemics leave footprints in routinely collected data, and you just saw some examples.

And we know that for quite a number of epidemics, and different types of diseases, including water borne, food borne, influenza, contagious diseases, like rubella and measles. And we know it for quite a number of data sources, including health services research data, which I guess is a broad category that would include the data that we just saw on the screen.

We know it for grocery data; sales of tylenol, cough syrups. We know it for clinical data, data being collected by clinicians. And we also know that there are quite a number of automatic methods for analyzing the data to actually detect epidemics.

And we feel that the way in which we have partly answered the hypothesis is through all the years in medical informatics research which have identified ways to integrate these data at a national scale.

And we have also seen examples, and so that is my reason for believing that the hypothesis is half-answered or two-thirds of the way answered. I think it is probably answered sufficiently well that we are sort of at the same point of the Manhattan project and the space race of the 1960's, where at the beginning—namely that the scientists and engineers—that they were pretty confident that the job could be done, and a decision was made to do the job.

They weren't certain, but the collective opinion was that given the circumstances that it was worth making a try for it. What steps would be needed to go from here to there? I think incentivizing industries, like Mr. Russell, that have access to certain types of data that are known to show early evidence of epidemics is one step.

I think incentivizing regions and other data providers that are outside the scope of fortuitous national data collection schemes such as this one is another step that we would have to take on that path.

We have to do it at a regional level because the number of scientists and the number of engineers that are going to be required, the talent is out there, but it is going to take a concerted effort by all the talent to build that kind of a system.

I think that actually the analytic part that sits on top of this rocket if you will is made dependent upon that infrastructure, but also an important piece, but not actually the most critical piece. I think we pretty much know how to do the analytics, but getting the data is going to be the critical piece.

Mr. GREENWOOD. Thank you. Mr. Russell.

Mr. RUSSELL. Mr. Chairman, I agree with a lot of what Dr. Wagner said, but in particular the good news is that we are probably further along than we think as far as being able to put together the national system that you are talking about.

I mean, I can speak for what I just showed and what our company's capabilities are. We have to start from somewhere, and we could start right now. I mean, our system would answer queries on a near real time basis and does.

We have worked with CDC on a bioterrorism pilot project in the year 2000 and where some of these issues were explored. I think to get a national system that works on the automatic reporting that is already done through the health insurance network, you are talking about a matter of weeks.

I mean, you are talking about putting or taking a system that I showed you and putting together surveillance indicators that we call the sentinels. You are talking about neuro networks which would then begin to intelligently sort the data and normalize it against baselines.

You are talking also about a communications system coming out that would allow alerts to go out. That type of thing is not far away. I mean, as I said, it is a matter of weeks that we could adapt the system that I showed you to that particular specification.

Mr. GREENWOOD. Dr. Zelicoff, and if you would also in your response just make a note about with regard to the cyber-security of the system, because obviously if we had a national system, we would want it to be quite tamper proof.

Mr. ZELICOFF. Okay. I will pick up on the positive points with Dr. Wagner and Mr. Russell. I do think that we are a lot closer. Understand that in order to have a so-called national surveillance system that you do not have to have the system everywhere.

Fortunately, statistics help us out a great deal. By my calculations, they show that if we can survey 5 percent of the clinics, and I would choose the 5 percent of doctors that are most flexible in doing reporting, and believe it or not there is such a 5-percent.

Then you have indeed covered the country with a high level of confidence and you have minimized the amount of noise. What does that mean? 2,500 clinics around the country, and it is a few thousand dollars per site to buy a computer, and another few hundred dollars a month to have an Internet connection, and poof, you are done.

I would agree also with Mr. Russell that there are automatic analysis tools out there that are in development, and having written several papers on neuro networks myself, let me warn you a little bit about the mystery of neuro networks.

They require an extensive training set against which they can compare the data that is coming in. That means that you have to have a lot of data already, and you have to know what it is that you are looking for.

Having so done that, it is possible, and in fact automatically train computers to do that. But I personally believe that we are a long way away from that. That is why we have put the human in the loop, which is the local public health official, because they are the best neuro network that we know of, and as was correctly stated earlier.

But having said that, we also do have a neuro network model working in the background all the time, and that has nowhere near enough data to actually make a call itself, but local public health officials do.

With regard to security, our fundamental—and I think the fundamental issue that confronts anybody who engages in a system like this is protecting patient confidentiality. And the we do that is three-fold.

There are no names, and we can smear out identifiers that are not necessary. For example, the precise age. We smear it out because it doesn't matter for an epidemiologist to someone who is 18 or 19 years old in an epidemic, and if they are 75 versus 30, it speaks volumes.

And then finally all of our data is encrypted, going in both directions, and authenticated; by which I mean that the only people who can do data submission are people who have recognized hardware addresses on their computer.

Anybody can go to the demo site and check it out, but it would take quite a hacker to—it is not impossible, but it would take quite a hatchet to break the authentication system that we have.

So I believe that we have again the 90 percent solution as far as security is concerned, and our most important concern, if only to get this through institutional review boards, is protecting patient confidentiality.

Mr. GREENWOOD. Thank you, Dr. Zelicoff. The Chair would announce that we have a series of votes—we have three votes now—and it will be at least 15 to 20 minutes until we can complete that process.

So with your indulgence, we will recess until one o'clock and if you ask around, you can find out where the Rayburn places to eat are, and maybe you can grab yourself a bite in the meantime. We will recess until one o'clock.

[Whereupon, at 12:33 p.m., the subcommittee recessed, to reconvene at 1:15 p.m., the same day.]

Mr. GREENWOOD. If the witnesses will resume their stations, we will resume the questioning, and the Chair recognizes the ranking member, Mr. Deutsch, for 5 minutes to inquire.

Mr. DEUTSCH. For the three of you, are you suggesting that basically we junk the NEDSS system? Is that your recommendations? Are you suggesting that we basically get rid of the present system, the NEDSS system, assuming that we adopted NEDSS?

Mr. ZELICOFF. I think you may be a little bit confused about something. NEDSS is intended for epidemiologists, and not doctors, to do reporting to the CDC. No clinician that I know has or ever

would entertain NEDSS in their office. I am sure that there is some rare exceptions to this, because it is a big on-line reporting form that gives nothing back.

As a tool between laboratories, or epidemiologists, and the CDC, yes, it is just fine. But it is really bolstering the laboratory side of surveillance, and I think the point that you are missing, or maybe I have not made it clear, is that there are two types of surveillance.

There is the laboratory type and there is the clinical type, meaning what the doctor sees in the office or in the clinic. The importance of that is two-fold, as I think Dr. Bloom mentioned earlier.

You need the clinical information for knowing when to trigger your laboratory system, and that is surveillance; and then you need the clinical reporting system to know how many people to test.

If we were faced with a large scale exposure and not necessarily infection, but exposure, to anthrax spores in Washington, we will never be able to test a million clinical samples in a reasonable period of time.

What you need to be able to do is to decide where you are going to apply your laboratory resources, and that is what the clinical surveillance will do as Dr. Bloome correctly pointed out. So, NEDSS is between the local public health authority or laboratory and the CDC, and not from the clinician's office.

Mr. DEUTSCH. Do you want to respond?

Mr. RUSSELL. Yes, I would like to respond. I think that these systems are complimentary. I don't believe that the NEDSS system as I understand it, and as it relates to our system at least, is in any way in conflict.

What our system does is that it takes a very, very large sample, one out of every three people in the United States, over a couple of billion data points, and shows disease trends that can be national or completely local on a near real time basis.

And I do think that the NEDSS question though brings up something that I have noted in this discussion this morning, which is that there seems to be a false conflict between the local and the national here.

I mean, I really don't see that. The system that we have, for example, really acts at a State level, at the local level, and at the national level. You can make it very specific for certain indicators in any city, in any State, in any zip code, and then across the whole country.

So that kind of dichotomy between should we fund local efforts and knit them together nationally, or do we have a national system, and is it inside the Beltway or outside the Beltway. I think the technology exists here not to have that even be a debate, and that is the way that I would look at it.

Mr. DEUTSCH. Dr. Wagner.

Mr. WAGNER. I have some experience with NEDSS because I helped write the Pennsylvania successful NEDSS proposal about a year ago, and I have participated, and I think NEDSS is an excellent project that has no shortcomings, and it is very complimentary with everything that everyone else is trying to accomplish.

And what it is really providing is a set of specifications for infrastructure. This is the data base model that every system that does

public health surveillance in each State should adhere to so that the data can be merged to form a national picture.

The NEDSS project does not limit what kind of data is used in public health surveillance. So in addition to the laboratory data, the main stay of public health surveillance for the past few decades, and reportable diseases, the NEDSS project is going to incorporate all of these unusual types of data that we have been talking about.

Mr. DEUTSCH. Let me at least give the opportunity to Dr. Davidson and Dr. Barry, who are still here, to try to respond to that. Would you like to respond to that and to my question? My question is whether this is a complimentary system, or is this an alternative system?

Mr. GREENWOOD. If either of you would care to comment or response, please take one of the available chairs at the table and use the microphones.

Ms. BARRY. Thank you very much. I think technology has a lot to offer, but I have some very specific concerns. For example, in the system that the Quantiles has developed, I am sure that they can pick up aberrations in data, but who is going to follow up on those aberrations in data at the local health department. It is me and my five nurses.

Where are we going to get the resources to follow up on whatever signal that might or might not be detecting. And the other concern that I have is timeliness of data. I see denying data, which is a disease coding process, typically takes some time.

We tried to get this into our Boston system, but we don't know diagnosis until 30 to 60 days after the person leaves the emergency department, and that is too late. We have got to know within 24 hours if something is going on.

So I think technology is the answer, and we should use it, and we should try to work to resolve some of these issues, but I have some concerns both about timeliness and for resources for follow-up with signal detection systems, which I think some of these are.

With regard to the New Mexico system, the touch screen technology is really quite nice, but there is no way in the city of Boston—and I think I have excellent relationships with the health care providers in the hospitals, but there is no way that they are going to fill in a separate extra data screen to try to give us data. We have got to mine what is there.

Mr. RUSSELL. I would like to clarify one thing, because this is complicated and I wanted to respond to what Dr. Barry said. If you took the city of Boston and you were trying to get daily reads on a disease trend, then what you would have in our system would be all the private doctors offices.

You would have all the drug stores, and you would have the entire panoply of what the providers are, both on the pharmaceutical and the medical sides. So you would not be relying entirely on what the hospital said and how they filed their ICD-9 forms.

The ICD-9 forms are actually filed promptly by a lot of doctors' offices and not as promptly by others. But you would have a sample so large that you would have a trend line developing. So it is complicated, and I take what you say that it is hard to get the hospital themselves to process the ICD-9 forms.

Mr. GREENWOOD. Dr. Davidson, did you want to respond?

Mr. DAVIDSON. Yes. I think one of the things that we need to work toward—and this was brought up by one of the members of the committee earlier, was establishing criteria for surveillance systems.

There are some criteria for surveillance systems that have been promulgated by CDC. And most recently about 4 months ago there was a publication. We need to put those criteria out there and see how they work with both of these systems. See whether they meet the appropriate criteria for a surveillance system.

In terms of timeliness, our experience is that the ICD-9 codes are coming in later than the syndrome-based systems. That we found in our analysis, and that there is a delay, and typically in our system—and that may not be typical of all systems, especially in the private sector where they may be getting these bills in quicker than we do in the public sector.

But we found that it could be a 10 to 20 day delay even in a good clinic. So I think that is a concern for us. That is the timeliness factor, and one of the criteria. The issues of specificity and sensitivity are discussed in that document, and I think those are some things that need to be addressed as well, in terms of both of the systems that have been presented.

Let me get back to one point that Dr. Zelicoff mentioned earlier about my comment, stating that this would not work in some emergency rooms. I think I agree with Dr. Barry that many physicians would not want that there.

I want to specifically speak about Denver Health, and where we have this integrated electronic medical record. Here we are trying to create a computer on every physician's desk, to enter data into an organized data system to allow us to collect all the information you need.

That system is built by our vendor. Now we have another system that may be able to collect important public health information. But we don't want to have to put that one on top of the one that we are already entering data into.

So there may be a place for us—and once again using those industry standards—to take what our vendor is building, and put it through a process such as this. I don't know whether that is possible. I think once again working toward standards is the most important thing, and NEDSS pushes us toward that.

Mr. Russell earlier mentioned about a false conflict between national and local efforts. I don't see this as a conflict at all when we talk about NEDSS. They are methods to integrate data across all jurisdictions. There is no conflict here.

Mr. GREENWOOD. The time for the gentleman from Florida has expired, and let me indicate to Drs. Barry and Davidson that if you are willing to, you can stay at the table in case others want to consult with you as well. The Chair recognizes the gentleman from North Carolina, Mr. Burr, for 5 minutes, to inquire.

Mr. BURR. That you, Mr. Chairman, and I am not sure what I have come back in the midst of, but I will try to focus my thoughts and legitimately say that I don't know that any of us have the answers.

I mean, if we did, I think that you would hear it in our opening statements, and you would certainly see us on a legislative track to try to present some solution. Thank god for once that Congress has turned to not only the public entities, but the private entities and said what are our capabilities today.

What we found in a very short period of time is that there is a wealth of data. There is a wealth of effort that has been put to try to create a system that works, a system that can cross-check things, and a system that stretches outside of just big cities and gets into rural America.

I would ask all of you as you are asked questions and as you answer them to please understand that if everything we do is turf related—well, this is already here, and so we can't be replaced; or CDC already has this initiative, and so we can't change.

What we are looking for is a solution now. It disturbs me, and I think I made that very clear, that we didn't have a goal today of 50 States on NEDSS. I don't know how the problem can get more pronounced than it is right now. This is a domestic threat.

Our ability to do the right thing is how we will be judged and ultimately how the infrastructure for health will be judged, and potentially each one of you who are connected to it.

But we also have a responsibility not only to see that large areas have access of connectivity, and access to data bases, and accesses to everything that is happening in the health community, but to make sure that the small ones do, too.

I would have hoped that there was a request from Congress to connect the third of public health that is not technologically connected to CDC today. But I have yet to hear that request. I am sure that it won't take Jeff Koplan longer than next Thursday when he testifies in front of this committee to understand that that request should be made.

But even with a substantial amount of resources there was very little devoted to what all five of you are here to talk about, our ability to respond to the public health threat in communities that you live in, or communities around the country.

I am delighted with what the labs are doing. I am delighted to know that we are trying to create a system out there, and whether it overlaps something else or whether it can be integrated into it, for once we are ahead of the game, and we are working on something.

And, John, to Quintiles, you know, the question is why didn't we look to a data base that we had that gave us some clues before we had a problem? And I think that those are certainly some of the questions that we have got to ask of those entities that are responsible.

Not you at the table, but the entities that are responsible for the network of public health in this country, because what I heard both of you in the first panel talk about was that data is invaluable to us when we get to the point that we have a problem.

And our ability to look at it and to analyze it, and to go specifically where we see a problem, is our ability to treat that threat. I think Ms. Harman and I are the only ones on the Intelligence Committee and she is not here right now.

But I can only thank God every night that this was not a contagious disease that we were trying to address initially, but that it was one that gave us some degree of flexibility, and treatability.

And that time was not necessarily of the essence, but the reality is that we have also had examples that this myth that we worked under, that education alone, that dissemination of the threat alone to our health care providers assured us that nobody fell through the net.

And when we relied on that, we had two people that fell through the net. We will deal with the other things, but I think that we have got to stay focused on the fact that you can fall through this net.

So, Mr. Chairman, I don't have a question. I just want to thank everybody who is here—the witnesses from the first panel, and our witnesses from the second panel. And I do hope that in a coordinated way CDC and HHS will look at how we use the combination of tools that are there today to try to put together a solution to the problem that is here today.

And if in fact it requires resources on our part, and that there is a request, because I think we are willing to address it, and if it requires new partnerships that are public and private, then I would like for those partnerships to be created today or tomorrow, and not next year or 2003.

Because I assure you that the threat will change, the challenge will change, and there is some things that we know that we just can't accomplish without an infrastructure in public health to accommodate those types of threats.

And my hope is that next week we will hear that request for at least the infrastructure, and then we can talk about facilities at CDC and other places. And I yield back.

Mr. GREENWOOD. Okay. I thank the gentleman, and I also thank him for bringing to the attention of this committee Mr. Russell and his work, which has been very helpful to us. The Chair recognizes the gentlelady from Colorado for 5 minutes to inquire.

Ms. DEGETTE. Thank you. Dr. Zelicoff, in order to implement your system, and to really have it work from an epidemiological standpoint, it would have to be pretty much universal with doctors and emergency rooms, correct?

Mr. ZELICOFF. No.

Ms. DEGETTE. Why not?

Mr. ZELICOFF. I don't know if you were here when a somewhat similar question was asked earlier.

Ms. DEGETTE. I probably wasn't; otherwise, I would not have asked it again.

Mr. ZELICOFF. Statistics helps us out here a great deal. All you have to do is sample about 5 percent of the population.

Ms. DEGETTE. So does that mean that you would only have to have your computer program in 5 percent of the doctors' offices in this country?

Mr. ZELICOFF. As long as you have them reasonably distributed, accounting for geographic, racial, and socioeconomic examples, yes.

Ms. DEGETTE. Well, here is the problem that I have, and as I looked at what it cost to do that, did someone ask that also?

Mr. ZELICOFF. Yes, \$2,000 a site. So we actually got a little bit further in the questioning. We estimate 2,500 clinics roughly, at \$2,000 a site, and call it \$15 million.

Ms. DEGETTE. So it would cost about \$15 million to do this?

Mr. ZELICOFF. Right.

Ms. DEGETTE. And would it mainly be in private doctors' offices or in public hospitals, or both?

Mr. ZELICOFF. We have it in both, and the reason that we have it in both—

Ms. DEGETTE. Well, I don't need to know the reason. I want to know—

Mr. ZELICOFF. We have it in both right now.

Ms. DEGETTE. Okay. And at those 25,000 (sic) sites or whatever, they would be in both also?

Mr. ZELICOFF. Oh, sure.

Ms. DEGETTE. And those would be sites that volunteered to do it?

Mr. ZELICOFF. The way we have done it is to ask local public health officials who know the docs in the community best to nominate sites.

Ms. DEGETTE. Like the doc in my community who is sitting next to you, they may not need it in Denver, because they have already got a vendor that has an integrated system, and they are tied into the CDC, and so they wouldn't need it, right?

Mr. ZELICOFF. Not in my view.

Ms. DEGETTE. So, my question—

Mr. ZELICOFF. Let me finish the question. In my view, I think your conclusion is incorrect.

Ms. DEGETTE. But it would be voluntary on their part, and you are not going to force them to do it?

Mr. ZELICOFF. Oh, sure. Of course. They are doctors and they can do anything that they want.

Ms. DEGETTE. Well, that is generally the view of every doctor that I have ever met. So, you are right. But here is my problem. Denver Health says we have got a very good system, and it is working great, and it is integrated, and we can't put your system in our vendor. So go somewhere else.

Go to New Mexico, or go to wherever, and then we have some kind of biological or chemical weapon that is dispensed over Mile High Stadium during a Bronco game. So by using your statistical derivatives, you would not get that through your system because you wouldn't have it in that city, right?

Mr. ZELICOFF. Let me try to shed a little light on this question, because I think there is a little bit of a misperception. As long as any of the systems that are out there, ours included, have compliance with the existing medical data base architectures—COAS is the standard one, H-7—and ours does, there is no problem in sharing the data.

It is solely then as a matter of the interface, and getting the system sustainable so that people will use it.

Ms. DEGETTE. Right. But what you are saying is that you are extrapolating data through 25,000 sites.

Mr. ZELICOFF. No, 2,500.

Ms. DEGETTE. I'm sorry, 2,500 sites throughout the entire country.

Mr. ZELICOFF. Yes.

Ms. DEGETTE. When we are talking about biological or chemical welfare, we are not necessarily talking—and the recent attacks are a perfect example. We are not talking about attacks over San Diego, California, or Chicago, Illinois, or Denver.

We are talking about attacks apparently at this point isolated in a few cities. So if they weren't tied into your network, that wouldn't necessarily be the best tool in predicting the attack, correct?

Mr. ZELICOFF. Well, if what you are saying is that we are gathering data and no one is looking at it, correct. It won't work. But the data—

Ms. DEGETTE. Well, the—

Mr. ZELICOFF. And let me finish the answer. I am supposed to tell the truth and the whole truth. The answer is that the data structure is such that all existing commercial medical data base compliance systems will be able to use the data that we are gathering, and it is up to the local public health officials if they want to release it.

Ms. DEGETTE. Right, but they are not required to fold in, and so you don't know. Now, this hearing is called, "Review of Federal Bioterrorism Preparedness Programs: Building an Early Warning Public Health Surveillance System." And this is—and we are all really concerned. I mean, I was listening to what Mr. Burr was saying, and I agree with much of it. Unlike what many people think right now, Congress is not an unlimited pot of money.

We have to try to figure out where we are going to put our resources, which frankly are becoming more strained every day. My concern with the recent attacks that we have seen—and like Mr. Burr, I think we have to extrapolate.

We have to say let's not assume the next attack is going to be some letters with anthrax in it. Let's say it is going to be a poison gas attack, or a communicable disease attack. The question we have to answer is, No. 1, are our existing public health systems sufficient to have early detection of that.

And if the answer is no, then we had better do something fast. But it seems to me that in the recent attacks we actually had pretty good early detection by physicians in Florida, and other places, of risks.

And tragically some people died, but at least we were able—I mean, a physician was able to diagnose anthrax, for example.

Mr. ZELICOFF. All right.

Ms. DEGETTE. So my question is if we had your system or any other new system in place, and we had a massive attack, what would be better, having a computer system in place to know that we are having a massive attack, or having the extra resources going toward public health officials or beds or quarantine units, so that we could actually treat those patients.

I think that those are the very real decisions that we are making in a public health context right now.

Mr. RUSSELL. Could I respond to that? I think that to answer your question where is it better to put the money—I mean, that is always the choice. I think, however, that if we are at war and the

President says so, and I believe him, then you have got to have at least several types of intelligence to deal with.

And I think to say that you are going to choose among several systems, and choose one that is the very best one, and the silver bullet is not going to get you there. But I do think you can do something.

One message to take away is that we don't have to start from scratch. I think all these systems are good. The virtue of the existing data base that we have introduced is that it is not a development project.

If you are looking for money that will go to work now, then you could—and it is not just our data base, as you have data bases that are there.

Ms. DEGETTE. And what your data base basically does is it tells physicians that there is a lot of cipro being prescribed here and what does that mean, right?

Mr. ZELICOFF. Well, that's not—let me say that in order to make a working prototype of a surveillance system from what you saw on the screen, you would make it much more specific, and I alluded to this in the testimony.

You would take sentinels and markers, and they would say exactly what you wanted to look for, in Denver, or in Boise, or wherever.

Ms. DEGETTE. Right, based on drug prescriptions.

Mr. ZELICOFF. Well, based on a combination of drug prescription and medical diagnoses.

Ms. DEGETTE. Okay.

Mr. ZELICOFF. And the match of those against—

Ms. DEGETTE. And what do we do with that information that we don't have the ability to do now?

Mr. ZELICOFF. Okay. Let's say that you wanted to measure an increase of flu-like symptoms in Denver against a baseline, and because the data base is longitudinal, you could establish a baseline.

And then you would have an alert that would come up, and it would be communicated out to whoever in Denver wanted to have it. Would it be the public health official, or would it be a network of physicians.

Ms. DEGETTE. Well, excuse me. My time is way up, and the I appreciate the Chair's indulgence. Don't we have that ability right now under the NEDSS system and other systems?

Mr. DAVIDSON. No.

Mr. ZELICOFF. No, I am sorry to say that you don't. You don't have that ability.

Ms. DEGETTE. I would like to have Dr. Davidson respond.

Mr. DAVIDSON. Currently, we don't have that available. NEDSS is built to allow us to collect that information, the same way that they would be collecting it from ICD-9 codes using billing data.

Part of the issue as I mentioned earlier is whether this is timely. Does this meet criteria for an effective surveillance system, and that is the question.

Ms. DEGETTE. I just have one last question, and then I know that my time is long up, because something really leaped out at me in your written testimony, Dr. Zelicoff, and it is a little bit off-subject, but I would like to get a clarification.

Mr. ZELICOFF. Sure.

Ms. DEGETTE. Which is that you said that 60 percent of antibiotic prescriptions written in the primary care context are unnecessary and inappropriate partly because of the lack of knowledge.

Mr. ZELICOFF. Right.

Ms. DEGETTE. I am wondering if you can extrapolate from your data how many cipro prescriptions written in the past month would fit into this category.

Mr. ZELICOFF. Well, I couldn't other than to make the general statement that I think it has been vastly over-prescribed.

Ms. DEGETTE. But you don't have a scientific conclusion based on any data?

Mr. ZELICOFF. I have not seen the raw data on the clinical cases. I would have to do that. I would have to correct one thing that you said early on, which was with regard to the success of the existing public health system. No scientist would ever declare a success based on an end of two.

There were two cases that were diagnosed promptly. We know from many studies that have been done that when you take pictures, for example, of classic smallpox rash into academic medical centers all over the country, and just say what is this, nobody, and I mean nobody, gets the diagnosis right. Now, this week, they might get the diagnosis right, but 6 months from now, I don't know.

Ms. DEGETTE. Well, thank you for the clarification. I guess I am just not seeing how if in that hospital where the anthrax was found and diagnosed, if they didn't have this system, how it would be of any additional help. I tend to be sort of a budget hawk, and so that is what I am looking at here. Thank you very much.

Mr. GREENWOOD. The gentlelady's time has expired. I think that part of the answer is that we are talking about two very different scenarios, and the anthrax scenario is very isolated at least so far; whereas, we are talking about epidemics, and in the case of infectious disease, that if a particular clinic was not equipped with this data, this data collection system, the assumption is that other clinics would be picking it up in the environments.

I want to ask Dr. Wagner a question, and that is just simply would you just take a couple of minutes and explain in detail how your system works, because I am not really sure that we have that quite on the record quite yet.

Mr. WAGNER. Thank you for that question, because I felt like I had not explained it sufficiently in my spoken testimony. As I said, the system relies most heavily on data that is delivered computer to computer in real time.

The most early data about illness that is collected at present by the system is the symptoms of the patient when they first present to the emergency room. And those symptoms are either coded in ICD-9, and so the comment that ICD-9 codes are inherently late is not accurate.

ICD-9s are just a coding scheme, and when it is applied, it determines whether it is early or late; or the pretext, where the patient has a cough and shortness of breath, and we use natural language processing to extract the nature of the symptoms.

So for a large sample of patients, there are symptoms where when they should up at the emergency room, and prior to the time that they see a physician, are known immediately regionally, and available for analysis. That is the earliest data.

Then the additional data that flows in behind those initial data about patients are their tests that were ordered, and then subsequently the results of the patient that is seen in the emergency room as blood cultures are ordered, and that information is known at the time that it is ordered, which is usually pretty early in the case.

And then subsequently when the results come back, they are available, and there is natural language processing that determines whether the gram stain of a blood culture is growing gram positive rods, which is a specific finding, or a relatively specific finding; when coupled with chest x-ray findings, which are also being automatically processed by natural language processing.

So the combination of gram positive rods in the blood, with a wide medium stannum, or some other finding on the chest x-ray, triggers an alert that there is an anthrax patient potentially that needs to be followed up.

One related thought that I just want to mention is the issue of whether public health will be overwhelmed by the output of these systems in electronic lab reporting, and if all of these features are necessary.

And we have been operating for 2 years, and we see very few false alarms. I can understand why the impression is out there that these systems should have more false alarms than they do, because that was our expectation.

But we are seeing an alarm a month, and we are monitoring for respiratory disease, diarrhea, rash, encephalitic. botulinic, and the anthrax detector, the single case detector, went off once.

Mr. GREENWOOD. Thank you, Dr. Wagner. I thank all of the panelists for your generosity with your time, and for your testimony, and for your health. This hearing is adjourned.

[Whereupon, at 1:47 p.m., the subcommittee was adjourned.]

