



# **The U.S. Medicine Institute**

## **For Health Studies**

*Proceedings — Forum for Decisionmakers*

**Surge Capacity —**

**Is It Time to Move Beyond “Just-in-Time”?**

**Washington, D.C.**

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## ***USMI Purpose***

**The U. S. Medicine Institute for Health Studies (USMI) stimulates and promotes analysis, interaction and debate on critical issues in medicine. Believing federal health programs can be a national laboratory for research and practice, the USMI provides constructive opportunities for discussion across public and private sector lines. It works to translate innovative thinking into practical application through open dialog. USMI particularly endeavors to support and develop critical examination, initiative, and creative thinking within leaders of the future.**

**Managing Directors**

**Nancy E. Tomich and John S. Zapp, DDS**

# *Executive Summary*

The U.S. Medicine Institute for Health Studies, which seeks to enhance communication between federal officials on significant current issues — and among the federal and the private sectors — held a forum on June 17, 2002, to address steps that can be taken to enhance our nation's surge capacity, that is, the ability to care for a sudden, large-scale influx of casualties into the healthcare system. The most likely scenario would involve a chemical, nuclear or bioterrorist incident.

Panelists and participants in this forum, who included more than 100 high-level officials in government, industry and academia, agreed that too little attention has been paid thus far to surge-capacity requirements. They did not, however, always agree on what those requirements may be or who should have responsibility for ensuring that they are met.

These proceedings present the remarks of forum panelists and the ensuing discussions among participants. Slides that accompanied several of the panelist presentations can be found at the USMI website: [www.usminstitute.org](http://www.usminstitute.org).

The following issues were particularly prominent in the forum discussions:

- ***Stockpiling vaccines and pharmaceuticals.*** The National Pharmaceutical Stockpile (NPS), which is managed by the Centers for Disease Control and Prevention, has been given a substantial funding increase following the September 11 attacks and the October 2001

anthrax incidents. Currently, NPS maintains 12 push-packages around the nation, each of which contains sufficient stocks to treat 1 million individuals in the event of a terrorist attack. But there remains some uncertainty as to which items need to be stockpiled on a large-scale basis, as is being done with smallpox vaccine. Rotation of stockpiled items remains a concern.

- ***Vaccine shortages and production difficulties.*** Vaccine manufacturers have shed excess production capacity in order to remain profitable. Consequently, there is no quick way to ramp up production to meet perceived requirements for surge capacity. The current federal contract for production of smallpox vaccine offers a workable paradigm for meeting national vaccine requirements, in that it guarantees federal purchase of a specific amount of vaccine while allowing the manufacturer marketing rights outside of the terms of the contract. Additional actions that might be taken to facilitate a ramp-up in vaccine production include easing current regulatory burdens, allowing discussions among involved parties without fear of anti-trust action, and easing product-liability concerns. Remaining questions: who is responsible for maintaining a surge capacity in pharmaceuticals, and who pays for what?

There may be a need to stop production of routine vaccine products to meet public health requirements. Mass immunization would be made easier by moving away from injectables toward oral vaccines.

- **Personnel concerns.** There is a significant shortage of personnel needed to meet surge capacity requirements, particularly in such fields as nursing and laboratory sample processing. A new program now being developed hold potential for easing personnel deficits during a terrorist incident — a Reserve Medical Corps composed of retired medical personnel who would be called to provide care in the event of an emergency. Formalized refresher training for these individuals is being considered.

Should there be federal licensing for health care providers to enable them to provide care at any site during an emergency situation? One answer may be to make them federal employees, which also would provide indemnification.

- **A shortage of beds.** Hospitals currently are not prepared to handle a large influx of inpatients, as most have downsized and transferred a maximum amount of care to the outpatient setting, in order to remain cost-efficient. Currently, one in eight hospitals diverts emergency care because of lack of capacity at least 20 per cent of the time; one of every three hospitals shows a negative return on the balance sheet. This lack of inpatient capacity must be addressed at the local level, with guidance from the federal government. Solutions must be scalable and expandable.

During an emergency, as happened in the wake of the September 11 attacks, hospitals would move out elective patients to make room for casualties. Alternate sites that might be used, because they have bed space and the necessary utilities, include hotels, schools, and the like. Some hospitals are reconfiguring their hallways and other spaces to accommodate beds and equipment if needed.

- **Need for coordination.** Creativity is essential in moving from just-in-time capacity to a more stable model for meeting emergency requirements. There must be coordination between all levels of government and all players at the various levels. There needs to be a way that officials from government, academia and the private sector can sit down, roll up their sleeves, and dig into issues without fear of stepping on toes or violating anti-trust regulations. There is an urgent need for candor and flexibility in planning for surge capacity, and it is essential to determine just “what we are planning for.”

Above all, there needs to be someone in charge — someone who can mandate the requisite planning activities, ensure and direct the flow of resources and determine that planning actually reaches fruition.

# Forum Proceedings

## **Introduction — John S. Zapp, DDS, USMI Managing Director**

We're very pleased that so many of you who are significantly involved in this timely and important issue could join us and your colleagues this morning. As most of you are aware, U.S. Medicine Institute for Health Studies is a 501(c)(3) not-for-profit organization, and these programs are made possible through the sponsorship of corporations, businesses, organizations, and some individuals who have a vital interest in this topic.

## **Moderator — Hon. P.T. Henry**

I'm pleased to be able to be here and join you today as USMI addresses the question of the nation's Surge Capacity. You know, if nothing else, the events of the past several months have sharpened America's awareness of our nation's vulnerability to attack and have called in to question our nation's ability to respond to a mass casualty scenario occasioned by a biological or chemical attack.

Today's topic, that of Surge Capacity, could not be more on point or timely. Those of you



that have attended the forums in the past know that our goal here is to provide an interactive forum in which we try to bring together decisionmakers, high-level officials from industry, from academia, and from government to take on the tough issues, to discuss them, and if possible, to offer solutions.

## ***Panel 1: How Can We Effectively Stockpile Drugs and Vaccines?***

***Steven Bice, Director, National Pharmaceutical  
Stockpile, CDC***

***Lance Gordon, PhD, CEO, VaxGen***

***John S. Parker, MD, Senior VP for Chemical  
and Biomedical Homeland Security,  
SAIC, and former commanding gen-  
eral, Army Medical Research and  
Materiel Command***

***Daniel S. Shapiro, MD, Director, Clinical  
Microbiology & Molecular Diagnos-  
tics Laboratories, Boston Medical  
Center***

## **Steven Bice:**

Just to give you a brief outline of the National Pharmaceutical Stockpile, I'll run through an overview of it. Our program mission is fairly straightforward: It's to maintain a national repository of lifesaving pharmaceuticals. We received this mission in fiscal 1999 — And CDC discovered out of the 7,000 pages of the National Budget Reconciliation Act that, in fact, we did receive this mission, discovered that we had to staff it and spend the initial \$50 million by January of 2000. In December of 1999, we had our first, what we call a "push package", to respond to Millenium events as

forecasted by the intelligence and law enforcement communities. Fortunately, we didn't have to do that, but within that year, we had to spend our first \$51 million on pharmaceuticals, a modest amount of medical material and supplies.

In the subsequent years, funding was stabilized at around \$50 million, until after September 11th, at which point in time the Congress of the United States increased our budget substantially with an emergency supplemental, so that we're budgeted for around \$644 million for this fiscal year, all of which has been spent.

When you have pharmaceutical supplies and equipment that you have to get out the door relatively quickly, "logistics" is going to be a cornerstone. The operations team coordinates within CDC to get the technical advisors out the door quickly. So, we have a fair number of former military personnel who run the operations cell. "State program preparedness" is in fact in charge of outreach to state and local governments in concert with national medical response teams and other assets in the National Disaster Medical System.

We strongly believed right from the beginning that \$50 million a year could not buy much in the way of pharmaceutical supplies and equipment, if you're looking at an all-hazards approach. You can quickly spend that kind of money in the pharmaceutical arena. So we had to reach out to the private sector to maximize our ability not only to purchase pharmaceuticals — but also not to reinvent the wheel. To do that, we had to secure their participation with the NPS. We're very proud of our private-sector partners. Obviously, the pharmaceutical vendors and manufacturers both in this country and in Canada are key partners.

We feel strongly that we couldn't do what we do in the time that we do it without the pri-

ate-sector transportation capabilities around the country. Although, clearly, we do work with the Department of Defense, DoD oftentimes has missions that tie up its air frames, and therefore, DoD officials suggested and we agreed to go to private sector for transportation assets, such as trucking and air frames.

The 12-hour push packages — we have 12 of them around the United States, each of which can treat about a million people depending upon what the disease is, and a few thousand people for chemical events. They're called "12 hour push packages" because they get anywhere in the United States in 12 hours or less. That does include places as far-flung as Guam, Puerto Rico, and the Virgin Islands, as well. The 12-hour push packages located around the United States are put together under an all-hazards approach; they are quickly deployed, nobody has to stop and think about it. They are packaged in cargo containers. There are about 50 tons of supplies in each of the 12 push packages, and they're located at secure facilities all over the country. They comprise about 20 per cent of our inventory.

Fully 80 per cent of our inventory is in vendor-managed warehouses. Vendor-managed inventory in the truest sense means that we have contracted with pharmaceutical corporations and prime vendors to house and rotate the product. We are at the ceiling of our partners' ability to rotate certain pharmaceuticals, as many of you can imagine. We own more doxycycline than any country in the world, let alone any hospital group or corporation. So, we are right at the ceiling of being able to rotate that product successfully to keep it fresh.

The storage and rapid deployment of vaccines is something relatively new for us. When we first started, DoD had what vaccine for *Bacillus anthracis* there was on the market. We had a modest amount of smallpox vaccine; that

will change dramatically by year's end. We will have in the hundreds of millions of doses of smallpox vaccine. We will store it and we will get it out the door in an unbelievable short period of time, if required. Should that response be required of us, we now have vaccine repositories — very sophisticated locations, sophisticated meaning scientifically sophisticated, and the science of logistics and the science of medicine combined to make these repositories very, very unique in the United States. There are three, soon to be four, such repositories in the country with the ability to store vaccines, the two vaccines that we have. Soon, we will have antitoxin in sufficient amounts to treat far more than we have today. I can't be too specific about the amount.

“Technical assistance” is a cornerstone of CDC activities, and in connection with the disaster medical teams and the Office of Emergency Preparedness, we get out to the states and the local jurisdictions to ensure that they know what we're bringing to the table. It's not easy to plan for 50 tons of stuff that will show up at the local airfield or warehouse, and so we spend no small amount of time out with our colleagues from OEP and our colleagues in the states.

Our “buying power” really concentrates on why we're here today to do; that is, to talk about the ability to surge and the ability to buy. We've been blessed with more than adequate budgets, even from the \$50 million days through the \$600 million that we have today. We spend no small amount of money on contingency clauses and clauses that allow us to work with our partners to enable them to surge in production to meet the nation's needs. We don't want anyone to get stung financially, so we pay for storage fees and a variety of other fees that allow us to get these products out the door.

But we also work with the manufacturers very closely as they tell us of their abilities to surge product.

For us, surge is in hours and days. Unfortunately, when we go into a campaign, we have not planned that campaign, so we do not have the ability to surge in 60 days or 90 days. We must have what we have very quickly on the tarmac around the country. So, unlike DoD, we have purchased a vast amount of product, hard product that sits in warehouses. This is harking back to the old days, but for those of you who remember the Cold War, those storage facilities don't represent anything compared to what we do today. So, I think we've learned from our colleagues in the past, and I think that our product is cared for properly under strict quality assurance/quality control guidelines.

#### **Lance Gordon:**

I am going to be speaking principally on the vaccines front. I have 20 years of experience in the vaccine field and only two as medical director at a small molecular drug company, but I think many of the principles are common.

The development of drugs and vaccines typically takes more than six years. In some cases, such as varicella vaccine, it took 17 years to get that product to market. When you look at the manufacturer's position, capacity utilization is a key factor in profitability. Over the last several years, particularly over the last 10 years, this has resulted in companies' shedding excess manufacturing capacity, consolidating into a smaller number of facilities where utilization is higher.

The greatest shortfall we have today, or limitation on our capacity to manufacture, is in the filling and packaging area. This isn't just because of consolidation. Over the last few years, the use of thimerosal as

a preservative has become unacceptable in the United States and the other developed countries. Consequently, we've had to go from filling in 10, and in some cases 20, dose vials, down to single-dose vials. That's a 10- to 20-fold increase in the number of filling operations involved, and is a major contributor to the shortfall we're experiencing domestically in products such as DTP and a number of others. So there really is not surge capacity today for filling and finishing.

The expansion of manufacturing capacity by building new facilities and by expanding existing facilities is not any easy matter.

It typically takes over three years. Keep in mind that vaccines, as biologic products are regulated by the Center for Biologics Evaluation and Research, are not just licensed based on the product specifications, which is the standard in the drug industry, but also on the facility in which the product is made. Historically, separate licenses were needed for the product and for the facility in which it is made, requirements that still exist but have been merge into a single license. So, you're required to demonstrate consistency, equivalence, and a number of other things for the product made in each facility. You really don't have the flexibility in the biologic product world o just say, well, let's add another plant. The reality is, to respond to immediate need, faster, we will have a price not only in dollars, but also in the quality of the products and the reliability of their performance in the field. It takes time to go through the clinical trials to fully validate a product.

For some needs, such as pandemic flu, smallpox, and some other defense vaccines, it may be impossible to get ahead of an expanding epidemic. I firmly believe, and I think history shows, that with adequate notice and a reasonable recognition of the business realities, U.S. manufacturers are capable of meeting any need. That said, current

capacity is inadequate. If you look at the global supply of vaccines, the world consumes about five billion doses a year. However, United States manufacturers supply in a range of 100 million doses, in aggregate. We don't supply the developing world from U.S. manufacturing sites. So, our volume capacity is not tremendous. We do have the capacity to design efficient systems for meeting surge demand, but that really will happen only through a process of negotiation and collaboration. I'll have a few words later about what I think some of the limitations are in the current systems available to set up relationships with industry. With regard to a company's decision to develop and supply vaccines for stockpile, one of the overriding issues is the opportunity cost. I'm focusing here on products that have little or no commercial market beyond biodefense, like smallpox, anthrax, Q fever and tularemia. If a manufacturer has the opportunity to deploy scientific expertise, development resources, and manufacturing facilities, for a product like omeprazole, which has enjoyed well over \$5 billion in annual sales, using the same resources to supply a product which may actually never be used isn't very attractive. You have a high opportunity-cost barrier.

There is an inherent unpredictability in "requirement" contracts. This was the nature of the National Stockpile contract for smallpox at its original award in 2000. There was no commitment by the government to actually *buy* product once licensed, and that leaves a great unpredictability for the company involved, so I strongly urge a minimum ongoing purchase commitment.

Maintaining surge capacity has significant idle facilities costs, not just the cost of keeping the bricks and mortar in place and paying your debt service, but to really be able to provide surge capacity, you have to maintain a trained and qualified staff ready to produce the product on demand.

That facility has to be kept in validation, and that's a very expensive proposition. You can only really maintain a manufacturing Capacity by continuous use. I'd like to call to the attention of those who are thinking about ways to handle our surge capacity needs, the experience that the public sector, and here I'm thinking about UNICEF, who buys about 60 to 70 per cent of the world's supply of vaccines for the second- and third-world countries.

Ten years ago, there were 14 suppliers of vaccines to UNICEF. Over the last several years, UNICEF has procurement practices, including demand forecast that far outstripped actual purchase and strong pressure on price, that were very damaging to manufacturers. As a result, over the past four to five years, 10 out of the 14 suppliers to UNICEF have either closed production units or diverted capacity and no longer sell to UNICEF.

We've gone from a situation for the global supply where four years ago, we were only using 20 per cent of the global capacity, to today, when we're using 95 per cent of the existing capacity to supply the third-world markets. Ten years ago, virtually all of the vaccines for the UNICEF markets were sourced by the major multi-nationals. Today, 50 per cent of those doses come from third-world manufacturers in India and other places. So it's not just the U.S., it's the developed world industry has really been changing.

That said, I'll have to admit, profitability is up in the vaccine field. Major multi-nationals' profits are higher than they've been in the last 10 years. However, that's been done by discontinuing the manufacture and marketing of mature products — one of our major domestic manufacturers dropped its tetanus vaccine and combination vaccines having which include tetanus, such as DTP. Their profitability has increased by focusing on high-value proprietary products such as the

new pneumococcal conjugate vaccine.

A few issues on the commercial side here. I strongly urge a continuation of what happened in CDC's smallpox procurement process. The government in this case, much to their credit, kept its focus on its objectives, and that is, sourcing a stockpile of 40 million doses of vaccinia vaccine. However, while assuring that the need was met, they did not constrain the manufacturer. Exclusive commercial rights were left with the contractor. This included the right to sell to sell any other federal, state, local, private, or foreign entities. That secondary market opportunity is what made the smallpox contract commercially feasible. So, keep in mind the goals and don't overreach is my rationale here.

A couple of things I think might help in securing surge capacity. Select manufacturing technologies capable of rapid transfer to additional sites. No one manufacturing facility has the capability in the timeframe we might need it to supply product for the entire country, not to mention those allies. A common practice in industry, when products are out-licensed is to assemble a technology transfer package including all protocols, standard operating procedures, biologic materials necessary for the control of the products, and records of non-clinical and clinical information that can rapidly be handed to another party. My suggestion is the creation of a network of prequalified sites, that is, other manufacturing sites that have teaming agreements with the primary manufacturer to allow for the rapid expansion of manufacturing capacity. Certainly, there are ongoing considerations of possibly creating a GOCO [government-owned, contractor operated] or a COCO [contractor-owned, contractor operated], or otherwise funding the private sector to create government service divisions.

One final issue which I think this is an enor-

mous dynamic in the biologics field, is preservatives. In order to provide product in multi-dose vials, a preservative must be used to insure sterility. The only preservative approved for use in vaccines in the U.S. today is thimerosal. However, since it is a mercury derivative and now considered potentially unsafe, it no longer is being used in the U.S.

Vaccines are now supplied in the U.S. only in single-dose presentation. That will significantly increase the cost of building a stockpile of vaccines for biodefense as well as strain our capacity.

The program to build a national stockpile of smallpox vaccine shouldn't give us confidence regarding other products, since, for unique reasons, vaccinia vaccine is being supplied in 100-dose vials. To supply the same vaccine in single-dose containers would be physically impossible, and I think that needs to be kept in mind as we arrange for national stockpile.

I suggest a loosening of the constraints that the Federal Acquisition Regulations put on negotiating the best arrangements. Product liability is a continuing issue. Many of the specifications for these products are dictated by the government. My recommendation is that, to the extent the government dictates the specifications of the product and how it's to be developed, the government should provide indemnification. Further, that for doses sold outside of the national stockpile, these vaccines be put into the National Vaccine Compensation Program, and that companies be responsible for any product liability associated with international sales.

#### **John Parker:**

I'm going to drop some facts and factors here. I think of the world in a series of triangles. And to get to a right decision, especially in Washington,

involves not just the scientific facts. If you ignore the political decision, or if you ignore the financial decision, or if you avoid the law, you're not going to get to the workable solution. You may get to the right decision, but you won't be able to execute it. So, the idea is to try to keep that compass point fairly north as much as possible, but be ready to be flexible with a few degrees to the right or a few degrees to the left to get that.

Now, if we continue with this goal of a surge capacity, we need to think of do we have the manpower to do it, do we have the dollars to do it, do we have the political will to do it in this nation, and are there policies and statutes in place that allow a surge capacity? Why do we want surge capacity? Well, our real goal is consequence management, and that's why we do all these other things; it's so that we can handle a situation if we're faced with it. On the manpower side of consequence management, there are multiple types of manpower from industry and the government for consequence management. We're talking about multiple products and services. We don't even know all the products that we need for consequence management, and that's a basic problem, and we don't know all the services that we need for consequence management, because we have experience only with an anthrax outbreak. On the dollars, if we're really going to have a program for consequence management and a surge capacity and a capability, that's going to take major coordination on the Hill with budgets and programs down into the agencies, and I hope with Governor Ridge and with the new Homeland Defense Agency, the ability to coordinate will be much better.

On the bottom, we have will. I'll tell you, this is a remarkably resilient nation. There are people who are already putting 9/11 in the deep, dark

history books in their lives, and the biological terrorism is in the deep history already, and so maintaining a will in this country to drive that is very, very important. If we look at consequence management, we have a huge area of distribution and storage; we've got manufacturing production lines and we've got a tremendous need for raw materials.

At this moment in time, the standard in industry is just-in-time delivery of the raw materials, running the production line, distribution to the user, and are we going to have to change that a little bit? Even with the great work of the CDC, we haven't changed the just-in-time Business, because CDC has the money, the manufacturer will produce the product just-in-time so that the storage can be fulfilled.

Now, surge capacity. Number one, there's not a national program. If you look at the law today, the only person in government who has the authority to change the production for a national disaster or a national security problem is the Secretary of Defense, and it's in public law where he can tell industry that you can't sell to the public, that you must move all your industrial production toward national security.

Do we want that just to be invested in the Secretary of Defense, or do we want to take a look at where that other should be? Lance mentioned the cost of idle production facilities. Idle production facilities are a tremendous cost in the pharmaceutical area of the vaccine industry, because if a production facility is idle for one year, to start it up again, you have to go through a regulatory nightmare, and during the course of that year, the FDA may have changed the regulation, and you find that your production line is ancient.

We talk about surge capacity, but our history is usually with weapons and ammunition, and we have some examples. In the upper Midwest, we have tank production, and every year, we have Congress making a few more C-

130s to keep those lines open, but those lines are costly to keep open, and a part of keeping those lines open is that the Defense Department is asked to take on tanks that they might not want, and the Air Force and the Guard to take on C-130s that they think they might not want.

So who pays to keep the production lines up to date and functional? Well, in the course of weapons and ammunition, the taxpayer is paying that. Now, do we want the taxpayer to take on this additional burden? And then the production of biologicals is far more complex, due to the FDA regulations, and if you want to sit with me for a little bit, I'll tell you how a change in the FDA regulations can change your renovation program, and anthrax vaccine is an example of that.

Do we ask industry to build-in this capability for the potential market? Do we use market forces here? Do we ask industry to build excess infrastructure for surge potential? Who should be the prime mover, government or industry?

Surge capacity usually refers to a product that is in normal production on a daily basis, and we look for ways where we can increase that production. Generally speaking, the drugs, the diagnostics, and the vaccines that we need to manage a "weapons of mass destruction" disaster are not normal, everyday production. In fact, some that we will need aren't even *in* production. So when we need the surge, it's usually product-specific: anthrax, botulism, *Yersinia pestis*. We won't know which one we will need next.

How do you set up your production lines to meet that surge? Competition. Who's going to be responsible for the orphan drugs? Everybody knows there's going to be a market for anthrax vaccine now, everybody knows there's a market for doxycycline, Cipro. What about the other list? How are we going to handle the

competition for the other list? How will we deal with the anti-trust law? I'll give you an example. We worked for a year on HIV, TB, and malaria, and we finally got to sit with the President about sitting down with Pharma to talk about drugs for HIV, TB, and for malaria, and everybody in the room was just antsy as all get out, because we were meeting in one room discussing how we were going to do that together. Anti-trust is a very interesting law and it needs to be looked at when we're talking about surge capacities and competition.

Will we leave this to the marketplace? So far, we have in a way, because we've only added dollars to make the marketplace alive. Should we build redundancy into the plan? Should we have idle production lines, idle facilities? What should they look like so that they can be ramped up and meet FDA compliance? Should the federal government own and operate the facilities or some sort of a permutation of that?

Storage and depot stocks. The Department of Defense learned a lot of lessons in this area. As long you have a ton of money, you can manage the potency issue and dated items. The cost is astronomical when you're talking about depot and prepositioned stocks. The positioning costs money, maintaining those in position and then moving them; the rotation of the stock, and then you have a possibility that it might not be the right stuff, and then if you get into a situation, how are you going to use your dated material?

### **Daniel Shapiro:**

The number of non-clinical specimens sent to a variety of laboratories in the United States in response to what happened last fall due to the anthrax issue was tremendous, ranging from letters to powder on the back of pizza. More were sent to laboratories in

states with no reported anthrax incidents than in states in which had anthrax. So, for example, New York State, which had cases, at the New York State laboratories, they were working around the clock 24/7 in their laboratory, and in addition, they were having to deal with legal issues in terms of chain of custody. They placed cameras so that each phase of this could be recorded; something that had never been done before. This sort of thing was done in other states. Some of them — for example, I think it was Wisconsin — were only working 18-hour days, but with no cases, no evidence of it going on. This indicates something of the public fear factor.

The vast majority of laboratories in the United States are those that serve immediate clinical needs — hospital laboratories, doctors' office laboratories, and reference laboratories. The triangle that is now commonly looked at is where laboratories at the base of the triangle are so called level A laboratories, such as the laboratory in my hospital. We cannot definitively identify *Yersinia pestis*, *Bacillus anthracis*. What we need to be able to do is rule out those organisms, and for those that we cannot rule out, forward it up to a level B laboratory, such as a state laboratory. At the very top of the apex, level D, is the Centers for Disease Control and other laboratories with specialized abilities to look at such things as the genetic sequence of these pathogens, to look for perhaps chimeras and other sorts of nightmares.

But the level A laboratories are the ones that take care of the specimens when the patient comes in with community acquired pneumonia, urinary tract infection, and all of the normal sorts of things that we see in the hospital. If you compare clinical microbiology with clinical chemistry or hematology, it remains the single most manual of all laboratories, and therefore, the single most labor-intensive form of work, and that's a problem. The number of specimens that were processed by the Lab Response Network totaled more

than 121,000. Recognize that this was with a very small number of actual cases.

You can envision many scenarios, including some very bad ones, such as during a large influenza season over a winter, with people coming in who also have one of the many BT agents that affect the respiratory tract. This would of course flood emergency departments, and we talk about that routinely, but it would also flood clinical microbiology laboratories with specimens of everything ranging from rapid viral diagnostic testing to cultures of blood, sputum, et cetera.

One of the main problems is the number of medical technologists we have. We have a significant shortage of medical technologists in the United States. Incrementally, just to maintain a steady state, approximately 9,000 new jobs need to be filled each year. In all American schools currently, on the order of 5,000 graduates are coming out a year. About a third of those do not enter clinical laboratories; they go into the biotech industry and other areas. So actually, the shortfall of American graduates is higher. So what do we do? We hire technologists from other countries. My laboratory, for example, has people from the Philippines. I know of other laboratories with people from Sudan, other countries that might make people nervous in terms of their access, potentially, to some of these agents.

So, the vacancy rate is significant. And one of the reasons is, these are educated individuals who have the same level of education as do nurses. Their salary is at best two-thirds of that of nurses, and it's really a poor career choice if money is of any importance to you, where at age 22, you may essentially have very little upward mobility. I mentioned the many foreign workers. Beyond that, there are other problems in clinical microbiology labs. One is that surge capacity is constrained by production facilities. We've heard about this with pharmaceuticals, we've heard about

this with vaccines. But the production of media that is adequate to grow bacterial specimens has to undergo quality control, as do other materials, vaccines and such, and sterility testing, so this cannot be done quickly. It also is typically transported via interstate trucking. Labs nowadays rarely make their own media. There are a number of media companies in the United States, and the ability of these companies to gear up production is very unclear. One of the more concerning ones relates to blood cultures. When people have serious infections with bacteria, they often have bacteria growing in the blood. Blood is normally sterile fluid. There are three companies that combined comprise well over 95 percent of the U.S. market for blood cultures, and most of these are done on automated instruments.

In laboratories, the number of spaces on an automated instrument depends upon the laboratories' anticipated volume of blood cultures. So that, for example, if our laboratory had twice as many patients requiring blood cultures, we would be unable to do so, much less 10 times. Other constraints. We have a limited number of bio-safety cabinets. So if we have an organism that might be brucella, we do not have enough bio-safety cabinets, and this is true in every clinical laboratory in the country. Inability or severe difficulty to staff odd hours or around the clock. We're not public health labs, and in many city institutions, there are workers who are unionized, and some of these contracts require a minimum of two weeks of notification for a change in hours and may have provisions regarding forced overtime. Another issue is virology. The great majority of level A laboratories perform very limited or no virology services. Many of the BT agents that we're concerned about are viral.

So in summary, we really have no surge capacity. One of the potential things that can be done is to recognize that the media have "outdates" measuring from weeks

in the case of petri dishes, solid media, to months or years in some other cases. The other issue is that the sensitivity of the assays varies. So, for example, viral antigen testing for influenza is at best 70 per cent positive. A physician orders this in the emergency department, and if it's negative, it certainly doesn't rule out influenza, and on the other hand, if it's positive, it doesn't rule out a co-infection with a BT agent.

Inability to rapidly obtain the commercial products, and lack of ability to increase the labs' capacity for cultures due to a shortage of medical technologists and the other issues. And in part, this is due to the current health care environment in which hospitals compete with each other, and it would be perceived as unprofitable to have a surge capacity. Finally, of course, the issue — would these people show up for work in the environment of a disaster, and that's a true unknown.

## Discussion

**Col. David Danley:** I'm with the Joint Vaccine Acquisition Program. We struggle with the surge capacity problem all the time, and what's really ironic about it is that the best place to store a vaccine is inside a human and not inside a building. I'm wondering if maybe we're at the point where we must change — and I hate this word, paradigm — the way we think about using vaccines, from products that we inject that give a certain high level of immunity to something that may be less onerous to receive but give a lower level of immunity, and accept the fact that we're going to be in a period of vulnerability until we can figure out how to make vaccines so that people just take them as part of living — in food, in nasal sprays, those kinds of things. We need to really move dramatically away from injectables, because, quite frankly, when we take a look at the anthrax vaccine problem right now, where are we going to give it, are we going to store it, it all gets down

to user's acceptance of that product. If they don't want to take it, then you're left with sticking it somewhere until you have to use it, and then you create consequence management, and I don't know that there's a simple solution to that, but I'd like to throw that out into the panel for consideration.

**Lance Gordon:** I'll give it a shot — no pun intended. With regard to the point on oral vaccines, you know, that's been a holy grail of the vaccine enterprise for many years, but it's a particularly difficult one to accomplish. The only really successful oral vaccine so far are live viral products, and that covers a very limited spectrum, but certainly research is ongoing. With regard to the question of safer products, you've hit on a slight hot button of my own. The decision on the National Stockpile's smallpox vaccine was made at a time when we generally thought that the probability of a terrorist taking massive action or really using it as a weapon of mass destruction was lower. I think the airline attacks on heavily populated areas have changed that perception.

The selection of a product or the specification of a product to be equivalent or bioequivalent to the old vaccine which had a high adverse reaction rate was logical when you were trading off a 30 per cent or higher fatality rate in the event of an attack, with a few deaths per million of using it in today's population. In the 1960s and '70s, when smallpox was becoming eradicated, many, many groups, countries, and companies were developing attenuated products. I think it was somewhat short-sighted, in my own view, to limit ourselves to an old-style, highly reactogenic product, when much safer candidates were available and still are available. So, I would second the recommendation to look at using attenuated products which could be used on a population basis with little or no risk of serious adverse events, but yet providing a very broad population level of protection.

**Daniel Shapiro:** With respect to that, one question I've had is, given the known frequency of adverse events from the literature with vaccinia — and that was in the pre-HIV era — are there plans afoot to deliver these vaccines rapidly and to coordinate it with rapid HIV testing, essentially point of care HIV testing for millions of people?

**Lance Gordon:** Prior to September 11th, and I should say, as one of the parts of my background, I was the head of OraVax, the company that won the national contract for smallpox, and I was the principal negotiator and project director for that. At the time of award, the CDC's stated intention at the term of the contract was that the product be identified for use without regard to contraindications. And at that time, the thinking was: In the event of an attack, it would be difficult to impossible to actually control usage, so it would be used without regard to pregnancy, compromised status or other underlying risk conditions.

That's subject right now to very, very heavy rethink. There have been four regional meetings already held. There was the IoM meeting yesterday, and there's a final decision coming up. I understand there are rapid diagnostics available today for immunocompetent status; there's the thought that as rapidly as 12 hours, it might be possible to assess an immunocompetence. That's still difficult in an emergency situation, because it means you have to bring in everyone, test them, send them home, and I guess my own assessment is that in a post-exposure setting, that's going to be very difficult to do.

**John Parker:** I'd like to speak to the oral aspects, and also to not only the specific oral medications, but oral medications that may boost the immune system. In the pharmaceutical world of the FDA and manufacturing and what we've been used to today, we don't move for licensure of a drug unless it's 90 per cent or greater effective. So efficacious is a

very important thing in our culture today. Well, what would you pick? Would you pick nothing, or would you pick something that's 30 per cent effective, 50 per cent effective, or 90 per cent effective? Now, there are some oral medications that are efficacious, but at a very, very low level considering the population. I think there's a lot of work in complex sugars, two, three beta glucon is a promising area. There's lots of small companies that would like to work in this area of investigating the use of oral compounds for protection against bacteria and virus. But the venture capital for these folks is not there, number one; number two, because it's not traditional, the research grants aren't available there for them; and then probably most critically is that the animal models that they need to do that are not available.

And then fourth, and probably extremely critical at this point in time, is, because of the anthrax event on Capitol Hill, there is a constriction of the ability to get bacteria and viruses that you need to do this work unless you're an absolute labeled government facility. So how do we stimulate innovative, small companies to work on these things, if when it comes time to do their testing, they cannot get the pathogen because they're not certified; they don't have this, they don't have that. And so really, at a time when we need to make a lot of things available to innovative industry, we're constricting.

**Michael Langford:** I'm with DynPort Vaccine Company. I think success in this arena is certainly all about changing paradigms. We've addressed, a little bit, the national will issue, and I guess the uncertain demand. The grease that drives industry in this country is demand, and if there's no demand outside of national interest or military interest, then there's no demand. I think it's very important to address those two issues.

The question, I guess, comes down to the thought of an IND stockpile. I've been aware

of conversations in HHS talking about national stockpiles. They've at least discussed the possibility of putting IND stockpiles in place. I think the military went through that game, if you will, up to Desert Storm, the recognition that we need to have licensed products if for no other reason than confidence. And I think in terms of the new anthrax vaccine, for example, if you have an IND vaccine that you're going to stockpile versus the availability of a licensed vaccine, how do you justify that to the public? So the question to them is their views on a stockpile, certainly in terms of an IND stockpile.

**John Parker:** An IND stockpile — first of all, let's take it from the rudimentary need of the researchers to be protected. Right now, there is one small stockpile of IND vaccines that can be used to protect the researchers and the industrial developers as they produce vaccines for those entities that are on the threat list. This is a finite supply, and on top of that, it's a finite program that has a single point of contact in it, to the point where the Department of Defense is looked at as the single purveyor of the IND vaccines for the research community.

As we expand our capability and capacity to do research and development, the demand on this short stockpile is going to be severe. So if we put this in different phases, I would say that the IND stockpile that exists today needs to be looked at and expanded. And then I think what you bring up about the capability of a capacity to increase that IND stockpile, or actually make a bigger stockpile needs to be looked at very seriously, because we all work with what we think is the threat list. But we're working in an asymmetric world, and what we get next, we may not be ready for.

**Steven Bice:** Two points. First, we work closely with FDA, and as an aside, it's easy to beat the FDA up. Sometimes they're put in a very difficult position by Congress, and these are just folks like me, so you know, it's tough.

And I think that what has to change, Parenthetically, is their ability to reach out to industry and invite industry in as we have done, without ending up in a lawsuit of some kind or getting fired as a result of what they do. So that parenthetical.

But the answer to the question is, we do have IND product in our national pharmaceutical stockpile. We work very, very diligently to limit the number of IND products. But the answer in some cases is, we're dealing with threats; it's threat-driven, so we do what we have to do. It would seem that investigational new drug policy may be able to be worked on in a relatively quick-time environment, and that we can, in a national emergency situation, pare down the onerous requirements of IND product while at the same time assuring safety for the American people, especially given benefit versus what you think of as cost.

**Lance Gordon:** I believe I can take a position which probably represents most, if not all, of the industrial capacity: that we would be much more reluctant to take on a product which was not intended for actual licensure. I think very strongly that we would prefer in all cases to take them through licensure; it's more protection for us.

I think you have to realize also that an unlicensed product, as Gen. Parker said, is of limited availability. If the product is licensed, then it is much more readily available to those who might need it. So, speaking for industry, I think we would far prefer to see them licensed rather than kept under IND.

**Joel Gaydos:** I'm with the Department of Defense Global Emerging Infection Surveillance and Response System. I'd like to take a high-level look at what the panel has been discussing and focus in on two questions; and that is, who is responsible, and who pays? I think the basic problem that we're dealing with is that we don't have a defined functioning health structure in this organization that

can really attack these problems. If you go back about 15 years, the Institute of Medicine issued a report that said that we don't have a working public health structure in the country. One of the old definitions of public health was that industry took care of its part of the pie and it was driven by profits and driven by other incentives; that private health care took care of its part of the pie, and what was left became the domain of public health.

We've been grappling with the idea of what public health infrastructure is, and I don't think that many people on Capitol Hill can begin to address what that is. But it would seem to me that when we're looking at the problems we're trying to deal with today, that we need some part of the health care organization to come forward and say we have the responsibility for pulling this together and we have the responsibility for paying for this. Dan Shapiro mentioned a lot of things about laboratories. I think all of these things were known years ago. The American Society for Microbiology issued a report about five years ago, and I believe everything [Dr. Shapiro] said was in that report. We knew what was happening. But I don't think we've moved that far ahead.

Now, we have attempted to do something in the area of the national pharmaceutical stockpile, and I think for some reason, a public health group, the CDC, took that on. But I think we've got to look at the vaccine issue, I think we've got to look at the laboratory issue, and we've got to ask the question, who is at a very high level with the authority and the responsibility for pulling this together and will have the resources to do this?

**Daniel Shapiro:** I agree fully. I guess one of the questions is, is public health politically an adequate cause in this country to give money? Of late, unfortunately, the answer has been no; biodefense has been. So, the lack of medical technologists, the inability to supply these sorts of agents, culture media and such can

either be looked at as a public health issue, which it clearly is, or as a biodefense issue, which it clearly is. My bet is it would be more likely to get funding as a biodefense issue. I don't know if there are any culture media or diagnostic kits as a part of the national antibiotic stockpile, but that would be one consideration, whether it be public health or whether it be biodefense.

**John Parker:** I just want to give credit where credit is due. Things don't happen overnight, and we know that in this country. But I will tell you that Health and Human Services has been working extremely hard all along—and probably accentuated right now—to bring authority and an operative capability to that agency to do the things just talked about. I think never before in history has the need for a public health infrastructure been more amplified to the American public than in the last 30 years, perhaps. And so I want to tell you that CDC, Health and Human Services, Secretary Thompson have really been grappling with this.

They've been given money so that they can buy certain things, and I think with the new agency, we will move toward strategy and policy that will drive things even further down the road. I think that's the missing link right now, to get strategy and policy on top of this awareness.

**Lance Gordon:** I want to sort of highlight what was said. First, a rather shocking statement: Vaccines do no *one* any good. You can't demonstrate that because you got vaccinated, you wouldn't have gotten sick. Chances are you wouldn't have, anyway. Consequently, we do not enjoy the pharmaceutical margins of something that prevents a bleeding ulcer or gets rid of your headache in 20 minutes.

Vaccines prevent disease at the population level, prevent it for the country. We had 55,000 cases here of whooping cough before the vaccine was out. We had 40,000 cases of

infant meningitis in this country every year until the vaccines were licensed in the late '80s. Vaccines are the only medical intervention actually cheaper than not using them. When compared to other segments of the pharmaceutical industry, vaccines do result in savings to the health care system. Those savings are not returned to those providing the benefit, so it really is a public health need.

**Steven Bice:** Just one quick comment. I have, through my 30 years at CDC, always grappled with my colleagues on the Hill and other places in capitals around the country. Prevention is always difficult to fund. No one can get their hands on it. We're dealing now at CDC with a windfall of money, there's no doubt about that, a blessing to the infrastructure of public health, because we are in a place now where we can fund public health, which has been underfunded for a number of years, and we're doing it under this dual-use mantle. So, you know, amen to the need for it.

**Cdr. Mary Chaffee:** I'm from the Navy Medicine Office of Homeland Security and have a two-pronged question for you. In the event that we exceed domestic capability or capacity for a specific pharmaceutical, what type of agreements or contracts do we have with international trading partners to tap into their resources? The second part is, in the event of an international outbreak or problem, what is our policy for sharing the stockpile?

**Steven Bice:** Well, let me answer the second question first. Secretary Thompson has recently put together a group of his counterparts. The first meeting was in Canada; the second in London. It's working on this international response issue. Legal complexities notwithstanding, it is a knotty problem, and it is being worked on. It is understood as an issue. We will in all likelihood respond on the international side based on a variety of political considerations.

The first question had to do with our ability to

reach out internationally to pharmaceutical corporations around the world, and we have done that in exercises. We have not done it in fact, although we're certainly working with corporations in other countries, Canada, for example. But the real key to the answer is, somehow, with Department of Defense colleagues and the public health sector. We have to work with our own U.S. base personal opinion only, they can reach out to the international side much more readily and much quicker than we can as governmental agencies. If we work closely with them, this kind of enlightened cooperation can turn that around much faster than we can as government.

**John Eisold:** I'm from the Capitol. Just a couple of comments. First of all, in reality, vaccines are losers. They don't make money. So I think there is truly a public health role and a government role for indemnity, for the vaccines. I think we have to think in a broader scope about how it is a national responsibility to take care of the population, and how do we pay for that.

That's number one. Number two, the IND issue is a major issue, about how you give these vaccines. The post-exposure vaccine program that we did at the Capitol for anthrax for 73 people was difficult at best. So now, you know, the smallpox is still on IND. Now, you cannot do broad-based vaccinations on an IND. Trust me. On the other hand, there may be some small areas where you have very specific programs that you need to do that. But in terms of the practical issues which people have talked about, whether it's distribution or just people handing them out, there are some very practical issues here that need to be solved that are very, very simple, but they need to be addressed. And one of them clearly is the IND and how you're going to deal with that.

**Lance Gordon:** Briefly, with regard to the new smallpox vaccine being developed by

Acambis, the contract as originally awarded calls for licensure of the product, so there is every intention to license that product. The FDA has compassionate use rules which cover use under IND, and I think those are probably adequate to the purpose.

**Robert Claypool:** I'm from Department of Veterans Affairs. A question and then two comments. The proposed or imminent rule change by the FDA that will allow for drugs not ethical to test efficacy in humans to use animal surrogates is somewhere over the horizon and I'm not sure where. Do you think that will make an impact in terms of the ability to bring from farm to market to licensing for some of these agents?

Assuming that's a given, I have a follow-up statement: Number one is that even if drugs are licensed under that rule change, I suspect that the post-marketing compliance is going to be significant, because of the fact that these drugs will not have been tested for efficacy for humans, so I think that's going to be a significant impact if they are used. Secondly, regarding the IND question, for stockpiled drugs, that I think the drugs that are licensed for a certain use, but off label for another use, may be different than a product that's not licensed at all. I think to that end, I think the incident involving the anthrax vaccine used in Washington, D.C., was a significant lesson in not how to exercise health risk communication.

**Lance Gordon:** Actually, as I was responding to the last comment, I meant to include that I was mentally kicking myself for not noting that the FDA rule change did take effect. It was finalized, I believe it was a week ago last Friday, June 7th, I believe it was, or 8th. And yes, it certainly does allow for the licensure of product based on not only animal efficacy to general accepted animal models, but also evidence of safety and immunogenicity in humans. Also relating to the question of intent to license, the FDA in its comments, which was part of the publication, made it

very clear that they do not intend to restrict the use of products which were approved under this new regulation. They specifically said that the reason for not generally intending to restrict use, other than they might have for any product, is that the ability to commercially sell it would make the vaccine more readily available; therefore, meeting the defensive need, not just through the stockpile, but through local stockpiles or private individuals.

As to regards to the post-marketing surveillance, part of licensing any product, particularly any vaccine, is post-marketing surveillance. The largest of clinical trials might approach 100,000 people, but we're talking about the use of the products in tens or hundreds of millions of people. It is impossible through the license process and the clinical development process to know where adverse events will come up. It will be a particular challenge in the case of biodefense vaccines where there will be no use except in an emergency situation. Post-marketing surveillance studies typically involve enrolling physicians as part of the study and carefully capturing the history of each patient or subject receiving the product. Under emergency conditions, I think that's going to be extremely difficult to do. So people are still agonizing over that question. But, yes, this was a very important move forward in enabling the rapid development and availability of biodefense vaccines.

**Lew Miller:** I'm the Public Policy Chair of the Sabin Vaccine Institute. Just a comment about what was said earlier about "vaccines are losers". I think the issue here is not that vaccines are losers — it is that they need to be winners. Manufacturers have to be able to recover at least a fair return on their investment in the development and maintenance of GMP, their ability to provide surge capacity. If manufacturers don't do it, the government needs to do it itself. The cost is probably not going to be a lot different. I think if we came to the realization that we needed to pay a fair price for whatever we need to do to be pre-

pared, we needn't be so concerned about what sector pays for it. In the end, if the government feels that we as taxpayers feel it's a good investment, we need to pay somebody for it.

**Speaker (unidentified):** A couple of comments were made here I'd like to address. With respect to the international issue, we'll be having meets up at Fort Detrick for the next three days with Canada and the U.K., not only on vaccines, but on medical, chemical defense products and diagnostic products as well. But what we're finding is that there's this remarkable capacity in our allies to manufacture vaccines, but they have very much the same interest that we would have; that is, they would like to make their vaccine or the vaccine in their country and not necessarily in the other two countries, but each country would like to have that production capacity.

Secondly is moving these products back and forth. These biodefense products are getting some rather interesting import/export restrictions placed on them, and it's not necessarily easy to move these products back and forth. But given the fact that if you had capacities in other countries to make these vaccines, you certainly could enlarge your surge capability, and there's certainly interest along those lines. We're resolving some of these issues, and we'll see if things come to fruition. But the biggest issue, of course, is licensing. There are differences in the way we license vaccines. Even though data is good between countries, the various regulatory agencies would like to see studies done under the auspices of their own rules. Things are improving.

**Lance Gordon:** Yes. There certainly are quite a few precedents for products manufactured overseas to be used here. Generally, the overseas manufactured product is licensed by FDA. FDA inspects the manufacturing facilities; they have to meet all the same requirements domestically manufactured products do. And the yellow fever vaccines that are used in the U.S. are exclusively a French manufacture.

Smith-Kline certainly is very active in marketing its hepatitis B and has the majority of the market share, and that comes from Belgium. There are also examples of intermediate products being manufactured overseas for compounding and finishing here. The pertussis components of the DTP Vaccines — for many years, two companies in the U.S. were supplying DTP or diphtheria-tetanus-pertussis, where the acellular pertussis was manufactured in Japan. I will say that one of the things that I experienced personally: I was with Connaught Laboratories from 1980 through '87, and I believe it was in 1986 we had a particularly bad flu year. Well, Connaught manufactured flu vaccine in the U.S. Given that we were a subsidiary of the Canadian company, we, of course, supplied the Canadian market as well. It was a bad flu year, and we were prohibited from shipping vaccine to Canada until the U.S. needs were met. So there certainly are precedents in all of these regards.

**Daniel Shapiro:** I have a question with respect to vaccines, and what we're talking about right now clearly are pathogens of concern circa 2002, and there's certainly enough of them for all of us to lose some sleep. What thoughts are there with respect to the ability to gear up — as we're talking about surge capacity, the concept that there could be a novel bioterrorism agent has perhaps gone from science fiction to something less fictitious. There was a publication a year ago on the insertion of interleukin 4 virus, which is a mouse-pox virus, and mice that normally would have been immune died. There's obviously a lot of concern in that case, and I'm sure you can have, you know, every nightmare imaginable in every bad made-for-TV movie.

But in terms of surge capacity, once a novel agent is identified, what could potentially be done, I guess would be the question.

**John Parker:** This is probably not the right

forum to really get into that, but I was asked personally to address this about six months ago. It has been addressed. There are significant amounts of money put in this direction, and there is concern.

**Lance Gordon:** Just to add slightly to that. I think I noted that U.S. vaccine or manufacturers can address any need, given time and reasonable incentive. The scientific capacity in the U.S. is truly phenomenal. I have no reservations about our ability to rapidly direct scientific efforts into finding answers. It does take time, however, to translate those answers into production systems, and certainly in that kind of scenario, I think we'd be looking at supplanting other products and looking at what was the greatest public health need, and it may mean for a period of time shutting down the production of other routine public health products to provide immediate capacity.

**John Parker:** The part that I want to clump into this is, perhaps there are other antibiotics that are successful against some of these threat agents but are not yet licensed or mentioned in the brochures. What we're running up against right now, if you look at money and facilities and then you look at animals, the critical shortage is the experimental animal today, not money, and not infrastructure. Until there is some translational research from the macaque to some lesser expensive animal or to less than a primate, we're in big trouble in moving forward very rapidly.

**Steven Bice:** Not to put too fine a point on it, but unlicensed/licensed, let's not get confused here. In the National Pharmaceutical Stockpile, these are all licensed drugs. Their off-label uses is what we're dealing with. I think we would be constrained, and certainly heavily opposed, to an unlicensed product being used in any event unless it were truly the last ditch and people were dying and that this was all there was — based on microbiology, this was all there was that could interdict. But clearly off-label versus unlicensed.

**Nancy Tomich:** I'd like to ask each of the panelists if he were king, or head of the new Department of Homeland Security or whatever it's going to be called, what is the first big practical step you would take to get us moving to solve the surge capacity problem?

**Steven Bice:** Without being too political and what's left of my career not going down the drain, I think getting the considerable private sector, universities, of course, colleges and universities across the country, together with my DoD colleagues, FDA colleagues, and coming up with something where non-attribution — something where we can truly take our coats off and say this is where we're headed, this is what we need. No offense to attorneys; have them there, but please, you know, put the book away for a minute and then just let's talk.

If we could do that, I honestly believe, given what we have been able to accomplish in the stockpile, we could not have accomplished without our private sector colleagues. They always come to the plate, and it's not the bottom line. Believe me, they are not making money off of us, they're just defraying some costs. But that's what I would do.

**Lance Gordon:** It really is very much as Mr. Bice said. Set aside the regulations which prohibit discussions regarding contracts; get the public health people, the government authorities, the industry folks and a reasonable representation of the academics, but not run by the academics, put them in a room, not just to talk, but put them in a room to negotiate a solution. You know, it's probably the bulk of what my career has been is negotiation. It's through a process of negotiation that we will get a best fit of the needs and the ways to handle those needs. So put the group in the room and don't let them out until they have thoroughly run through it and negotiated a workable solution.

**John Parker:** I think indemnification needs

to be looked at very clearly. Drugs have side effects; vaccines have side effects. Vaccines possibly in the right human being can cause the disease or cause death. Those are facts. It doesn't matter how good your product is; you're going to have adverse reactions and bad effects.

Now, are we going to leave that to the tort attorneys or are we going to address it up front and say these things are going to happen when we move forward with drugs and vaccines, and it is impossible to expect Dr. Gordon's company to buy enough insurance to cover him for a vaccine or a drug that's going to be used nationally. We've got to have a national indemnification program that takes that burden off of innovation and production. That's what I'd work on first.

**Daniel Shapiro:** I think two things; I know you wanted one. One is the funding. And people can argue about where the monies are going is dispersed in a peculiar way. Emergency room physicians, with all that they do, do not establish the diagnosis of anthrax, tularemia, plague, et cetera. They know an individual has a particular presentation; they send off laboratory tests. The group of laboratories that have received monies are not the frontline labs. In a public health setting, you need to be able to decentralize things. We have what would be called a crisis currently without anything bad going on to add to it in terms of our staffing of the laboratories and our ability to have surge capacity is absolutely non-existent. So I think funding needs to not merely go to emergency departments and public health laboratories, but there needs to be an overall game plan to increase the number of people who go into medical technology as a career.

The second thing which is lab-related, I think, is — as some background, we all know that people could acquire from groups such as the American Type Culture Collection pathogens, and this has been done, and now there are a

number of constraints upon that. An individual can no longer order *Yersinia pestis* as was done by Larry Wayne Harris, and have it delivered to his doorstep. However, there are 100 of these or more globally. So the other thing that I would do is the following: I would get researchers who know who conducts research on each of the major agents; *Yersinia pestis* and go down your list, and with those countries that are willing to work with us, say yes, these 12 people who ordered these type strains of *Yersinia pestis* all seem to make sense, because the group of people who conduct funded research on that pathogen know these people as people with genuine research interests who publish and who are taking care of it.

And these three stick out like a sore thumb. Maybe one is in Germany, maybe one is in — you know, whatever country, and an international effort has to be made to track them down from a biosecurity issue. I don't know if that's been done. We can't look at the United States as the only source. There's clearly a black market of these agents. I think if we can prevent it from reaching our shores, so much the better, and that's one approach that I don't know of having been taken. Some countries will be friendlier to us than others. But I think the researchers in each area absolutely know who conducts real quality research and would use these organisms.

**John Parker:** I just want to make a comment on that. The CDC is a major player here, and they're doing a good job. Now, we don't go down to the individual researcher level. But for an agent to be moved from one laboratory to another, both laboratories must be registered with the CDC. If both laboratories are registered, then the carrier must be certified to be able to move that pathogen under very strict criteria laid down by the Department of Transportation. I think to get to the level of registering and certifying each researcher may be very difficult.

**Daniel Shapiro:** I'm not saying to register and certify the researchers. What I'm saying is, if you get five principal investigators in the room, each of whom has worked with *Yersinia pestis*; maybe a couple from Europe and several from the United States, who go down the list of who has ordered these from the 100 reference laboratories globally, maybe 50 of them would be willing to provide this information, and figure out which ones are not known to them; it gives leads that can be investigated. That's all.

No, I think we do not want to quash legitimate research, that's quite clear to me. But where there is no clear basis for why someone is ordering this, it needs to be looked at.

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**Panel 2: How Do We Expand Treatment Surge Capacity?**

**Robert Claypool, MD, Deputy Director, Office of Operations, Security, and Preparedness, Department of Veterans Affairs**

**Hon. William Winkenwerder, MD, Assistant Secretary for Health Affairs, Department of Defense**

**Rear Adm. Robert Knouss, USPHS, Director, Office of Emergency Preparedness, HHS**

**William Winkenwerder:**

The agenda you have set here addresses an issue that really is urgent for all of us in government and it's urgent for the nation. Certainly, it's as important for the private sector as it is for the government, given the role that the private sector plays in the provision of health care services in this country. I want to lay out a few thoughts for you on where we stand in DoD today and some of the initiatives that we have underway, primarily focused on the goal of building relationships and interrelations across government and the goal of building relationships with the

private sector. From a purely medical supply perspective, the military health system has adopted a just-in-time medical logistics support for a number of years, and I think it's fair to say, with much success. Nonetheless, there are important elements of that strategy that we need to revisit, and I think now is an appropriate time to do that.

From the perspective of assessing surge capacity, particularly as it relates to both drugs, vaccines, and hospital beds, it's important that the federal government look across the entire system rather than looking at just the component parts, and that's really one of the messages that I'd like to leave with you today. So, as we look at surge capacity, I think it's not just what exists within DoD, or what exists with VA, or what exists within some of the component parts of the Public Health Service and HHS, but really, what does it look like if we look across the whole?

In some respects, another thought about this is that the government capacity may in fact be the national capacity in certain circumstances, and that's particularly true as we think about vaccines. Certainly with respect to the anthrax vaccine, the only "national capacity" we have is what we have procured through the government contract between Department of Defense and BioPort. Pretty much the same thing is true with respect to smallpox vaccine and what HHS has procured and is procuring for that vaccine. I think it also might well in many ways apply to the flu vaccine. So, government capacity doesn't always equal national capacity, but in certain cases, these among them, I think it does. That concept might, depending upon how we move forward, be extended to other threat agents or other areas.

One of the steps DoD has taken with HHS — is now taking — is to look at this whole idea of defining a national set of requirements for vaccines and the concept of a national vaccine council. The council would be established to look at federal requirements for vaccines,

particularly as it relates to bioterror products, and to present a single face to the pharmaceutical and biotechnology private sector industry, so that we can tee up the questions, tee up the requirements priorities — the priorities first, and then the requirements — and then the dollars and where they might flow or should flow, and sort them out. Right now, we have numerous good efforts going on, but they are occurring primarily in an ad hoc kind of way. We don't have any formal mechanism to coordinate this activity. I think it's fair to say that the establishment of the Department of Homeland Security, with a Focus — one component of it — on bioterrorism, is clearly an effort to do that. My concern, candidly, is that in the best of all worlds, that is going to take many months, if not a year or two, to be fully stood up and working properly, and in the meantime, we've got to work together and move the agenda forward. So, I don't think we can afford to wait a year or two to see how that new department unfolds.

In advance of the establishment of such a mechanism, we've already begun to improve our coordination. As an example, on the anthrax vaccine, our approach has not been just to look at what DoD's "requirements" are, but also to really have a number of very in-depth discussions with Health and Human Services, with others like the State Department, Department of Justice, Homeland Security, to really think of this more as a national challenge and not just a DoD challenge. We've done that, and again, it's been done in an informal but deliberate way. We met with Secretary Thompson, Governor Ridge, Dr. Rice from the National Security Council, and others, and I think we are poised to come forward with something that will be a coordinated national approach.

The same thing is going to need to take place, in my judgment, with respect to dealing with the threat of smallpox. We are working together with HHS on this issue as well, and I'll have more to say on that. I think, to switch

subjects just for a second to the whole issue of what we need to do at this point, that, in light of the events of September 11th, we need to relook at the Federal Response Plan and the way that was set up — set up, I think, around 10 years ago. NDMS was set up 10 before that, but really became more formalized in this last decade. We've got to, I think, go back and take a look at those mechanisms, which were principally about federal assistance to local authorities, with a definite focus on assistance, with the presumption being that much of that would need to occur in the case of some sort of natural disaster, such as flood, fire, earthquake, tornado, et cetera, but not a wartime situation. So, we have to look at these things differently. We've got to look across all of our federal assets and make sure that we're using all of them effectively, not just more beds potentially, but better use of what we have, better integration.

We're working with the VA as we speak. Part of what's going on with the Presidential Task Force is to look at VA and DoD cooperation, to look at our capital asset planning — what kinds of facilities and structures we have in different markets and locales across the country. We can do a better job, in my judgment, and better coordinate how we spend dollars within our respective systems merely by sitting down and working with each other years in advance of when these facilities are built and constructed. We've not done such a great job of that in the past. I think that as soon as the Task Force report has the endorsement of the President, it will be asking us to do that kind of thing.

We've got an interesting possibility to explore a very innovative concept in the Denver, Colo., area, where we might combine DoD and VA and university medical center assets to look at how we share across both government and private sector. I think those kinds of joint initiatives have the possibility for truly strengthening the private-public partnership, giving us an opportunity to share what we

know in the area of education and training for preparedness, and at the same time, maybe creating a structure that allows us to operate more efficiently.

Let me touch on one other area, and that has to do with surge capacity that relates to laboratory services. Last fall, we were in the height of the anthrax attacks, and of course, if you go back to it, it really was only four letters, and I guess the letter to the newspaper, the tabloid newspaper in Florida — four or five — so it really wasn't very many. But we saw what that did when that coursed through the postal system. You had thousands and tens of thousands of laboratory samples that needed to be processed quickly, and it really did stress the system. Part of it was that not a lot of people had done that kind of laboratory work before, so people were doing it for the first time. But also, it was just a pure volume problem. There was a lot of volume coming through, and I think we need to look at that kind of surge requirement and carefully ask if what we have in place is what we need in place. So that would be an area I'd have us focus on.

Before we ask the question of "How Do We Expand the Surge Capacity?", I think we ought to ask the question, "how do we establish the requirement to begin with, what is it that we're planning for, what do we plan for?" I think that requires a very specific thinking about the different kinds of scenarios and events.

### **Robert Claypool:**

Before we discuss ways to increase surge capacity, I thought maybe we'd back off a bit and, number one, make an assumption. The assumption that a lot of my comments are based on is a true WMD, with an emphasis on M, mass destruction, because a lot of the experiences that we've had in America recently with some of the 9/11 events, and prior to that, really haven't generated the

kinds of numbers of casualties and severity of casualties that are capable under a catastrophic WMD scenario. So in some ways, I think you can look upon my comments as framing this in the context of it being actually a Cold War-like scenario in terms of numbers of casualties, except that it would be incurred in the United States. I think we need to focus on looking at what the unthinkable would be.

I thought I'd back up a minute and discuss a little bit about trying to define surge and capacity. Surge — everybody has a concept of what surge can be, but if you tease it into three parts, I think it has various independent variables that can influence the outcome. Those independent variables include volume of the surge, they include the case mix of the kinds of casualties that result, and they involve the time, that is, the time from the onset of the incident to the appearance of casualties, to the peak into the waning of the appearance of casualties. To elaborate further on that, for instance, say in a conventional traumatic event involving explosives, very often, the time from onset of the incident to appearance of casualties is very short. On the other hand, following a biologic event, there's more time from the onset of the incident to the appearance of casualties; we do have some time to react to that.

The case mix is important, too, of course. If several patients with multiple post-traumatic surgical problems present to a community hospital, this would often represent a significant surge for that hospital. So, relatively few numbers of complicated patients may pose a greater surge problem when compared to a greater number of people with less complex health issues. For instance, using the issue of post-exposure use of antibiotics or vaccine following the anthrax episode didn't represent a complex case mix; it did represent a logistical and communication issue. So surge is one component of the surge-capacity problem. The point I'm trying to make regarding a surge is that it does not necessarily represent the same

problem in all clinical circumstances. There are different qualities as to what makes up a surge. The second word is “capacity”, but what we really may be talking about is “capability”. I think we at least need to develop the mindset that the capacity is not a fixed constant, that is, it’s an elastic capacity. Really, the important item isn’t how many people we can put into the system. The more important thing is what can we do with the capacity to allow us to effect a clinical decision. These characteristics of the surge that we’re talking about help calibrate how we would form the capacity.

I’d like to shift to some thoughts, some of which are meant to be provocative thoughts, as to what kinds of tool kit we could establish and what kinds of mechanisms we could use to impact upon this. Right off the bat, I’d at least like to comment about the title of this panel, “How Do We Expand Treatment Surge Capacity?” I understand the focus of the title, but I think before we get there we should look at the ways we can prevent the need to treat. There are ways we can influence the surge to try to optimize throughput. One of the things that we don’t pay enough attention to, and it doesn’t fall generally under the health care rubric, has to do with training prior to an event. I understand that after the bombing of the World Trade Building several years ago, there were tremendous steps taken to enhance the safety and evacuation of the building, and that training resulted in a significantly reduced loss of life. HHS is putting out guidelines for buildings in terms of safety and training to mitigate the amount of casualties that would occur in the event of some kind of an incident involving our buildings. So non-medical training things can help decrease the surge when we’re dealing with catastrophes involving buildings.

Other things, of course, that decrease the surge include things we’ve talked about, such as pre-event vaccination or post-exposure use of antibiotics and vaccination. Under a smallpox

scenario, for instance, if we don’t employ pre-event vaccination, the concept of a ring containment and vaccination really would then hopefully decrease the amount of surge of patients that would appear in our facilities. Along the same lines, I think there are some things you can look at to decrease the surge following chemical attacks. As you know, during Desert Storm, the use of pyridostigmine bromide as a pre-treatment has at least some animal suggestions that it would decrease the consequences following a nerve-agent attack. In the event of a non-lethal radiation attack, there are some investigational new drug products now that may mitigate the effects of a radiation exposure.

Lastly, in terms of looking at the surge, you know, the Defense Threat Reduction Agency, at the behest of Office of Homeland Security, has an interagency effort looking at trying to improve surveillance of this country, surveillance with the intent of detecting to warn and detecting to treat. If we can do a better job of detecting to warn, then we would presumably be able to decrease a surge following particularly a biologic event. Focusing on the capacity, as I said, we should consider it being elastic and then look at things we can do to enhance that elasticity. I broke this down into two categories, one being clinical management decisions and the other being triage. Traditional triage, as we know and love it in terms of American medicine, is NOT the kind of exercise that we would experience under a WMD event. American medicine and the American public are Not actually, prepared for the kind of triage issues that would have to be addressed. As you know, we’re used to pulling out all the stops and taking care of critical individuals, and it would be a tremendous culture shift for our society, I think, to recognize an individual who’s had a lethal exposure to radiation, you know, to set them aside and say I’m sorry, and focus on others that you can do something about.

The point I’m trying to make in this is, I’m not

suggesting that we create an American board of medical specialty of triagology, but I think the individuals who are responsible for triage in our facilities, the emergency departments and the surgeons and the interns who run these, do triage. I think we need to focus on perhaps developing competence towards a mass event in terms of providing effective triage. The other part that fits into this, of course, has to do with experiences with DoD and the sense of providing surgical support. You know, the definitive one-stage surgical procedure to treat a civilian trauma case may not apply in the sense of a mass trauma event. DoD, of course, has adopted a salvage surgery-like approach to take care of sequentially patients with surgical problems. The point is that you would approach a traumatic event in mass casualty situations surgically differently than you would do in a peacetime scenario. These are comments coming from a non-surgeon, I'll have you know.

The last thing I think in terms of management decision has to do with home care. There is tremendous telephone call-in care capability at our VA medical centers. Maybe there's a way to turn that around so that individuals who present for care that don't need to be hospitalized, could be handled at home; if you can turn this telephone system around and use it to help extend care to homes, that would indeed extend or leverage the capacity of our ability to take care of patients. So, these home care call centers, I think, then would be an effective way to extend health care and influence management decisions. For instance, an individual who had been exposed to smallpox, yet he doesn't have particular symptoms or signs, could actually be followed with some kind of a system to support that from a central source.

Now, looking beyond management decisions, in terms of resources, as to what we would do, number one has to do with beds. As you know, in America right now, there's a tremendous shortage of beds to take care of acutely

ill patients. I think this raises the question as to whether or not we should look at establishing a warm-basing approach similar to what the Department of Defense had for the Cold War — a system where there were hospitals that were mothballed across Belgium and France and Germany, that under a turnkey operation would be able to open up and accept large numbers of casualties. Is that the kind of thing that we should look at in America? I must admit, hearing Mr. Bice's presentation on a \$600 million pharmacy push-capability, there seems to be sort of cognitive dissonance; we had a great pharmaceutical response, yet we don't have the platform in which to be able to practice the medicine. So I think we need to look at developing this kind of a capability.

Veterans Affairs is operating a program, a CARES program. The acronym CARES stands for Capitol Asset Realignment and Enhancement Services or Survey. But the idea is to look across the VA system as to the best optimizer. The VA has lost approximately 9,000 beds in the last number of years in terms of taking care of patients, and so I think before we decrease any further, as we look across and look at our capital assets, we need to examine whether or not what we're doing makes the most sense in terms of our national security. The second thing besides beds has to do with equipment. We've talked about the pharmaceuticals. But in addition, there are other things I think we need to consider, and not the least among them is ventilators. We heard from Mr. Bice, I think, in terms of the availability of a botulinum toxin anti-toxin contained in a pharmaceutical stockpile. Well, a companion strategy would of course be ventilator support to take care of individuals perhaps from botulinum exposure who would need ventilator assist. We wouldn't need to have volume cycle ventilators, we could get by with lower tech pressure cycle ventilators to take care of these individuals. Therefore, in terms of stockpiling things, we shouldn't necessarily focus just on pharmaceutical agents.

Lastly has to do, of course, with people. You know, the people who would be used to support this initially — the surge would come from our own doctors, nurses, and staff that we have working for us. I think we, obviously, under an emergency, would be able to extend the work shift from a 40-hour week to an 80-hour week. Individuals can sustain that for a finite period of time. Following that, I think, of course, we would have to look for other solutions. Other solutions might be to include looking at a deployable use of the Department of Defense within VA and civilian infrastructure to move people around to where they're needed to provide care.

The last thing I'll mention has to do with, of course, the Medical Reserve Corps. As you know, the President under the Freedom Corps has established a plan to look at getting health care workers to volunteer to work to support America. I think maybe there's a way to leverage the use of a tremendous resource. In fact, I'll bet you some of us in the room would fall in that category. If we weren't involved in patient care, we'd be involved in recordkeeping, or perhaps involved in an outreach program. But there's a way to extend, I think, the ability to do this through a volunteer network. So, looking at these resources, beds, equipment, and people, I think they constitute the second part of what I was trying to get across in terms of helping to support management decisions.

**Robert Knouss:**

I'm going to take a little bit different tack in responding to the challenge of addressing surge capacity. I want just to illustrate some of the challenges that we faced during the past year, because I think that the system is capable of providing some surge capacity now, and we've had some examples of that over the last 12 months. I will cite a couple of them, three of them, as a matter of fact. One is that during Tropical Storm Allison in Houston,

Texas, when we lost half of the capacity of the Texas Medical Center in a matter of hours, we were able to respond with a fairly robust response that was able to step in and actually provide part of the health care delivery system resources for Houston citizens.

In fact, we took over one of the Cashman-area services, and we did that by combining the resources from the United States Air Force, the resources from the National Disaster Medical System, and the resources for hospitalizing patients in unused capacity at the VA Medical Center in Houston. We also were able to tap almost 100 critical care nurses to bring in to Ben Taub and other hospitals, because of the increased demand that was being placed on them, and we expanded capacity in what was left of the resources in the city.

When it came to the World Trade Center response in New York City, we took a different tack. There, we moved in teams of people who were able to provide for some care that was better organized than some of the volunteer response that occurred around the World Trade Center site. But it's interesting to note that within a matter of hours, not only was there a very robust local response to the victims that might be brought to local hospitals in the surrounding area, but there was also the ability of the city to create capacity by moving patients out and by discharging people who were there in the hospitals occupying some of the capacity for elective reasons. So actually, the capacity to absorb 1700 additional patients, as I recall the numbers, was created within a short period of time after the initial events took place on the morning of September 11.

For the anthrax prophylaxis, we were able to actually launch the prophylaxis of 35,000 people just using federal resources, not including what Virginia and Maryland, as state resources, were able to deliver, and we did a lot of that within a matter of hours after the initial determination was made that the insult was being caused by *Bacillus anthracis*.

So, I don't want to leave the impression that we have no surge capacity. We have some, and we're learning better how to be able to mobilize some of the resources that we have available, because one of the things that we forget is that it's not just the resources that we have to access, it's how we manage those resources that is critical. Managing the resources that we're mobilizing, when we have a need for increased elasticity to face increased demand in the system rapidly, is critical to success. We need to pay attention to managing some of those resources.

Up to the present time, what we've designed the systems to do is to move unused resources from one part of the country or one part of the system into other areas in order to be able to increase the ability of the system to deliver those services. That may not always be possible. For example, if we were faced with an influenza pandemic that in a very short period of time created an enormous demand on the health care system universally, around the country, we would not be able to use the solutions that we've applied up to the present time when we've been called upon to expand that kind of treatment capacity. The surge capacity is dependent, and we need to look at this in its complete context. It's not just a matter of creating space or beds. There are a lot of other pieces that have to be put together in order to deliver and to make real that increased capacity. It's not just space and beds, it's personnel, it's — and I'm listing obvious things — it's equipment and supplies, it's all the support services, how to feed people who are going to be in this kind of additional surge both locally or nationally, and how do we manage those systems. That's just in terms of treatment.

For prophylaxis, we really haven't been challenged to deliver the kind of prophylaxis that would be required to do if we, for example, had a smallpox release in our population. In New York City, in 1947, it took over three weeks to prophylax 6 million people,

and that was during a period of time when we really still had available to us and accessible many of the systems that were used during World War II. If we were challenged now to provide in a very short period of time a prophylaxis to a very large number of people, our systems would be overburdened. The challenge for us is coming up with ways of being able to provide that additional capacity and exercise that additional capacity so that it can respond very rapidly.

When it comes to treatment capacity at the local level, we've been trying to deal with this through our metropolitan medical response systems which have now been started and in some places have been operating now for several years — in 122 of the largest metropolitan areas in the United States.

I would leave with you the idea that there are five basic ways that you can expand treatment capacity. One is that you can install the capacity; that is, in the institutions that are already operating, you would expand their ability to be able to receive and treat patients, putting patients in halls, bringing in additional pharmaceuticals, bringing in additional supplies, keeping personnel on 12-hour shifts instead of eight-hour shifts, and soon. There are ways that one can take existing systems and expand the ability to be able to absorb additional patient demand. We can start looking at developing alternate or alternative facilities and space for treatment in communities, including schools, auditoriums, gymnasiums, hotels, and so on, but I would just say again that you need all those additional systems around which one can mobilize those additional resources at the community level, including this new idea under the Freedom Corps that we would develop a civilian medical reserve capacity at the community level.

One of the things that we tend to forget, but that has to happen, is that we also have to change the standards of care that we expect.

You are just deciding that you're going to mobilize a cadre of our legal friends following one of these events if you all of a sudden implement auxiliary care capacity using standards of care that are different than the usual community norm. You can move health care resources in, as we did during Allison, you can move patients out, as we almost did during Allison, and use the National Disaster Medical System, which is a system that's been around now for 15 or 20 years, but which is now being reinvigorated because it is one of the possible options that could be used to help a community respond to this kind of surge and demand.

Home care, as mentioned by Dr. Claypool, is really a growing option. It's a more viable option now than it had been. The Israelis used this quite well in a variety of circumstances, and I think we now have the capability through our internet, through roving health care professionals. We've used this in other settings, including the ice storms in New York. We were able to provide expanding capacity for home care to some of our citizens who may be at need.

I would just point out that the new legislation that was just on the Senate side — introduced by Senators Frist and Kennedy, and on the House side, HR-3448 — provides for some additional relief that we need in terms of some of the building blocks in order to be able to achieve surge capacity. One is this whole issue of waiving the emergency medical treatment legislation that provides for penalties of hospitals that just send patients on because they no longer have the capacity to be able to take care of them. That legislation, it's possible to waive that, and the Center for Medicare and Medicaid Services is going to have to work on new regulations in order to figure out how we can bypass some of those requirements in existing legislation. Another is interstate licensing, providing for medical practice act amendments. Another is dealing with the issues that I mentioned earlier around

standards of care and so on. NDMS now also has some liability and job protection issues being solved through this new legislation

In conclusion, there are four things that are really critical for us to be clear about in terms of our surge capacity and our ability to achieve surge capacity, and these are four things that I think are really key. One is that we need to be able to stimulate the ability of our communities to find local solutions to their problems. We need local planning. We can't just do this as a top-down issue, it has to be a bottom-up planning system. The second is that we need to be able to assure that there are adequate resources in their entirety, not just space resources or pharmaceutical resources, but all of the other things that we need to be able to provide in order to be able to provide for institutional care of patients who are in need of it.

We need to have modularized solutions. We cannot have a "one solution fits all" kind of approach to this. We need to be able to know where our resources are and how best to manage the response based on the challenge that we're facing. The fourth is that we have to remain very flexible in how we put together that response.

## Discussion

**Daniel Shapiro:** I guess there is a real conflict, and this was brought up quite clearly with the ICU beds, and this seems to be the common theme, that hospitals have exactly what they need or maybe less so cooperate.

Again, the issue is, we have a competitive health care environment. For any individual hospital to decide we are going to add intensive care unit beds just in case hell happens would be inefficient. They'd be potentially underutilized, it would be expensive, all that; the same thing with staffing, equipment, anything else along those lines. So I guess my

question is, if we're going to use currently available hospitals and have some process whereby, for example, rooms could be converted to ICUs in some flexible way, or additional intensive care unit beds are actually built, that's obviously a source of funding. But beyond that, there also has to be some sort of requirement. It has to be mandated by, for example, the Joint Commission, with the idea that a hospital *must* do this, that this is obligatory to being part of the American health care system, that it's not merely being an efficient hospital, that's simply not good enough.

Any thoughts on how that can be accomplished or that should be a component of it, in addition to the idea of not shutting down VAs. We shut down a lot of TB hospitals before, in the early '90s, and we started to have some increased in tuberculosis.

**Robert Knouss:** Well, that obviously is at the core of all the issues that we have to deal with at the present time. Hospitals are suffering from, and other institutions at the community level are suffering from, a lack of financial resources in order to be able to pull this off. I think that is being addressed by certain parts of the legislation and certain parts of the appropriations process now that are going to start pouring literally hundreds of millions of dollars into the health care delivery system in order to build some of this capacity.

But the thing I would like to get back to more than anything else is that I really believe firmly that it requires a good deal of community-based planning, that a lot of this — you can provide the potential for solutions, but you can't really come to grips with all of the local issues that impact on being able to create that capacity. What we tried in our metropolitan medical response systems is to say here's what we'd like you to try to achieve, but you use it the way your community functions in achieving it, and we'll try to look for how we get the resources for you to be able to do that. It really requires communities to

come together, bringing people who traditionally don't talk to each other together to start working on how are we going to solve this as a community.

**Daniel Shapiro:** Agreed, and I think in general, Americans are going to step forward and do what they must. The example of people giving blood after 9/11 is a great one. It also let us know how unprepared we were. Numerous units of blood could simply not be tested for infectious agents and were discarded, indicative of real problems with surge capacity and a lack of planning, at least prior to 9/11. So, yes, these disparate groups are going to have to talk to each other in a nice, reasonable way in every community.

**William Winkenwerder:** I'd urge a little caution here, as implied in your question or comment, that surge capacity equals more ICU beds. I would not start there. Building on what Adm. Knouss just said, I think the place to start is with local planning and with a determination of what we're seeking to plan for, defining the requirement, not assuming that, you know, oh my gosh, we don't have enough ICU beds.

Another issue that someone has already mentioned is the standard of care. I think we have to be careful. You know, Generally, if you're very ill and you deserve ICU care, and you're in a very sophisticated ICU unit, that may not be the smartest and the most efficient way. We still have the goal to and the need to be efficient in the way that we do this. But just building more ICU beds I think is the wrong way to approach this. So I would urge starting with scenarios, starting with local planning, starting with requirements, and determining what are we are trying to prepare for before we get to the answer of what it is that we need.

**P.K. Carlton:** I would suggest his begs the question. Have you thought out a coherent response plan that focuses on the local and

the state assets, because the feds take a long time to get there. I think there are a lot of things we need to learn as a community, and it includes the federal government and the state government and the local government basically thinking through every issue.

**Speaker (unidentified):** In the context of the critical care capacity, for example, I think Adm. Knouss's remarks about creating local plans and thinking creatively about resource management is absolutely critical, because if you think about it, the actual critical care capacity in a hospital is probably twice or even three times the number of ICU beds. All you have to do is shut down the operating rooms and you have post-anesthesia care units that can stand-in immediately as critical care capacity. And those are the kinds of solutions that we're going to have to look for, not creating new capacity, but using the capacity that we have in a very creative way.

Also in that vein, after the attacks of September the 11th, New York Downtown Hospital, which is a level two trauma center, it's not even a level one trauma center, had a throughput in the first four hours, according to the director of the emergency room, of about 400 to 500 patients, which is a tremendous surge. It's almost incomprehensible that they were able to clear their emergency room by 2 p.m., but they were able to do that because of the arrangements in New York City that allowed the patients who needed to be moved rapidly to be moved out to more of satellite facilities. So I think the focus on local coordination and local planning is absolutely critical.

**John Parker:** I'd like to hear the panel talk about two areas that I think are critically important: number one, the possibility of having a federal license for physicians and nurses, so that when you move that manpower pool, they are licensed at the federal level; and number two, how do you feel about having a public law that disconnects private insurance from the casualty during a weapons of mass

destruction effect and transfers the cost of that care directly to the federal government, so that, on a day-to-day basis, our premiums aren't going through the roof because of the possibility?

**William Winkenwerder:** I'll take the second question first with respect to insurance. I was just visiting last week with the national annual meeting of the American Association of Health Plans, and I know they are giving this issue some thought. My inclination would not be to look for an immediate government bailout, if you will. Number one, that creates, I think, some perverse, or potentially some perverse incentives, and it may be very difficult to define what kind of situation that would require that kind of relief.

I think the private industry has an opportunity to come forward with some shared insurance — I'm blanking on the term I'm looking for — like Lloyds of London insurance types of vehicles, in which they may contribute as an industry to a pool of funds that would take care of that kind of situation with government almost as a third line of defense. But I wouldn't underestimate the desire for, at least from what I was hearing from some of the industry leaders last week, to just step forward when the situation requires it. I think they did on September 11th, at least I'm told that, to just pay for things, not ask questions, make sure that people get the care that they need. So that would be my thought; that would be the first line. The second line would be some sort of shared mechanism like FDIC that they could all contribute to.

The third line would be direct support from the federal government. But really, I think we'd almost have to be into massive, mass casualty sort of situation for that, and even then, you know, I'm not sure the government can pay for the cost of something of that kind of magnitude. I'll stop there.

**Robert Claypool:** I think the portability of

both licensing and credentialing are an important topic to consider. At least in the federal government, there are issues on both fronts, as I know you know, and I think it is something that we have to address, because, indeed, we need to ensure that not only people are capable of doing what they say they are doing, but also that, you know, when they go into another location, they're permitted to practice up to their levels of credential, so there are efforts to do this. I'm not up-to-date in terms of what actually is happening, but I think important consideration.

**Robert Knouss:** Just on the licensing issue, I would mention two things. One is, the new legislation does deal with licensing issues for people who are going from one state to another under the auspices of a federal response; but secondly, for National Disaster Medical System and the folks that we have under the Federal Response Plan, we actually bring them on to federal service, so they're already protected then by federal tort claims and liability issues and authorities.

**Terri Malone:** I'm with Northrop Grumman. The new NorthCom that's being set up by the Department of Defense, do you see it being able to provide surge capacity in the way that they can now for overseas things that are happening, setting up mobile hospitals here or in other ways providing the same kind of surge capacity internally in the United States?

**William Winkenwerder:** We don't have all the details yet on how that kind of question will be worked out. But I would envision that if NorthCom is another combatant command the way other CINCs operate, that a request for that kind of support would either be filtered through the Joint Staff or to a central point, and that it really comes to the three services, and Health Affairs has a role as well, to look at how best to deploy those assets. I think we could save ourselves not just time and possibly dollars, but we could maybe do a better job at dealing with that kind of event-

ality if we did planning ahead of time to determine how it would work in a given situation. I've been working with the three Surgeons General and the Joint Staff on thinking about how we should integrate our planning efforts across all three services, and now with a new Northern Command — I don't view it as a complicating element, I view it as a facilitating element, but it would still have to go back through sort of central leadership of the department to determine how those assets would be deployed.

**Arnauld Nicogossian:** I'm from NASA. I would like a comment our surge capacity for decontaminating a large number of victims and our ability to transport them.

**Robert Claypool:** I can tell you a little bit about what the Department of Veterans Affairs is looking at. I think one of the things that may be important to do is to distinguish between decontamination as an event occurring in a hot zone or an incident that's occurred as opposed to decontamination in the setting of a hospital. As you know, what happened— the only recent experience is in the Tokyo Sarin attack— is that individuals came by bicycle, by taxicab, by whatever means to the facility, so there really wasn't any kind of decontamination efforts that were conducted at the site themselves.

VA really believes that this is an important adjunct to emergency management, so they are embarked upon, I think, an aggressive program to look at this. Dr. Susan Mather, who's sitting here, actually is heading this up within Veterans Health Administration by looking at a program to aggressively set up the ability to have a hospital-based decontamination system with appropriate level of personal protective equipment to take care of individuals who arrive at the medical facilities. In terms of the first-responder capability, we do not have any response to that — in going out into the hot site, hot zone and setting up decontamination stations.

**Robert Knouss:** Again, when it's coming to a decontamination challenge for a community, the resources have to be existing in the community, and so the approach that we have been taking is to try to expand or strengthen those resources at the community level. It really, for many communities, means expanding what their hazmat capability has been. The second is that hospitals themselves are now developing a large number of different kinds of technologies in order to be able to expand the ability that in the past might be used to decontaminate one or two people who were exposed to a chemical spill or something of that sort in a community. There are a lot of myths that are being burst and a lot of new concepts that are being implemented around the country in terms of what it really takes to decontaminate someone.

The third thing that I would just mention is that there is a prohibition about transporting people who are contaminated or who are infectious, and therefore, part of the issue around how do you create some surge treatment capacity is, you can't necessarily move out the people who have been directly affected, but you can move out people who are using some of the local capacity in order to use some of that capacity for the people directly affected by a local incident. So there are a variety of different ways of being able to deal with the issue of decontamination and transportation of patients. Again, it's a matter of knowing the principles, having a choice of resources and solutions to problems, and choosing among those potential options that is going to really stand us in the best stead. It's spending the time and effort to develop the plans and create the resources to be able to mold the response to the circumstances being thrown at us.

**Sanford Garfunkel:** I'm from the VA. As we look to stimulate local planning, is it necessary to free up federal facilities from their usually defined role as to exactly who they can or can't take care of, so that federal

facilities can be a full partner in the local planning efforts?

**William Winkenwerder:** From the Department of Defense perspective, I think we need to take a look at that question. I don't know. I'm reluctant to give a specific answer to it. We have a primary mission, and we have to be careful about making ourselves vulnerable to not being able to carry out and conduct it. Because this notion of being able to respond to a homeland situation is so new, I think it's fair to say we haven't — I mean, it's not like we haven't thought about it, we are thinking about it, but the model for how we ought to respond and participate I think is yet to be fully developed. We are initiating discussions together with the VA as a combined set of federal assets in many communities to think about what would be the best way to interact and support the local community. Obviously, in a disaster situation, I have a hard time envisioning that we or the VA would stand by and do nothing while the local private sector or state or local hospitals would be overwhelmed and we'd do nothing; I just don't think that's the way we would respond. But how best to coordinate a response is yet to be fully fleshed out.

**Robert Claypool:** There are cost incentives or disincentives, depending on what side you sit on, as to whether or not the Federal Response Plan is activated. So, the federal government, like Veterans Affairs, for instance, certainly does provide care for non-traditional eligible beneficiaries; but without activation of the FRP, then the cost alignment to support that becomes somewhat problematic. As Dr. Knouss has just whispered into my ear, under Tropical Storm Allison that occurred down in Houston, which was a tremendous success from the health care standpoint, the reimbursement mechanism for that really hasn't allowed the VA to be recompensated for the expenditures that occurred there.

So, I think maybe this whole issue is some-

thing that probably should be considered, along with what kinds of rule changes or legislative changes that need to occur. In fact, we suggested to some of the people in Homeland Security that as they're looking at changes to improve the nation's readiness posture, that these kinds of rule changes should be considered.

**Robert Knouss:** One of the things that gets in the way is all that paper pushing, because after we respond, then the next thing that happens is an army of auditors arrive, the lawyers and the auditors arrive. So what we really are talking about here is finding better ways in order to make it a far more responsive federal and state system that can help local communities and do away with some of this burdensome bureaucracy that has to go along with it, because we have the resources to be able to do it, it's just a matter of being able to make sure the systems are flexible enough and agile enough to be able to respond rapidly.

**John Parker:** The federal facility is a part of the community. So if P.K. Carlton is in San Antonio and I'm in Denver and something happens in our back yard, we don't have to ask "mother, may I?" We're a part of the community and we leverage our assets at that moment to support whatever disaster it is, and then as time goes by, headquarters would either support us or gradually take us out of the situation, depending on the other needs. No federal facility is going to sit there in the community and just say that's not our problem.

**Marian Balsam:** I'm on the American Academy of Pediatrics Task Force on Terrorism. My question: is anyone aware of any specific plans or even specific thoughts regarding decontamination of children and infants?

**Robert Claypool:** I cannot speak with a great deal of authority about that. I do say that, as I mentioned, the Veterans Affairs Department is looking at purchasing decontamination equip-

ment. I went up to a fair up at Fort Detrick actually to look at a bunch of vendors and so forth, and some of them do actually have processes to go ahead and allow the decontamination of children. We don't deal with too many children at the VA, although they certainly might come to our facility. So I think that that's probably a beginning; it's not clearly well developed.

**Robert Knouss:** I think you're raising an excellent point. Most of what we have focused on are adults. We have not focused on the two ends of the spectrum of the young and the old, and that they really present different kinds of challenges to the health care system. It's starting, but it is far lagging far behind even the place where we are for planning for the rest of the response.

**Marian Balsam:** One of the goals of the Academy of Pediatrics Task Force on Terrorism is to sensitize the people who are involved in planning preparation response to a terrorist act, that children are not simply small adults and have some very specific medical, as well as psychosocial needs.

**Fred Sanford:** I'm the Executive Director of AMSUS, and I have a question that I've been trying to figure out how to phrase. It goes back to a question asked to the last group. I can't think of any other way to ask it other than who's in charge? Specifically, with regard to the new proposed Cabinet agency, where are the medical issues coordinated within that proposed structure — or are they supposed to be, or are we going to be dependent upon coordination of the agencies that now exist? I haven't seen too much about medical in that new structure.

**William Winkenwerder:** I'll give you my read, and it is just that, it's a read of the newspapers and the magazines, as it's not all spelled out and fleshed out. My sense of it is that the focus is on procuring the funds and the focus and the programs to support some of

the things I talked about with the national vaccine effort, vaccines and medical treatments and so forth. But obviously, the departments that do that work are HHS, at the National Institutes of Health, and the CDC, and the Department of Defense, largely, and then a little Agriculture. So I think that remains to be spelled out. I'm looking forward to participating in some of those discussions and hopefully shaping them in the right way.

There's clearly a need for some coordination, but I also think we have to be careful about taking things out where they're, you know, they're best. We don't have an FBI/CIA competitive problem, in my judgment, between the DoD and the HHS. I think we're working together very collaboratively. But we do need some additional formalized mechanisms to ensure that our planning and strategy is synched up. To the extent that Homeland Security can help play a role in that, it would be good. To the extent that it actually created three entities to try to coordinate programs, it could make things complicated.

**Robert Knouss:** The real issue is going to be what is the relative priority for the use of the resources that we have available. One of the things that we have been very careful about in our planning has been not to assume that resources that are going to be required for the country's defense are going to be pledged to providing the only solution available to protection of the civilian population. That really is a critical element within the planning of how this response might happen. So, for example, and I would cite this as being one of the critical issues that tends to get overlooked, if we need to transport resources from one place to another — the available resources are largely going to be in the military for the kinds of transportation that we have to do, and yet they're going to be used for other purposes likely before they are used for a civilian response to a local threat. So there are a lot of things that come into play in

terms of what really is going to be able to be done and managed and how that response is going to take place, which again brings me back to the issue of, we really need to know what assets are available and how they can be managed in the most flexible way possible in order to make the decisions on the spot when faced with a challenge as to how best to launch a response.

**Robert Claypool:** My impression is that there is perhaps a heavy emphasis on the crisis response aspect to how Homeland Security is set up, and I'm not so sure that's totally inappropriate. But it does seem to outweigh a bit some of the consequence management part, the health care part, which is, of course, what we're involved in. I think there is progress on some of the policy coordinating committees that are set up underneath Homeland Security to make sure that public health issues are receiving their appropriate light of day.

**David Danley:** Everything in Washington, D.C. has a half-life, and the crisis we're involved with right now will have a half-life, but it shouldn't have a half-life. In other words, the plans that are being developed right now should be sustainable. So, I guess I have two questions. One is, what do you think the half-life of this problem is going to be, and how do we sustain it, particularly given the importance of resources. We have an aging population of baby boomers; we're not going to be there to provide health care, our children will, and there are few of them, fewer of them than there are of us. So the plans we're making now have to change over time.

It's our inability, at least from my experience, that failure to see into the future has been at the crux of why we almost had an anthrax vaccine crisis, why we do have a crisis in adenovirus and some of these other issues that we're not looking far enough into the future and sustaining an interest in maintaining what we're doing.

**Julie Susman:** Im with the Jefferson Consulting Group, and also Chair of the NDIA Health Affairs Committee. How do we encourage and expand our providers in the professional areas in time and in coordination, collaboration with what we're doing at the federal level?

**William Winkenwerder:** I have a couple thoughts on that. My first thought is, it's about leadership. In my view, we, collectively, the country, allowed the public health system to go from a place of importance in our whole health care system to a place of secondary or tertiary importance. We did that. It's the culture of American medicine to focus on the individual and high technology, forgetting that at the end of the day, safe water, safe food, clean and safe air is what sustains us as a people, as humanity. You know, I think we only have ourselves to blame for it. I place the leadership of the academic medicine and the research community at the head of the list. We've forgotten, we lost sight, you know, that there's these basic things that we've got to do.

I think, fortunately, and it's been my good experience that we haven't lost sight of it in the military health system, because we realize that this is at the end of the day, you've got to take care of a population of people, and you've got to think about everybody, not just the individual. So I think we've got to get back to thinking that way. How we sustain it, I don't know. I think it comes back to leadership, more dollars are important, but ultimately, we need good people, we need good people in the public health community, we need good people who are state health officers and local health officers who are not just, you know, retired physicians or providers who couldn't find something else to do. We need the best, and I think that's the challenge I would lay out.

I don't know how we get to provide the adequate number of providers, but I would

start with the issue of leadership and strengthening the public health system at the local level.

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### ***Panel 3: Realistic Solutions to the Surge-Capacity Deficit***

**Robert Vowels, MD, MPH, Supervisory Medical Officer, D.C. Public Health Department**

**Roslyne Schulman, Senior Associate for Policy Development, American Hospital Association**

**Jerome Hauer, Director, Office of Public Health Preparedness, Department of Health and Human Services**

#### **Robert Vowels:**

I think there were four major issues or lessons that we learned from the anthrax incident in Washington, and they were in the areas of event management, communication, dispensing operations, and resources. One of the interesting things that has been tossed around in a number of debriefing sessions since the event in October was that there was not an official emergency declared at that time. Due to the nuances of D.C. law, that caused certain challenges for us at the Department of Health in being able to access certain resources, both locally, and in some cases, federal resources. That was something which we dealt with the first time, and I'll talk a little bit later about some solutions that we've come up with locally.

We also responded to the event, but we lacked at the time dedicated pre-planned support of other agencies, and that caused the department then to perform non-health functions to get the job done. We worked in close partnership with our federal partners, with the Office of Emergency Planning and Support, HHS, and with a number of individuals who were lead-

ers in the earlier session, Rear Adm. Knouss and a number of other — the Centers for Disease Control and Prevention also participated. Along with that was also the U.S. Postal Service involvement. One of the things I wanted to bring up was, the Postal Service was a great partner with us, but because of the concern of some of their employees about the confidentiality of their medical history, at times, that was a challenge in having them complete the forms correctly for fear that their supervisors might learn something new about their medical history. The other things that we learned, obviously, is that the Department of Health feels it needs to be in charge of the event for future health-related events that effect the District of Columbia. Obviously, I think it goes without saying, but I'll say it anyway, that there's a need for a more widespread incident command system training for our staff, and that goes really pretty much from upper middle management down through line staff.

The sum of the things that we put in place, and these are really lessons learned, but we're in the process right now of implementing solutions for them, is getting clear intelligence information for better planning, defining regional leadership roles and responsibilities clearly, identifying in-house skills of particularly some of our physicians and other health care providers, and then establish protocols and actions based upon really the type of event and the scale of the event. We also learned that we needed to consider invoking the worst-case scenario, and then to scale down our response as indicated by the event. Also, one of the things that seems, I think probably for many of us in the room, a simple, a commonsense thing but we found difficulty with was just keeping a record of the events, and that's another piece which we're putting a solution in place for future events.

The other piece which I think is an exciting piece is that the Mayor had passed new legislation which is fairly sweeping legislation

related to criminalizing certain events that are bioterrorist-related events; part of that legislation gives the Mayor new authorities to evoke certain public health emergency resources or to activate those resources without declaring, per se, a public health emergency. That new legislation will help us in being able to access some additional resources that we need which we didn't have in the October event.

Communication is a very big challenge for us. It was a challenge during the anthrax event in that information was not necessarily entirely accurate or consistent. For those of you who were involved with it, you may recall there were frequent changes of treatment protocols, and getting that information out to the health care providers in the community was certainly a challenge for us at the time. We also thought that, oftentimes, CNN would get the heads-up on us before we got the information out; we're putting in place solutions to improve that response in the future.

We have a command center that we activate during the time of an event. One of the things we realized is, we really need to establish a permanent call center, to have that staffed up, and we're in the process of establishing a permanent call center so that that will be up and running at all times. Another thing that was a good lesson for us was the cultural sensitivity issue, particularly the message that we communicated to the public. We had a number of publics we were serving and we continue to serve. Those include, obviously, the health care provider public, but it also includes, for example, the U.S. Postal Service employees, and the message that we sent out needs to be and needed to be, I think, a little bit more culturally sensitive for those in place, and so we're looking at ways to do that better.

We also found we have a need for developing a regional syndromic surveillance system. We have one in place now, but we're talking about strengthening it so that we have ready information that can be transmitted immediately to

health care providers, and we've established relationships with the D.C. Hospital Association, the Medical Society of D.C., the Medical Chirurgical Society of DC and a number of other organizations so that we can get this information out. I should mention that the Metropolitan Washington Council of Governments has played a tremendous role in assisting us to get the information out to the public. Another thing that we found out is, we have approximately, I think 1,600 employees at the Department of Health. For us, essentially, to handle a large scale event, if we used all these employees, there's an issue with being able to carry on day-to-day public health activities. What we need to do is look at utilizing our human resources better, particularly with looking at ways of extending some of the health care services into the volunteers — making, if you will, a volunteer force that can provide some of the services such as dispensing medication. We're in the process right now through our General Counsel for evaluating legislation that could be adopted which would allow pharmacists and other individuals to be able to dispense medication during the time of an event. The Board of Pharmacy, the District of Columbia Board of Pharmacy is looking at that matter as we speak.

Finally, let me just address resources. We know that we have a need for developing better information systems within the Department of Health and to network those information systems with our partners in the community, our public health partners, American Hospital Association, et cetera. What we really want to do is to ensure that we get an information system in place where we can get the information out to the public and to connect with the public in a timely fashion. We're in the process now of reviewing specifics offer applications to help us with that particular function.

**Roslyn Schulman:**

There are three things I'd like to talk to you today about. One is a bit about the barriers

that face hospitals in surge capacity. I'm also going to update you on the hospitals' current state of readiness based on a survey that we recently conducted of our members. Then last, talk a little bit about some of the approaches that our members are taking to addressing surge capacity in this new world of terrorist threats.

I think it's been raised a few times over the course of the day that hospitals are in dire financial straights. The Balanced Budget Act was just the beginning of it. Seventy-one billion dollars in hospital losses came out of that. There are also fewer hospitals as a result of it. In some states, up to 20 per cent of hospitals have closed. And when hospitals are struggling simply to keep their doors open, the ability to use those limited resources for getting ready for terrorism becomes quite a challenge. Also, our hospital costs are rising rapidly in numerous areas. The point is that in an environment of rapidly rising costs, disaster readiness costs, the costs it takes to get ready for disasters to be prepared, unless they're already building upon other every day priorities, become also a difficult challenge to invest in.

One out of every three hospitals has a negative total margin. But the real issue in surge capacity limitations is also people, ensuring an adequate number of trained staff who are available and willing to respond. We've all heard about the nursing shortage. There's also a severe shortage of pharmacists, radiological techs, and other important professionals who would contribute to a response. We've also all heard about emergency department crowding and the growing problem of ambulance diversion. We recently did a survey looking at these issues of emergency department capacity and diversion, finding that one in eight hospitals reported being on diversion 20 per cent of the time or more. The majority of hospitals report that they are at or over capacity. This is a problem everywhere — but especially in urban hospitals, large hospitals, teaching

hospitals, and on the two coasts, East and West Coast. We've also heard today about the rising volume in the emergency department and general lack of acute care beds. Again, nursing shortages come in play, also the shortage of on-call physicians and the increasing numbers of the uninsured. I don't want to put too much of an emphasis on this, though, because, although this is a warning sign, ambulance diversion is a warning sign of capacity constraints; it applies primarily under normal circumstances. In disasters, of course, hospitals activate their disaster plans. As we heard, in New York, and in Virginia, and Washington, and New Jersey, when that happens, hospitals discharge patients, and they cancel elective surgeries, and they call in additional staff, and they increase the length of shifts. As a general rule, what we've heard is that you can free up about 20 per cent of your hospital capacity through those kinds of measures.

The basic message here is that mass casualty readiness does compete with other issues that stretch the already tight budgets that hospitals face. This is why we, as a national association, are advocating for flagship legislation that will improve the overall financial condition of hospitals, as well as ongoing federal investment in hospital disaster readiness.

I'm going to briefly tell you about a survey that we did recently of hospitals. All hospitals, of course, have disaster plans, but the events of September 11th and the anthrax attacks did lead to review and an upgrading of hospitals' own disaster plans, particularly in the areas of these new threats of terrorism. So we did a survey about six months after September 11th to see where hospitals stood. The basic findings are that hospitals are taking some important steps to increase their readiness to respond, however, more needs to be done. The steps they've taken tend to be those that are easier to do that don't involve a lot of resources, and the more costly things are things that are left undone.

Hospitals do have inserted components related to bioterrorism, chemical terrorism, and nuclear terrorism. The majority of hospitals are putting those into place. Hospitals have — a vast majority have put into place back-up internal communication systems. Communications are one of the first things that fail in a disaster. Hospitals are also reaching out to their community partners. The vast majority have reached out and have met with, are getting to know these other partners in the community, the first responders in public health. Hospitals are also working with their communities in participating in community-wide disaster drills. They are training their medical staff in biological and chemical agents. They have processes in place to report unusual trends in cases to the public health authorities, although often those kinds of procedures are not very time sensitive.

Then the last finding is that is that the vast majority of hospitals that responded to the survey indicated that there are certain things they feel they should be doing, but cannot currently do with regard to disaster readiness because of a lack of funding. Again, those are primarily things that are resource-intensive, like installing more sophisticated real-time disease surveillance systems, specialized training for their laboratory personnel, interoperative communication systems so they can talk to the other partners in the community, first responders, personal protective equipment, that sort of thing.

This, again, is why the AHA is advocating for an ongoing, sustained federal investment in hospital disaster readiness. Again, disaster readiness is competing with a lot of other very important priorities, priorities that relate to patient safety, privacy, and other things. You know, clearly, this is a key priority as well, but you have to recognize that there are other things going on, other priorities that we don't want to sacrifice. One of the keys to addressing an effective response, of course, is

to recognize the difference between sort of a run-of-the-mill emergency compared to a disaster or a mass casualty incident.

Emergency hospitals can use their own plans and their own resources to respond. In a disaster, they have to go beyond their own capabilities. By definition, a mass casualty incident will overwhelm a hospital's capacity to respond, and in fact, may overwhelm the capacity of the entire community hospitals to respond.

So the way we look at it is, surge capacity is actually a community issue, it's not just a hospital issue. The planning and the resources must come from within the entire community. Therefore, hospitals, along with their partners in the community, must plan in advance, and that's just definitely a key here. The new components, the way we look at it is, law enforcement, fire, EMS, emergency management, public health, public health in concert with hospitals and physicians, all of this planning should start to take place in advance. Of course, you don't want to be exchanging business cards during the disaster, and you have to understand each other's role, parties have to understand the role of their partners, and there definitely are different cultures between these different partners, and you need to understand that, as well, in order to have an adequate response.

In terms of surge capacity, a question arises, what is it that hospitals need to plan for? What we've heard is from HHS and from the Office of Homeland Security is, about 500 additional patients within a community. In a document that we released shortly after September the 11th, we made slightly higher recommendations of 1,000 patients in urban communities and 200 in rural. There's a number of different models for addressing surge capacity. There's distributed resources models, where facilities either stockpile individually or they have access to memorandums of understanding so they can access resources at these other facilities.

The other way to approach it is through centralized resources that can be quickly deployed, such as vendor managed inventories or the National Pharmaceutical Stockpile

The American Hospital Association believes that all facilities need some minimal capacity to respond on their own. Some of the approach needs to involve distributed resources, with the recognition that when it gets too large, it would go beyond — to state and federal centralized resources. It's not necessarily just beds that limit surge capacity, it's also the number of staff you have, not just shortages, but also how do you guarantee that the staff are going to show up, particularly in a bioterrorism event. Specialized equipment such as ventilators, isolation capacity, and if a surge means that you're moving people outside of the hospital system, you need to have community systems in place to address food, laundry, transportation, and public safety; protection and law enforcement needs to be a part of that, as well.

We've had a number of conversations with our members about the approaches that they're taking to address this issue of surge capacity, and there's a whole variety of approaches that are in different stages of development. Some of them are engaging in some limited stockpiling of personal protective equipment so they can ensure that their staff will show up. Vendor managed inventory is a solution for some kinds of supplies and equipment. A lot of communities are actually creating hospital mutual aid agreements so they can share resources between themselves. One of the key issues that needs to be addressed here is how you perceive the hospital. Most people look at the hospital at being a safe haven. So as we saw on September 11th, a lot of people come and overwhelm the facility; that could actually really isolate a facility. They ought to be doing the things that they're best at, which is providing critical care and other kinds of care for the wounded and the ill.

Some of the approaches that we've heard our members using regarding alternate care sites, that is, moving out what you can move out from the hospital site to other locations and just keeping the critical stuff in the hospital — we've heard members are using long-term care facilities for these purposes, psychiatric hospitals, schools, churches, one of the more innovative ones is Nevada casinos, because they do have some limited health care capacity there, state fairgrounds, lots of different things. In terms of staffing, that, of course, becomes a key issue. You've heard a variety of solutions that our members are looking into, including using students, medical nursing students to help with some of this capacity, surge capacity, as well as using non-clinicians to distribute medicine, prophylaxis. You've heard some people using community leaders like bankers and law enforcement officials for that purpose.

### **Jerome Hauer:**

First, I think it's important as we look at surge capacity to define what surge capacity is, because so much of the planning has gone into trying to find beds. I think as you just heard, there are really three components of surge capacity — beds, people, and equipment. Planning for beds is actually quite easy. Planning for people and equipment is a little greater challenge. As we look at what can be done now, I think it's absolutely critical that this be a bottom-up kind of approach, that it not be dictated from Washington, but that we provide some models, which we are doing to communities, on how to address the surge capacity issue.

As we look at it, what we're asking cities and states to do are look at, as they do their pre-planning, is identifying sites, identifying staff, and identifying equipment needs through modeling. At the same time, we're also asking them to look at how they would do mass prophylaxis and mass vaccination,

because you've got to realize that, particularly in a bioterrorist event, you're going to have competing demands on local communities. You heard about anthrax and the demands on the health department and trying to do a mass prophylaxis with antibiotics; you're going to have demands on the community from the health care system to treat both those that are real and the worried well, and you've got to provide mass care, but at the same time, you've got to have significant numbers of people to do mass prophylaxis.

I'm not quite as concerned as D.C. is about distributing antibiotics. During a major incident, pretty much anybody can hand out antibiotics as long as there is some medical oversight. In fact, that's most of the modeling that's been done. When we looked, six years ago, at giving out antibiotics to the total population of New York City, we looked at two models, one was door-to-door, as the Israelis do, the other was setting up POD's, or points of distribution; we had to identify 300 locations in New York City that could be set up in 12 hours that people could come into and receive antibiotics. To go door-to-door, it would take 45,000 people just to prophylaxis Manhattan in 36 hours, and I have no idea where I would have gotten 45,000 people in that period of time. To do the whole 8 million people in the city of New York in 36 hours, all five burroughs, if we set up POD's, it took 41,000 people. These are very labor-intensive types of issues.

We're doing some modeling right now with CDC, because by the end of the month, we are going to be releasing guidelines for cities and states to use on mass vaccination for small-pox, and the numbers are equally difficult. So as we look at surge capacity, we have to keep in mind that these events are just not mass care, but can have other components, as well. The same type of thing for a nuke or a rad device, if we had to give out KI in large quantities, the likelihood is small because KI needs to be used in a short period of time and

it needs to be on hand, but we have to focus on that, as well. But I think as cities and states — and I have to follow on to what we just heard, we just gave \$135 million to the states for use for hospital preparedness, 80 percent of which had to be given out to hospitals. In the '03 budget, there's \$530 million that will be going out to hospitals for preparedness, and again, 80 percent of that has to go out to the hospitals in the states. What we're asking them to do is, last year, as you heard, it was a model for surge capacity of 500 beds in the region. We're not looking at isolated incidents just one hospital, we're looking at a regional approach.

Next year, we're going to be asking the states to look in the regions at 1,500 beds as the surge capacity. Once they've gotten through that first two, we want to crank it up a little. But it's critical that they look at sites. Hospitals cannot handle surge capacity, with the exception of maybe one or two. Washington Hospital Center has an excellent model, the ER-1 project, where they've got a scaleable approach. They're pre-wiring and pre-plumbing a lot of their hallways and atria within the facility so that they can plug in pretty much anywhere and they can add 200 or 300 beds in a very short period of time.

But the reality is, most cities and most hospitals can't add large numbers of beds quickly, so you have to look at what we call alternate care facilities, and that may be a hotel, which is a model, because you've got pretty much everything you need, you have beds, you have convention facilities, you can secure it, you've got cooking facilities, all the logistics are in place. The real challenges are going to be where do you get staff and where do you get equipment. You have to start to model at the local level. If you have 200 or 500 additional people, what is it that you need to equip an alternate care facility?

Again, in New York City, we looked at two types of alternate care facilities, those that are

not contaminated, or contagious, and those that are contagious. For contagious, for a smallpox outbreak, we would use something like a convention center, where you could put 200 or 3000 beds, quarantine the people, treat them aggressively, but keep them in an isolated facility. We also had alternate care facilities proximate to the emergency room, because clearly, emergency rooms are going to be overwhelmed. What you want in the emergency room is, you want critically ill patients, you don't want the worried well. So you've really got to triage people before they get to the emergency room. You've got to have a mechanism to secure your emergency room. People who are walking wounded, by definition, don't need to be in the emergency room right away. They go to an alternate care facility proximate to the emergency room, they get sent home, if all they need is chemoprophylaxis, they get their drugs and they go home, or if they need to be triaged to the emergency room or to an alternate care facility, they are. All of this can be planned in advance. All of this can be tested in advance.

I think it's absolutely critical that this be done at the local level. We can provide assistance and modeling from Washington, but basically it's something that has to be done at the local level. No city is alike. The demands in the cities are not alike. The people you'll use, you've got to rely on resources. We're looking now at volunteer medical corps as part of the President's initiative. Looking at that, you've got the whole issue of retirees. There's a whole cadre of retired physicians, retired allied health professionals, and retired nurses who are available, but one of the greatest inhibitions at the local level is malpractice. If states can provide coverage, many of these folks, and we've talked to a lot of folks, are more than willing to help out. It's a matter of providing some kind of malpractice coverage or good samaritan coverage.

I think at the end of the day it's absolutely critical that anything you do at the local level

be scaleable and flexible, depending on the type of incident. We don't recommend that communities stockpile drugs or vaccines, and in fact, the vaccines are not available for stockpiling, and we are not going to release vaccines for stockpiling at the local level. What we recommend for hospitals is they have a 48-hour supply of antibiotics to treat any surge in patients and to treat staff and their families. One way to keep staff at work is by ensuring they have coverage with antibiotics for themselves and their families should chemoprophylaxis be needed. The same is true of vaccination.

As you know, this week, ACIP is going to be meeting at CDC to make their recommendations to the Secretary on pre-vaccination for smallpox. We should have those recommendations sometime later this week or early next week, and we'll see where that goes. But the general sense is that there will be some recommendation on pre-vaccination for some cadre of people, probably the first responders for bioterrorist events, which are not cops and firefighters, it's the folks in emergency rooms, ICUs, and infectious disease docs. So with that in mind, you know, I think there is a lot that can be done now. I don't think we have to build a whole lot of new beds. I don't think that we have to look to hospitals to increase capacity solely within the facility. We have to get creative. We have to look outside of hospitals for surge capacity, as well.

Certainly, we want to start in the hospital and put the most critical people in hospitals, but a lot of people don't need the kind of critical care that you get in ICUs or in hospitals and can be managed in alternate care facilities. We have to look at how we're going to staff these facilities, and then communities have to look at the types of equipment they're going to need. Some of the equipment will come from us. The National Pharmaceutical Stockpile has a significant amount of medical equipment that can be dropped in. That can be done within 12 to 24 hours by and large

anywhere in the country. But a lot of this has to be done at the local level as well

### **Discussion:**

**Terri Malone:** I'm from Northrop Grumman. Ms. Schulman, have you found any difference between non-profit and for-profit hospitals in their level of preparedness or desire to be prepared? A question for Dr. Hauer is, what's the difference the Office of Emergency Preparedness and the Office of Public Health Preparedness in HHS?

**Jerome Hauer:** The Office of Public Health Preparedness oversees all the activities, both for preparedness and response for all public health and all emergencies within HHS. OEP reports to me, so it falls under me, and then I oversee a lot of the activities at CDC. I work very closely with Steve Bice on the pharmaceutical issues and the National Pharmaceutical Stockpile. All the budget authority for the grants, as well as for all emergency — it's about \$3.5 billion this year in the supplemental bill — falls under my office, and the Secretary looks to me to oversee that.

**Roslyn Schulman:** On your other question, why we haven't looked specifically at the differences between for-profit and not-for-profit health care facilities, I can tell you that, in speaking just to members, based on my experience, there doesn't appear to be any difference. In fact, some of the for-profit systems have made some of the biggest advances in terms of planning and development of systems. So there are not any differences that I'm aware of.

**Lew Miller.** I'm with the Sabin Vaccine Institute. Could you clarify — when you spoke about a restriction on stockpiling vaccines locally, how you're going to handle that?

**Jerome Hauer:** Well, what we're doing

now is, we are aggressively producing the a campylobacter smallpox vaccine. We expect to have 260 million doses of the new vaccine by November 1st, somewhere around there. We have 15 million doses of Dryvax which can be diluted one to five. The Dryvax is spread around in strategic and secure locations around the country. We've got about 75 or 80 million doses of the Aventis vaccine, which as you know, is already in liquid form, can't be diluted, and that is, again, strategically located around the country.

Steve Bice is overseeing that, and the vaccine, when we get that in-house, will be located around the country, as well, at secure facilities. We're working closely with Bill Winkenwerder on that as well. By and large, if, in fact, we need to use the vaccine, we can get it pretty much anywhere in the country in about 6 to 12 hours. It's all kitted. We've got bifurcated needles for the smallpox vaccine. Anthrax vaccine is a little different. There's not a lot of anthrax vaccine available. Most of that's at a couple of locations, DoD is in the process of letting a contract for a significant additional stockpile of anthrax vaccine, and we should start seeing that in the next year or so. That's already being produced. That will be, as we get our inventory of anthrax vaccine, stockpiled around the country, as well.

**Speake (unidentified):** A follow-on question. I understand that the national stockpile will be held and managed and released only by the federal government. Once the national stockpile of either smallpox, anthrax, or anything else that may be deemed necessary is met, is there any thought that states, cities, or other local bodies will be discouraged from acquiring an additional local stockpile?

**Jerome Hauer:** Well, we're not going to pay for it. We are discouraging it. In New York City five years ago, I made the decision, after talking with the mayor, not to do it, because managing an inventory of antibiotics, particularly Cipro, is expensive, the shelf life is not

such that we needed those quantities in-house. We did have a small quantity available. But by and large, we depended on the NPS. Again, we did a survey in 1997 of all the hospitals in New York City to look at what the on-shelf, we looked at atropine, and then several antibiotics, as well as valium, and ironically, we had four-day supplies of valium and only about two- and-a-half-day supplies of most of the antibiotics.

Our recommendations to hospitals are, you know, something a little over a 48-hour supply of antibiotics until the stockpile gets in is probably adequate. That way the staff can get antibiotics if need be. Obviously, if we had a smallpox outbreak, the hospital staffs would be the some of the first to get vaccinated, along with patient contacts. But we just don't recommend that states spend their money on this. I'd rather see them put it into the hospitals and put it into preparedness rather than stockpiles. I just think it's going to go to waste. We seeing that with antidotes right now. A lot of fire departments and police departments bought kits. I bought about 100,000 for New York City to put on all the ambulances, and turning them over is difficult. You have to have an ongoing budget to buy new ones and turn them over, and a lot of it goes to waste.

**Kristi Koenig:** Department of Veterans Affairs. A question for Mr. Hauer on the stockpile. How sophisticated is the modeling that looks at the numbers of patients that we can treat? Does it take into account differences in children and the elderly and the different scenarios and the amount of dosage you might need to give and that type of thing?

**Jerome Hauer:** Yes and no. Historically, there has not been as good a focus on pediatrics as there should be. That has been part of the modeling recently. In fact, some of the things that have been purchased historically have been adult doses only, KI for one. That is changing. We're now looking at buying 65

milligram tabs of KI rather than the 130, so that you can treat kids. Bob Knouss did that for the OEP stockpile of KI, and it makes a lot of sense. There was just an exercise two weeks ago that looked at throughput modeling for chemoprophylaxis, and it tested some of the notions we had developed about five years ago, and we are now doing some ongoing modeling on both distributing drugs and vaccination. The vaccination issue is a difficult one, because right now we're dealing with an IND product that requires informed consent, so the throughput is not going to be easy. We're looking at auditoriums where you could show a video for five to ten minutes, get people informed, 200 or 300 people at a time, and then have them go through and get vaccinated for smallpox.

We have to take into account kids and the elderly, because historically, most of these things have come out of military models. The Mark-1 kits, for instance, for organic phosphates were manufactured for soldiers. Pediatric Mark-1 kits at .5 milligrams and 1 milligram atropine auto-injectors are available, but the FDA doesn't license them here, they're only shipped over to Israel. They're made here, but they are not licensed here because Meridian has not been able to prove efficacy and safety in kids, and we're working on that. But we've got to do a better job of looking at some of the most vulnerable populations as we do the modeling.

**Speaker (unidentified):** On that question, are the estimates, do they also include people who are likely to present in the setting of quite a bit of concern who may not have the disease?

**Jerome Hauer:** Yes. The worried well modeled this about six years ago in New York, that for every person who showed up for medical care, 10 to 15 people would show up who were the worried well, and that's where you become overwhelmed. You have to have a way of triaging those people before they get into the emergency room or you are

absolutely overwhelmed with people. So you've got to have a pre-stage where people are triaged before they get to the ER. It's going to be the same thing at your PODs. People who probably don't need chemoprophylaxis in a big outbreak will show up demanding antibiotics, and that's where you're going to get into real trouble with confrontations. You know, when we started modeling this four or five years ago, our big concern was there was not enough of a stockpile, so we would have had limited antibiotics, and we would have had to do some very difficult triage decisions, because some people might not have gotten the antibiotics. That's changed. We now have enough antibiotics to treat 20 million people for 60 days, or 40 million people for 30 days, and then backfill with antibiotics, so dynamics have changed a bit.

**Robert Vowels:** I was just going to add that with the experience in October at the D.C. General anthrax prophylaxis unit, we did fortunately have the services of the Department of Mental Health, and we had a set-aside for the worried well and for some crisis intervention counseling that we needed definitely on the site, and that was, of course, very effective in maintaining the comportment and the operational efficiency of the unit.

**Jerome Hauer:** Yes, D.C. did a great job at this. I've got to tell you, being down here during most of that, they really moved forward very aggressively and did an excellent job in communicating. New York and D.C. were really learning, despite all the modeling and all the work that had gone in. Because this after September 11th, the level of anxiety was so high that the psychological component of this really became an overriding issue.

**George Anderson:** Potassium iodide was mentioned a couple of times in this, and I'm going to get around to asking a question about that, but I'd like to put it in context first. I'm Immediate Past President of the American

College of Preventive Medicine, and this spring we had a huge meeting of preventive medicine specialists down in San Antonio, during which we had a policy forum on potassium iodide. Great expertise in the room, well intentioned people, and you have a hard time coming out with a definitive answer about what to do. This is where a really medical issue becomes a matter of public policy. So now, a further context, as a young Air Force flight surgeon, we did broken arrow drills all the time, because the Air Force, in its early history of nuclear weapons, had some misadventures where we contaminated some things, and we had to learn how to decontaminate. So in the matter of either nuclear mass casualties from nuclear weapons to treatment of radiation sickness, the use of potassium iodide appropriately, there is science behind all these things, and it's particularly well known in the military application. In this case, chemicals have been mentioned also.

The point is, we now have a different population at risk. When I was in the Air Force, we had base populations, military populations at risk, now you have citizens of the United States. Back to potassium iodide. Given that population at risk, the authority and responsibility issue, how do you handle that at the American Hospital Association, for example?

**Roslyn Schulman:** It was there as an example of different approaches for addressing surge capacity. Since it's such a time-sensitive issue — you have to get it within four hours in order to protect your thyroid — it would seem that a more distributed model might make more sense for potassium iodide in particular, although we haven't advised our members in particular on this issue. But it seems logical that might be the way to approach it since it's so time-sensitive.

**George Anderson:** Well, is it a cost-effective thing for the population served to stockpile it

in the first place?

**Roslyn Schulman:** I'm not a clinician, so I don't know what other purposes there might be for potassium iodide. But certainly, if you are in a hospital that is located near, for instance, a nuclear power plant, it might make a lot of sense to have it on-site, whereas if you're not, there would be less of an incentive to have it actually within your facility. But it's certainly something that policymakers at a higher level than me would need to really discuss in terms of this new threat of nuclear and radiologic kinds of attacks.

**George Anderson:** Actually, I think that's a superb answer. There has been some very responsive and responsible reporting. The *Wall Street Journal*, *New York Times* come to the same conclusion you do. Are there other comments from the other panelists?

**Jerome Hauer:** I can just briefly say that we are looking at it very carefully. We are buying KI for the stockpile. The issue of how far to go as far as distributing is one we're struggling with right now. I'm not convinced at this point that we're at a point where we need to give it out as you do with Mark-1 or atropine in Israel, when you look at the threat. We're doing some work on — and have done some work on — the impact of both RDDs and nuclear devices. As you look at the impact of those, we've actually got some pretty good modeling on the types of patients we would see.

I think the longer term, and I'm not going to minimize the KI issue, because we are struggling with that and we are focusing on it, but there are some longer term issues that we've got to address, as well, because particularly with a nuclear device, the long-term impact and the demands on health care would be so significant. We're looking at some of the new therapies, Neupogen, and some things that are just not available in large quantities. The CSF and whether or not we could stockpile some of

that. You know, some of the companies that make it are very small, the quantities that they make are small, and we're struggling with some of that, as well. These are difficult questions, and prepositioning of some of this is not easy, and stockpiling of it is not easy. So I'm not sure I've got a good answer for you, but I can tell you we are dealing with it, we are addressing it, and we are trying to make some logical decisions about how to move forward. But we are also buying KI so that we have some available in the event we need it.

**Saralyn Mark:** I'm from the Department of Health in NASA. One of the offices within the Department of Health — we created a task force to look at reentry issues for physicians wishing to resume clinical practice after an extended leave, such as doing administrative work, policy, political work. Our recommendations will be published in September, and we had advocated for a formalized training program such as a mini-residency or shadowing program. Do you envision for the Medical Reserve Corps that there will be some type of formalized training, and also, will there be any certification of skills?

**Jerome Hauer:** I don't know about certification at this point. We've been talking about that. We've been talking to a number of the associations the AMA and trying to decide about certification issues. But we are looking at formalized training. We've actually had some folks come in to talk about year-long fellowships in the whole area of terrorism, chemical, biological, nuclear.

There's a lot going on. We are, through training hospitals, going to be getting a lot more aggressive in our training programs for health care providers. We're going to be adding a number of courses down there. If, in fact, we move forward in the direction we're going right now with the Medical Reserve Corps, we're going to have to ensure that they're trained in everything from dealing

with nuclear events to vaccinating for smallpox. Smallpox vaccination, at least with bifurcated needles, is not easy. To do it right and to get a take, you have to be trained, and training during an event is not the ideal setting, so we have to do some of that ahead of time

**David Danley:** Dr. Vowels, I was taken by one of the comments you made about the difference in the populations and the way they responded to the anthrax event. I sort of gathered, at least reading in the *Washington Post*, that some staffers on the Hill liked the vaccine, but the post office didn't. Was that an example of the kinds of situations where we would get into cultural differences and the way people perceive the risks of exposure or was that just something that seemed to show up in the newspaper?

**Robert Vowels:** I'm not sure if I can say that was real. I can tell you that personally there were at least two postal workers I can recall who expressed concerns about the vaccine. Now, those were personal expressions. I don't know if there's been anything done that's looked particularly at the reaction of the employee population and the postal service in regards to the vaccine question. But the kind of thing I was really getting at was the message, also the media outlets that are used by different parts of our community, and the different ways that we, not just the media outlets, hear things. The person who's bringing the message is important, I think, in being able to make a message that's trustful to different parts of the community. I think we were aware of that, and we need to do more.

**Nancy Tomich:** We have two national hospital systems in this country, one in the Defense Department, the other in the VA. Do they form any sort of a bioterror safety net for our country? Is there any effort to use them along that line?

**Jerome Hauer:** Yes, absolutely. We've got a very close working relationship with the VA. I've been meeting with the VA on a regular basis, and we are forming a very important partnership with the VA, because VA hospitals are in many communities, as are DoD hospitals. I've been talking with Bill Winkenwerder about this. The VA is developing its own stockpiles of antibiotics that could be useful. They are good resources for surge capacity. They are good resources for training at the local level.

So, from my perspective, using particular VA hospitals that tend to be off-base versus military hospitals on-base — it's an ideal resource for communities and for a host of areas, not just bioterrorism, but chemical terrorism, as well. VA hospitals in a lot of communities hold our stockpiled Mark-1 kits. We have an excellent working relationship with VA and with DoD.

**Michael Wyrick** I'm a citizen in this area. That's probably the most important credential I'll bring here. I'm a retired Air Force officer, and also, I've been involved in emergency preparedness from a health care standpoint for the last several months since September 11th. I'd just like to make a comment, having gone to what seems like innumerable seminars, lunches, dinner talks, telephone conversations, and a lot of thought-provoking efforts with regard to this issue, and I still have a nagging concern.

It's been nine months and one week since September 11th, and we've had a lot of knowledge transferred among really knowledgeable people. I've come to these so many times, I feel a lot more knowledgeable, but my concern is that there's not one scintilla of knowledge transferred to that person down on the street, the person that's driving a taxicab, the kids that are in the schoolyards, the people that are here as tourists, and also to the college students that come here, and I know there's a grave concern about that because I work with

a coalition of universities who say they're experiencing a record number of people turning down approved applications to come to school here because their parents don't want to send them to Ground Zero. I want you to test this yourself. Go to a cocktail party tonight and talk to your neighbor next door, ask your husband or wife what they know to do in the event that we were attacked and they were affected somehow.

I think one effort that we need to focus on in the future is how to educate our people and transfer the knowledge that we're accumulating in these seminars like this to the person out there who will become the sole amount of authority that's available to him and her in the event that there's some kind of catastrophic event.

I think the purpose is to educate them on what the objective of terrorism is, and that is to truly scare the hell out of everybody in the local area. As was said right after the anthrax event, it was terrorism, killed five, and terrorized 300 million people. The objective of terrorism is not to kill everybody in sight, it's to scare everybody in sight and bring a nation to its knees. I think if we were to implement an effective communication program, we'd have significant measurable impact on the types of things we're talking about today, as well as a wide array of emergency and other types of response to terrorism. I think we need to educate our people as to what the objective of terrorism is. Second, I think we need to educate them as to how to take care of themselves in the event some kind of catastrophe would happen. As we put troops in the field in the Army, Navy, Air Force, Marines, and other groups, we communicated to them, and oftentimes they would be separated from any kind of source of authority as to how to take care of them, and they need to be able to take care of themselves. Second, they need to be able to take care of the person next to them. Let's teach them first-aid like we used to learn it back when we were in high school and boy

scouts, girl scouts, and other things like that. We also need to educate these people how to respond in the event something happens.

For example, don't leave the building necessarily, don't make a telephone call necessarily, don't send an email, because it isn't going to work for several hours, don't get on the Metro, and don't get in a car. Communicate only after a solid amount of time has passed that your communication system has stood up. If you teach all these different types of things, it's relatively inexpensive and effective. You can do it now, long before these things happen. If you listen to the Israelis, about four months ago downtown, they said you people are so blessed because you've not experienced what the rest of the world has experienced. We live with this every day. Our people are extremely educated, all the way down to as young as they can talk about how to respond to situations like this.

Now, the benefits would be that we reduce the demand for health care in emergency situation, we reduce the congestion on the road so that the emergency vehicles can respond to a situation, we reduce the effect of terrorism in that the objective is thwarted. This would be something that would be easily implemented, and I think with a relatively small grant. My challenge to someone as we go into the 10th, 11th, 12th, and finally into the anniversary of the World Trade Center, let's put something effective out there in people's minds. Instead of 300 to 1,500 leaders knowing how to take care of themselves or to operate the health care system, let's have the one to two million people in this district knowing how to take care of themselves individually. I'll tell you, my wife knows how to respond the best she can if she's alive and not injured. I would encourage each one of you to start tonight. Go home and talk it over with your kids and your spouses and your neighbors how to do the same thing.

**Jerome Hauer:** Let me respond to that.

because I think you're absolutely right. As part of the grants that went out to cities and states from HHS, we are requiring them to have risk communication strategies as part of their plans, so that they can educate people. A number of cities are now doing that. I was in New York over the weekend, and they are preparing a fairly significant public relations campaign. It needs to be done all over the country, I agree with you. I think by having educated people, we can reduce the demands on the health care system, and reduce the number of worried well, and reduce the fear.

I disagree with you about one thing. I think the media have done a pretty good job about educating people about the goals of terrorism, but I think we need to reinforce that. We are pushing very hard as we get our grants in to ensure that there is a good risk communication strategy, because you're right on target, we have to educate the public. I couldn't agree with you more.

**Robert Vowels:** I agree with your comments. Let me just add for the group, and group information for the District of Columbia, the Mayor, I believe this was approximately six months or so ago, together with the Emergency Management Agency, distributed a domestic preparedness manual for District of Columbia residents. A copy of that is on the Emergency Management Agency's web site. So if you just go to the DC.gov web site, you can actually download that directly to your printer. That has a lot of background information about general emergency preparedness, domestic preparedness information there for the public.

**Lance Gordon:** I just wanted to second one of the comments and really make sure it doesn't get lost. I think there is a need for something in the nature of a prescription for the general population. Out on the West Coast, it's a constant question. The newspapers ask it, the people on the street ask it. Just a base prescription. I agree that I think the media are

doing a very good job of education, however, there is nothing in the nature of prescription. What do you do if you open an envelope and you see a powder? Basic prescription of what are the steps you take, I think that should be put out and very simply.

**Roslyn Schulman:** There is another aspect of media — media can be your biggest help or

your biggest hindrance in a disaster, particularly as it relates to allowing a health care community to respond. It's critical that communities bring the media into their local community planning to make sure that in a disaster, they're not sending the wrong message out and disrupting the ability of a hospital and other health care community to develop an appropriate response in a disaster.



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