

Symposium Series Number 1



**The Role of “Home” in
Homeland Security**

Public Health

*The Challenge for State
and Local Government*

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January 31, 2003

**The
Rockefeller
Institute
of Government**

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PREFACE

There is no doubt that September 11, 2001, dramatically elevated the role of the federal government in assuring homeland security. Not only did the events of that day precipitate the largest reorganization of the federal government in decades but also created new challenges for the 87,000 state and local governments which are the first line of defense and response to terrorist events. Although much of the nation's attention on homeland security has focused on the role of the federal government, less attention has been paid to the role of state and local government, which play a critical role in responding to terrorist attacks.

To focus attention on the challenges for state and local government, the Rockefeller Institute of Government, a nationally recognized center on federalism, developed a symposium series, titled "*The Home in Homeland Security: The Challenge for State and Local Government.*" This series features nationally recognized experts, who are convened to contemplate the most acute challenges for state and local governments in assuring homeland security. This series of symposiums features in-depth discussions from these experts in an effort to identify what government must do to make our nation more secure.

The symposiums focus on the following topics:

- Public Health
- The Federalism Challenge
- The Detection and Prevention of Terrorism
- First Responders
- The Role of Civic Organizations

This report contains the discussion at the first of these symposia, held at the Rockefeller Institute of Government on January 31, 2003. Dennis Whalen, deputy commissioner of the New York State Department of Health, presided over a panel of speakers that included Dr.

Carol Ann Rauch ,Chief of Clinical Pathology at the Baystate Medical Center in Springfield Massachusetts; Dr. Georges Benjamin, Executive Director of the American Public Health Association, and Dr. Harvey Fineberg, President of the Institute of Medicine. While the discussion was wide-ranging, four points appear to be particularly worthy of note:

- Responding to bio-terrorism has many commonalities and a few significant differences with the traditional public health function of responding to disease outbreaks. In both cases, public health officials must identify the disease agent, discover its origin and means of spread, provide appropriate therapy, and communicate with the public and policy makers about risks and appropriate actions .Bio-terrorism is the result of intentional human action rather than natural processes, and can potentially be diverted by preparation, hopefully in a less harmful direction;
- The public health and health care systems are not well integrated with each other organizationally and neither has much experience working with the police and fire departments who constitute the traditional emergency management agencies. Developing effective informal connections and working relationships among these agencies who do not deal with each other on a routine basis is one of the more important, and more difficult, tasks in preparing to respond to a bio-terrorist attack.
- Communicating effectively with physicians and other front line workers such as school nurses and emergency room workers about how to recognize and treat diseases that are the result of a bio-terrorist incident is difficult, particularly because the underlying science changes frequently. While the public health system on the whole responded well to the anthrax attacks, for example, this experience suggested that much of the conventional wisdom about the dangers of anthrax was mistaken. Keeping physicians and other medical personnel who are likely to see the first cases of diseases resulting from a bio-terrorist attack up to date on an on-going basis is a difficult proposition.
- Communicating with the public about the risks of a bio-terrorist attack and the proper actions to take in the event one occurs is also a complex task. All three speakers recom-

mended a single “talking head” be responsible for public communication about risks and responses and that efforts be made to articulate a single message about risks and responses to avoid public confusion and panic.

It is a pleasure to acknowledge the contributions of a number of people to the success of this symposium and the publication of this transcript. Funding was provided by Blue Cross/Blue Shield of New York. Courtney Burke of the Rockefeller Institute staff organized the symposium and, with Michelle Kelafant, managed the meeting’s logistics. Michael Cooper handled the layout and other production chores for this publication. In addition to serving as moderator, Dennis Whalen provided much excellent advice on the selection of topics and speakers. Our thanks to them all.

James W. Fossett
Senior Fellow
Rockefeller Institute of Government



Welcome — *Richard P. Nathan*



Dr. Nathan makes opening remarks

We welcome you to what we hope will be an important kickoff to a series of programs that we're initiating today. This is a series on the home in homeland security. The key point is that people need to give attention to the federalism and intergovernmental and state and local dimensions of this huge new challenge in our country and in the world to be secure in these new and troubled times.

Today is the beginning of a series of five symposia. We are here not only to hear from distinguished speakers but we have an excellent chair who has done a good job organizing today's program. We are going to make and publish a record with insertions from the speakers and discussion; we hope to have sufficient time to hear from the audience as well.

The Rockefeller Institute is the public policy research arm of the State University of New York. Our special interest and focus is on state and local government, American federalism, public management, what happens in the field and on the ground as policies play out in our political system.

Today's subject is public health. The next symposium on March 24, will be on American federalism and the challenge of homeland security. Frank Thompson will be the chair. I'm happy that the chair for the third meeting, Tom Constantine, is here today. That one will be on the challenge of detection and prevention, policing and interdiction. Tom Constantine was head of the New York State Police, Director of the Drug Enforcement Agency, and is a noted expert on policing and a wonderful neighbor. We also plan a symposium later in the year on "First Responders" and possibly also a fifth symposium in the series on the role of civic organizations, like the Red Cross, in Homeland Security.

We will publish proceedings as we go along and also compile all of the materials from this series. Our purpose is not just to listen, but to build a record and to work in this field in a way that we hope the Rockefeller Institute can have a good voice.

So I'm delighted to welcome you and am looking forward to starting this series. Courtney Burke has organized this series and has done a wonderful job. I thank her and Jim Fossett for arranging not just today's symposium but this series.

One of my favorite people is the moderator, and I'm now going to turn to him. Dennis Whalen is the Executive Deputy Director of the New York State Health Department. He's one of the people who spends a lot of time here and brings a lot of wisdom to many things we do at the Rockefeller Institute. We get a lot of special understanding of things we care about from Dennis and his colleagues with key roles in state government.

Dennis Whalen is a long-time public servant, a man who has devoted himself to getting things done in government. That's hard work. He is the top deputy in the Health Department, which has a budget of \$30 billion and 7,000 employees. He was previously Director of the Office of Health Systems Management before becoming Executive Deputy Director and is a graduate of Marist College. He's a model public servant. He is going to moderate the program today. Thank you very much, Dennis.

Moderator's Opening Remarks – *Dennis P. Whalen*



Dennis P. Whalen

Thank you very much, Dick, for that kind introduction. It's appropriate to think of this morning's discussion as an exploration of challenges; the challenge for local and state governments and our public health and health care providers as they strive to be prepared; the challenge for our national government to ensure an effective and sustainable level of preparedness across the country.

Today's Albany *Times Union* features a front-page article reporting that the state has received its first shipment of smallpox vaccine from the Centers for Disease Control. So the imperative of preparedness is very real and compelling; all the more reason to think about the challenges involved. Those challenges are composed of a wide-ranging set

of both simple and complex problems and successfully meeting those challenges requires examination and a definition of solutions.

Today's discussion is designed to identify the difficulties that we face and to understand why they exist. More importantly, today's discussion should try to guide us to the right ways of crafting solutions. Some of the questions are straightforward. Is training and education sufficient? Do we have the public health authority that we need? Is funding at the level required? Others pose questions of balance and proportion. How do we balance the desire for speed of preparedness with the need for deliberateness and caution? How do we balance the desire for full and complete understanding with plans and actions that are evolutionary? What proportion of effort will deter the problem? What should the proportion of our preparedness effort be in relation to our core public health and health care functions and are those efforts and functions different? How do we balance and effectively mix the cultures of those who now form these new partnerships in pursuit of preparedness — homeland security, intelligence, law enforcement, and defense — with public health and health care? How do we balance the need for strong leadership with the desire for consultation and partnership? How do we achieve a coordinated national capacity to respond with local government structures that are not monolithic?

These kinds of questions are not new for government and they're certainly not new for public health and medicine. From the immunization clinic to the surgical suite, from the emergency room to the boardroom, we struggle every day with these same questions of balance, of risk-benefit, of choice in the absence of complete information; we have done so for many years and we have learned many lessons as a result. A challenge for today is to determine how those lessons can be applied. That is exactly the challenge for our distinguished panel of speakers — to help us understand the problems, to help us turn them over carefully for examination, and to guide how we can best think about them in ways that offer lessons and solutions.

Each speaker brings a unique perspective to this discussion and I'll introduce each of them at the time of their presentations, beginning with our first speaker, Dr. Carol Ann Rauch. Dr. Rauch is Chief of the Division of Clinical Pathology and Medical Director of Microbiology at Baystate Medical Center in Springfield, Massachusetts.

She is Assistant Professor of Pathology at Tufts University and Assistant Clinical Professor of Laboratory Medicine at Yale New Haven

Hospital. Dr. Rauch is a graduate of Dartmouth; she received her M.D. and Ph.D. degrees at Johns Hopkins University School of Medicine and did her postgraduate work at Yale New Haven.

She is a self-described laboratorian who because of her background and training, understood early on the potential for bioterrorism to cause severe harm and disruption. As a result, she's played a key role in the preparedness efforts underway in Massachusetts in both the public health and health care systems. She serves as a member of the Governor's Bioterrorism Coordinating Council, the Massachusetts Bioterrorism Preparedness and Response Program Committee, and the Massachusetts Hospital Preparedness Planning Committee. She sits on the Springfield Metropolitan Medical Response System Steering Committee and the city's Biological Disaster Preparedness Group.

At Baystate Medical Center, she serves on the Emergency Management Committee and the Biological Disaster Preparedness Group. So she joins us today with a unique perspective and set of experiences from the front lines. As you can tell from her range of involvement, she is the front line in Massachusetts and there is a continuing set of challenges that she's faced in contending with federal and state actions and requests. She'll help us to understand what it is like to face the task of conceptualizing, planning, and implementing all those things that constitute "being prepared." Please join me in welcoming Dr. Carol Ann Rauch. (*Applause*)

Speaker's Remarks – *Dr. Carol A. Rauch*



Dr. Carol A. Rauch

Thank you, Dennis, and thank you for having me here today. This is very exciting and I appreciate the opportunity to have a room full of people interested in examining and turning over those rocks, looking for problems and seeing what we can come up with collectively in order to address these problems.

As a laboratorian, I'm both an insider and an outsider to public health. Right now I'm from the other side of health care; I work in a hospital. I will share my experiences from the front line. I will talk about

life “in the trenches” and I will leave it to my co-panelists to talk about public health in general.

Brief History of National BT Threat Awareness

- Up to early 1990s: general state of ignorance and complacency
- Mid-1990s: shocking revelations
- Late 1990s: early preparedness attempts
- 9/5/01: DAH congressional testimony*
- Post-9/11 and anthrax attacks: pervasive sense of vulnerability

* D.A. Henderson, www.hopkins-biodefense.org

I’ve been working with state and local governments in order to define what we are hoping to achieve by “bioterrorism preparedness.” I will be addressing some comments related to the role of hospitals and what it takes to incorporate them in preparedness.

We have suffered a rather rude awakening in a very rapid time frame. I don’t know where to say things began, but one point in the time line that is significant is in 1972 when the biological weapons convention was promulgated and subsequently ratified by countries all around the world. We felt that this had put the issue of offensive bio-weapons programs to rest. We developed a sense of complacency about bioterrorism. It was too abhorrent to think that someone would utilize these agents as weapons and we ignored it for a long time.

It wasn’t until the mid-1990s, when information became more widely available, that we were shocked to hear some of the things that were going on around the world and significantly in the former Soviet Union. Large stockpiles of agents had been prepared, weaponized, and made more virulent. This was really hard to hear and it took a little bit of time to react. It wasn’t until around 1997 that it caught anybody’s attention.

I will refer you to one of my favorite summaries for those new to this field. It is congressional testimony by D.A. Henderson that was pre-

scient since it occurred just shortly before 9/11. It is a good summary of the forces at work that lead us to be so concerned about this topic today.

Certainly since the events of 9/11 and the anthrax attacks, we are now suffering from a pervasive sense of vulnerability and there's an emotional overtone that colors our perception of what happens when you hear the phrase "bioterrorism."

The Baystate Medical Center is right up the road. I'm delighted that I'm so close and I have some new friends on this side of the state border. I was here minding my own business, working in the clinical microbiology laboratory.

How Did I Get Here?

- Sverdlosk incident discussion
- At Baystate, I could not answer "what would I do?"
- National symposia
- Initial preparedness efforts behind the scenes

I thought I would briefly share how I came to be in this position. As a fellow some years ago, I recall a journal club discussion of anthrax. We were looking at, what decades prior, had been attributed to some bad meat and human deaths associated with anthrax. It had taken years to discern that these cases were actually due to inhaled anthrax. I remember looking at the figures, at the wind patterns, and where the casualties were. The person presenting the information was from a VA hospital; I assumed that this was either his personal interest or of military interest only and had nothing to do with me.

Even as a fellow in microbiology I did not fully understand the threat. When I came to work at Baystate, I was no longer surrounded by peers who could handle something for me and I felt a little bit isolated. Also, I oversee reference laboratory work that causes me to directly interact with a wide variety of clinicians scattered all over western Massachusetts. I became aware that there's a whole world of clinical care beyond the major academic centers where I had primarily trained.

I began to be troubled when I heard the phrase "bioterrorism" because this time I couldn't look down the hall at someone else to take

care of the problem. I was troubled that I didn't know how to answer the question: "What would I do if anything ever happened?"

I went to Washington to the national symposia in 1999. This time the message hit fertile ground in my mind; I saw that it had everything to do with me; it had everything to do with anyone in the audience. There were military people, law enforcement, first responders; there was a wide variety of people there, all of whom could legitimately see not only were they a front line but also that they needed to begin to study and prepare to work with each other in the event of an attack.

When I came back from those meetings I didn't want to seem crazy. People asked me why I was spending my money on this. "This will never happen; this is theoretical; this has nothing to do with us; we're just out in the middle of nowhere; this would not ever hit here." Most of my work at that time was behind the scenes by design. I started writing some disaster plans and training my own staff, but I was very hesitant to let my administrators know that I was spending time on preparing for these things.

My Own Experience

- Response to Florida anthrax case: protect pharmacy
- Teaching! anyone and everyone
- Biodefense advisories
- Promote connections

That preparation put me in a good position when, for example, I was on the phone with a family member on October 4, and just as I was hanging up, he said, "By the way, there's a press conference. There's some guy in Florida with anthrax. Have you ever heard of that?" I knew this was it. I said, "Hang up the phone, find out is it on his skin or did he inhale it?"

From the second we learned that this was inhaled, the world changed. My first actions that day were to notify the infectious disease physicians, the pharmacy, and the vice president that I wanted antibiotics moved to an increased level of monitoring and increased security. This could have represented the first of many cases in a large epidemic.

We had previously learned when there was a hoax perpetrated at a hospital that there can be a run on antibiotics. That didn't occur, thankfully, and our actions were overkill, but should it have turned out another way, we would have been protected.

There was also an immediate need for teaching. Many needed information instantly, especially our clinicians. However, it seemed that everyone was anxious to understand these new issues. When I was giving rounds to the clinicians, for example in the ICU, there were people who were administrative support staff, housekeepers, and others who have nothing to do with direct care of ICU patients, clamoring to get into the room. This was troubling and I did not feel comfortable showing them photographs of victims.

We responded by hosting employee open forums and tried to be available to those in the community who had a legitimate need to be informed because this was shocking to the lay public.

Just a few comments about bio-defense advisories: There was a constant need for more information and it was not easily available. There was a lot of information on "official" web sites such as the Department of Public Health in my state, as well as the CDC. But not many knew how to access this information. To passively post information is not good enough — more has to be done to orient people that it is there.

People came to me with questions and concerns. As a result I created an e-mail system intended to look something like a weather emergency but instead distributed synthesized clinical advisories as they were written by the state. There clearly needed to be a better governmental communication system. My own messages always included: "Go to the Mass Department of Public Health and the CDC." I tried to point people in the right direction.

Another major effort was the promotion of connections. Emergency department staff and infectious disease clinicians need to give the same advice and have the same algorithm. That would not have happened passively without a significant effort to get them in the same room, make them work it out together, and make sure that we were all speaking off of the same page. No one was prepared at that time, in spite of a variety of training efforts, to rise to the challenge of the complexity surrounding powder incidents. Law enforcement, health care, public health, the FBI, and the postal service all had to work in lockstep.

Just a few comments about western Massachusetts: As we developed working connections, the mayor convened a group of various enti-

Local Response: Western MA

- Working group of traditional first responders and health care formed to handle powder incidents
- Morphed into Springfield MMRS steering committee
- Good size — large enough to have resources, yet small enough to know others personally

ties to handle powder incidents. This eventually became the Springfield MMRS (Metropolitan Medical Response System) steering committee. To have an MMRS, you have to have a significant population density and availability of resources. At the same time, our group is small enough that we can learn about each others' roles and get to know each other personally.

In contrast, any one entity in New York City might have thousands of members in it, with incredible sub-specialization. However, this size also promotes insularity.

Massachusetts Response

- Office of Commonwealth Security
- Bioterrorism Coordinating Council to advise governor
- Identify issues and priorities; plan strategies and task forces
- HHS funds and cooperative agreements
- BCC role of oversight, troubleshooting

Last January, Acting Governor Jane Swift created the Office of Commonwealth Security. Dick Swensen, from a long history of working in the FBI, was named as the director.

Mr. Swensen chairs a six-member bioterrorism coordinating council which was created because of the unique challenges of bioterrorism.

While disasters share many features, bioterror is considered sufficiently unique to need particular expertise.

This group was trying to determine what areas needed to be addressed, such as updating our laws, plans for vaccines, etc. We were about to identify task forces when almost immediately, the federal government came out with the funds for the CDC and Health and Human Services cooperative agreements. The issues in these grants matched almost exactly those we had identified.

The council then took on the role of oversight and troubleshooting. We put on the table issues like restructuring our state into matching regions for different functions, without much success so far. If it could be accomplished, this would drive having the right people in the room for meetings, and drive where the interfaces are located.

Some of the Many Challenges at This Time

- Orientation and context
- Education and training
- Coordination (vertically and horizontally)
- Good communication: the common thread!

Of the myriad of challenges, I'd like to focus on the following: orientation and context, education and training, the need for coordination in all directions, and communication.

Goal:

- All affiliated with public safety and health care must achieve a minimal working level of knowledge!

One goal is to have a minimal working knowledge for anyone affiliated with public safety or health care. There needs to be a floor established for what is considered an acceptable level of working knowledge.

Orientation: Get in the Game!

- Spectrum of interest in bioterrorism:
denial/distance (“not me” syndrome)
fascination/trend seekers
those who promote fear
- Those who are in the know: read, find resources, attend training, and participate in the process
- Those who are in denial or distance = vulnerabilities
- We are only as strong as our weakest link
- We need to provide context: What does this all mean?

What do I mean by orientation? When the word “bioterrorism” is used, whether it’s in the media or in another forum, there is a spectrum of reactions to the phrase. One is known as the “teenage syndrome” – “it’s not going to happen to me; it’ll hit somewhere else; I’ll worry about it later; I’ve got enough things to do.” There is another group of people that are fascinated with what has come to be a sexy topic; they’re trend-seekers and maybe even money-seekers. There are even those who may be in the business of promoting fear, and health officials must do a good job at orienting the media.

Those who are “in the know” are often engaged in a self-perpetuating cycle. They go to meetings; they read — they go to more meetings, they get their name on e-mail distribution lists, and they are “in the know.” Then there are others who are not as informed and they can represent vulnerabilities. The first case of smallpox could be a child going to the school nurse. Therefore broad nets should be cast for identification and surveillance that include people like that school nurse.

We are only as strong as our weakest link. Most conversations I had during last year always started with “How did we get here?” You need to give people a context in order to effectively communicate your message — like preparing the soil to be seeded.

We need to communicate that this is serious business. As Dr. Benjamin was saying before this session, “We can’t play Chicken Little running around saying ‘there’s danger, there’s danger!’” Well, there re-

Importance of Context

- The risk is real; this is serious business
- However, it is irresponsible to motivate with "Chicken Little" mentality
- This is especially a problem if we defer to the media too much
- Must be deliberate and rational, use principles of risk communication

ally is danger and we really do have problems and we certainly don't have enough money in our budgets. We have all sorts of threats, but yet no one should say "the sky is falling." We need to be deliberate and rational, and we must use the principles of risk communication when speaking with the public.

Broad-based Orientation:

- HCW and public safety are all on the front line
- Their knowledge base is critical to their effectiveness in surveillance and response
- HCW with lack of knowledge could have dangerous effect on patients during an incident
- As individuals and as members of groups, they need to view preparedness as a professional responsibility
- Others need orientation: politicians and decision makers, the public, the media

Everyone on the front line needs to be participating in surveillance. We can do a good job with electronic data surveillance but nothing can replace the skills of an astute clinician or an astute person who is taking a 911 call.

In order to have a prepared frontline, workers need the support of their directors. For example, nurses may have to leave the hospital and go off to take training elsewhere for a whole day. The challenge is determining a reasonable expenditure of resources to support training. That goes for politicians as well, and their allocation of government personnel resources.

Education & Training

- Critical to early detection and effective management
- Essential to mitigate effects of a crisis
- Traditional approach is to offer conferences, advertise, passively accept demographics of the audience
- This approach relies on individual attitudes and motivation
- Unprecedented concern for our national security requires consideration of alternative approach

Education and training are critical and will help mitigate the effects of any crisis, whether it is a large scale outbreak or a smaller event that is ongoing (we are still dealing with the remnants of last year's anthrax attacks). The traditional approach is to rely on a passive system of offering training sessions. Whoever signs up for training has a combination of free time, interest, and self-motivation. In this new area of national security, we need to be sure that everyone participates.

Education & Training

- My vision: metrics
- Track training with respect to:
 - Target population
 - Geography
 - Time and/or level of knowledge

- Active process will reveal gaps and vulnerabilities
- Message is content and system
 - Know what to look for
 - Know what to do

We need to track training; I call this metrics. A list of target audiences should be developed to include 911 call takers, ambulance drivers, school nurses, emergency physicians, etc. Then a map of where those people are should be developed so it can be determined how these target populations are distributed through segments of geography. By presenting this information visually, we will see where our vulnerabilities lie. Education is needed to learn to recognize and clinically manage victims of bioterrorist attacks. In addition, individuals need to learn also how to work within the context of a larger system that addresses criminality and disaster management aspects of the event. These front-line workers should know who should be calling the FBI and who should be communicating with whom.

Physicians:

- Independent-minded group, and reasoning has not been adequately articulated to them
- Obstacles* to physician participation:
 - influences of managed care
 - low probability events
 - not required or rewarded
- Questions for board certification exams? Required (temporary) CME?

* John Bartlett, MD, 2nd National Symposium on Medical and Public Health Response to Bioterrorism (2000)

Physicians are difficult to connect into the communications system because they are usually more focused on individual patients than public health. Bioterrorism is low-probability event and nobody has hereto-

fore required or rewarded physicians for participation. Should we start looking at putting bioterrorism on board certification exams as a topic? Should we make this a temporary, or even a permanent, requirement of category for continuing medical education? These are bureaucratic challenges that need to be put on the table in the interest of national security.

Coordination Challenge

- Current paradigm:
entrepreneurial spirit
value opportunity to compete
- New paradigm: How will we achieve the greatest good for the whole (as opposed to furthering each individual component)?
- Growing theme in military is interoperability, “born joint”*
- Need for technical standards in data management

* Gen. R. Myers—IFPA-Fletcher Security Conference (2001)

In our society we have traditionally valued entrepreneurs. As good as many innovations are, they need to be tested to see how they link Part A to Part B and much further. An example of a product that we recently examined for connectivity was a bar coding system with an in-the-field laptop scanner. It worked great in the field, but we found that only some of our hospitals had systems compatible with this technology. We need to think everything through the entire chain very carefully in the area of applying new technology.

Last year the Fletcher School of Law and Diplomacy at Tufts University hosted a conference where there were a number of military speakers. General Myers described the emphasis now placed in weapons system design on interoperability, the plug and play, how to immediately fit a variety of needs of different segments of the military or even coalition forces. The phrase “born joint” for new systems is a very good concept. It means that we need to be able to use all types of systems, particularly for data and information management — according

to some rules and technical standards that promote coordination with other systems. The CDC has thought of this, for example, in tracking the smallpox vaccines. They are either providing their own software or they are certifying alternative software. Interoperability will be essential as public health workers design and use new systems.

Coordination Takes Time and Communication

- Strong chain of relationships from CDC to state public health departments, but connection does not extend to hospitals and other elements of medical care community
- "Get it done" mentality assumes military or corporate-like alignment, where all that is needed is decision, announcement, and logistics
- System cannot function without prior awareness, participation, and broad communication
- Difficult to go back and fill in reasoning after distrust develops or decisions not to comply are announced

My experience has shown that there are strong links from the federal level down through the state public health system and then there's a significant gap before we get to the hospitals and the individual providers. There is a federal "get-it-done mentality" that assumes that we all work like the military or a big corporation, where a leader makes a decision, announces it, and all the dominoes start to fall over. In public health, the dominoes can stop falling over when we they reach the front-line health care system. For example, a hospital can decide not to comply with certain recommendations. Once a hospital has a press conference stating that they won't comply, it is too late to try to convince them why should comply. What we need to do provide information and reasoning for the recommendations to support their decisions early on.

I will defer these slides on smallpox to my colleagues, except for the point that there are some issues that evolve very quickly. For these issues, there is a delicate balance between getting the message out quickly versus the need to have the right message, a dynamic of speed versus quality.

Casualties of Urgency

- Artificial emergencies are extremely disruptive — may have short term advantages, but also drawbacks in longer term
- True preparedness should minimize risk to other successful programs
- Avoid pendulum swing with backlash
- This effort needs to be permanent, and needs to be perceived as permanent
- Response to forces in biotechnology and global sociopolitical arena more than reaction to national open wound from 9/11

One point about the casualties of urgency; other issues are getting pushed off of desks while we're all focusing on bioterrorism preparedness or smallpox. Many other programs are put aside, and some are questioning whether this is a passing phase. We need to get the message out that this is permanent. This should not be seen as an emotional reaction to 9/11 or a political response, but as a legitimate issue that will remain forevermore. Every time a virulence factor is identified in an organism that causes an infectious illness, we are interested in that finding to help determine new ways of treating people suffering from that illness. But we've also potentially armed a terrorist.

Implementation Hurdles

- Feedback = vertical communication
Sensitivity (mismatched deadlines remain)
- Learn from peers = horizontal communication
- Develop creative approaches to get around obstacles as they are identified
Example: Even if money were available for hiring people, and if appropriate people were

There are several hurdles for implementation. There's a constant need for communication and for the provision of feedback from those down in the trenches. That means they must have the opportunity to say, "We can't get this done in thirty days." Also, there need to be opportunities for peers to share their experiences (such as frequent conference calls) in order to learn of each others' successes and failures.

Hospitals

- Dire financial situation
- Dire staffing situation
- Dire regulatory situation

Bioterrorism might be the straw that broke the camel's back for hospitals. The financial situation for most hospitals is not good. Furthermore, hospitals are critically short of nurses, pharmacists, laboratory technologists, and other staff. What can be done to minimize the impact of this additional burden on hospitals is to provide training in a way that minimizes the burden by making it repetitive and easily (locally) available. Also, many smaller hospitals need to write better disaster plans and don't know where to start. They don't have infectious diseases expertise on staff. The ideal would be to provide them with templates and guidance from state officials.

How to Share Responsibility for Preparedness?

- Public health and private health care are now making extreme demands on each other and need to work out clear expectations
- How far does the responsibility of government and public health extend? Is there a line of demarcation?
- In a crisis, clearly physicians, hospitals, and public health will need each other!
- In routine situations, these professional communities are quite distinct

At some point the individual clinicians and hospitals will need to accept personal responsibility. We are all looking at someone else to fulfill our needs. The professional communities of public health and traditional health care are generally rather distinct; more than ever before, we need to work together as partners. In an event, public health needs to provide recommendations based on epidemiologic information, and clinicians will need to work within the context of a dynamic public health situation.

Surge Capacity:

- What should it look like?
- How do we mediate hospital relationships with each other when they are often competitive?
- How do we use private facilities?

Surge capacity! We're all saying hospitals should work together and develop memoranda of understanding. Hospitals need to know how to share patients and perhaps resources. I see hospitals as primarily competitive these days and I've always looked to the state to mediate and broker those relationships. My state has delegated much of this challenge to the hospital association. Although there has been progress, it is even more difficult to see how private facilities might be incorporated in the event of a disaster.

Challenge for States:

- Clearly one size does not fit all — we have different needs
- Increased focus on large cities is justified: target rich environment, population density
- But patients can and do present anywhere and infectious illness likely to be delayed with a mobile society
- Cannot neglect smaller communities
- Systems must be designed to be inclusive of heterogeneity

One size does not fit all and there must be different approaches. Smaller communities cannot be overlooked because these events could be perpetrated anywhere. Some increased focus on large cities is justified because they are target-rich environments and typically are centers of mass transportation where many can be exposed.

Because of the nature of infectious diseases, no matter where they may be exposed, patients can and do present anywhere. People from my community go to Broadway in New York City, or go to Boston, and then they come back home to Western Massachusetts. Some may even attend high profile events like the Super Bowl and then fly home. They do not stay where the exposure might have been, waiting perhaps days for their symptoms to develop; they're going to travel and bring their illness potentially anywhere. A bioterrorist attack can leave a footprint that is blurred through both space and time, so we all need to be prepared to respond, yet some aspects of our approaches may be different in different locations.

Challenge for States:

- Need to take advantage of, but not completely defer to available academic expertise
- Questions asked to state often answered by Boston, and they are not the same!
 - Is it a model or pilot?
 - Is it or will it be available to others?
 - Is it appropriate for others?
- Need "affirmative action" program for inclusion of smaller communities

Where there are academic experts, state leaders can rely on and even defer to these partners, but not completely. We cannot lose the focus on the perspective of the whole state. We also cannot neglect the smaller communities, since a tax-paying citizen has some right to coverage wherever they are. I refer to this as a need for an affirmative action campaign for inclusion of smaller communities.

Challenges of Broad Inclusion:

- Public health process traditionally focused on consensus building
- Many participants are new at the process may advocate for their own needs rather than the state perspective
- We all have to work with the same mental model
- Issues need clear framing by leaders, reasoning must be explained
(in smallpox planning, frequent confusion about scenario)

In our state, the consensus-building process of public health has led to work groups for implementing the cooperative agreements which have diverse membership. We have a very prominent risk communicator, for example, from Harvard, but also people who are entirely new to this field. This creates a challenge for public health leaders to orient everyone and frame the topics of meetings.

Challenges for States:

- How to achieve defined outcome in varying circumstances
- Must develop achievable and reasonable goals that adapt to local situation, yet fit needs of the larger system
- Ideally, public health and public safety have 24/7 coverage by experts who have access to appropriate technology
- Need to consider regional coverage

There's an issue of consistency. We need to handle heterogeneous entities and the answers might be very different in different places. For

example, in an ideal world local boards of health would have fully trained and experienced staff available around the clock. Realistically, we often have someone who works four hours a week, possibly even at night. Preparedness plans need to accept this limitation and aim at some appropriate level of regional coverage. In terms of regional coverage — it can be a difficult issue for us in Massachusetts because we don't have county health departments. We are trying to restructure things now to adapt in a way that creates regional approaches that previously we didn't have.

Challenges for States:

- Avoid overcommitment of resources
Facilities: sites for vaccination clinics or NPS distribution may also be Red Cross shelters
Personnel: military reserve, volunteer fire department, smallpox community response team, work at hospital
- How do we achieve coordination?

We have been discussing, "where should our vaccine clinic be, and where should the distribution of pharmaceuticals occur?" Potential facilities such as the local high school gymnasium may already be utilized for other purposes in someone else's disaster plan. At this time, we don't have good databases that cross-track either facilities or people. Right now we have shortages of disaster responders because many are serving in the military. We have to be aware of overcommitment in our disaster planning.

Communication Challenge:

- Prudent not to rely completely on the Internet
- It is not available to all
- May be vulnerable during incident
- Need robust systems, low and high tech
- Updates should be predictable to the degree possible in planning for and managing of incidents

We can use the Internet but web sites are a passive system and are only going to provide the capacity needed if people are aware what information is available and if they can access it. There still is a segment that cannot access the Internet, which is one thing we are addressing in my state by providing computers and online high speed Internet access to health departments. But the Internet is not a panacea.

Communication Challenge:

- Current focus on planning incident management
- Ongoing needs exist for information and meaning
- Where does the media fit in?
 - Broadest access system currently functioning
 - The facts vs the story: we pay if this is neglected

Planning in communications is currently focused on incident management, but there is also a need to reach large groups of people, possibly through the media or other means. The media really has instantaneous access to a wide audience. Unfortunately, the information that the media provides is not unfiltered, and facts may not be communicated directly. If we don't address how to get this information out in an accurate and appropriate manner now, we will pay for it later.

What Are We Aiming At?

- Mental paradigm shift
- *Connectivity* is a buzzword in many arenas
 - Engineering and information management context
 - Human/social context
 - Important concept for BT preparedness

(Len Marcus, Harvard Center for Public Health Preparedness,
Tom Inglesby, Johns Hopkins Center for Civilian Biodefense Strategies)

What are we aiming at? First is a paradigm shift. We're now learning how to work together. My friends in data management are all talking about "connectivity" and connectivity also has a human and social context. Dr. Tom Inglesby was providing congressional testimony and applied "connectivity" to the area of bioterrorism preparedness. Len Marcus, a faculty member at the Harvard School of Public Health and at the Harvard Center for Public Health Preparedness, is also now taking advantage of the meaning of that word in our preparedness efforts. We are beginning to appreciate the value of a strongly interconnected public health system.

Where Are We Going?

- Our national experience with anthrax attacks went a long way towards making the case for value of public health system
- Public health must play the lead role in preparedness and management of bioterrorism
- Our wise investment will give us greater strength and flexibility to respond to manmade or natural disasters

We need to get public health at least as well-resourced as its partners in public safety and the traditional first responder community. We also have to aim at an incredible degree of interconnectedness. We will have to be keeping up with the pace of biotechnology. Hopefully we will be able to achieve a whole greater than the sum of the individual parts. Thank you so much and I think the questions will be in the discussion session later. Thank you. (*Applause*)

Introduction of Second Speaker — *Dennis P. Whalen*

Our next speaker, Dr. Georges Benjamin, was named in November 2002 as the Executive Director of the American Public Health

Association, the nation's oldest and largest organization of public health professionals.

He came to that position after serving as Secretary of the Maryland Department of Health and Mental Hygiene where he oversaw an operation of 10,000 employees, 24 health departments, and a \$4.6 billion budget.

In 2001, Dr. Benjamin also served as president of ASTHO, the National Association of State and Territorial Health Officers, which advocates on behalf of the nation's departments of health.

His career has included work as Chief of Emergency Medicine at Walter Reed Army Medical Center, Chair of the Department of Community Health and Ambulatory Care at the District of Columbia General Hospital, Director of the District's Emergency Medical Service, and Commissioner for Public Health of the District of Columbia. Dr. Benjamin is a graduate of the Illinois Institute of Technology and the University of Illinois College of Medicine.

His dual role in 2001 as Health Secretary of Maryland and as ASTHO president, is especially noteworthy. From those positions he had to manage his own state's pivotal role in responding to September 11 and the subsequent anthrax attacks, and he also had to represent and guide the nation's health departments as they sought to define their responsibilities in a time of rapidly changing priorities.

He brings to us today three critical perspectives. First, as a commissioner of health who played a key role in both responding to bioterrorism and developing his state's bioterrorism plan. At the same time, he continues to manage those core public health responsibilities that are part of a state department of health. Second, he was ASTHO president at an important and formative time when state health departments across the nation were called upon to respond to the threat of bioterrorism and thus to fulfill new roles and responsibilities. And third, in his current role as Director of APHA, where he is vitally concerned about the role of health and preparedness and all the implications of that responsibility in the context of existing core public health functions and continuing concerns about the public health infrastructure. Please welcome Dr. Georges Benjamin.

Speaker's Remarks – *Dr. Georges Benjamin*



Dr. Georges Benjamin

Dennis, thank you. Good morning. What I want to do today is talk about why the public health community ought to be in the business of homeland security at all. I think any time you do something, you ought to ask why do it? Does it make a difference? Are we the right people? Is there a historic role? You need to talk about the capacities and if you're going to do this. You need to talk about the quagmires of preparedness — such as those surrounding the smallpox vaccine.

Many of my colleagues in public health say that we shouldn't be in this business at all. My response is very simply: "We've been in this business a long time; this is not new. Disaster preparedness activity is a core public health function. We've done it for a long time."

Natural Events Requiring Public Health Response:

- Severe Weather
- Hurricanes
- Earthquakes
- Volcanic Eruptions
- Floods
- Severe Heat/Cold

For instance, let's talk about what's recently happened in Maryland. A year or so ago we had an F4 tornado that demolished a very beautiful town in southern Maryland. Our public health system was involved as other agencies were involved in providing acute nursing care, shelter care, and access to tetanus toxin vaccine. You may remember there was a tetanus vaccine shortage and the only way you got it was through the health department. We also provided long-term and short-term mental

health care, in addition to making sure the water was safe to drink and the food was safe to eat and that we had animal control activities in that community. Certainly we've been involved in accidents.

**La Plata, MD Tornado
Local Health Department Activities:**

- Providing nursing at shelter
- Securing perishable foods
- Ensuring potable water
- Providing medical supports
- Disease control
- Vaccination (tetanus)
- Mental health supports

In Maryland you may remember the infamous train fire. I discovered we had a train tunnel that went under the city of Baltimore; I didn't know it was there. (*Laughter.*) Lots of other people, old-time Baltimoreans, knew it was there; It was interesting that this big cloud of, fortunately, nontoxic smoke, blew right across the city for days, across the health department, my office, the State University of Maryland, hospital system, the VA Hospital, and Oriole Stadium.

Lots of people would have been impacted had that been a toxic plume and in effect it would have taken out a huge part of our infrastructure. So anyone who thinks that the public health care system would not have been engaged in that is fooling themselves. We now have a new range of events called domestic terrorism.

On September 11, 2001, when those airplanes hit those tall towers, no matter how that occurred, the public health and medical response to that was in essence to respond to a high-rise fire. When those buildings fell, the contextual relationship of that response was one of responding to an earthquake. Think about what that means for state, local, and federal planners in terms of preparing for a response. A high-rise fire response is quite different than the response to an earthquake. With a high-rise fire, you have burns, smoke inhalation, and people who trip

What Did We Learn?

- 5 letters containing anthrax spores sent in mail
4 regions initially affected in US
Florida
New York / New Jersey
Washington Metro
Connecticut
- Mild contamination of other US postal facilities
- Nationwide Effects: Threats, concerns
- 18 confirmed human cases in US — 11 inhalation (5 deaths), 7 cutaneous, 33,000 + people prophylaxed

and fall as they come down the stairway. That contextual relationship is quite different than the explosion that occurs with an earthquake and the crush injuries that occur and intensive need for dialysis centers or a need to pull people out of rubble. The fact that you now have a search and rescue activity is quite different than the high-rise fire search and rescue activity.

Planning for this type of an event would have been difficult because the event changed. We also have to begin to think more and more about not the fact that domestic attacks can come in twos. In the fall of 2001, they came in threes.

I'm going to talk about the anthrax attacks. Only five anthrax-contaminated letters, as far as we know, resulted in over 33,000 people being put on antibiotics. There were many complications associated with those antibiotics. Five letters and I ask: "What would have happened had there been ten letters or fifteen letters or twenty letters all around the country, which were strategically mailed in a focused manner. We would have certainly had a much different event. This was a big deal throughout our country and we need to think of this as a national response and not just an east coast event.

Anthrax Attacks, What Happened:

- Public health performed well overall
- Exposed severe shortcomings in basic public health systems
- Another major event would have been serious problem!
- Adequate response requires a partnership between feds, state, locals & community

We learned some things but public health actually performed well considering the resources. You have to think about the fact that had people not been put on antibiotics, we would have had many, many more deaths. I'm absolutely convinced of that, knowing the context of the type of anthrax that was opened up in the Senate building and the number of people there who were exposed. I am convinced we would have had more deaths. This is also true of the postal workers.

But the anthrax attack did show our weaknesses. It showed the fact that we had neglected the public health system for far too long. And it showed the fact that people did not know they had a public health laboratory and that the public health laboratory was fundamentally different than a clinical laboratory at a hospital. That even though you had a public health laboratory, we had to pay a lot more attention to the security around that lab and the kinds of work we did. We had to be accountable

Must Prepare for Several Types of Presentations:

- Overt event
- Covert release
- Threats and hoaxes
- High-risk events (Olympics, Inaugural)
- Public safety actions that uncover sites
- Public concerns & fears

for the organisms that we kept and the organisms that we tested in our facilities. It was clear that if we were going to do this right, we needed to have a partnership within the local and the state and the federal government, both in the private sector and the public sector.

We also need to learn how to respond to several types of threats from the overt to the covert and learn how to respond to public fears.

I like to define a disaster as any time your resources are overwhelmed, whether that be a clinic that's designed for five people and fifteen show up or whether it is like the tragedy we had in New York City or Oklahoma City. This means that we have to prepare for this concept of preparedness as a relative thing.

Definition of Disaster:

"A disaster is the result of a vast ecological breakdown between humans and their environment, a serious and sudden event (or slow, as in a drought) on such a scale that the stricken community needs extraordinary efforts to cope with it, often with outside help or international aid." (from Noji, Gunn, and Lechat)

I have four points that I'd like to make: Everything we do is based on our experience. I like to argue that public health practice has fundamentally changed and I'll show you what I mean by that in a moment.

Four Important Points:

1. Our knowledge base on terrorism is experienced based
2. Public health practice has fundamentally changed
3. There is evil in the world combined with dangerous organisms
4. Nature is also dangerous

Second, there is evil in the world. On September 11, 2001, I was with one of my state senators and we were very much concerned about core public health activities, cardiovascular disease, and cancer. We

talked a little bit about preparedness that morning but we were fundamentally talking about cardiovascular disease and cancer because I wanted some funding for these activities.

Then the planes hit the World Trade Centers and the Pentagon. We learned some things; we learned that our knowledge base was inadequate, that a lot of our knowledge base was based on old assumptions that were not true: that if you're clinically vulnerable, you can get sick from anthrax with far fewer spores than 8,000. Eight thousand is the mean, not the exact amount needed to get someone sick.

I think the real key is that we need to spend the money and effort for good solid research in the public health practice and the science of bioterrorism from a civilian perspective. The military environment is not the same as the civilian environment. What was fascinating was when we looked at civilian aspects of bioterrorism; we looked at the whole issue of whether or not the military model and military toys and tools worked for the civilian environment. We said "no, absolutely not." There are some things we can learn; there are some tools we can adapt but the fact is that dealing with this in the civilian sector is fundamentally different from dealing with it in a war environment or a military environment.

During the Anthrax Attacks Our Knowledge Base Was Inadequate!

- False assumptions
- Anthrax hard to weaponize
- Hard to deliver in mass
- Stays put; e.g., no reaerosolization
- Must open letter to get exposed
- 8,000 spores required to get sick
- Inhalation anthrax is 90% fatal
- 60 days of antibiotics is enough

Now, public health practice has fundamentally changed. Five years ago we would do our research quietly and secretly and contact the people who were potentially exposed to anthrax and not make a big deal

with the media or the press. Our first response was this was an "accidental" event or a naturally occurring event. Now the first question is: "Could this have been intentional?" That fundamentally changes the way we behave and what we do.

Must Enhance State & Local Infectious Disease Capacity

- Prevention
- Detect disease
- Conduct epidemiological investigation
- Confirm through laboratory
- Inform stakeholders
- Treat & contain disease
- Link to supports
- Recover

We now think about engaging law enforcement personnel early in the response. There are also new assumptions about an intentional event. In this country we've had many naturally occurring events. We would have thought the anthrax attacks were naturally occurring — initially. We certainly have had anthrax in animals in this country for years but our first response after September 11th was that it was probably intentional and we worked backwards from there.

Improving Disease Surveillance Capacity

- Increase local & state capacity
- Invest in human capacity first
- Build technology to support people
- Must be sensitive to find small numbers
- Increase routine disease reporting
- Address global reporting

We need to enhance state and local capacities in a broad range of competencies and we need to be able to recover quickly. Recovery is one indication of whether we're prepared. Understand, there's no single measure of preparedness; it is a very complex issue. There are some prevention aspects. We need to spend a lot of time talking about security; we need to invest in bio-security in our laboratories, both in knowing what's there and tracking them and accounting for them and making sure people don't have access to them.

Increase Routine Disease Reporting

- Poor reporting for routine diseases
- STD's
- CNS infections
- Other
- Must know who to call & when
- Must know what to report
- Need increased supports for these "everyday systems"

We need to make sure that we have an adequate legal basis for public health. Many public health laws are ancient and they need to be updated. There are lots of reasons we don't want to open those statutes for political purposes. We do, however, need the authority to do something when someone expects us to act.

We also need to be able to manage an epidemic. We have lots of people walk in our doors all the time, asking us to spend money for lots of automated computer systems and I'm glad Carol mentioned this earlier. We shouldn't buy every trinket that comes in the door. Most of them simply count things. They don't manage the outbreak; they don't help us track the outbreak; they don't help us analyze the outbreak; they don't do all those things and return us quickly to recovery. For me, they haven't solved my needs at all as a disease person.

Early detection is critically important to controlling disease outbreaks. The goal is to get a couple days of early detection. If we can get even a couple of days heads up on an event there is a tremendous im-

pact. Knowing something's in the community early can save lives. I believe we demonstrated that through the anthrax event.

Improving Disease Surveillance Capacity

- Increase local & state capacity
- Invest in human capacity first
- Build technology to support people
- Must be sensitive to find small numbers
- Increase routine disease reporting
- Address global reporting

It clearly is important that we invest in disease surveillance but we also need to invest in human capital first. You need to have a system that can detect a disease. I would much rather spend money and effort and time in people who understand what they're looking at and are able to identify that something has gone wrong, know who to communicate with, when to report, what to report, and how to report and then share that information electronically — especially when the machines go down. Anyone who's had their e-mail systems out for two days knows how paralyzed we become. On September 11th that's exactly what happened. The Internet slowed and for many of us, the communication modes were slowed.

If it wasn't for the television media at that time and radio, we would not have had rapid communication. The best way to do that of course is to make sure that we get our systems geared up for routine reporting. If clinicians know to report, say STDs, then they'll know who to report to and how to report anthrax, plague, and tularemia.

We also need to address the whole issue of global reporting. These are everyday things and people do best what they do every day. If you craft an emergency system that sits on the shelf, when an emergency comes no one will use it. They won't know how to use it; it will impede your efforts. So you need to use everyday systems and then have a way to enhance them when you have an emergency.

If you look at this chart (next page) of where the anthrax cases were identified you can see that they were spread over a sizeable geographic

area. When these people presented they presented in a quite different pattern. This is where they probably were exposed but the first index case was down in southern Maryland.

Anthrax Attacks: What Happened?

- 5 letters containing anthrax spores sent in mail
- 4 regions initially affected in U.S.
 - Florida
 - New York/New Jersey
 - Washington Metro
 - Connecticut
- Mild contamination of other U.S. postal facilities
- Nationwide effects:
 - Threats
 - Concerns
- 18 confirmed human cases in U.S.
 - 11 inhalation (5 deaths)
 - 7 cutaneous
 - 33,000+ people prophylaxed

The first identified case of anthrax was a Maryland resident who was exposed in Washington, D.C. and was hospitalized in Virginia. This points to the need for regional coordination and a regional system. Luckily there was a regional surveillance system that was turned on during this time period. And the reason it was turned on was because of 9/11. The reason it was created was for the presidential inauguration the

Building Electronic Surveillance Systems

- Avoid data overload
- Avoid the promise of “I can build it”
- Don’t make it too large & too fast
- Unique technology results in unique codes, difficult to repair and difficult to link to others
- High tech solutions to low tech problems
- Don’t create single points of failure

year before. It was also used or was planned to be used if needed for the IMF meeting. So we had a disease surveillance system in place.

It wasn't just the D.C. area that was affected by anthrax. New York, Connecticut, and Florida were all engaged in anthrax events. It was a global event.

I think electronic systems have a role in health. There are some things to avoid in building these systems. Number one, don't build something that has all the bells and whistles you can possibly want. You won't use them all. Don't build systems with too much data that you can't use. Don't believe the promise "I can build anything" because anyone who's had a computer database project built for them knows that they never come in under budget, on time, or do what they say they're going to do. So don't build them too large; don't build them too fast; don't buy any technology that is not interoperable with any other technology. If you do that, then you will pay every time for the source code as you go forward. We need to be able to change the information if you're going to build a national system.

Carol said it best: Don't use high-tech solutions for low-tech problems. Pick up the phone, walk down the hall. Don't send an e-mail to the person in the booth next door. It is important that you use low-tech solutions as often as possible in order to not have communications failures or confusion. And certainly don't create single points of failure; try to have alternative routes, multiple communication routes, backup laboratories, and backup systems as you go forward.

Public Health Laboratory Capacity:

- Laboratory has several roles
- Surveillance
- Confirmation of disease
- Forensic
- Probably a state function in general
- Local public health labs may have a role (volume, facility & capacity)
- Need redundancy for backup capacity

Our public health laboratory has several roles, including the disease surveillance and confirmation of disease. One of the important roles that's new is forensics. Things that come to the lab under chain of custody also have to be disposed of through that chain of custody. So when somebody brings you a wooden duck with powder on it and asks you to test it, you have to send it back through the chain of custody the same way.

We were stretched with anthrax. Our labs will be stretched if we have a smallpox outbreak because every person who has anything, every rash, every case of chicken pox, is going to be cultured. When those cultures reach our labs we need to have the capacity to rule out very quickly whether or not that person does or doesn't have smallpox. If they do or if we can't rule them out, there are a lot of people who will have to get vaccinated.

You also have to be able to explain when tests are negative. Vaccinating someone with smallpox because they were potentially exposed is a different explanation to the patient than putting them on antibiotics for anthrax, even though I wasn't real excited about doing that when we did do it. There are potential complications with the vaccine, different from the complications from Cipro.

Capacity For Disease Control:

- Update State Policies Concerning
 - Environmental surety & decontamination
 - Prophylaxis and vaccination
 - Isolation & quarantine
 - Monitoring of rescue workers
 - Hospital closure & reroute

I think the laboratory function is primarily a state function although I know there are some public health labs that are university-based. We need to be extremely careful of contamination. We need to pay attention to the whole issue of isolation and quarantine and monitoring the rescue workers. We need to update policies to make sure this happens.

Capacity To Link To Others:

- Intelligence agencies
Early linkages essential
Must be improvements in sharing
- Veterinarians
- Medical examiners
- Police, Fire, EMS & disaster prep
- National experts and resources
- Practicing medical community

The capacity to link to others when an event happens is not the time to become comfortable and learn your local FBI person. It is the job of security individuals to keep things secret, even if they're not really that secret. It's their job to not share information. In order to develop a relationship so you can confidentially share nonsecure but sensitive information, or have the appropriate security clearances so that you can share secure information, you need to make those relationships now. It's not the time to do it when an event happens.

It's very important that the public health and hospital and medical community make those linkages now. During a terrorist attack, it's also not the time to learn who your local media are. You need to be able to have frank discussions. There's never anything off the record but there's off the record and then there's off the record. You need to be able to have those kinds of discussions with both your media and your intelligence community.

Capacity For Effective Risk Communication:

- Must educate before event
- Appropriate at all levels
- Don't reinvent the wheel
- Build on existing capacities
- Single message statewide is goal
- Coordinate with locals, feds & media

Carol talked eloquently about the importance of having a good message and having a proper spokesman who's credible and a single message to the extent that you can get one. You also have to deal with all the talking heads, the split screen where someone is saying the exact opposite of what you are saying. I've had the experience of being on television and I didn't realize I was on a split screen with somebody else in California saying exactly the opposite of what I was saying.

Anthrax Is Not Contagious Smallpox & Plague Are:

- Smallpox
 - Last outbreak in New York City in 1947
 - 12 cases & 2 deaths
 - 6 million vaccinated over 1 month
 - Some vaccine deaths

One question in everyone's mind is: "Can we handle smallpox?" Well, in 1947 we took care of six million people in a month. I think we have a much more sophisticated communication system now than we did then. We can do this but we will have to stop doing everything else to do it. So I don't want to be quoted as saying we can do it...you can do it with a bunch of caveats. The purpose of having 500,000 people vaccinated was to give us a jump start with the understanding that about a third of those people are not going to feel well when they get first vaccinated.

From a logistical model and operational model it makes common sense to simply have people prepared, trained, and ready to go if we need to have vaccinations, risk or not. So I've always been an advocate for vaccinating the first 500,000. I have more reservation about vaccinating ten million and I certainly don't support vaccinating the whole population.

As you know, Harvard did a survey on people's opinion about getting the smallpox vaccine. There was one survey that was released in May of 2002, which basically said that lots of people would want the smallpox vaccine if it was offered and certainly more would want it if there was smallpox in the community. They've done this survey basically twice and they've seen similar results. Another complicating factor is the fact that people don't really know there is a vaccine that can

prevent you from getting smallpox if you get it early. There's still some confusion about whether there's a cure or not and I think that's the confusion between the vaccine and the disease. So we need to do a better job communicating in those two areas. People aren't sure whether their doctors are ready to treat it or not. In every hospital there are people, interestingly enough, who'd get a smallpox vaccination who've seen it. But many people are still reluctant. Interestingly, many practicing physicians have never administered the vaccine. Personally I have never given a smallpox vaccination although I was vaccinated as a child.

ASTHO Members Survey of ACIP Options

- 91% recommended against pre-event general prophylaxis (Option 1)
- 79% vaccination of pre-designated team of direct responders (Option 2)
- 67% recommended ring vaccination plus either expanded responders (36%) or affected community (31%)
- Some vaccine must be stored in every state for rapid use in an outbreak. Rapid deployment of vaccine is essential

The association of state and territorial health officials did a survey over a year ago when we were just beginning to talk about smallpox. Everyone had a lot of mixed positions and opinions but felt overall that we needed to have enough vaccine and we needed to have ready access to vaccines so we could move very quickly.

We felt that we needed to have a clear recommendation. We also felt it was important to communicate with people in their own language especially when we did childhood vaccination programs. This means we need to have people who know ten to fifteen languages. We also know we need to have culturally sensitive providers to deliver the message so that there's some trust and believability in that message.

We clearly need to have trained vaccinators. In Maryland almost all of our childhood vaccines were done in the private sector. We don't have public health clinics that deliver a lot of vaccine. We do have some

Educating The Public

- A clear national recommendation about vaccination is essential
- Clear national message by medical spokesperson
- Address multiple audiences
- Medical providers, media, general public, elected officials
- Must educate in multiple languages
- Childhood vaccination program materials in 10-15 different languages

clinics in some areas, such as in Baltimore but we have primarily privatized the vaccination process.

Vaccine Delivery:

- Need an adequate number of trained vaccinators
- <10% of routine vaccines delivered by public health in Maryland
- Must ensure equal access to vaccine for poor & underserved
- Need mechanism & funds to pay for vaccine complications in uninsured?
- Must address employee issues
- Lost work time
- Workman's compensation if work related vaccination

We clearly have to deal with liability and compensation issues. And if we're only going to do the small groups, we do have some issues around vaccine wastage as we go forward. We also have to protect peo-

ple that are immuno-compromised as we go forward. That's why the consent process in this country is so important as we go forward because we do have a litigious society and we need to make sure that we have adequate protections in place.

Smallpox Attacks: What Could Happened?

- Delivery method may yield disease in tracks different than natural infection
- Multiple U.S. regions may be initially affected
- Briefing the public
- Lots of school & community meetings
- Lots of legislative hearings
- Confirmed human cases
- Vaccination demand will be high. Just like in meningitis cases
- Public reaction will result in increased, threats, health concerns, fever, rash, "I'm sick" visits, increased mental health needs

The lesson you'll learn from anthrax is that we should not make the same mistake in smallpox. The delivery mechanism could be different and we need to ask ourselves what happens if the delivery mechanism is different? What happens if multiple regions of the United States are impacted? Again, that is why it's important to have these teams all over the country.

Local health officials spent as much time or more at PTA meetings and community meetings briefing the average citizen on anthrax and we're going to do more and more and more of this as we go forward. We're going to need the resources to do that. Whatever happens, public reaction is going to result not only in responding to the event specifically but having to deal with threats. I think I'll stop here. Thank you very, very much for your attention.

Introduction of Third Speaker — *Dennis P. Whalen*

Dr. Harvey Fineberg has been President of the Institute of Medicine (IOM) since 2001, following thirteen years as the Dean of the Harvard School of Public Health, and four years as the Provost of Harvard University. He was educated at Harvard where he earned his bachelor's degree, his doctor of medicine degree and his master's and doctoral degrees in public policy.

His past research has focused on the process of policy development and implementation, the assessment of medical technology, the evaluation and use of vaccines and the dissemination of medical innovations.

Dr. Fineberg helped found and served as president of the Society for Medical Decision Making and also served as a consultant to the World Health Organization. He is the co-author of the books *Clinical Decision Analysis*, *Innovators and Physician Education*, and *The Epidemic That Never Was*, an analysis of the controversial federal immunization program against swine flu in 1976.

When I had the pleasure of introducing Dr. Fineberg at our State Department of Health's Centennial Lecture Series last July I described him as "a great complexifier," a term coined by former Senator Daniel Patrick Moynihan. The connotation is not one of confusion but quite the opposite. It's the senator's description of those uncommon thinkers in whose hands a problem is carefully examined so that all the implications and consequences, apparent or hidden, are turned and studied. The result is a kind of rigorous and rich analysis that is in generally in too short supply and which leads to clarity and completeness of understanding of problems and their solutions. Not surprisingly, that's an equally apt description of the work of the organization he now leads, the Institute of Medicine.

Throughout 2002 the IOM issued a series of reports on various aspects of preparing for terrorism, including the issue of smallpox. Within the last two weeks, the Institute published its report on the implementation of the smallpox vaccination program. That report urged a cautious and deliberate approach and an ongoing careful evaluation of the implementation.

Dr. Fineberg joins us today with his perspective as the head of the IOM, reflecting its role as the objective and authoritative health advisor to government and the public. He also brings his insights based on his

in-depth study of the swine flu vaccination program. I am certain his comments will build on the discussion thus far today and help form and define the key policy questions and how we might best think about them. That will serve as a strong foundation for our discussion and question and answer period. Please welcome Dr. Harvey Fineberg.

Speaker's Remarks — *Dr. Harvey Fineberg*



Dr. Harvey Fineberg

Thank you very much, Dennis, for your very generous introduction. It was indeed a pleasure for me to be able to join you today to get reacquainted with Dick Nathan and to hear the wonderful presentations from Carol Ann and from Georges earlier today. They were very informative, very much to the point, and illustrative of the reality that national policy on a matter such as bioterrorism may be made centrally but it is implemented locally. The reality of that for our nation's capacity to prepare and respond in bioterrorism is a fundamental concern that goes to the heart of the issues of federalism, government operation, and program design that have comprised the work of the Rockefeller Institute.

These issues represent a valuable backdrop for our discussion today on the specific case of bioterrorism and homeland security and the more general implications for the operations of government, indeed of society, in a political system such as ours.

I want to make just a couple of background comments and to share with you some of the major thrusts of the work from the Institute of Medicine on smallpox vaccination, and then hope that we can turn, benefited from the wonderful presentations earlier and these remarks, to a good discussion.

Background on Infectious Disease Vaccination

In public health terms, the rationale for preparing and protecting against the usual recurrent infectious disease threat differs in fundamental ways from the rationale of preparation against a potential,

one-time, or sudden catastrophic intervention from an organism or intention of a human terrorist.

In the usual case for public health, such as vaccine against measles or pertussis, the population risk-benefit calculation could be predicted with very high confidence. That is to say, we could know with a very high order of assurance that if a certain population of individuals are all immunized — given what we know about the nature of the infectious organism's epidemiology — we can predict with very high assurance that that population on average is better off than it would have been had the immunization program not been put into place.

I hasten to add that this is not exactly the same as saying that every individual vaccinated is better off than that individual would have been if left unvaccinated. A priori, for all individuals, on average they are better off, but any one individual may suffer dire consequences. When you weigh those, however, against the benefit across the whole population, you return to the near certainty that the population will have been better off with the immunization program than without.

The case of smallpox, like the case of the swine influenza threat in the mid-1970s, is a case where we cannot be as certain that the population benefit is going to outweigh the population risk. It may still be, and in my opinion is worthwhile in the current case of smallpox to act, but the calculus, the rationale, is different. In a way this reflects the difference between thinking purely in public health terms as we classically have done versus thinking in terms of bioterrorism and homeland security as a rationale for action.

It is revealing, too, to contrast protecting against a public health threat with the case where we buy insurance as individuals. When we individually insure against theft, for example, the insurance companies know it is of more value to us individually to protect against the possibility of loss than on average it will require for the whole population to be protected against the cumulative loss. That is why insurance companies make a profit. In the case of insurance, the community pays more than is required to protect the whole population because individuals are willing to pay more than the average population loss to guard against catastrophic loss for the individual.

In public health, often the situation is inverted. The benefit to the population is virtually certain to outweigh the cumulative individual risks. The case of smallpox — as a low likelihood-high consequence

event — has more uncertainty about whether the population benefit will outweigh the cumulative individual risks.

Naturally Occurring Disease Versus Intentional Infection

A second point of difference between what we have in bioterrorism and what we have had traditionally in the public health preparation for infectious diseases was alluded to already by Georges Benjamin. That relates to the difference between a natural phenomenon and an intentional phenomenon. I would like to emphasize one particular aspect of that difference, and it may be illustrated this way: When a public health program immunizes against influenza, you don't expect that the flu virus is going to decide then it's just not worthwhile trying this year to infect the population. (*Laughter.*) There is no countervailing intelligence that is going to respond in that way to the preparation. However, in the case of bioterrorism, a result of an intentional act, preparation may in fact deter the threat. Or putting it more realistically, protection against one threat may deflect a would-be terrorist toward another, potentially less severe threat.

There's a corollary to this which is sometimes referred to by the engineers as the $(n + 1)$ problem. The $(n + 1)$ problem goes like this: You guard against n possible threats; the terrorist picks $(n + 1)$. You protect the airplanes; you protect the buses; you protect the subways; the terrorist will go after the train. You protect the train; the terrorist will remember shipping. You guard against n diseases; the terrorist will pick $(n + 1)$ disease to go after. That is not a very comforting reality, but the counterpart of it is important; namely, that what we do in preparation also can have value in deterrence, unlike against the natural phenomenon. So these considerations, I think, are rather salient to our thinking about smallpox, the threat of smallpox, and the response to smallpox.

What I would like to point out in a few minutes is a little bit of background about the way in which the Institute of Medicine approached its task, the rationale for it, and the preliminary results. I should mention that available is a complete copy of the first letter report that was issued earlier this month by the Institute of Medicine on the implementation of the smallpox vaccination program.

The Role of the Institute of Medicine (IOM)

I'd like to give you a little background on the Institute of Medicine, then say something about the origin of this request to the IOM for advice, and then come to four key points that emerge from the initial level of analysis. As you will see, these points have been reflected in various ways in the comments which we've already heard this morning.

The Institute of Medicine is a part of The National Academies, and acts under a charter granted to the National Academy of Sciences by the U.S. Congress in 1863. That charter establishes an independent body whose purpose is to advise any agency of government — we now say, to advise the nation — on any matter of science or art. Now art at the time, I hasten to add, referred to the practical arts, what we would think of as technology today. From the beginning, this entity was structured outside of government yet founded to help the government and the nation understand complicated problems and formulate sensible policy. This independence, yet relatedness to government, is in my mind an “arm's length, tightly-grasped” relationship and a very important part of why the Institute of Medicine serves a distinctive role.

When asked to assess a problem and to give advice, the Institute of Medicine typically assembles a committee of experts who always are volunteers not compensated for their time, who come together and over a period of time deliberate, investigate, hear testimony, and sometimes organize workshops. They are able by a special provision of the Federal Advisory Committee Act to hold closed sessions of deliberation and, in the end, produce a public report on the subject.

Even with classified reports, The National Academies always publish a public report. I would like to stress that what the Institute of Medicine has done on smallpox was requested by the Centers for Disease Control and Prevention (CDC). So it is not a matter of individuals coming together under some auspices to think about the problem. It is from the beginning, from its conception, a searching request from the CDC to do everything they can to make the program work more effectively. That request came to the Institute in September of last year.

The mandate to the committee specifically was to cover eight topics: the informed consent process, the screening for contraindications to vaccination, the system in place to assess the safety of the smallpox vaccine, guidance to the nation on coping with complications of vaccine, the training of people throughout the nation to carry out the programs that the

CDC is developing, the communications strategy that was being pursued and specific activities, the guidance that the Centers for Disease Control and Prevention were in turn sending to the states for the development of state-based implementation plans, and, finally, an overall assessment of the progress being achieved to reach the goals of the program.

It is a wide-ranging and well-framed request. Typically, when the Institute of Medicine undertakes a study it produces a single report at the conclusion of a searching, deliberative process typically extending over many months. In this case, the Centers for Disease Control and Prevention asked for a series of reports that would provide closer to real time guidance as the program unfolds. They were not looking for someone to judge in retrospect, "How well did we do? What about next time?" Instead, they were asking for an advisory group prepared to assemble, to evaluate, and to report on a regular and ongoing basis, "How can we do better as we are proceeding?"

IOM Committee on Smallpox Vaccination Program Implementation

The committee met in mid-December for the first time over a two and a half day period. They heard from a wide range of individuals, including some with international experience, a number of people involved in preparations for the program at all levels. They had a public workshop as a part of that program. On the basis of those initial deliberations and, of course, the expertise that the committee itself brought to the question, they were able in the space of about a month to issue their first report. The report contains, in all, twenty-three specific recommendations. What I want to share with you today are four key messages that emerged from the report and use that as a springboard for us to return to our discussion.

Committee Recommends Vaccination as Part of the Public Preparedness Policy

The first important message was the stress laid by the committee on understanding smallpox vaccination as a public health component for the national bioterrorism preparedness policy. This was the committee's way of emphasizing what I take to be the kind of perspective that I spoke about at the outset of my remarks. The committee said it was crit-

ical to focus on scientifically based information and to make certain that in all the communications, particularly in the informed consent form, that volunteers understood that they were serving a public preparedness purpose, a need for service to the nation.

I will add parenthetically that I believe that this public service feature provides the most powerful and compelling rationale to put in place a sufficient compensation system for side effects and consequences to vaccination. The volunteers in this phase of the program are not taking the vaccine for self-protection. They are taking the vaccine to protect the community. I believe there is a concomitant responsibility to provide them the assurance that they will not suffer from loss of income and for additional medical expenses because of that public service. I think it more resembles service in the military than it does a traditional public health vaccine program. This is quite apart from the practical question of whether the absence of this kind of assurance will diminish the number of people who are going to volunteer. However, in public policy, Dennis always reminds me, he never objects when pragmatic concerns and principled concerns happen to coincide. (*Laughter.*)

Committee Recommends Proceeding Cautiously with Vaccinations

The committee went on to its second key message — really, the heart of its report — and that was to proceed cautiously. By cautiously what the committee meant is to allow for a continuous opportunity of adequate review and reflection as one proceeds through phase one, which is the initial 500,000 vaccinees in the medical community, and contemplates moving beyond that to the larger number of vaccinees. I want to emphasize, this was not a recommendation to delay initiation of the program or even to slow down the initial immunizations. It was rather to emphasize the importance of learning as we go. I want to stress that in part because some of the news reports tended to lump stories about the committee's recommendations with announcements from some hospitals that they were not planning to participate, or with letters from public unions urging the government to delay vaccinations.

I want to stress that the caution expressed by the committee was about learning as we go, not about failing to begin. To me, that is a very important distinction. I personally believe that one of the strengths of our system of local variation, and there's huge variation locally, is that

we may be able to learn from that natural experiment in order to see what has worked effectively and what has worked less successfully. That will be true within a state, certainly one as diverse and populous as New York, as well as for the nation as a whole.

Committee Recommends Proactive Communication About Vaccination Risks

The third key recommendation from the committee was to use a range of appropriate methods to communicate proactively, to train across the board, and educate diverse audiences as well as the potential vaccinees about the relevant understanding they require to fulfill their role. This is a huge undertaking and at the heart of what Carol Ann stressed so cogently in her remarks.

We can expect that there will be coincident-adverse events with vaccination, particularly as more people get vaccinated. You have to anticipate that, prepare for it, prepare for the way you treat that kind of occurrence in the media and not just nationally, but everywhere. This is but one small example of what needs to be anticipated and prepared for above and beyond the fundamental educational requirements.

Committee Recommends National Spokesperson for Vaccination Campaign

The fourth recommendation of the committee was that the program at the CDC and for the nation should designate a credible, trusted scientist as a national spokesperson, an individual who can sharpen and expand communication at the time it is most needed, when the public is most concerned. That is not the time to begin to wonder, "Who do we put in front of the camera?" Rather, it is now the time to decide who that will be and to prepare adequately with the media with all of the cooperation required to get accurate and timely information before public and not to get scattershot stories, potentially alarming the public unnecessarily.

When you think through all of the elements of this program, and then you amplify that by every possible biological threat that must be prepared against, and you amplify that by all of the threats to other vital elements of infrastructure in society, whether it is our transportation system or our energy system or our information system or our commu-

nication system, etc., you can anticipate how substantial the challenge is to us at every level to prepare adequately for the new world of homeland security. However that task is carried out, one thing we can be certain is that it will still require local implementation of national policy. That remains a dramatic challenge for us, and it is why discussions such as this and institutes such as the Rockefeller Institute have such a key role to play.

Dennis, I'd like to suggest that we open the floor to comment and discussion. I'm really eager to hear from the reflections of those here as well and look forward very much to participating with my colleagues in the discussion ahead. Thank you all very much.

Questions and Answers

1. Question from Bob Westfal:

In the roughly sixteen months since the five anthrax letters have been around, we've had five people die of anthrax. We've had several of those and I don't know how many died from E. coli and other things. How can we engage our decision-makers to look at not bioterrorism but biologic security as the national concern?

Response from Dr. Carol Rauch

Well, just to make a tiny comment and then defer. I have for a long time promoted not using the word "bioterrorism" in the hospitals. I attempted to call everything the infectious disease emergency. Whether it's natural or manmade shouldn't matter as much as in someone's semantics. The names that you give things do carry some weight as we move forward.

Response from Dr. Georges Benjamin

Yes, we do always try to emphasize the importance of every type of infectious disease. There's always this huge tension, as you know, between the locals who are advocating for the dollars and building core public health infrastructures in the states, which use the word "bioterrorism." The truth of the matter is that if you put these systems in place and use them every day for everything and again show policy makers the importance of these systems in everyday life then hopefully we will get some support for them.

Response from Dr. Harvey Fineberg

I'll just re-emphasize the point that Georges is making about dual use. It actually has two parts to it. One is that investment in laboratory capacity, in human capital, in information systems, in all of the surveillance capacities, actually provide us with protection against the natural as well as the intentional infectious emergency. Georges noted earlier that familiarity with the operation of the system on an everyday basis is a very critical part of being able to utilize that system in an emergency. So it wouldn't do us any good to have a separate emergency capacity that wasn't incorporated into the daily responsibility of our critical public health and other front line service workers. This creates an added impetus for the dual character of the investment for protection.



Dr. Fineberg responds to a question

Response from Bob Westfall

The point of my question is that we're irradiating the mail but we're still discussing (and not acting) on irradiating the ground beef. I'm afraid the public health agenda is getting captured by the "weapons of mass destruction" agenda as opposed to the need for biological security for a variety of diseases

Response from Dr. Harvey Fineberg

I personally think that's a valid point.

Response from Dennis Whalen

Part of that as well is to try and avoid the political expediency that sometimes comes with money. There needs to be a discussion about the larger issues and the realities of being prepared on a whole range of things. Frank Thompson has a question?

2. Question from Frank Thompson

I enjoyed all of your remarks. There were several mentions of the communication challenge, the false assumptions about anthrax, the desire at the Institute of Medicine to base their recommendations on science. I'm thinking about the anthrax event. We had a profusion of public figures get out and say, "not to worry, we know about anthrax." Then one unexpected thing after another happened. My question is, in terms of sort of the lineup of major bioterrorism threats and obviously smallpox plague are we pretty confident that our scientific knowledge is better than it was in the case of anthrax? So as we talk about planning, we're not go-

ing to have the sort of embarrassment and perhaps reduced trust that resulted from some of the pronouncements in response on anthrax?

Response from Dr. Georges Benjamin

I think it would not and I'll tell you why. I think we spend a lot of money, time, and effort on basic science and I think that's good and I think that needs to be done. But I think there's a whole range of applied public health science that just is not being funded and done with public health practitioners in mind. A study that was done by the Canadians where they had a room and they simply opened up a letter with anthrax showed that opening up a letter can inundate a room with spores, was a very, very important study. It had been floating around for months but the general population, public health population, didn't know about that. It would have made a tremendous difference in responding to the anthrax attacks. Can you take smallpox and put it on a letter and mail it? I don't know. The science just needs to be done and I think we need to ask ourselves all of those questions. Some of them are odd but they need to be asked and tested to reassure the public. Practitioners need to be part of that process. We need to think about the patient community as well.

Response from Dr. Carol Rauch

First of all, I support Dr. Benjamin's comments and I recall that I was lecturing just a few days before the anthrax cases that even if you got one of those letters and you opened it, unless there was a dispersion device, don't worry about it. So obviously it was a very painful lesson.

I was weighing your question and your comments around the issue that much of our basic science knowledge is based on the naturally occurring disease. We certainly at some point need to factor in whatever was done in the offensive bioweapons programs to engineer resistance. Also, we've never taken the basic science arena or public health knowledge and added in the role of intent. The unique features of the anthrax spores all along, to me, weren't the numbers. It was all related to the milling process and that means that it wasn't anthrax somebody's playing with to learn how to vaccinate the cattle. These were people were in the business of knowing how to do maximal damage. The basic science that is needed is not just the organism or what does the disease look like as we have seen it in a textbook. You won't find anything on inhaled botox anywhere; there is no natural basis of information in the literature. We're going to have to start from imagining what that looks

like when it's used for intentional efforts to do harm. That's a very scary undertaking and I agree the key is to do research and focus at that.

Response from Dennis Whalen

This speaks to the importance (and I'll ask Dr. Fineberg to comment on the recent NIAID, RCE proposal) to build exactly the scientific capacity that is needed in the state. I also wonder about the first part of Frank's comment, which in some way speaks to the IOM recommendation for a trusted, credible spokesperson because these situations are often ones where the government propensity is to speak with certitude absent full evidence.

Response from Dr. Harvey Fineberg

Dennis, you're leading exactly to the point I wanted to make — the need for a two-part strategy. One part is to conduct the research, the inquiry that will inform more and more securely what is possible, what is likely, what is not likely. The second, however, is that the state have prepared the individual or individuals who have the credibility, the knowledge, the access to current information, and who can in turn reflect accurately (not with greater confidence than indicated and not with greater alarm than warranted) what the situation is, what is being done, what now individuals should do in a way that is reassuring, not because the situation is itself calm but because the confidence one can then have that those in charge really know what they're doing and what they're talking about.

3. Questions from Karen Ballard

You're discussing something that is an ongoing concern to me. If we remember what it was like in the early days of the HIV/AIDS epidemic; it was like a moving target. The information you would get from credible people changed as our knowledge increased. It seems to me that we're having a similar problem with biological weapons. I've spent the last few months of my life now coming to meetings on smallpox and I was at the New York Academy of Medicine and a very credible speaker from the New York City Department of Health did a presentation. A week later, they changed their recommendation and that has happened on the national level. If you read recommendations in June as opposed to October, there are significant changes. So, yes, you need a credible person but how do we address and handle the shifting in the information so that it doesn't diminish people's sense of safety? I think that's be-

coming increasingly problematic as we look at the types of messages that are being delivered.

Response from Dr. Georges Benjamin

The concept of shifting information is very important. It's not new to medicine. When I was an internal medicine resident, the giving of nitroglycerin to someone who had a fixed coronary occlusion (i.e., he was having a heart attack), was grounds for throwing out your residency because it was believed that it did not work. The point is, by the time I finished my residency, it was the drug of choice for acute coronary occlusion, a three-year period. It's not uncommon for us to change dogma.

What is uncommon, or what the general public are uncomfortable with, is that we don't have an adequate explanation for the shift in dogma. What we found in anthrax was people making recommendations who had more knowledge than we did and we were unwilling to accept their recommendations because we didn't understand the reasoning behind some of the decisions. I have to admit in some cases the decisions were faulty. For example, the assumption that you can only get sick from 8,000 spores. I think we have to become comfortable with not just telling people the dogma has changed, the rules have changed, the recommendations have changed, but saying why.

People that do natural disasters, EMS people, are very good at that. They instruct the public to "go over this road when there is a disaster." When they get back on TV they say, this road is now flooded out and therefore we're going to change the recommendation for this reason in terms of traffic management or this or that. They've gotten pretty good at doing that and I think we just have to be as good at it as they are.

Comment from Dennis Whalen

Carol, one of the key points in your presentation was this aspect of communication. We are set on a landscape now where time frames are squeezed so it's not the three-year change, it's the three-second change; the speed of communications, the desire to have every bit of information. What's your view of this question?

Response from Dr. Carol Rauch

I'm supportive again of both of my colleagues here and I think it's a brilliant plan to have a spokesperson be an idea that is promulgated at the highest level from CDC. That person ideally would be able to be honest and would be able to provide their reasoning process behind

some of this. We went through this with the Cipro change to Doxycyclene and everyone was saying, "Oh, anthrax is getting resistant to Cipro." The subtlety is we were a little nervous about respiratory passages, etc. We need someone who has the credibility because they know that from their own understanding they are able to say this is the limit of our knowledge and this is our current assessment.

I think what Dr. Benjamin said about the disaster management, "this road is out and now we're moving here" needs to be the frame of any communication that goes out. We have a joke in Massachusetts that the Xerox machine has "Draft" permanently written on the glass, especially for anything with smallpox. You just get in the habit of saying, "Our current understanding is this; here's a couple of reasons why," etc.

One of the points that I made earlier to some members of the media is we don't hear that "Someone made a mistake: someone is at fault; this was wrong and now we know this way." None of those ways are every fully right; they're always an integrated assessment of current thinking and whatever resources we have. That could change and should be expected to change in everyone's mind on an ongoing basis. One of the challenges is to keep up. This is akin to when people say they never get a straight answer from their doctor. You're never going to say, "do this or do that" as if it were black and white; it's always within the contextual framework that is subject to change with time. I hope whoever is the public health spokesperson is able to verbalize that.

Comment from Dennis Whalen

We need to have an increased time tolerance to avoid the thirty-second sound bite or the one-sentence answers that are so common in today's media.

Response from Dr. Harvey Fineberg

I think the responses have been wonderful, but the problem will remain. I think we are in a mode of learning always about what is the best thing to do. Maybe we could improve a little as if there were better understanding of the contingent character of all the recommendations, indeed of all scientific knowledge. The whole purpose of science is to continually learn which of your current convictions no longer can be supported by evidence because you've refined your knowledge by further experiment or further observation. Sometimes the public expects science to be predominantly enduring truths. Scientists every day are working to learn which of their current beliefs isn't

exactly the truth. That's a very different frame of mind. I think the capacity of people to appreciate that contingent character of such recommendations is going to be tested again and again as we confront new threats.

4. Question from Thomas Constantine

I come from a law enforcement background and I can't tell you how important I believe that you'll be in the future. If there is a threat of biological instruments and weapons of mass destruction, I think it's going to be important to remember that the terrorist usually will be an organization, maybe state-sponsored. Their purpose is not necessarily to kill people; their purpose is to destroy this country and bring the country to a halt. If there is an outbreak of smallpox that's attributed to an act of terrorism and people are afraid to go to work, people are afraid to associate with each other, industry stops, everything. Their ultimate goal would be achieved: to destroy the United States at that point in time. It's going to be critical that there be calm voices with intelligence who are able to advise all of us.

I'm somewhat concerned now in looking at the smallpox situation and I can't get a full handle on it. Why are we starting to say that smallpox is this great eminent threat as opposed to other threats? And secondly, most lay people don't look to you almost as with godlike qualities, to understand these things. But when directors of hospitals announce that they are not going to go ahead and provide immunizations at their hospital people to people in a critical care situation, it causes a lay person to sit back and say, if they say that, they must know what they're talking about. I think it's going to be extremely critical. As tragic as 9/11 was, if you hadn't had a mayor who rose to that occasion to make this country feel confident, I can't tell you what would have occurred after that. A different reaction might have been catastrophic. So anything that you can do is going to be extremely important for the rest of us.

I've done a lot of work in Northern Ireland where there has been a lot of terrorism and the IRA can say, we only have to be lucky once not necessarily lucky all the time. So there is no way to protect everybody from all of these situations.

Response from Dr. Carol Rauch

I have just a comment on the (n + 1). We will benefit from the deterrent effect of smallpox vaccinations. But I would also add that during

the process of preparing, removing whatever the n's are, we're practicing the whole concept of preparedness. We are not switching business cards on the fly during an incident. We're having the meetings, we're working it out, we're learning about each other's needs and what is required for the system to work.

I think that there is value beyond just the deterrence in preparing for the n. But it teaches us something; just going through the motions and all that, I think will be a very good experience to have under our belts.

5. Question from Jim Fossett

One of the things I think that all of you have said is that dealing with this effectively requires a lot of complex organizational and small "p" political kind of interactions with different levels of government and different kinds of actions. I guess my question is, is that side of the house as well developed as the clinical side? You've all talked about the big cultural clashes as we try to get the medical care community and the public health community to see eye-to-eye on things. If you bring in law enforcement, it gets more complicated yet. The rule of thumb is that everybody wants to be in charge and they want somebody else to pay. Is there a stable, sensible kind of organizational structure that we need? Do we have some idea of what it looks like or is this going to be ad hoc with everybody scrambling around trying to find a business card or somebody to get in touch with? Can we respond to this in an organizationally stable kind of way where everybody is on the same page and has a rough idea of what they're supposed to be doing?

Response from Dr. Carol Rauch

If you could answer that, I would give you a Nobel prize. I'd say you're correct. You're a little behind; it is ad hoc from my level anyway. I'm at the front line and the other presenters today are up a bit higher. For example, Ben Marcus, the Harvard faculty member I referred to earlier, went to Israel during their recent revaccination campaign for smallpox and has been relaying his experiences and attempting to put that together as a model of what it looks like for them. They have a whole different way of life; they live with a whole different impetus for daily preparedness that they've had for a long time since the Scud missiles. I'm not sure that that model will directly translate to us; I don't easily see our health care and military aligning into one workable unit the way theirs is.

What it should look like here? I'm less certain. Whether it's the right word or whether it's the right image, I'm certainly not there and I think it's going to take some time. I've been thinking about this and reading and every book on my night stand has the word "plague" in it somewhere. I still haven't achieved what this should look like but I think you've hit on what is the essence for why we're here and why this is in the media every day. What is it that we're aiming at? What does it look like? Otherwise, we're not going to know if we've gotten there. This type of group, the people that are assembled in this room is potentially a very critical type of experience to have. To have these types of backgrounds brought together to discuss how the different parts should work together. I don't see it being an agency.

The concept of homeland security is intriguing and, to me, I see parallels of it all over the place. In my hospital, for example, the committee on infections versus emergency management, they don't really work together very much but that's what it will take to address this issue.

Response from Dr. Harvey Fineberg

Well, I think we can do a lot better than exchanging business cards at first recognition of emergency. I am equally confident that there is not a perfect organizational solution to this problem that we could ever achieve and say, "Ah, now we have resolved the communication problem and no longer have to be worried about it.

It's evident to me that some organizational impact is desirable and maybe more at every level will need to be done. The formation of the Department of Homeland Security in itself at a national level represents a reorienting of a collective mission of a group, a quite large group of federal agencies around a mission that is somewhat different than the missions previously construed for many of the pieces.

I'll leave it to those who are more experienced than I in analyzing bureaucratic reform, but my personal impression is that many of the components of other federal agencies drawn together around homeland security did not play in their originating agency a core part of the mission of that agency to the extent that they now can play, organized around homeland security. You'll notice that the FBI and CIA remain in their respective relationships, that biomedical research, which in an early formulation was thought about in terms of security, has been left within the Department of Health and Human Services through the NIH and the CDC.

All of this leads to me to the fact that however we structurally adapt, we are going to continually need to establish linkages across natural bureaucratic organizational boundaries. If we are going to cope with these exceptional circumstances, we have to have ways of making those communications as natural a part of the working life of people in various agencies as service within the agency itself is. That's a big challenge; a task that is like constantly working against inertia. If you ever let up, things revert to their original state. How we can instill that sort of constancy of pressure to establish and maintain the levels of interactive response capacity, that's really the biggest organizational challenge, which is not structural but operational.

Response from Dr. Georges Benjamin

I think the whole issue of intergovernmental relations is difficult. You can't just set up a structure that's uniform and universal. I do think that planning is everything in terms of making sure that you have some understanding relationships. If you don't practice them, nothing will happen. You have to recognize that you have to have a broad collaboration and that you have to be flexible enough. Whoever said that the plan will never survive engagement with the enemy is absolutely correct. So the minute something happens, it is relationships and the knowledge base as developed in the planning process that engaged you to be innovative when things change and they always do.

6. Question from James Crucetti

Thank you, Dennis. Thanks to the panelists for a very interesting presentation. I'm a local health professional and this is my home. I am working with a lot of community partners outside this building to implement locally this federal policy. I deal with whatever is pushed at the federal level and goes down through the state health department and down to the county level. The domino is teetering outside the county boundary. Some people who are in the county have tried to play dominoes and they have trouble playing dominoes.

My question is all the panelists mentioned the importance of communicating clearly and effectively. One of the participants questioned what do you do when science changes — but right now the question that I'm hearing is: "What is the risk?" There's no imminent threat but we've being asked to volunteer to do something when there's a known risk, albeit small, the potential to have an adverse reaction to the small-pox vaccine. So people are saying why should we do that? Those of us in

public health don't want to be in a position where we are advocating something that can do harm. So we're trying to deal with what is the threat of the disease of smallpox and how can I balance that as a potential volunteer to the known risks of the smallpox vaccine?

Also, I think we run the risk of sending a mixed message. After September 11th, we put together a plan in this county that would be a typical public health response plan. If we had a case, like September 12th, of smallpox, if we had a case tomorrow, I have a high degree of confidence we would have an effective smallpox control program with an unvaccinated health care response team, a public health response team. I think we could minimize the exposure to health care workers, to public health workers, to patients in hospitals. What we are saying with the current pre-event vaccination program, is that we need health care workers to be vaccinated, to be available 24/7, to care for smallpox patients. Then the question arises of "Well, we thought we were O.K. without having a pre-vaccinated work force?" It sounds as if you have to be vaccinated to provide care so those who cannot be vaccinated, because they have contraindications, who work in hospitals, are not likely to show up if there's a smallpox case in the hospital.

We really have some important challenges when it comes to educating our potential partners or volunteers in this program. What we are doing, I think by default, is developing right now a smallpox vaccine response plan. All of the questions about giving vaccine are now focusing on things like the risk of transmission. In hospitals, these issues are occupying lots of time. It's affecting potential volunteers. We really need to be able to communicate clearly but the explanation sometimes is very difficult to communicate.

Response from Harvey Fineberg

I think every question that you've raised or conveyed on the part of what you're hearing is a valid question and a serious question. Part of the mentality that I think we need to bring to this exercise is a public safety mentality, not a conventional disease prevention mentality. That does imply that individuals who participate may be subjecting themselves to risk and that the screening for susceptibility to side effects is a critical part of the program that needs to be in place.

If so many hospitals have participated, has there been any case of transmission from a vaccinee to a patient in the hospital? If so, how did it happen? Some of the questions will be mitigated over time by experience. But that will be a group who will be relative resisters who will re-

quire that much more information. Remember that the program from the outset has been structured as a volunteer program. I think that is a very important element of the program.

I had mentioned earlier that the concomitant responsibility to provide financial protection for those who participate is evident and should be solved. It will eliminate one problem. But the others that you described are very real and need to be addressed patiently, sympathetically and honestly. And I believe that over time the data, the evidence, the learning that will go on, will help drive the program one way or another, hopefully to a point where you eliminate one element of being unprepared.

Response from Dr. Georges Benjamin

The other way of thinking of this is from a response team perspective. What we're asking people to do is create a team, public health teams, hospital teams, and that should be trained in a broad range of skills for each of those teams. You get vaccinated for smallpox as one component of the duties. The reason for that truly is a simple one since about a third of the people get sick after they get vaccinated. It makes no sense to have a team that you think is ready to go and vaccinate them on day one and then a third of them will be out of commission. You have to multiply the size of your team by three. If you really want to have a response team, you've got to have them pre-vaccinated so they're ready to go. That does not talk about the health care workers, and phase two doesn't talk about the whole population. I think we may have explained this role to people so the people better understand that.

Response from Dr. Carol Rauch

I have a few comments to add. In addition to the one-third of people who might be not at their optimal functioning capacity after receiving the vaccine, we also don't know who's had a take until a week after the vaccine has been given. So to all of a sudden wait till there's a case and we're doing a mass campaign and we are trying to figure out who's been successfully vaccinated or not, is not optimal.

In addition, certainly the logistics must be taken into account. To ask the nation to go from a standing start to a mass vaccination campaign without a cadre of trained, oriented and already-vaccinated people is very difficult. Even at the level of a hospital, someone was asking me earlier what do I think about the hospitals who have declined in participating in this. I know of about eighty across the country that have individually decided this isn't for them. To do this in a forthright planned manner with

enough time to go through the contraindications, etc., we're really making it as safe as we can under these relatively quiet circumstances.

To have a plan that says "we'll worry about it when there's a case" creates a chaotic environment. It's certainly better to start with some experience that has been documented in a calm environment. This campaign is a very safe, small baby step to get started. Those are things that I factor in to my reasoning. I agree that the whole reasoning process really has to get down to the implementers at the very lowest level.

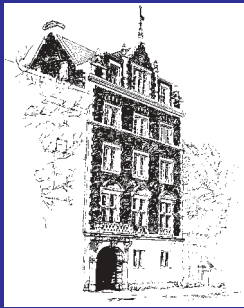
Concluding Remarks — *Dennis Whalen*

I want to thank the speakers for the level of discourse today. It is exciting to hear these topics discussed with an intelligence that can help enlighten the kinds of problems that we face, point us to ways that we can think about these issues, and perhaps even sort of push us along on the way to finding a solution. It's quite clear from today's discussion that again, this is the start of a much longer process and discussion, one that needs to be ongoing and deliberative as we try to contend with all of the issues of getting prepared at the state and local level. We are fortunate to have close at hand our great State University and its School of Public Health — which is a federally designated Center for Public Health Preparedness. And also to have the marvelous Rockefeller Institute. I want to mention that today's event is so reflective of the extraordinarily important role that the Rockefeller Institute can play in these public policy discussions. And with that, I'll ask Dick Nathan to give the closing comments.

Closing — *Richard P. Nathan*

Thank you, Dennis. This was great. It was just the kind of a kickoff I hoped to have for this series of meetings. To follow up on Jim Fossett's question, I want to make a comment. I want to think about how the people in this field, the public health field, deal with all the other actors and agencies and levels of government that have to be involved. It is, as many speakers have said, a challenge for federalism. It is a challenge for our political system. That's what we care about — that's what we want to work on. So we're going to continue this.

Most of all I want to thank our speakers and I also want to thank Dennis Whalen. Dennis talked to all the speakers beforehand and spent time planning this program. He's been very involved with us at the Rockefeller Institute in other enterprises. So to Dennis and the speakers, I thank you all.



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