S. HRG. 108–126

FEDERAL BIODEFENSE READINESS

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

ON

EXAMINING FEDERAL BIODEFENSE READINESS, FOCUSING ON THE PUBLIC HEALTH WORKFORCE, THE STATUS OF CENTERS FOR DISEASE CONTROL TERRORISM PREPAREDNESS AND EMERGENCY RESPONSE ACTIVITIES, THE EMERGENCY COMMUNICATION SYSTEM, SMALLPOX PREPAREDNESS, THE FOOD AND DRUG ADMINISTRATION'S ROLE IN COUNTERTERRORISM ACTIVITIES, VULNERABILITY AND THREAT ASSESSMENTS, LABORATORY ENHANCEMENTS, RESEARCH, OPERATION LIBERTY SHIELD, AND DEVELOPING THE RESEARCH INFRASTRUCTURE

JULY 24, 2003

Printed for the use of the Committee on Health, Education, Labor, and Pensions

U.S. GOVERNMENT PRINTING OFFICE

88–681 PDF WASHINGTON : 2003

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

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

JUDD GREGG, New Hampshire, *Chairman*

BILL FRIST, Tennessee	EDWARD M. KENNEDY, Massachusetts
MICHAEL B. ENZI, Wyoming	CHRISTOPHER J. DODD, Connecticut
LAMAR ALEXANDER, Tennessee	TOM HARKIN, Iowa
CHRISTOPHER S. BOND, Missouri	BARBARA A. MIKULSKI, Maryland
MIKE DEWINE, Ohio	JAMES M. JEFFORDS (I), Vermont
PAT ROBERTS, Kansas	JEFF BINGAMAN, New Mexico
JEFF SESSIONS, Alabama	PATTY MURRAY, Washington
JOHN ENSIGN, Nevada	JACK REED, Rhode Island
LINDSEY O. GRAHAM, South Carolina	JOHN EDWARDS, North Carolina
JOHN W. WARNER, Virginia	HILLARY RODHAM CLINTON, New York

SHARON R. SODERSTROM, *Staff Director*
J. MICHAEL MYERS, *Minority Staff Director and Chief Counsel*

C O N T E N T S

STATEMENTS

THURSDAY, JULY 24, 2003

FEDERAL BIODEFENSE READINESS

THURSDAY, JULY 24, 2003

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10:00 a.m., in room SD–430, Dirksen Senate Office Building, Senator Gregg, chairman of the committee, presiding.

Present: Senators Gregg, Kennedy, Murray, and Clinton.

OPENING STATEMENT OF SENATOR GREGG

The CHAIRMAN. Let me begin by thanking members of the panel for participating in this hearing, which the purpose of which is to update us on the status of our Nation's defenses and capability to deal with a potential biological or chemical attack.

As I look at this panel, the expertise, genius, and brilliance, and leadership gives me considerable confidence, and I am sure it gives the American people confidence to think that our key agencies in the area of defending our health care status as a nation are led by such talented individuals. We really are fortunate to have all of you involved in public service. It is a tremendous sacrifice financially on your parts, but it is a tremendous benefit to the Nation. I thank you for your service. It is something that is very much appreciated.

There are basically three issues that I would like to hear about. The first is, what is the status of the threat? We have talked in the past about the threat of smallpox. We have talked about the threat of course of anthrax, the attack on the Capitol. We have talked about the chemical threats that are out there also, and the threats to various health systems. In addition, are there new threats? What is the status of the threats that we know exist? Has it changed from our last discussion, and if it has, in what way?

Second, what is the status of our reaction to those threats and our preparation to try to deal with them? Obviously, we are now well into the issue of the smallpox vaccination initiative. I believe the example that was set in dealing with the SARS threat represents a very significant effort and exercise that we can take a lot of pride in as a Nation, and especially your agencies, especially CDC can take a lot of pride in the way you handled it. I would be interested in how that relates to dealing with the overall threat of the potential of a biological or chemical attack.

Third, what should we be doing that we are not doing? What should you be doing that is not being done? What do you need in the way of resources? What do you need in the way of people specifically? What should the Congress be doing that we are not doing?

How critical is it that we get the BioShield bill through the Congress? How critical is it that we address the issue of vaccine liability and other questions, funding questions for that matter, that you consider to be important?

Those are the three areas I would like to have addressed if you can. I understand that Dr. McClellan may have to head off here, and so I appreciate that. If that is the case, we understand.

At this point I would yield to Senator Kennedy.

OPENING STATEMENT OF SENATOR KENNEDY

Senator KENNEDY. Thank you, Mr. Chairman. Thank you for holding today's hearing on the Nation's preparedness for biological attack. Our goal is to do all we can to see that America is well prepared for bioterrorism.

It is a privilege to welcome the distinguished leaders of the Nation's public health agencies. Elias Zerhouni has brought his scientific talent to the helm at the NIH and has an ambitious vision for NIH in this new century of the life sciences. Mark McClellan has brought his skills as a physician and as an economist to the FDA.

The last time Dr. Gerberding was here, we were discussing the SARS outbreak. It is a tribute to the skill of the CDC and WHO and public health agencies in many nations that the threat of SARS has subsided at least for now.

It is always a pleasure to see Dr. Fauci, who is an old friend and a friend of this committee.

SARS has shown how well the Nation can react to a health threat. But as we all know, the best time to prepare for a threat is before it becomes a crisis. Many of us are concerned that the Nation is doing too little to see that we are properly prepared for bioterrorism. Across the country many local and State health agencies and laboratories are underfunded, understaffed and poorly equipped to respond to modern diseases. Strong hospitals are the foundation of our response to bioterrorism. They too are starved for funds because of the unwise budget cuts.

In one area where this administration has tried to take action, smallpox vaccination, the result has been a shambles. Instead of a coordinated plan to educate health care professionals about the risks of disease, evaluate the possible health hazards of vaccination, provide the compensation to those who were injured, the administration rushed forward with a poorly planned program of vaccination. The result is that the vaccination program is off course and behind schedule.

A major cause of the problem was the failure to include a compensation plan for persons injured by the vaccine. Three months ago, a broad bipartisan majority in Congress approved important legislation to establish the compensation program. Three months later there is still no working plan. So far, over 60 serious injuries have been reported from the vaccine. As of today, how many victims have received compensation? None. How much has been paid out of the compensation fund? Nothing.

The result of this of this failure is simple. The administration delayed in issuing the table of injuries needed to start paying the claims.

The administration has also failed to provide the adequate funding for States and local communities to implement the smallpox plan. Two years after the anthrax attacks we are still playing catch-up and reacting, rather than carefully planning and coordinating our local, State and national efforts. Understaffed public health offices are being pulled in too many different directions to achieve the preparedness we need.

We need a genuine preparedness plan for bioterrorism response and for coordination between the Federal, State and local agencies. Agencies need to know which issue and responsibility they have jurisdiction over. Who is deciding what the biggest biological threats are? How are the many different agencies coordinating their activities? Are we spending our financial and human resources on the most pressing needs? Does the administration have a comprehensive biodefense strategy? If so, what is it?

These are basic questions that need to be answered, and I hope our panelists today can shed some light on these issues. I look forward to their testimony and their responses to these important questions.

I thank the Chair for having this today. As we all know, the Government commissioned reports on the intelligence gaps leading up to 9/11, but the gaps also remain in our defense against bioterrorism as a result. We need a plan.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kennedy.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR KENNEDY

I commend the Chairman for holding today's hearing on the nation's preparedness for a biological attack. Our goal is to do all we can to see that America is well-prepared to deal with bioterrorism.

Today, a government commission reports on the intelligence gaps leading up to the terrorism of 9/11. But frightening gaps also remain in our defenses against bioterrorism. And as a result, millions of Americans are still at risk. As every mayor, police officer, hospital worker, and firefighter can tell you we need a plan.

NIH, CDC, FDA and all our other public health agencies spend just over three and a half billion dollars every year to help make our cities, our hospitals and our health agencies ready for the threat of bioterrorism. That may sound like a lot of money but consider this. All these agencies combined spend less in a year to keep us safe from bioterrorism than it costs every month to keep our troops in Iraq.

It's a privilege to welcome the distinguished leaders of the nation's public health agencies. Elias Zerhouni has brought his scientific talent to the helm of the NIH, and he has an ambitious vision for NIH in this new century of the life sciences. Mark McClellan has brought his skills as a physician and as an economist to the FDA.

The last time Dr. Gerberding was here, we were discussing the SARS outbreak. It's a tribute to the skill of the CDC, WHO, and public health agencies in many other nations that the threat of SARS has subsided, at least for now. In fact, dealing with the SARS emergency showed how effectively the NIH could mobilize

the talents of its researchers to confront a new health threat, and how well FDA can work with researchers to assure swift consideration of any new treatments or vaccines.

SARS showed how well the nation could react to a health threat. But as we all know, the best time to prepare for a threat is before it becomes a crisis, and many of us are concerned that the nation is doing too little to see that we are properly prepared for bioterrorism.

September 11th and the anthrax attacks of 2001 were a wake up call. Our sense of invincibility was shattered. Although we have the strongest military in the world to defend against conventional attacks, we were ill-prepared for acts of terrorism. Across the country, many local and State health agencies and laboratories are underfunded, understaffed, and poorly equipped to respond to modern diseases. Strong hospitals are the foundation of our response to bioterrorism but they too are starved of funds because of unwise budget cuts.

In one area where this Administration has tried to take action—smallpox vaccination—the result has been a shambles. Instead of a coordinated plan to educate health care professionals about the risks of disease, evaluate the possible health hazards of vaccination and provide compensation to those who were injured, the Administration rushed forward with a poorly planned program of vaccination. The result is that the vaccination program is off course and behind schedule. The target number of 450,000 vaccinated health care workers in hospitals and public health departments is far from met. In fact, seven months and $1 billion into the program, not even one-tenth of those 450,000 health workers have been vaccinated.

A major cause of the problem was the failure to include a compensation plan for persons injured by the vaccine. Three months ago, a broad bipartisan majority in Congress approved important legislation to establish the compensation program. Three months later, there is still no working plan. So far, over 60 serious injuries have been reported from the vaccine. As of today, how many victims have received compensation? None. How much has been paid out of the compensation fund? Nothing.

The reason for this failure is simple. The Administration delayed in issuing the table of injuries needed to start paying claims.

The Administration also failed to provide adequate funding for States and local communities to implement the smallpox plan. Coast to coast, hospitals and health agencies have been struggling with the inadequacies of the Administration's plan. Without needed funding, States were forced to use dollars from other public health programs to pay for the smallpox vaccination. Robbing Peter to pay Paul put other aspects of bioterrorism preparedness on hold. It also resulted in less attention being given to other public health problems. At the time the smallpox vaccination program began, Boston, Miami and San Francisco were facing outbreaks of syphilis. Seattle was facing the highest number of tuberculosis cases in 30 years. These problems were exacerbated because States and cities had to rob other parts of their public health budgets to pay for smallpox vaccination.

Two years after the anthrax attacks, we are still playing catch-up and reacting, rather than carefully preparing and coordinating our local, State and national efforts. Understaffed public health offices are being pulled in too many different directions to achieve the preparedness we need.

Nearly a quarter of all State Government employees will be eligible for retirement within the next 5 years. In the past month alone, one State lost a third of its laboratory staff to retirement. Another, because of the budget problems facing all the States, has been allowed to fill only 1 in 4 public health vacancies. These cutbacks are happening while we are supposed to be expanding our capacity to respond to terrorist threats.

We need a genuine preparedness plan for bioterrorism response and for coordination between Federal, State, and local agencies. Agencies need to know which issue and responsibility they have jurisdiction over. We should not have to guess who is responsible for ensuring that hospitals are prepared to handle mass casualties following a terrorist attack. We should not have to guess what the Federal plan for bioterrorism is. We don't have a plan for the next big flu season.

Who is deciding what the biggest biological threats are? How are the many different agencies coordinating their activities? Are we spending our financial and human resources on the most pressing needs? Does the Administration have a comprehensive biodefense strategy? If so, what is it?

These are basic questions that need to be answered, and I hope our panelists today can shed some light on these issues. I look forward to their testimony and to their responses to these important questions.

The CHAIRMAN. What is your time frame, Dr. McClellan?

Dr. MCCLELLAN. I can be here until at least 11:30.

The CHAIRMAN. That being the case, then I think we will just go right down the panel for your presentations, because I am sure that everybody is certainly not going to take anywhere near that amount of time.

We will start with Dr. Gerberding. And again, congratulations on your effort on the SARS. It was extraordinarily impressive. You were involved in the issue from the beginning, and I think the leadership that CDC showed in this was not only good for our Nation, but for the world. So thank you.

STATEMENTS OF JULIE LOUISE GERBERDING, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; MARK B. McCLELLAN, M.D., PH.D., COMMISSIONER OF FOOD AND DRUGS, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND ELIAS A. ZERHOUNI, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH, ACCOMPANIED BY DR. ANTHONY FAUCI, DIRECTOR, NATIONAL INSTITUTE FOR ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. GERBERDING. Thank you, and thank you for having me here on this panel today. This committee has really provided leadership in preparing our Nation against terrorism threats long before 9/11,

and without that support and wisdom, I do not think we would have made the progress that we have made so far, so I really appreciate the opportunity to be here and respond to some of your interests.

I would like to address three main issue in my few minutes. The first is the current status of preparedness. The second is a quick snapshot about the smallpox program. I am sure there will be more questions later. Then third, just a couple of comments on workforce, because that is something that is a concern to the entire public health system.

It is important, I think, to start out by recognizing that preparedness is not all or none, yes or no, off or on. It is a process, and it is going to be an ongoing process for a long period of time, because it is very complex, it is very difficult to achieve the full-scale preparedness that we need for all the kinds of threats that we are facing, and we are starting with the public health system that has been long neglected. So we have a great deal of work in front of us.

Having said that, I think in the last year there has been substantive progress in many areas, and let me just point out a few of the highlights that we have prepared for this particular presentation. First of all, as you know, one of the major aspects of preparedness is detection, and we now have, through the State and local health investments, a situation where more than 90 percent of jurisdictions can initiate a field investigation in response to a threatening report, 24 hours a day, 7 days a week, within 6 hours. That is a giant step forward in our ability to initiate a response.

In addition, we have an information network that continues to evolve, and is now highly standards based and able to integrate information up and down the food chain. There is more work to be done on that, but we have made substantial progress.

With respect to the laboratories, I think we have some amazing achievements. We have 117 laboratories now linked through our Laboratory Response Network. More than 90 percent of these laboratories can confirm a rapid diagnosis of anthrax, plague and tularemia, when 70 percent of them can rule out other conditions that would be confused with smallpox and we have already 50 BSL-3 laboratories funded in this network, which are the laboratories capable of working with infectious pathogens. That is three times more than we had when we started in 1999. We also have supported more than 880 trainings for those personnel in the laboratory networks. Actually, 8,800 people have been trained.

In terms of alerting, we have expanded our capacity to conduct health alerts 24/7 so that right now we can get 70 percent of the population covered in every State. In more than half the States we have the entire population covered through a health alerting process. Again, progress, not done yet, but a substantial change from where we were a year ago.

In terms of training and workforce development in the preparedness regard, we have extensive training. More than $96 million has gone out to the States to support workforce development and training. In addition to that, we have had some very specific benchmarks such as that 1.8 million health care providers have been specifically trained in smallpox recognition and response, and more

than 14,000 individuals have been trained to administer smallpox vaccine within the context of vaccine clinics. I think importantly, we also have developed an innovative emergency communication system which allows CDC to take content from the world's experts in whatever the threat might be, and repackage that information to meet the needs of a whole host of target audiences, clinicians, public health officials, the media, and so on and so forth, and use multiple channels, including the Internet, plus briefings, all sorts of channels to get that information out. That system is replicated now in an increasing number of State health departments, again, through the billion dollars of money that has gone out to the State and locals. We also have created a risk communication CD-Rom training, with several hours of training, to help local officials be able to do a better job communicating about risk in the setting of a crisis and postcrisis situation.

At CDC we have opened our Director's Operations Center, which is a command center that was built on a 24/7 basis, and was completed 1 year early, and we were able to get that open just in time for SARS, where I think we have now demonstrated the utility and the capacity of that particular facility as well as the personnel and support that goes into it to function effectively in the case of a public health emergency.

Finally, just to emphasize that although the Department of Homeland Security has the overall responsibility for the Strategic National Stockpile, CDC does have a collaboration with the stockpile in DHS, and we are managing the stockpile, we are exercising the stockpile. Just yesterday we ran a mission to one of the stockpile secure sites to check on the status of the stockpile and our ability to mobilize it if we needed to.

Let me turn now to some comments about smallpox. If I could have the graphic, and I hope you are able to see this, but I think you have some reprints of this in front of you. As I said, preparedness is a process, not an event. What I have on this diagram which is just an illustration, not a quantitative assessment, the various elements that are required for adequate smallpox preparedness, where we were a year ago and where we are today. What we would like to see of course is that all of those bars be full, brilliant green, and they are not. So we do have, as Senator Kennedy mentioned, we have work to be done. But we do have some I think important steps forward. First of all, in terms of vaccine supply, the new vaccine is being delivered on time and on budget. We have more than 155 million doses and we are initiating Phase III clinical trials, so that we should be able to get that vaccine licensed by next year.

In addition, as I mentioned, we have trained more than 1.8 million clinicians to be able to detect and respond to smallpox, and those efforts are ongoing through multiple channels. We have improved our capacity to detect and report smallpox cases. We have had many false positive missions where we have run people in our smallpox group or the stockpile to areas where someone has reported a fever and a rash. We have now used digital imaging to get that information back to us, but the reporting system is incomplete. It is not fully electronic and we need to do more in that regard.

Laboratory diagnosis we have improved. In addition to the 70 percent of labs that can rule out vaccinia or other orthopox viruses,

we have now 24 laboratories who can rule in smallpox definitely, and that has gone from zero to 24 over the last year, so significant progress there.

Hospital care we have improved. SARS helped us develop better quarantine and isolation protocols in hospitals, and I think made the threat real, but we have got a ways to go before we could begin to believe we could manage to take care of a large scale smallpox attack. We need regional planning for this as well.

Vaccine safety screening is a success. We have demonstrated both in the military program and the civilian program that we have fewer incidents of vaccine side effects than predicted based on historical experience, in large part because of the efforts of the screening process and the ability to weed out people who would be at the highest risk for the most severe complications.

Response team vaccination. If I could show the next graphic, I could illustrate where we are in this regard. This represents jurisdictions that have prepared health care teams to respond to the smallpox attack. You can see that there is incomplete coverage. Some States and jurisdictions are doing quite well. Others are lagging behind or have very little hospital preparedness at all.

On the next graphic I have a picture of the smallpox response teams, and this is a capacity to—the next graphic, please. I will have an image of where we are able to do clinics, so that those response teams can participate in a mass vaccination program. Here we are doing much better. Most jurisdictions have the capacity to set up at least some sort of vaccine clinic to initiate response to a large-scale attack to the population, but we are not done yet. Progress was made, but there is still a ways to go.

If I can go back to the prior slide just very quickly and finish up there. With respect to adverse event monitoring of the vaccine, I think we have the best monitored system for a vaccine that we have had for any vaccine for the smallpox program. We have multiple sources of data coming in. We were able to detect an unexpected problem with myocarditis and pericarditis. The system has also learned this to other potential side effects such as myocardial infarction, which our data indicate are not likely to be attributable to the vaccine per se, but until we know more, we have added exclusion criteria to our screening process to eliminate those hazards.

Finally, vaccine clinic planning. I showed you we have a widespread clinic capacity, but it is incomplete, and the planning for the mass vaccination is incomplete. We are still working on this in the next grant cycle, but there is a way to go.

Finally, just very specifically to address the issue of workforce, because this is a bottleneck in our preparedness process, there are a lot of reasons. The preparedness is complicated. The pool of eligible people for the workforce is very limited. We are competing over the same group of talented people. It takes time to hire trained people, and our pipeline in our schools is not a torrent, it is more like a trickle. But we have made some steps. We have hired more than 3,800 people in the States to support the Bioterrorism Preparedness program. At CDC our dedicated FTEs have gone from 174 and will be 529 in the next fiscal year. We have set up our public health training network and our national laboratory training network, which are satellite networks to help improve people's skill

sets, and we are moving toward a competency-based certification program, so it is not just are you in the job, but are you competent and certified that you know what you are doing and you have the expertise to really contribute.

We also have 19 academic medical centers funded to specifically train people on the various skill sets needed for bioterrorism. We have put $196 million out to States to support these activities, and we overall have a great emphasis at CDC on the retention, recruitment and career development, including use of retention bonuses and other incentives to try to retain our top scientists.

One final thing that we are able to do now that we could not do before is to put CDC FTEs in the field without counting against our Federal FTE ceiling. Right now we have 64 field epidemiologists. We have someone in every State, but by 2008 we expect to have more than 500 CDC staff deployed to the State to provide Federal support for the programs that the States are responsible for. A long way to go before we have filled in all the gaps, but again, I would like to emphasize the progress as well as the work that remains to be done.

Thank you.

[The prepared statement of Dr. Gerberding may be found in additional material.]

The CHAIRMAN. Thank you, doctor.

Dr. McClellan?

Dr. MCCLELLAN. Thank you, Mr. Chairman, Mr. Ranking Member, Senator. Very pleased to be here today, this morning, with my good friends from CDC and from NIH. We have been working together on the Nation's counterterrorism activities.

I also want to thank you all for your work that culminated last night in the passage by unanimous consent of legislation giving FDA the authority to compel pediatric studies when necessary. That is going to have a role in our preparedness for counterterrorism activities as well, because we need to know about the effects of medications in children in that area too, so thank you for your leadership there.

We are facing some real threats, and we all share the goal of being as effectively prepared for terrorist attack as possible. I would like to echo Dr. Gerberding's comments about how this is a process, one that we are very committed to. FDA's critical roles in protecting the Nation include making the food supply more secure than ever, helping to develop medical countermeasures and make them available quickly, and assuring a high-quality professional workforce that is able to carry out these responsibilities.

The safety and security of 80 percent of our food supply is our responsibility at FDA, and we take our leadership on food security very seriously. Yesterday Secretary Thompson and I issued a report that outlines our progress in implementing a clear and comprehensive approach to protecting the safety and security of our food supply. This report is entitled "Ensuring the Safety and Security of the Nation's Foods," and it outlines our progress in 10 areas. I would like to request that a copy of the report be included in the record of this hearing.

[The report may be found in additional material.]

Dr. MCCLELLAN. Overall, the changes that we are implementing now in food security amount to the most fundamental enhancements of our food safety activities in many, many years.

One of our 10 priorities is implementation of the Bioterrorism Act of 2002. I would again like to comment you, Mr. Chairman, Mr. Ranking Member, and members of this committee for your leadership in enacting this landmark legislation. As you know, it provided us with new authorities to protect the Nation's food supply against the threat of intentional contamination and other food-related emergencies. FDA has already published four major proposed regulations to implement the key provisions of this act: registration of domestic and foreign food facilities; prior notice of imported food shipments; the establishment and maintenance of records on where foods come from and where they go in the distribution system; and administrative detention of worrisome foods. After we take a full and careful count of all of the comments that we have received on these proposed regulations, we intend to publish final regulations to fully implement this law before the end of the year. These new regulations will enable FDA to act quickly in responding to a threatened or actual attack on food supply, and it will improve our ability to prevent and to contain naturally-occurring food-borne illnesses as well.

Another key area is food imports. Thanks to supplemental counterterrorism funds in 2002 FDA was able to hire over 650 additional employees to work on food safety and security issues mainly at the borders. We have increased surveillance of imported foods, increased our domestic inspections and enhanced our laboratory analysis capabilities. These are just a few of our many recent activities to enhance food safety and security.

I would also like to discuss briefly our work on medical countermeasures in Project BioShield. As you know, FDA's been engaged with other Government agencies, including the ones represented here, and the private sector, in an accelerated effort to develop and make available better medical countermeasures. For example, in recent months we have taken major steps to make available safe and effective treatments for certain nerve gases and radiological agents, and we have enhanced our stockpiles of vaccines and treatment for smallpox and other possible agents of biowarfare, with safe and effective treatments that have been reviewed by FDA. Working with other Federal agencies and private companies, we are taking more steps to determine as quickly as possible what other available products may be of benefit to Americans. We are engaged in interagency research to look at new drugs to treat plague, the safety of long-term antibiotic use, the use of medical countermeasures in special populations, including children, and the development of animal models to test drugs for biological threats such as viral hemorrhagic fevers where tests in humans just are not feasible.

While the countermeasures resulting from these activities are providing a deeper and more extensive stockpile for treatments in this Nation than ever before, in many cases they are based on old technology. Research and development into next generation countermeasures has been much slower than for naturally-occurring diseases in recent decades, largely because there is no clear finan-

cial reward for success. Project BioShield would correct this obstacle, and that is why its rapid enactment is critically important. This is a priority in the administration, and I want to thank this committee for your leadership on BioShield as well.

Finally, I would like to address FDA's efforts to recruit and retain an effective counterterrorism workforce. A key component of FDA's strategic plan is assuring a high-quality workforce. That is what our agency is. We do not give out many grants. We do not provide medical services. We ensure the safety and security of medicines and foods in this Nation.

Our workforce includes a solid cadre of highly-qualified and dedicated professionals. FDA currently has over 10,600 employees. Of these, there are almost 1,500 professionals with Ph.D.'s and well over 400 with medical degrees. We have created many new human resource policies to attract and to keep these high-caliber employees, such as the establishment of occupational retention allowances for hard-to-fill and hard-to-retain positions such as medical officers. We pay these positions an additional 10 percent of their salary. The creation of a pay banding schedule for scientific, supervisory and managerial positions. This allows us to set salaries up to $200,000 per year for our skilled scientific workforce.

In addition we have implemented flexible work schedules and telecommuting and other family-friendly programs to attract and retain the best employees.

Like other agencies that are represented here today, we play a critical role in the Nation's defense against terrorism. Although we are better prepared than ever before, much more work remains to be done, and I look forward to continuing to work with this committee to help keep our Nation as secure as possible.

Thank you.

[The prepared statement of Dr. McClellan may be found in additional material.]

The CHAIRMAN. Thank you very much, doctor.

Dr. Zerhouni?

Dr. ZERHOUNI. Thank you, Mr. Chairman, and members of the committee. I am really pleased to be here to discuss how the National Institutes of Health are responding to the threat of bioterrorism. I am really pleased to join the head of my sister agencies, Dr. Gerberding, and Dr. McClellan to describe how we are working together to strengthen and expand programs designed to protect the American people against the broad range of potential terrorist threats.

I am also accompanied today by the Director of the National Institutes for Allergy and Infectious Diseases, Dr. Anthony Fauci, who has led much of our efforts with great distinction.

The Nation's investment in biomedical research has put us in a good position to respond to the threats of bioterrorism. For fiscal year 2003 the NIH received a budget appropriation of more than $1.5 billion for biodefense research. The funds are being used primarily to build the necessary infrastructure and resources to step up the research programs on dangerous microbes and their toxins and in all relevant categories of biodefense research during this year, this coming year. We will also continue to address and expand our portfolio across all of NIH's institutes to address chemi-

cal, nuclear, radiological, as well as research into the mental health impact of terrorism on individuals and our society.

I will briefly describe our implementation plans in each of these four components and also talk about the issue of workforce development in these activities.

No. 1, we have focused almost exclusively our attention on developing the adequate countermeasures to the terrorist agents that we knew had the highest likelihood of being used in our country. Last year the NIH devised and developed the Strategic Plan for Biodefense Research, which contains short-, medium- and long-range plans for basic research and the development of vaccines, drugs, diagnostics and other countermeasures for Category A, B and C agents. As we implemented the strategic plans, NIH developed a total of 46 biodefense initiatives in fiscal year 2002 and 2003.

I have to say that the response from the scientific community was swift and strong. As we were keeping track of our applications and success rates in areas of research relevant to biodefense, we are observing that our lead biodefense agency, NIAID, has seen a 30 percent increase in number of applications and the vast majority of those applications are in the area of biodefense, expanding the portfolio of research in biodefense.

Implementation of Part I of our plan led to several advances in particularly the discovery that the existing U.S. supply of smallpox vaccine was still potent and could be diluted five-fold and retain effective protection. This discovery made it possible to greatly expand the number of doses of smallpox vaccine in the United States. Today we have stockpiled sufficient quantities of smallpox vaccine to vaccinate all Americans. NIH is now developing and testing the next generation of smallpox vaccines and interviral compounds that will be safer and more effective than those available today.

Progress on anthrax is following a similar pattern of success. Last year NIH-funded scientists identified the specific site on the human cell that binds the anthrax toxin, and developed a compound that may block its lethal effects. This is significant information because it will likely speed up the development of new drugs to treat anthrax. In addition, as of July 2003, there are four clinical trials of a next-generation DNA-based vaccine for anthrax called recombinant Protective Antigen, which are under way. This vaccine will allow protection of the population with a lower number of doses over a shorter period of time than currently existing technology.

We are also developing and testing candidate vaccines for Ebola and are currently in the planning stages for initiation of a Phase I clinical trial to evaluate a candidate DNA vaccine for Ebola. Over a dozen more research initiatives are planned for fiscal 2004, all of which will help accelerate the development of medical countermeasures against biological agents.

Similar planning is under way, across all of NIH, through an established standing committee for biodefense research coordination, which we established last December. The committee is tasked to address not only the threat of biological agents such as microbes and toxins, but the threats of chemical, radiological weapons that could affect the civilian population, as well as the psychological consequences of bioterrorism, to provide a research-based, evi-

dence-based approach to decision making that the public health authorities of the country may have to make in cases of attacks.

One important component that I think you have been extremely supportive and receptive to is the development of the BioShield legislation pending in Congress, which specifically authorizes NIH to investigate these other areas of biodefense in addition to the more obvious threats of microbes and new toxins.

Our activities have also focused on developing the research infrastructure of the country by promoting the development of the national network of Regional Centers of Excellence for Biodefense and Emerging Infectious Disease Research at both nongovernmental and governmental institutions. These facilities will serve as the national resources for biodefense research and product development as well as for the study of other infectious diseases such as SARS and the West Nile virus which require biocontainment laboratories of the same degree of sophistication.

We are also developing other research resources as quickly as we can. All of these investments will enhance our ability to rapidly attract both established scientists and new scientists to the field of biodefense research so they can support a national effort.

One particular characteristic in our challenge to attract scientists to the biodefense effort is that the core knowledge that, one, a scientist needs to have in terms of infectious disease and immunology, is similar to what the same scientist needs to have to attack biodefense organisms. So we are positioned in a way where one of our immediate strategies was to find incentives and appropriate pathways to convert the attention, effort and focus of our existing talent pool toward biodefense research. On the basis of that we are continuing to build the next step, meaning infrastructure, training, and the ability to be able to attract new scientists to the field. This is our strategy.

We are working in collaboration with our sister agencies both within HHS as well as with the Department of Defense. We have developed an extensive relationship with FDA in terms of developing products. I will not repeat the comments that Dr. McClellan made about the importance of BioShield and the need for us to expand the current statutory limits on our authority to develop new approaches for public and private partnerships that will entice industry to enter the field once research has been developed down to the point where advanced development of these products is needed. It will greatly strengthen our ability to respond to the many challenges of biodefense research and development by providing streamlined authority, increased flexibility in awarding grants and cooperative agreements, expediting peer review procedures, bolster authority for acquisition, construction and renovation of facilities, and more importantly, greater flexibility in hiring technical experts.

I would like to finish my comments on the issue of the development and sustaining of human capital. We must hire, train and retain the most highly-qualified and dedicated men and women to form the core of the NIH research enterprise. Our current manpower levels have been sufficient to foster the initial progress that I described in biodefense research.

NIH is committed to the education and training of biomedical research scientists focused on biodefense needs to meet future challenges. We have initiated a number of programs, as our sister agencies have, but as an agency we need to also remain competitive in attracting the best talent to Federal service. Much remains to be done in that regard and we are definitely focused on trying to have a strategic plan that pro-actively looks at the abilities that we have to maintain both outside of the Federal Government but also inside the Federal Government the best and brightest workforce we can have to maintain the research effort over the long-term.

Thank you very much.

[The prepared statement of Dr. Zerhouni may be found in additional material.]

The CHAIRMAN. Thank you. Again, I want to thank you all for your service. There may be questions that come up, Dr. Fauci, that you may want to comment on as we proceed. Just jump in, please.

We are, as I said earlier, incredibly fortunate to have people of your talent leading these agencies, and we very much appreciate your commitment to public service.

Let me start with the obvious, which is, Dr. Gerberding, you talked about the smallpox issue. Clearly we have not gotten the vaccine out as aggressively as we wanted. Why, and what do we need to do to be more successful, and has there been a change in the thinking in light of the reticence of people to be vaccinated as to how many we need to have vaccinated, and what areas they should be vaccinated in?

Dr. GERBERDING. Thank you. Let me first say that it is important to——

The CHAIRMAN. And also what the threat is; do you still maintain the threat as being a significant threat?

Dr. GERBERDING. I was just going to start with that because I think it is very important to be clear that from the CDC perspective and from Secretary Thompson's perspective, we are still operating with the assumption that the smallpox threat is real. It is not imminent, but it has not gone away and it has not been attenuated even in the aftermath of the war, and I think there is a temptation on the part of a lot of people to believe that somehow the threat has dissipated, and in fact, we are still operating under the expectation that we need to be prepared as a nation for the possibility of smallpox attack.

So with that in mind, I think we are, as I said, pleased with the overall progress because all of those elements have to be in place if we are going to successfully manage a smallpox attack. But we believe that pre-event immunization of the response team workforce is an essential component of preparedness, and we have not successfully accomplished that yet. The particular weakness is in the health care delivery side. The public health side has geared up in most jurisdictions, but we are still lagging behind in ensuring that health care workers would be able to take care of cases of smallpox should an event occur.

One reason for that is the concept that the threat is not present and there is no need to take these preparedness steps. Many of the barriers that we experienced when we started out have been lifted,

although Senator Kennedy is absolutely right, we were slow in getting the smallpox table together, and we cannot reassure people that their complications will be covered until that table is complete. The reason the table has taken a long time is because first of all we wanted it science based, and we wanted it to have adequate inclusion of all the things that can be attributable to smallpox. Right in the area of preparing it this new issue of myocarditis and pericarditis emerged, as well as the cardiac complications. So we had to very quickly get the data together from the DOD and the HHS side to try to get the information into a tabular form. And I am told by the Department that the table is very close to completion, and I do hope that we are able to get it out in the very near future.

The CHAIRMAN. Is that a legal issue?

Dr. GERBERDING. It is a legal and a scientific issue. I think it is also an equity issue of wanting to be sure that the table does adequately include all of the things for both the recipients of the vaccine as well as their contacts. So that remains a barrier. And last, I think, in truth, the workforce issue is relevant in the sense that in the middle of our smallpox program we did have to take the very same people and work on the SARS outbreak, and then a monkeypox outbreak, and now a West Nile outbreak. We have a number of very high priorities throughout CDC and the public health system that compete for the same personnel and the same enterprise, and so we have been in crisis mode for 2 years now, and it is very difficult to sustain a focus on smallpox when we have new and imminent issues in front of us, but having said that, we do intend to continue to work on this as a high priority, and $100 million new dollars will be going out through the next cycle of the preparedness funding to have more resources to support their smallpox preparedness efforts.

The CHAIRMAN. Dr. McClellan, you talked about the food risk. Basically, we were starting from what I viewed as zero on this issue. How far down the road are we? You said you have hired these inspectors, but the food supply is such a huge chain, and not only internationally provided but domestically grown. You have got the threat of hoof and mouth disease, any number of opportunities there. Where do we really stand on this whole issue of protecting food supply or at least having a sense that we could get an outbreak that was food supply oriented under control quickly?

Dr. MCCLELLAN. Well, you and Secretary Thompson have both identified this, even before 9/11, as an area where we need to be doing more, and as I said, we are better prepared than ever.

We released in this report yesterday some of the numbers to indicate how we have responded to the additional staff that has been made available, and what other steps that we have taken. For example, examinations of imported foods have more than quintupled this year compared to previous fiscal years, from around 12,000 to over 60,000, and the fiscal year is not even over. We have implemented guidances for every sector of this very diverse feed industry that you were describing, something like 60,000 domestic food producers, distributors and others that we regulate, and a couple hundred thousand farms they support. We are trying to get appropriate messages out to them about steps that they can take to increase security, and we are working hard implementing these regu-

lations. I envision us getting to a system where we will have good, accurate information about the imports coming into the country, the foods being produced, distributed around the country, that will match up with intelligence information on real threats to the food supply so that we can respond quickly and target our resources effectively. We have got more resources going into this than ever before, something like $190 million in support added over the last 2 years, and we are trying our best to make sure that we get the most mileage out of those resources to protect the food supply.

The CHAIRMAN. Maybe both you and Dr. Gerberding could comment on the coordination issue with the intelligence agencies that might have information that would be useful, to the extent you can without going to the point that it would be inappropriate? How is it working?

Dr. MCCLELLAN. It is working. We have had to change the way that we do business, with setting up a cadre of staff within FDA and throughout HHS who are cleared at the top levels of security, even above the top secret level, to get certain kinds of intelligence about specific types of threats. We get briefings on a regular basis. We have an emergency response office that is set up in coordination with the Secretary's Office of Public Health and Emergency Preparedness to handle intelligence information in an integrated way throughout the Department, and we are working more closely than ever with the Department of Homeland Security through the White House's Homeland Security Council, on making sure that information gets to us in an organized fashion.

One of the big challenges that we have had is that because a lot of the food security responses are steps that the private sector needs to take—this is a largely private industry, a very diverse one as well—we need to find ways to share important information with the private sector in a way that does not jeopardize sources, in a way that does not unduly alarm the public, but that does get steps implemented that we think are important, given the threats and vulnerabilities out there, for making our food supply more secure. And we are on the road right now to setting up a more extensive intelligence sharing program than ever. The Department of Homeland Security is coordinating with us, with the Department of Agriculture, and with representatives from throughout this very diverse food industry. So there is more coordination and more rapid and real-time sharing intelligence information than ever before. I think we have some more steps that we need to take, especially in coordinating with the private sector in how to respond to this information. We are trying to do that now.

The CHAIRMAN. Dr. Gerberding, how is your relationship on intelligence?

Dr. GERBERDING. We are very pleased with our relationship with intelligence. First of all, Secretary Thompson gets briefed basically daily with a high-level intelligence briefing and that information gets cascaded down to all of us. But in addition, at CDC we have two FBI agents on our staff, and we have our own elevated capacity at CDC, so we get the same intel stream that the rest of the high-level intelligence personnel receive in the country. We are integrated. In addition, we have a CDC liaison to the FBI who works on the WMD program, and we have now established across the

country a series of joint training programs, where we take field investigators in the FBI together with field investigators in the public health community, run them through a curriculum for a couple of days, where they learn how to investigate collaboratively and how to share skills such as chain of evidence or epidemiology.

So we are integrating in the field. We are integrating in the CDC and we are integrated across the Department. Then of course through the Office of Homeland Security and the White House we have some very high level opportunities to focus in on specific problems and look at the intelligence information as needed on that basis as well.

The CHAIRMAN. Dr. Zerhouni, on this issue of basic research and how quickly we can put in place a research response to a threat, do you have the people you need to do that? Do you have the resources outside NIH that are coordinated? In other words, the research centers around the country that are not independent? Is there a coordinated effort there, so that if we see a threat we can move quickly on it, and how that is that structured?

Dr. ZERHOUNI. Well, we have a network of laboratories both in the country and outside of the country as well, as you may know. In the SARS outbreak we collaborated very closely with CDC, with some of our grantees in Hong Kong. We have also very specific relationships with many of the biodefense institutes and inside of our academic institutions.

When an outbreak comes we do have a prioritization mechanism that goes through the trans NIH and Biodefense Research Coordinating Committee that Dr. Fauci chairs and reports directly to me. So that when we have the need to allocate resources quickly, we have a three-tiered possibility of response. One is our own program which can immediately move resources, and we have done that repeatedly over the past 2 years. The second is our collaboration with the Department of Defense at Fort Detrick in the USAMRIID, where we can immediately set programs for screening, countermeasures, drugs. For example, in the case of SARS or now smallpox, we have done a lot of—or anthrax—we have done a screening immediately. So those are short-term responses.

In terms of the development of the infrastructure, as I mentioned, this is the year where we are doing this on the scale that is required. We have competed regional centers for biodefense research this year. We have had over, I think, about 20 to 25 applications for four to six centers, which will be granted this year. That is going to be the real resource that we on the regional basis will rely on to establish priority areas of research focus for each one of these centers, depending on their excellence level coordinated with the trans NIH activities, not only to microbes and toxins, but we are looking increasingly at the issue of chemicals, radiological, biodefense for civilian population.

The CHAIRMAN. I wanted to mention that, but obviously I want to let other people have an opportunity. But as we look at the biologics issues, which is critical, and that is where the most aggressive threat is, we still—I do not think we can ignore the sarin gases and the VXs, which though their area of damage would be less in the sense of numbers and region, it is clearly a significant event, and I hope we are aggressively pursuing that.

Senator Kennedy?

Senator KENNEDY. Thank you very much.

And again, thank all of you. You have all shown extraordinary leadership in the areas of public health, and the country is very well served.

I was listening to the comments of all of you, and I think anybody that goes over and visits with Secretary Thompson does not go in there without going into his master center that he takes enormous pride in. You never know whether he has pressed a button and has everybody in there ready to go when you go over there, but it is incredibly impressive, and I think he does deserve a good deal of credit for all of the work in coordinating with you in attempting to try and develop a plan.

We have responsibilities that we have not come through with. One is in the BioShield, and others are in some very creative, innovative ideas and suggestions that made a great deal of sense. Senator Gregg and I have—he is a key member on our Appropriations Committee. We talked to members of the Appropriations Committee, Budget Committee and the administration to try and get that. I think we are very, very close to it, but that is something that we have to do if we are looking over the longer range and expect the private sector to be factored in this. We fail to meet our responsibilities unless we can find ways of including them. So we are certainly working on that.

And we appreciate the work that is being done in the area of the smallpox. It looks now like only 60 people have been hurt, and we pointed out very early in the process that as a result of the careful screening and the follow-through that would not be a large number of people seeking compensation. Therefore, with only 60 people getting hurt we ought to be able to be generous enough to make sure that these people are treated and treated well, which will be a source of inspiration to others to be included.

As I understand, there is also some question about one of the advisory committees considering about the safety issues in some of these as well, and therefore, there is sort of a general kind of a pause in terms of the program. Maybe you could just comment quickly on it?

Dr. GERBERDING. Yes. There is just actually a misunderstanding about the advice from the Advisory Committee. We asked the IOM to help us evaluate the safety of the program. We also have an Immunization Practices Advisory Committee and the National Vaccine Advisory Committee, so there are three weighing in on this. All three have said that we should continue to vaccinate the smallpox response teams, that that is an essential element of preparedness. We are not done yet with that part. But the committee has suggested that when we finish that part of the preparation, that we take a look at the experience before expanding out to include all of the police and firemen who may wish to be included for broadening the overall preparedness effort.

So we right now have a fair amount of confidence in our ability to get real-time information and evaluating so there is not a planned pause, but we are at a point where we do not have to worry about it too much because we still have a way to go before we get to that point.

Senator KENNEDY. The new report points out that there are new unanticipated safety concerns. That is what they included in the report what you are just addressing.

I have just a number of points in a short period of time. One is with regard to the safety of the food supply. What percent actually is being inspected now? It is still pretty small.

Dr. MCCLELLAN. It is under 2 percent.

Senator KENNEDY. Under 2 percent. As Senator Gregg pointed out, we have the continuing growth curve in terms of imported food.

Dr. MCCLELLAN. That is right, and more diversely and massively produced food and rapid growth imports as a result of all of the improvements——

Senator KENNEDY. So even with the additional kinds of resources that we have provided, we are still only at 2 percent, and this is—we can get to money does not solve everything, as my friend to my right reminds me of. But also, if it is only at 2 percent we need to try and make sure—I am not going to ask you what percent will guarantee the safety and security, but I think we could certainly do with additional kinds of resources, I imagine, in order to find additional kinds of capabilities in this area. I will just say to the record, that Dr. McClellan smiled, but did not nod or say yes [Laughter.]

Let me turn to another point. One of the important aspects of the legislation that we passed both in the year 2000, and it was the development of a workforce group to try and coordinate all of what you are doing, plus what the Secretary is doing, what all of the agencies are doing, and that is all spelled out in the act that was passed in December of 2000, before the September attacks. And then on the June 12th legislation that was also developed, which the President signed, was the National Preparedness of Bioterrorism, other public agencies. Very specifically, the importance of the development of the working group, and it illustrates all the different things that you have talked about and many others. I am not going to take the time to do it, but I would refer you to the Section 108, the working group. This is supposedly developed by, I imagine, Homeland Security, and it talks about the coordination of all the agencies that would be affected. It is an expansion of what we passed here in the Senate 2 years earlier, and takes advantage of what we have learned since then. But I would hope there is, as I understand—I do not know if we have any—you have given brilliant and very reassuring comments about the plannings that are being done by your agencies, but I do not know who we would call, who you would call here to speak, and is coordinating the whole comprehensive program in terms of bioterrorism. I do not know whether you know who it is. Is it the Secretary? The Assistant Secretary? Is it Homeland Security? Again, I do not want to spend a lot of time on it. But what I thought was particularly interesting, is that they had the hearings over in the House, and you could see in reading through those hearings, it just was not a located place. I do not know whether it ought to be Secretary Ridge or others who ought to be doing it, but at least from my personal impression—and it is not in your particular responsibility. You are key elements and I think no one can listen to what you have been

doing without being enormously impressed, but I do not know whether we are also missing out on some very important other kind of coordinating aspects which I think we probably ought to bring up.

This is the testimony of Paul Redmond, who is Assistant Secretary of Homeland Security, and was a representative selected by the Homeland Security Department to testify on bioterrorism in the House Homeland Security Committee. First of all, I guess he admitted that he had not read, even seen his own testimony, and then he admitted that there was no real plan.

This is Redmond. "I am sorry, Mr. Chairman, I am rather new to the process. I misspoke. It is my statement, certainly."

This is Congressman Shays. "I hope you don't say that. Tell me what you wrote in it."

Redmond. "I didn't see it until I got down here."

Shays. "Well, there is nothing in the statement that deals with your area, is it?"

Redmond. "No."

Shays. "So it is not your statement."

"No."

I just wonder in this area—and I will talk with the Chairman and get back—but I just think there should be the location and the coordination of these kinds of activities if we are going to really expect to get this job done.

Let me ask you, Dr. Zerhouti. I am very concerned that you—not just you—the NIH, are doing the work that you have outlined here, and that this is also short-changing our battle against cancer, against stroke, against Parkinson's. If we look over the number of new grants that you are going to have next year in these areas that have been the key concerns of the Congress, the American people, the families in this country, we are seeing a diminution in the total numbers. And I am interested, wondering if we are shortchanging the war on cancer or stroke or Parkinson's disease to fight the war on bioterrorism? And if that is so, what does that say about our responsibilities in making sure you have the adequate resources to be able to do both?

Dr. ZERHOUNI. First of all, let me say I did read my testimony. [Laughter.]

Senator KENNEDY. You do not need to.

Dr. ZERHOUNI. But this is a real concern because we have a sort amount of capacity of research, and you need to make sure that the portfolio is balanced. In terms of 2004 there is no doubt that the major increase that we are going to see in terms of number of grants is related to biodefense as we are building up the capacity. We try to protect, actually, the rest of the portfolio. We are not seeing a decrease in the rest of the portfolio. It is almost flat in terms of what the number of new grants is going to be afforded by NIH in all the other areas.

However, I think this is a valid question in terms of how do you balance the total portfolio of activities when you have a national priority like biodefense? As I said, and Dr. Fauci may comment, what our first strategy was, was to identify those who had the skill set to be able to do biodefense research with a minimal, minimal additional investment because they already had the fundamental

knowledge. They could vary—for example, the genomics of microbial agents for bioterrorism research is not that different than doing it for normal agents, for natural agents.

However, what we are doing, Senator, is we have formed a steering committee of a select group of directors, which was really formed to address those issues. We have a process called the Roadmap Planning Process, which is a trans NIH funding process in which we are trying to identify priorities of the agency that go beyond biodefense, so that we will avoid imbalance in the portfolio. So we are completely sensitive to your remarks, Senator.

Senator KENNEDY. It comes back to sort of who is in charge. They can find out that there are not the resources there in the NIH because we are diverting them in this, or we are only doing 2 percent in terms of food supply and we really ought to be doing something more, or the help and assistance, that is CDC, and that is a concern.

I know others want to inquire. One of the areas that I am very concerned about is what is happening in the hospitals. I know Dr. Gerberding gave an enormously interesting and impressive statement about what we are doing in the early detection, the expansion of the public health areas. I would agree that we have let that deteriorate dramatically. These first responders, how are we going to deal with that? It is incredibly important.

We find in just talking to people back in my State, Massachusetts, the Boston Medical Center, they have spent 35,000 on personal protective equipment, 15,000 on supplies, extra pharmaceutical, 30,000 training. Boston Medical Center spends 275 this year, 317,000 next year. Lahey Clinics, 109,000 this year, expect to spend a good deal more next year. Quincy Medical Center, 280,000. In Attleboro at Sturdy Memorial Hospital, 34,000. And it just goes on and on.

We have seen that Congress has appropriated 500 million, but also at the same time, our hospitals also, many of these major urban areas, graduate medical education has lost 750 million. We have seen the Medicaid slash that will attribute 300 million. The net result is the hospitals are losing $1,900,000,000 this year. Every hospital I have spoken to reports that they are trying, trying, trying in terms of the terrorism preparedness as a key cost, but they just are under so much financial pressure. I have mentioned this to Secretary Ridge and Secretary Thompson, anybody else that would listen to this part. But I think unless we are going to be able to provide some additional kind of help and assistance in terms of hospitals, whether they are the teaching or the community hospitals, and these things that will really be outside even first responders who are the containers on this kind of thing, we are going to really fail in an important way, even with the kinds of detection and the public health laboratories and all of the others out there, and even with the sophisticated ability to move vaccines around the country overnight, if we are not going to be able to have the centers that are going to be well equipped and well trained people with the equipment, I think that is going to be a major gap in the whole system.

Dr. Gerberding, your reaction?

Dr. GERBERDING. Well, first of all, I agree with you that our health care system is under enormous stress from a lot of different directions. I spent 2 weeks at San Francisco General Hospital, working on medical alerts in June, and I can only agree with you. I also do not think we can solve those problems through biodefense preparation, per se. We are, Secretary Thompson and HERSA are increasing the level of support to hospitals for bioterrorism preparedness this year, so we will expect to see some increasing returns on that investment. But there are other things that we are doing and need to do more of.

One is we need to have a regional approach. It is not realistic for every hospital in every jurisdiction to be able to be the bioterrorism hospital. We learned that with SARS. That just does not work. So we need to consolidate and invest strategically in preparedness resources.

Another thing is CDC and HHS can do more to help hospitals not have to reinvent the wheel every time they want to train or prepare, so we are putting together tool kits and other resources and using our distance learning systems, as well as our many colleagues within the professional organizations and the schools to create modules that say, this is what good hospital preparedness looks like. These are the benchmarks. These are the performance standards, and this is what you need to do, just to help give them more technical and infrastructure support to get there. That is going to have to be a very high priority this year.

Senator KENNEDY. Just finally, doctor, you talked about maintaining NIH as having the best in biodefense probably being a subject for another hearing, but I hope you will feel free to let us know about what we ought to be doing.

The CHAIRMAN. That is true of all these agencies.

Senator KENNEDY. All the agencies. I hope, as the Chairman has just said, that this is an open invitation to communicate with us about this, particularly——

The CHAIRMAN. What you all need.

Senator KENNEDY. If you are an appropriator you can say that.

But in a serious way, with all the agencies, maintaining these personnel, keeping the people that are really making the difference and that are the real backbone is enormously important and we should hear from you about those. There are a lot of things that we can do.

Thank you very much.

The CHAIRMAN. Thank you. And just quickly on that point, that is very important. We have done a lot of special things for a lot of agencies that have had unique personnel issues. I know in my appropriating committee we have done special things for the FCC and for the FBI. So we are interested in ideas you have for how to keep your talent.

Senator Murray, I would say that Dr. McClellan is going to be leaving in a little while, so if you could keep your questions to 10 minutes.

Senator MURRAY. I can do better than that. Mr. Chairman, I really appreciate your having this hearing, and really want to show my appreciation for each one of the panelists here. It is very clear that this country is well represented and has tremendous talent in

all of these agencies that are so critical to our public health system and to all of us as we live our daily lives, and I really want to thank you for your tremendous work.

I have had the opportunity to ask many questions of you through my committee assignments, a lot of questions focused on this issue. But I think sometimes when we are not at orange alert, we tend to forget all the work you are doing, and the work you are doing right now is so critical in case we ever get to an orange alert again. I know the threat of terror is real. We sometimes lose sight of that, but what I feel good about in this country is we do have great intellects, we have great creativity, we have great technology, and if we invest in those things we will be prepared, and I know each one of your agencies is working on doing that in your own way.

Dr. Zerhouni, let me start with you. I know in your testimony you indicated that NIH is working on a next-generation smallpox vaccine, and again, our creativity and engineering is going to get us to where we need to be. But I have asked you this before. I just want to keep you focused on it. It is a real concern of mine that as we do this new research for any new vaccine or any kind of prevention or any kind of medicine out there, that we remember our children, pregnant women, and other vulnerable populations. I want to ask you what we are doing to make sure that these kinds of vaccines are being tested for those vulnerable populations?

Dr. ZERHOUNI. First of all, I think this is an appropriate concern and an important consideration of strategic planning. In fact, the development of the MVA version of smallpox vaccine, the Ankara strain, which is a strain that has a much, much lower level of morbidity and mortality, from which a much kinder, gentler vaccine was developed and designed in fact to address the issues of populations that are vulnerable, particularly children and immuno-compromised patients. But as we see, it is also becoming very critical for us to develop in this area vaccines that have much, much lower risk profile to the recipient of the vaccine, because we have a risk-benefit ratio of threat versus risk of the vaccination computation that is occurring in our mind as public health officials that we need to improve by reducing as much as we can through research the risk not just to special populations which we care about and we worry about. We are really pleased to see that through the Better Pharmaceuticals for Children's Act as well as the BioShield contacts, that there is as much emphasis on those populations as there is in the general population.

Dr. Fauci might want to comment.

Senator MURRAY. I would love to hear his comment. We can hear about Cipro, but it has never been approved for children, and we are sitting here watching children unable to be protected, I think that is a real disservice to our country.

Dr. Fauci. You make a very good point. If you can remember a previous hearing we had when we discussed the ultimate approval or lack thereof of this smallpox vaccine that we currently use, was that in the clinical trial apparatus, we are actually doing a clinical trial on children so that we could give the FDA enough data for them to make an informed decisions. The institutional review boards themselves had a great deal of hesitancy of even doing the clinical trial on children, which really created a kind of vicious

Catch-22 for us because we could not do what we felt was right for the Nation or the children because we could not get past the IRB.

The subsequent vaccines that are in trial now, the major prototype of which is the one that Dr. Zerhouni just mentioned, the modified vaccinia Ankara, as a matter of fact, we do not anticipate that as a problem because of the well-known lack of toxic side effects in any population that we have used them in so far, antedating the smallpox problem, because we have used this in cancer patients, we have used this in HIV-infected patients. So your point is right on, and that is something that we will be addressing in the future endeavors.

Dr. GERBERDING. Senator Murray, if I could just add one thing. Secretary Thompson charged CDC with managing the National Advisory Committee on Children and Terrorism, and we have received the first round of recommendations from that advisory committee, so we would be happy to make this available to you because there are a number of things in there that are action steps for all of us.

Senator MURRAY. It is important not just because we need to be able to protect our children and our pregnant women, vulnerable populations, but if you have the population fearing being inoculated because of it has not been tested on even a small number of people, people will not go and get their vaccinations. So I really appreciate that.

Dr. MCCLELLAN. We would be happy to provide you all with the data that we put together on the use of many of these agents. In a control group, for example, in Cipro, as you mentioned, we put together a database of about 3,400 pediatric patients developed a profile of side effects and other complications that we are using as a basis for pediatric labeling.

Senator MURRAY. The information needs to be known right away because if a parent does not give their child something because they fear there may be side effects, their delay could be critical for that child's health.

Dr. Gerberding, I think you are the person I need to ask this question to, but anybody who wants to can answer. I have raised this issue so many times. I have raised it with SARS and with all the other issues we have gone through before. But what concerns me a lot is that these diseases know no boundaries, and a biological attack knows no boundary. Vancouver, B.C. is only 8 miles across the border from Washington State. I am sure New York shares this concern as well. And we saw it, like I said, with the SARS vaccine. The administration has told us before that they are working on bilateral agreements both for planning and in case something occurs. How are those bilateral agreements going with Mexico and Canada?

Dr. GERBERDING. Thank you. Two aspects to the answer. First of all, we have completed a bilateral negotiation with the border of Mexico, and so we have a memorandum of understanding and some support for activities across that border.

With Canada, so far the effort has been on a State-by-State basis. The money in the terrorism funding can be used by States to deal with jurisdiction over the border and to enter into bilateral agreements on a jurisdiction-by-jurisdiction basis.

In addition, Secretary Thompson, I think working through HERSA, is creating opportunities for more comprehensive planning with the border countries of Canada, which obviously would be one of your major concerns.

Senator MURRAY. Do you think we need to be doing more on this?

Dr. GERBERDING. I think right now that our interaction with Health Canada and with the Minister of Health is such that we are collaborating on a very high level. Canada, for example, is interested in creating a Canadian CDC, and so we are working on how we could collaborate, not just on infectious diseases, but on a number of disease——

Senator MURRAY. Did we learn anything from the SARS?

Dr. GERBERDING. We absolutely learned a great deal from Canada and the SARS, and we were very appreciative of their generosity in sharing those—particularly with hospital preparedness. In fact, we sent CDC teams up there twice now to learn about what is happening with the ongoing transmission. But more importantly, to bring back the protocols and all of the procedures that were successful in containment, and we have a—there is actually a committee at CDC taking those now and creating these protocols for isolation and quarantine, so that hospitals not only know how to isolate a patient, but know how to deal with a whole system of care if it had to change.

Senator MURRAY. Are our State agencies, particularly on the northern border, ready and know who to call? For example, if it was a bioterrorist attack in Bellingham, Washington or in the northern part of New York? Do those cities or counties or State agencies, do they know who to call in Canada, or do they call the national Government here and we call some Canadian agency? Is there a plan in place for that?

Dr. GERBERDING. I should know the answer, and I do not, but I will find out.

Senator MURRAY. OK. I would really appreciate knowing that.

One more quick question, Mr. Chairman. My concern always goes back to the fact that we do such great here in your agencies, but the first people to ever see a bioterrorist attack or SARS outbreak are the emergency room doctors as people start coming in. All the good information you develop, how does it get to those ER doctors so that they recognize it quickly and can notify whoever they need to notify and begin to start any plan that needs to be put into place?

Dr. GERBERDING. The answer to that now is we use multiple channels. First of all we have the "just in case" training and education, and the College of Emergency Physicians is one of our key partners to take CDC content and then redeploy it through their website and their national meetings and their information channels. So we have the "just in case" background ready.

And then in the time of an event, when we need "just in time" information because now there is a case or a potential case in front of them, we have additional amplification channels will include the Internet, the e-mail system, the health alert system, the secure information exchange. And we take our MMWR reports and bulletize them, and then we have many partner organizations including the

college that blasts that out to their membership. So we use multiple channels for both of those types of scenarios, and I think increasingly, we are filling in the gaps there and we are able to speed up the whole process. So that has been an area of great progress.

Senator MURRAY. It is an area I continue to be concerned about. Our emergency room doctors are overwhelmed right now. They are facing a health care crisis everywhere I go in my own State, and I am certain elsewhere. With a lot of doctors leaving, hospitals just struggling, and yet these are the people we are going to rely on to notice quickly and effectively and efficiently any kind of outbreaks. So making sure they have the resources and the training and the support, I think is really critical.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator. I would just note for the edification of everyone, we are going to terminate the hearing at 11:30. That will be plenty of time in case one of our fellow members just wanders in. I will have given fair warning on that.

Senator Clinton.

Senator CLINTON. Thank you, Mr. Chairman. Thank you for holding this hearing. I cannot imagine any more important subject, and I want to join with my colleagues in thanking and congratulating our four witnesses for their service to our country. I am deeply impressed and very grateful.

Let me start with asking that my full opening statement, if I could, be submitted to the record, Mr. Chairman.

The CHAIRMAN. Yes, of course.

[The prepared statement of Senator Clinton follows:]

PREPARED STATEMENT OF SENATOR CLINTON

I want to thank Chairman Gregg for calling this important hearing. I recognize the significant effort the Administration has invested into preparing for a potential biological, chemical or radiological attack. If we are serious about remaining prepared for a bioterrorist attack, it is critical that we continue to reassess our capability, and raise those concerns where they remain and not simply rest on the laurels of our accomplishments.

Unfortunately, a recent Council for Foreign Relations Report, entitled "Emergency Responders: Drastically Underfunded, Dangerously Unprepared" sounded a chilling alarm. Its report found that most states' public health labs still lack basic equipment and expertise to respond adequately to a chemical or biological attack. Seventy-five percent of state laboratories reported being overwhelmed by too many testing requests. We clearly need to devote more funding if we are serious about defending our nation against bioterrorism.

The smallpox vaccination effort championed by CDC exposed this critical weakness in our public health workforce. In order to meet the demands of Phase I of the Smallpox vaccinations, Onondaga County in New York has shifted staff members resulting in the reduction of services by more than one-third. There will be 835 fewer pediatric dental visits and a reduction of 221 visits for women who need breast and cervical cancer screening. Our public health departments are stretched thin already, and with the state and local

budget crunch, these departments lack the resources to even keep some of the staff they currently have.

In many of the states and localities most likely to be the victim of a bioterrorist attack, the existing public health infrastructure that would help us detect and respond to a bioterrorist threat is crumbling. In New York City, the key facility that handles and screens specimens for bioterrorist agents has a deteriorating roof and cooling system and has significant water damage in its interior. Yet New York City was 45th in per capita bioterrorism funding from CDC in Fiscal Year 2003, and New York State was 49th.

Currently, bioterrorism funding is not distributed based on threat level, despite the fact that Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes those funds to be distributed based on the threats that particular states and localities face. Historically, cities have proven to be at higher risk of bioterrorist attacks—for example, sarin in Tokyo and anthrax in Washington. We should also encourage those cities, such as New York, that have developed model programs in screening for and responding to bioterrorism that other localities can apply in efficiently implementing their own preparedness programs.

Another recent report from the Partnership for Public Service raises an equally alarming concern. The report tells us that fifty percent of federal experts trained to respond to a biological or chemical attack will retire over the next five years alone. Our public health professionals in the FDA, CDC, USDA, and other agencies have critical expertise that has given us peace of mind that we will be protected from a bioterrorist threat. Yet that peace of mind will soon crumble. At the state and local level, the problem is even worse; the Council for State and Territorial Epidemiologists tells us that we will need to train an additional 1600 epidemiologists over the next ten years just to prevent a worsening shortage of these professionals at the state and local level.

While the Epidemic Intelligence Service in CDC trains doctors and other health professionals to become the public health experts of tomorrow, the Partnership for Public Service report tells us that we need to prime our pipeline of public health experts if we want to avoid a crisis in biodefense. That is why I will be introducing an amendment to the Labor-HHS Appropriations bill that will ensure that we can have the expertise we need to protect our citizens from a bioterrorist attack.

My proposal would double funding for the Epidemic Intelligence Services, the "pipeline" program that trains and recruits federal public health personnel like those at CDC, and establish a new "pipeline" training program to recruit, train and retain desperately needed state and local laboratory personnel, epidemiologists and public health nurses. This amendment would also add funding to Title VII programs that currently train public health personnel, and would also increase funding for the CDC's Centers for Public Health Preparedness so that these centers can collaborate with state and local public health agencies in developing training programs for public health personnel. It would also ensure an annual audit of federal, state and local bioterrorism personnel with recommendations to Congress so that we can continue to monitor our workforce needs and intervene if necessary.

I hope Director Gerberding and Secretary Thompson will work with me on this amendment, and the authorizing legislation I plan to introduce subsequently. I eagerly anticipate a fruitful discussion with our expert panel, one that will move us closer to our shared goal of protecting our nation from terrorism.

Senator Clinton. Dr. McClellan, let me first thank you. Last night was a red letter day for American children and clinicians, physicians, nurses and others. We finally passed, by unanimous consent, the Pediatric Research Equity Act of 2003, which will add another tool in the tool kit that Senator Murray was discussing about how to best prepare our children, and how we get adequate information about the safety and efficacy of drugs that are prescribed for children, and I want to thank the Chairman and the Ranking Member, and certainly my colleagues, Senators DeWine and Dodd, for their perseverance. I particularly want to thank you personally and your staff for your technical input and your personal involvement.

I am hoping that we can count on your help in the House. Obviously, now that we have passed it in the Senate, if we could get it through the House, then we could get it to the President to be signed. So I would ask that you do everything possible to help the House, as you did with us, in moving this important legislation forward. And may I also assume that you are supporting undisputed authority for the FDA to enforce pediatric studies, and supporting the Senate in the position that we have taken?

Dr. MCCLELLAN. That is right. We are strong supporters of the bill that you and your colleagues here worked to pass. We deeply appreciate your efforts to get that done. We need the pediatric rule back in place for all the reasons that you mentioned. And Secretary Thompson and I issued a statement today, urging rapid action to get the bill to the President's desk, and I hope that will happen quickly. We will work just as closely with the House as we have worked with you to get this done.

Senator CLINTON. Thank you so much.

And I would be remiss if I did not thank Dr. Fauci for starting down this road with me and others so many years ago, and I am very grateful that we are nearly at the destination point.

I have a few more questions that I would like, Dr. McClellan, to submit for the record to receive responses on.

[The response to questions of Senator Clinton was not received by press time.]

Dr. MCCLELLAN. Certainly.

Senator CLINTON. Let me also turn to an issue that Dr. Gerberding talked at great length about in her written testimony, and I think it is one of the critical issues. The Chairman referred to it in his remarks, and he of course is in a very strong position to offer the leadership needed in his joint position here and on the Appropriations Committee.

Because the recent Partnership for Public Service Report, entitled, "Homeland Insecurity: Building the Expertise to Defend America from Bioterrorism," as you point out, has some startling figures about the impending loss of medical and biological experts who are on the road to retirement in the next 5 to 10 years, do you think, Doctor, that the Epidemic Intelligence Service and other

Federal training programs will be able to provide enough personnel to fill this potential workforce shortage and, if not, or if in doubt, what are some of the activities we should be pursuing right now to get in a position to avoid this collision course I see us heading toward?

Dr. GERBERDING. I will try to give a short answer. I think it is a long answer that would be most informative.

I do not think that the current system is adequate to sustain the public health workforce, particularly the workforce that we are going to need in 5 years because the skill set is changing. We need informaticians, we need molecular biologists, we need public health experts in genomics. And so there is a whole new generation of skills that we need for terrorism or for other issues.

There are some short-term steps that we can take, and just like I think you have heard from all of my partners here in HHS, we are developing a strategic framework for workforce development throughout the entire public health system, which includes going way back to junior highs and high schools, where we are engaging kids in the concept that public health is a great profession. We had Olympiad winners this year in epidemiology in the science contest in the field of epidemiology.

So we are starting way back at the beginning and trying to interest people in this career pathway, working with colleges and universities to support summer internships and training for students to make this field exciting, working with minority health organizations to get those students involved and to deal with some of our disparity in diversity issues, working with the schools of medicine, schools of public health and other professional organizations, academic organizations, to develop bona fide curricula and training.

And a very immediate step that we will be taking at CDC is to implement training grants in public health so that postdoctoral students who are interested in careers in public health have an opportunity for research experience in the same way that they would if they were interested in infectious disease or other fields of endeavor. So we will be creating some training grants in this field.

These are all going to take a long time to come to fruition, but if we do not start strategically, with the long view in mind, in 5 years, we will be in a crisis State.

At the other end of the pipeline, of course, we want the kinds of flexibilities that Senator Gregg was making reference to so that we can give retention bonuses and that we can compete salaries and the critical job classifications that right now Government is not very competitive in. So I think if we work together on this, the problems are going to be similar across our agencies, and we will probably be able to come up with a framework that makes some sense. And I am sure we will have Secretary Thompson's support in that, but it is nice to know that you are interested.

Senator CLINTON. Well, and I think the concern extends down to State and local public health departments, as well as the Federal workforce. The Council for State and Territorial Epidemiology tells us they will need to train an additional 1,600 epidemiologists over the next 10 years just to prevent a worsening shortage of professionals working at State and local levels.

And I am so concerned because, historically, as I read the data, professionals were trained by the Epidemic Intelligence Service that you are referring to, and the other programs, in conjunction with academic institutions and the like, usually choose to work in the Federal and academic public health positions, and we desperately need them there. So it is not an either/or kind of question.

The Centers for Public Health Preparedness, located at the Schools of Public Health, have historically trained the academic and Federal public health experts. So we also have to be thinking about a pipeline for the State and local public health professionals.

And I think that is a double challenge we face, Mr. Chairman, because not only in the area of biodefense, but even in the increasing awareness of environmental impact on health, we are not having enough personnel at the State and local level to follow up on legitimate questions that are raised, that maybe can begin to acquire enough information, we can make sense of cancer clusters or, you know, increasing spikes in other diseases.

So I think that we've got to think on both levels, both what, as the doctor clearly states in her oral and written testimony, we can do at the Federal level, but then I think we are going to have to provide some boosts at the State and local level. And I would appreciate thoughts that any of our experts have on this because you work with the State and local level.

Then, in another arena, I wish to briefly mention our continuing efforts globally and what we need to do to maximize our reach globally. And I want to commend all of you for the contributions that the American medical establishment made in the SARS epidemic, but any thoughts you have got that we should take and consider, with respect to the WHO. I mean, we have got, for example, this bizarre problem that Taiwan is not in the WHO, and so you have got political obstacles to figuring out what is going on with an epidemic in Taiwan.

These things are just hard to understand given the global village that we all inhabit. So any thoughts you have may not be directly in our jurisdiction, but if you need additional personnel, laboratories overseas, other kinds of protocols that we have anything to do with, we need to hear that from you because this is an increasing concern of mine.

There are some of my colleagues who do not believe in things like global climate change, but it does seem to me that some of these diseases are creeping northward. Disease that we never had at these latitudes, we are now finding. And certainly, even apart from that, all kinds of critters get on airplanes, and ships, and end up on our shores. So I think we have got to think more globally, as well as globally. So there are many, many levels to this.

Finally, Dr. Gerberding, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the distribution of public health emergency preparedness funds based on threat. However, in fiscal year 2003, New York City was forty-fifth in public health emergency preparedness funding at $2.59 per capita.

I think history has proven that our cities are the principal targets for any kind of attack. That is where sarin was used, in Tokyo, anthrax here, in Washington. Can you tell us how you are planning

to ensure that the funds are, in the future, distributed, as we intended them to be, on the basis of threat.

Dr. GERBERDING. Thank you.

Yesterday, I had a chance to talk with the commissioner of Health in New York City, and he brought the same issue to my attention. I do not think anyone would argue that New York City is a target, and we recognize that.

The dilemma is that we did not think of Boca Raton as being a target before the first case of inhalational anthrax was identified there. So it is a real challenge to make a hierarchical arrangement of our cities and really, ultimately, we have to concentrate on having no weak links in the system.

And so I promised the Commission that I would talk about this with Secretary Thompson and bring to his attention that there are inabilities to provide resources for all of the priorities in some of our major metropolitan areas. As you know, we do have special funding for four cities because we recognize that they are higher in population and also higher in threat. So we will look at the resource allocation and identify how we can get the balance right if it is out of balance right now.

Senator CLINTON. I would appreciate being kept informed about that. And I thank you for your attention to this.

Finally, I think that perhaps the Chairman and I could discuss further, and get the expertise from all of you, about whether there is anything we could do right now. I have prepared an amendment to Labor-HHS about this public health workforce issue because I hear it all over. It is not just a New York City problem, it is throughout New York State, but then many people around the country are, you know, they are panicked now because they do not think they have enough resources, and they look over the horizon, and they just see a terrible shortage developing. So perhaps we could discuss some about that.

Then, finally, Dr. Gerberding, I have one very local question, and I will be happy to provide additional information concerning this, but I want to thank you for your assistance and the aid of your staff in setting up the Health Tracking System for everyone who labored at Ground Zero—our firefighters, our police officers, our construction workers. This was such an important effort, and obviously it means the world to the individuals who are directly affected. But I think it is also significant to the data we are collecting about what the exposures might possibly be and the impacts that they will have when people are thrust in these unbelievable, dangerous situations.

We may need your help in another pressing matter at this time in Endicott, New York. In 1979, there was a release of approximately 4,100 gallons of industrial solvents at the former IBM facility in the Village of Endicott. The spill contaminated local groundwater and associated vapors have recently been found in people's homes, although this is now 20 years-plus after the spill itself.

The groundwater contamination is being addressed through a number of pump and treatment systems, and we are sampling local buildings, and we are trying to fix ventilation systems. It is a very complex environmental and public health challenge, but it is the kind of thing we are seeing more and more often across our coun-

try. And I think CDC could provide meaningful assistance in helping the local authorities and even the State try to come to grips with these indoor air situations, the problems that are associated with the contamination, and I look forward working with you.

The county executive, Mr. Jeffrey Kraham, has expressed a particular concern about trying to set up some kind of an assessment system, perhaps through the National Institute for Occupational Safety and Health so that we can, again, kind of track and learn from these kinds of massive contaminant events and apparently have long-term effects. It is not something that goes away in a year or two. So I will provide you additional information on that.

Dr. GERBERDING. Thank you. We do have the expertise to address those kinds of issues, so we will definitely follow up.

Senator CLINTON. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

I think you have sensed a real interest in this committee at least in doing something about your personnel issues. I understand there are bureaucratic issues that may limit your capacity to be aggressive in this area, but this committee would like to be aggressive in the area, so hopefully we will get some counsel from you as to what we should be doing.

Again, we thank you very much for the extraordinary work you do on behalf of the American citizenry in all sorts of areas, obviously, not only protecting us from the threat of terrorism, but protecting the health of the Nation, and we are very, very lucky to have talent of your level and capabilities involved in public service. So thank you again, and I appreciate your taking the time to be here.

[Additional material follows.]

ADDITIONAL MATERIAL

STATEMENT OF JULIE LOUISE GERBERDING, M.D.

Good afternoon, Mr. Chairman and members of the Committee. I am Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention (CDC) and Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR). Thank you for the opportunity to testify today about terrorism preparedness and emergency response at CDC. The United States is experiencing threats to its national security that require preparedness for potential biological, chemical, radiological, and mass trauma attacks and other public health emergencies. Helping lead this effort is the Centers for Disease Control and Prevention.

HHS has set a strategic course to ready our nation for any potential public health threat including terrorism and CDC has played an important part in this strategy. CDC's public health emergency preparedness vision, "People Protected—Public Health Prepared," and the mission statement, "Prevent death, disability, disease and injury associated with urgent health threats by improving preparedness of the public health system and the public through excellence in science and services." are wide reaching concepts that convey our sense of purpose and commitment. CDC's preparedness strategies include: timely, effective and integrated detection and investigation; sustained prevention and consequence management programs; coordinated public health emergency preparedness and response; qualified, equipped and integrated laboratories; competent and sustainable workforce; protected workers and workplaces; innovative, relevant and applied research and evaluation; and timely, accurate and coordinated communications. These strategic imperatives target our agency's core competencies to prepare the public health system for all types of emergencies. CDC is committed to protecting people by preparing for and responding to acts of terrorism and other public health emergencies.

In today's testimony, I will speak to three specific issues: the public health workforce; the current status of CDC terrorism preparedness and emergency response activities: and smallpox preparedness.

PUBLIC HEALTH WORKFORCE

The recently released report of the Partnership for Public Service entitled "Homeland Insecurity: Building the Expertise to Defend America from Bioterrorism" pointed to the critical need of addressing the Biodefense Workforce. CDC recognizes that a significant challenge exists in developing and retaining a qualified and competent workforce to address the needs both at CDC and within Local and State Health Departments. In fact, nearly half of CDC's physicians and biologists will be eligible, although only 10% will actually take early retirement, for retirement in the next five years and it has been estimated that one-quarter of all government employees will be eligible within that same time period. In order to prepare for these retirements and to increase the overall number of qualified and competent workers in public health preparedness and research, we are looking to new strategies for recruitment and retention of scientists, physicians, emergency planners responders, and managers. Successful programs like the Epidemic Intelligence Service, the Preventive Medicine Residency and the Public Health Prevention Service can assist in addressing this issue and we are looking into new strategies to reach out to fill laboratory diagnostic and critical research positions.

Prior to September 11, 2001, CDC had a total of 174 FTEs designated to support bioterrorism activities. Internally at CDC in FY03, 444 staff are now employed in various skills sets to support terrorism preparedness and response. In FY04, this will increase to 529. CDC has increased to 64 the number of field staff (epidemiologists and public health advisors) assigned to State and Local Health Departments. CDC is planning to move additional staff into the field and has been given authority to assign CDC staff to State and Local Health Departments as FTE exempt. Through the state and local grant program, at least 3,850 people have been funded (in part or whole) within the past 18 months to support (scientific, programmatic, administrative) public health preparedness activities.

A competent and sustainable workforce is one of the strategic imperatives within CDC's National Strategy for Terrorism Preparedness and Emergency Response. CDC's support to address this imperative will focus on:

Increasing the number and type of professionals that comprise a preparedness and response workforce.

Delivery of certification and competency based training.

Recruitment and retention of the highest quality workforce.

Evaluation of the impact of training on workforce competency.

Support for Schools of Public Health, Medicine and other Academic partners to increase the number of individuals entering the field and trained throughout their career. Currently, CDC funds Academic Centers for Public Health Preparedness at Schools of Public Health to address workforce training and "workforce pipeline" issues.

Through the CDC State and Local Preparedness Program, CDC made funds available to each grantee, and charged them with training and educating their public health workforce regarding preparedness and response activities. CDC is also the home of the Public Health Training Network (PHTN) and National Laboratory Training Network (NLTN) using distance learning mechanisms as the framework for delivery of training to the widest possible audience across the public health system. CDC also provides funds through the National Association of City and County Health Officials (NACCHO) to support "Public Health Ready," a pilot program to develop and test competencies of the local public health workforce, in 11 local health agencies.

STATUS OF CDC TERRORISM PREPAREDNESS AND EMERGENCY RESPONSE ACTIVITIES; UPGRADING STATE AND LOCAL CAPACITY

In FY 2003, CDC is providing $1.03 billion to continue upgrading state and local capacity to prepare for bioterrorism and other public health emergencies. This funding includes a $100 million supplemental funding for smallpox preparedness activities. To support the state and local programs, CDC has developed the following goals, including: 1) to rapidly detect public health emergencies involving biological, chemical, radiological and nuclear agents: 2) to rapidly investigate and respond to public health emergencies involving biological, chemical, radiological and nuclear agents; and 3) to rapidly control, contain, and recover from public health emergencies involving biological, chemical, radiological and nuclear agents. Each goal is paired with longterm performance measures that will provide a framework to increase the nation's preparedness. Examples of long-term performance measures are: 100% of LRN laboratories will pass proficiency testing for bacillus anthracis, yersina pestis, Francisella tularensis, Clostridium botulinum toxin, Variola major, vaccina, and varicella; 100% of states will have level 1 chemical laboratory capacity, and have agreements with and access to (specimens arriving within 8 hours): a level-three chemical laboratory equipped to detect exposure to nerve agents, mycotoxins and select industrial toxins; and 100% of state and local public health agencies will be in compliance with CDC recommendations for using standards-based electronic disease surveillance systems appropriate routine public health information collection, analysis, and reporting to appropriate public health authorities.

CDC conducted numerous activities with resources provided in FY 2002. Within 90 days of the FY 2002 appropriation. CDC provided all of the appropriated $918 million to states and selected cities. Because of this quick action, states were able to fund urgent needs. Up to 20% of the FY2003 funds were made available on an expedited basis to the states and other eligible entities, should they opt to seek it, for smallpox activities and other ongoing initiatives that could benefit from enhanced funding. In FY2002, CDC provided training for more than 1.5 million health professionals in terrorism preparedness and response; and, trained approximately 8,800 clinical laboratorians in terrorism preparedness and response. CDC, also provided reference materials to approximately 4,600 clinical laboratories following September 11, 2001. CDC is helping public health laboratories in all 50 states identify bioterrorist threat agents and efficiently communicate laboratory findings. In addition, CDC is providing 117 public health laboratories with the capacity to detect and respond to critical agents and is increasing national response capacity to include food, veterinary, environmental and chemical laboratories in the Laboratory Response Network. This work continues during the FY2003 awards process.

With support from CDC, some states conducted mock exercises to prepare for terrorism events involving numerous state, county and local agencies; undertook initiatives to develop near realtime syndromic surveillance systems; trained large numbers of staff from public health agencies, health care facilities, emergency management organizations, police and fire departments and other key institutions; created and tested communication systems linking local public health staff and first responders with senior staff from state public health departments, emergency management agencies and other critical state agencies; and enhanced critical capacity at their public health laboratories.

UPGRADING CDC CAPACITY

Emergency Preparedness and Response

CDC has strengthened its internal Emergency Preparedness and Response by establishing the new CDC Director's Operations Center and in support of further infrastructure to provide enhanced technical and programmatic assistance to states. Some examples include: improved rapid identification and characterization of potential biologic agents; expanded the Epidemic Intelligence Service to assure that well-trained, first-line responders are available to respond to public health emergencies; and developed a secure information infrastructure to provide enhanced Geographic Information System (GIS) capability at the federal, state and local levels.

Emergency Communication System

CDC moved quickly to assure that its Emergency Communication System can comprehensively, efficiently, and rapidly respond to communication needs associated with terrorism. This system, currently used to respond to SARS and adverse events related to smallpox vaccinations, can develop critical information; arrange for immediate direct communication with key collaborators and stakeholders around the world; provide real-time updates to the media; make sure essential information is available to the public through the CDC Web site; maintain a public health response hotline; develop training for clinicians; and develop public service announcements. A centralcomponent of this system is the state-of-the-art Marcus Emergency Operations Center. This facility is a unique example of a public/private partnership, and was completed in only six months.

In addition, CDC has made great strides to help enhance communications with state and local health departments through a variety of platforms including the Health Alert Network (HAN), Epi-X, the National Electronic Disease Surveillance System (NEDSS) and the Public Health Information Network (PAIN). All of these systems are meant to increase the ability of CDC to communicate quickly and directly with health officers providing them with emergency messages 24/7 within 30 minutes (HAN) and via a secure, interactive web portal that allows for exchange of important epidemiological information (Epi-X). Both of these systems fall under the rubric of PHIN. NEDSS is currently being implemented at the state level to provide a common standard to all states and localities for disease reporting to help maximize the ability of CDC and states/locals to stay up to date on emerging infectious diseases.

Strategic National Stockpile

CDC continues to be responsible for managing the Strategic National Stockpile (SNS, now supported by the Department of Homeland Security resources, but operationally managed through the CDC). The mission of SNS is to ensure the availability of life-saying pharmaceuticals, antidotes and other medical supplies and equipment necessary to counter the effects of nerve agents, biological pathogens and chemical agents. The SNS Program stands ready for immediate deployment to any U.S. location in the event of a terrorist attack using a biological, toxin or chemical agent directed against a civilian population. It is comprised of pharmaceuticals, vaccines, medical supplies, and medical equipment that exist to augment state and local resources for responding to terrorist attacks and other emergencies. These packages are stored in strategic locations around the U.S. to ensure rapid delivery anywhere in the country. Recently, the SNS has prepared specific guidance, and provided technical, planning assistance to states as well as providing funding to them to help them effectively manage the deployment of the SNS at the state level. CDC will now be working closely with DHS on stockpile issues.

Smallpox Preparedness

In order to better prepare the country for a possible smallpox attack, the President, in December of 2002, announced the establishment of the National Smallpox Vaccination Program, outlining the government's intent to offer voluntary precautionary smallpox vaccination with licensed vaccine to selected health care and public health workers, traditional first responders, and, in time, to individuals in the general population interested in receiving the vaccine under appropriate protocols. CDC moved swiftly to do its part to assure the availability of smallpox vaccine for every person in the United States.

To improve national smallpox preparedness, CDC has increased its focus on elements needed to assure acceptable levels of preparedness. Based on knowledge of the disease and public health response strategies needed to control and contain an outbreak of smallpox, the following preparedness elements are being addressed:

1. Preparing key responders before an event occurs,

2. Rapid detection, identification, investigation and response to suspect or confirmed casts of smallpox, and

3. Protection of the public including provision of mass vaccination clinics.

As of July 18, 2003 nearly 38,000 civilian public health and healthcare professionals have received the vaccine. Participation in the vaccination program has varied widely across the country, with 10, states (TX, FL, TN, OH, CA, MN, NE, NC, MO, LA) having vaccinated over 1,000 volunteers.

The fact that the participation rate is lower than some projected has been generally attributed to: 1) the low perceived threat of a smallpox attack, and 2) continuing concerns about the risk of adverse reactions to vaccination. CDC has conducted at least 74 training and education sessions, reaching 1,847,112 health care professionals. Thirty-nine different training products are, available for public health and healthcare professionals. At least 14,036 individuals who have been comprehensively trained have the capacity to administer smallpox vaccine, if necessary.

Last spring, Congress enacted legislation that addressed vaccination-related compensation and liability concerns. This legislation, the Smallpox Emergency Personnel Protection Act of 2003, established a no-fault program ("the Program") to provide benefits and/or compensation to certain individuals, including health-care workers and emergency responders, who are injured as the result of the administration of smallpox countermeasures, including the smallpox (vaccinia) vaccine. The Program will also provide benefits and/or compensation to certain individuals who are injured as a result of accidental vaccinia inoculation through contact.

To date, the incidence of adverse reactions in both civilian and military populations has been lower than anticipated. The military smallpox vaccination program provided an unprecedented opportunity to better characterize the safety profile of smallpox vaccine when 450,000 military personnel were vaccinated. The low adverse reaction rate appears to be directly attributable to the efficacy of pre-vaccination screening that has ensured those at risk for complications do not receive the vaccine. The occurrence of possible vaccine related heart problems, however, did surface as a possible adverse event that required further restricting the possible use of the smallpox vaccine in those at risk for heart disease. As a result, CDC issued further guidance to modify the screening criteria to keep the volunteers safe. CDC, working with our medical/scientific partners, continues to investigate Whether these particular adverse events are causally related to the vaccine.

Precautionary vaccination is only one element of overall smallpox preparedness and we continue to make progress in other crucial areas that contribute to preparedness.

All states and four designated cities have developed detailed pre-event and post-event smallpox response plans.

Public health teams are now organized nationwide to respond to a suspected smallpox outbreak within 6 hours.

A national information system has been implemented that can support smallpox and other emergency vaccination administration needs. It advances our preparedness to know who needs to be vaccinated, to monitor vaccine "take" results, and track adverse vaccination events. The system produces information that decision makers and response teams need to support the protection of the population from communicable diseases in an emergency setting.

Clinical and public health laboratories have improved their ability to detect and diagnose rash illness within 24 hours of presentation. Twenty-three laboratories nationwide have the training and reagents to screen for smallpox and differentiate it from other pox related diseases (e.g. chickenpox and monkey pox).

Current vaccine supplies and projected production continue to meet the goal of having sufficient smallpox vaccine for every American in the event of an emergency.

Over 290,000 doses of vaccine are currently deployed, with vaccine available in every state and four major cities (New York, Chicago, Los Angeles, and Washington, D.C.).

CDC, along with State and Local Health Departments, will continue to enhance smallpox preparedness in the coming year. We are creating performance standards to guide and assess state and local smallpox preparedness. Performance-based evaluation will target activities in the areas of: public health and health care response teams formed and trained, members vaccinated and trained as vaccinators, increases in the number of Laboratory Response Network (LRN) labs that can perform confirmatory testing for vaccina and Variola major, progress on developing real-time electronic disease reporting, demonstrated proficiency in receiving large quantities of smallpox vaccine, and, identification and training of volunteers needed to run mass vaccination clinics capable of vaccinating the entire population in 10 days.

Performance standards are being developed to incorporate tiered levels of achievement based on performance standards associated with the activities I just described.

Actual performance will be monitored through a dual evaluation process: self-evaluation by grantee, and formal and informal CDC program evaluation.

In closing, CDC has refocused it priorities to be sure the nation is prepared for all types of public health emergencies including biological, chemical, radiological, and conventional terrorist threats. CDC will continue to implement the successful strategies begun in previous years, while remaining flexible in its capability to respond to known and emerging threats. As we continue these efforts, I want to thank the Committee again for its support and for enabling us to do this essential work.

PROGRESS REPORT TO SECRETARY TOMMY G. THOMPSON—PREPARED BY: U.S. FOOD AND DRUG ADMINISTRATION

MESSAGE FROM THE COMMISSION OF FOOD AND DRUGS

On July 23, 2003, the Food and Drug Administration (FDA) submitted to the Department of Health and Human Services Secretary Tommy G. Thompson this progress report entitled, "Ensuring the Safety and Security of the Nation's Food Supply," which summarizes the leadership demonstrated at FDA in combating the terrorist threat to foods.

FDA is responsible for ensuring the safety and security of 80% of the U.S. food supply. FDA's legislative mandate is to protect the public health by ensuring the safety of the production, processing, packaging, storage, and holding of domestic and imported food except those products (meat, poultry, and processed egg products) that are under the jurisdiction of the U.S. Department of Agriculture.

Although food safety and security are different aspects of food protection, they are inherently connected. FDA, at the direction of the Department of Health and Human Services (DHHS), has established a 10-Point Program for ensuring the safety and security of the food supply. Based on activities in FDA's 10-Point Program, the Agency is employing overall strategies to (1) develop increased awareness among federal, state, local, and tribal governments and the private sector by collecting, analyzing, and disseminating information and knowledge (Awareness); (2) develop capacity for identification of a specific threat or attack on the food supply (Prevention); (3) develop effective protection strategies to "shield" the food supply from terrorist threats (Protection); (4) develop capacity for a rapid, coordinated response to a foodborne terrorist attack (Response); and (5) develop capacity for a rapid, coordinated recovery from a foodborne terrorist attack (Recovery).

Within the food safety and security strategies, FDA's program features 10 areas of focus, based on the following principles:

Food security and safety are integrated goals. By building upon the Nation's core food safety/public health systems and expertise, while strengthening expertise and capabilities needed to address the terrorist threat, FDA is enhancing food security and is improving food safety in the process.

The food safety and security system is comprehensive, addressing the full range of assessment, prevention, and response needs, throughout the food production and distribution chain. The system must be efficient and in the context of both safety and security, address the most significant threats first whenever possible.

The food safety and security system is also built on a solid foundation of a national partnership with other entities involved in food safety and security that fully integrates the assets of state, local and tribal governments, other federal agencies, and the private sector.

Americans must have confidence that the Government is taking all reasonable steps to protect the food supply, and is providing Americans with timely and relevant information about threats and will provide timely and relevant information about an attack if one occurs.

The events of September 11, 2001, heightened the nation's awareness and placed a renewed focus on ensuring the protection of the nation's critical infrastructures. A terrorist attack on the food supply could pose both severe public health and economic impacts, while damaging the public's confidence in the food we eat. Several food incidents since the fall of 2001 highlight the significance of FDA's food security activities. In the fall of 2002, a competitor of a restauranteur in China added a chemical compound to his competitor's food and killed dozens of people and sent hundreds more to hospitals. Also in the fall of 2002, three individuals were arrested in Jerusalem for allegedly planning to carry out a mass poisoning of patrons at a local cafe. One of the arrested individuals worked as a chef at the cafe. In January 2003, several individuals were arrested in Britain for plotting to add ricin to the food supply on a British military base Each of these incidents shows the potential for the nation's food supply to be used in an attack.

Even before September 11, DHHS was taking steps to improve food security. As part of the initial response to these heightened concerns after September 11, Congress provided FDA with new statutory authorities and some additional resources for food inspection. As a result of new threats to the food supply and new opportunities, FDA has made fundamental changes in how we implement our mission of protecting our food supply, so that all Americans can have confidence that their foods are not only safe but also secure. The attached 10Point Program reflects a risk-based strategy to achieve the greatest food security and safety improvements with the least additional costs or food restrictions for consumers. In these efforts, FDA will continue to work with the White House Homeland Security Council, the USDA, and the Department of Homeland Security (DHS) to further enhance our ability to detect, deter, and respond to an attack on our food supply.

Mark B. McClellan, M.D., Ph.D.

ENSURING THE SAFETY AND SECURITY OF THE NATION'S FOOD SUPPLY

"Securing our food supply against terrorist threats is one of our most important public health priorities, especially at a time of heightened alert," said Tommy G. Thompson, Secretary of Health and Human Services.

FDA FOOD SECURITY STRATEGY

In the months before and after Sept. 11, 2001, Secretary Thompson led the effort to encourage Congress to increase FDA funding to protect the nation's families from an attack on the food supply. In fiscal years 2002 and 2003, Congress enacted more than $195 million for food safety programs, allowing FDA to hire 655 new food personnel and conduct more than double the previous number of food import examinations. In President Bush's fiscal year 2004 budget, the Department of Health and Human Services (DHHS) is requesting $116.3 million, an increase of $20.5 million over FY 2003, to further protect the nation's food supply.

The Agency is employing overall strategies to (1) develop increased awareness among federal, state, local, and tribal governments and the private sector by collecting, analyzing, and disseminating information and knowledge (Awareness); (2) develop capacity for identification of a specific threat or attack on the food supply (Prevention); (3) develop effective protection strategies to "shield" the food supply from terrorist threats (Preparedness); (4) develop capacity for a rapid, coordinated response to a foodborne terrorist attack (Response); and (5) develop capacity for a rapid, coordinated recovery from a foodborne terrorist attack (Recovery).

Within the food safety and security strategies, FDA's program provides 10 areas of focus. The table below illustrates FDA's 10-Point Program and how each program area fits within the overall food safety and security strategies.

FDA has worked and continues to work closely with the states and other food safety, law enforcement, and intelligence agencies to collaborate on research, emergency response, and information exchange, all of which significantly strengthen the Nation's food safety and security system.

	Strategies				
FDA 10-Point Program	Awareness	Prevention	Preparedness	Response	Recovery
Stronger FDA-New Staff	X	X	X	X	X
Imports – Strategic Approach		X	X		
Bioterrorism Act Regulations		X	X	X	
Industry Guidance and Preventive Measures	X	X	X		
Vulnerability and Threat Assessments	X	X	X		
Operations Liberty Shield	X	X	X		
Emergency Preparedness and Response	X			X	X
Laboratory Enhancements		X	X	X	X
Research		X	X	X	X
Interagency and International Communication and Collaboration	X	X	X	X	X

PROGRESS AND NEXT STEPS

1. Stronger FDA—New Staff

In the wake of September 11, 2001, HHS, working with bipartisan Congressional support and action, obtained funding for the FDA. FDA moved expeditiously and quickly to establish this additional investigative and scientific team by rapidly hiring and training 655 additional field personnel. Of the 655, 97% are allocated to food safety field activities: 300 support the conduct of consumer safety investigations at U.S. ports of entry, 100 support laboratory analyses on imported products, 33 are for criminal investigations of import activities, and the remaining personnel support domestic efforts.

The Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act) was enacted in June 2002 and by the end of the year, FDA had started to place additional, trained investigators and analysts at targeted locations. Training of these new personnel has been paramount. Utilizing the platform provided by the Office of Regulatory Affairs' University (ORA U), FDA has retooled its existing "new hire" curriculum for investigators and its "new hire" curriculum for analysts so that new investigators and new analysts are prepared to do basic work within three months of employment. This basic investigatory work includes recall audits, sample collections complaint follow-up investigations, and import exams. The basic analytical work includes basic lab operations and sample preparation. The curricula continue through the first 12 months of employment, culminating in an on-the-job audit of performance where the new employee demonstrates job competency to an auditor using standardized criteria.

U.S. borders are flooded with FDA-regulated imports from all over the world, and the continuous threat of terrorism requires FDA to remain vigilant in its effort to retain a competent, trained workforce if we are to maintain a high level of readiness. With FDA's limited resources to meet the challenge of assuring the food safety and security for more than 6 million entries per year, FDA must strategically develop hiring, targeting resources and succession planning to be prepared in the event of a terrorist attack.

FDA not only mobilized new staff but redirected, trained current investigators and scientists to integrate and strengthen its food safety and security mission and ensured that the agency has the necessary scientific and logistical expertise to re-

spond to an event that could threaten the safety and security of the food supply. FDA has hired or re-trained scientific experts in biological, chemical and radiological agent research, detection methodology, preventive technologies and acquired substantial knowledge of these agents to help support domestic and import activities. FDA's Office of Regulatory Affairs (ORA) has developed a succession plan to ensure that the agency will continue to have highly trained and competent scientists, investigators, analysts, and managers to accomplish the agency's overall mission of consumer protection. FDA realizes that recruitment and retention of our highly skilled and sometimes very specialized workforce requires thoughtful planning so that we will be ready to effectively and efficiently meet the future challenges FDA faces.

2. Imports—Strategic Approach

FDA continues to adjust its import program via the development of an Import Strategic Plan (ISP) to reflect the changing nature of risks and trade associated with imported goods. This approach encompasses and addresses the full "life-cycle" of imported products. As part of the ISP, FDA is assessing information derived from foreign and domestic inspectional operations, adverse events, consumer complaints, recall activities, and information technology. The goal of the ISP is to better protect the public health and safety by decreasing the risk that unsafe, ineffective, or violative products will enter U.S. commerce through our borders, ports, and other import hubs. Moreover, when implemented, the ISP will provide FDA with the critical flexibility it needs to shift resources as import trends alter the risks and change priorities for public health and safety protection.

Historically, the volume of U.S. imports of FDA-regulated products was relatively small and consisted of raw ingredients and bulk materials intended for further processing or incorporation into finished products. Therefore, FDA could rely more heavily on physical examination and domestic inspections to ensure that imported raw ingredients and bulk materials were properly handled, received, quarantined, released and processed according to good manufacturing practices and sanitation principles.

Even with the recent increases of personnel for counter terrorism efforts, border inspections cannot manage the changes in the nature of risks and trade. FDA is taking steps to implement a risk-based approach towards covering the importation of FDA-regulated goods. These proactive steps will assist FDA in identifying patterns of transportation while goods are in international streams of commerce; increase our ability to conduct effective, efficient foreign inspections; and will aid FDA in making admissibility decisions before goods enter domestic commerce. Moreover, the riskbased approaches we are contemplating include exploring the feasibility of forming regulatory partnerships to provide better information to FDA—and, ultimately, better protection to U.S. consumers.

FDA is supporting this enhanced import strategic plan by providing a greater import presence at our nation's borders. FDA is enhancing our capacity and capability to perform normal import operations such as sample collection and analysis, field examinations, and inspections across all our programs. In 2001, FDA provided coverage at about 40 ports of entry. By 2002, FDA had more than doubled its presence to 90 ports of entry.

In addition, since 2001, FDA more than quintupled the number of food import examinations. In 2001, FDA conducted 12,000 food exams. FDA has conducted over 62,000 food exams already this fiscal year and has surpassed its 2003 year-end goal of 48,000 food exams. This increased coverage was due to redirecting resources dedicated to assure increased import coverage during Operation Liberty Shield when the Nation was at a heightened security alert.

FDA is working to increase import filer evaluations to ensure integrity of importers and import entry data and to increase collections of samples for laboratory analysis.

FDA is working on additional enhancements to the Operational and Administrative System for Import Support (OASIS) to include real-time screening with multiagency import databases to help target inspection resources.

3. Bioterrorism Act Regulations

FDA is on schedule to publish four major new regulations in accordance with provisions of the Bioterrorism Act. The agency intends to publish two final rules in October of this year and two additional final rules by the end of this year. These rules implement new authority that FDA received in the Bioterrorism Act and, are one of the most significant enhancements of FDA's statutory authority to keep food imports secure.

On February 3, 2003, FDA and the Department of Treasury jointly published in the Federal Register a proposed regulation implementing the provisions in the Bio-

terrorism Act that would require owners, operators, or agents of a foreign or domestic facility where food is manufactured/processed, packed, or held to submit a registration to the FDA that includes basic information about the facility, emergency contact information, and the categories of food the facility handles.

On February 3, 2003, FDA and the Department of Treasury also jointly published in the Federal Register a proposed regulation implementing the provisions in the Bioterrorism Act that would require FDA to receive prior notice before imported food arrives at the U.S. port of arrival.

On May 9, 2003, FDA published in the Federal Register a proposed regulation implementing the provisions in the Bioterrorism Act that would require manufacturers, processors, packers, transporters, distributors, receivers, holders, and importers of food to keep records identifying the immediate previous source from which they receive food, as well as the immediate subsequent recipient, to whom they sent food.

On May 9, 2003, FDA also published in the Federal Register a proposed regulation implementing the provisions in the Bioterrorism Act related to FDA's new authority to detain any article of food for which there is credible evidence or information that the article poses a threat of serious adverse health consequences or death to human or animals. The administrative detention authority granted to FDA under the Bioterrorism Act is self-executing and currently in effect.

FDA published each of the regulations with a 60-day comment period. We received many comments on each rule that suggested ways the rules could be improved to minimize the impact on commerce, while accomplishing the statutory objective. FDA is considering these comments and will make appropriate changes to the rules before issuing them in final form. These rules primarily are designed to give FDA additional information about food intended for consumption in the United States and the facilities that handle that food. As such, these statutory provisions do not raise the "science issues" as many of our rulemakings do (nor did the Agency receive comment in that area), or as other provisions in the Bioterrorism Act do.

FDA held two major satellite downlinks to explain the proposed regulations to affected parties around the world. The first was held on January 29, 2003 and discussed food facility registration and prior notice proposed requirements. The second was held on May 7, 2003 and discussed the proposed administrative detention procedures and the proposed requirements governing the establishment and maintenance of records. The broadcasts were made available in English, Spanish and French and were viewed at over 20 FDA sites, in Canada, Mexico, and South America. Viewers included importers, brokers, manufacturers and processors of foods and feeds, transporters, state officials, foreign embassy officials, foreign governments, and representatives of trade associations. In addition, the agency has conducted outreach regarding these regulations in other forums.

FDA has trained a cadre of speakers and has participated in over 80 meetings in many venues such as the Alliance for Food Safety and Security in Washington, DC, the World Trade Organization in Geneva, Switzerland, and at a meeting hosted by the government of Japan in Tokyo, Japan, giving presentations and talks on the proposed rules. FDA senior officials involved in developing the rules also attended meetings with government officials and industry representatives in Canada, Mexico, and the European Union.

FDA is intent on reviewing the many comments concerning the proposed regulations and is taking steps to implement these regulations with recognizing current business practices and emphasizing efficiency to implement and meet the intent of the Act.

FDA also developed and conducted demonstrations of the rapid, easy-to-use online registration system that companies can use to register starting in mid-October 2003.

FDA is working with the Bureau of Customs and Border Protection (CBP), to streamline the implementation of the prior notice requirements of the Bioterrorism Act. This will allow food importers to provide required information on food imports to both agencies using a single IT process.

FDA is working to finalize these regulations. We are currently considering all the timely comments that were submitted, and where appropriate, making appropriate changes to the regulations for food facility registration, prior notice, establishment and maintenance of records, and administrative detention before issuing them in final form. FDA is planning to host satellite downlinks and regional meetings to assist stakeholders in understanding and complying with the final rules. FDA is also developing "user-friendly" materials to serve as aids and to assist stakeholders.

4. Industry Guidance and Preventive Measures

On January 9, 2002, FDA published in the Federal Register and made available on its Website two draft guidance documents related to food security. The first,

"Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance," is designed to aid operators of food establishments. The second, "Importers and Filers: Food Security Preventive Measures Guidance," is designed to help food importers. Each document recommends the types of preventive measures that companies can consider to minimize the risk that food under their control will be subject to tampering or criminal or terrorist actions. Following public comment, FDA issued final versions of the guidance documents on March 21, 2003, in conjunction with FDA's efforts during Operation Liberty Shield. We discuss Operation Liberty Shield in more detail later in the document.

On March 21, 2003, FDA published in the Federal Register and made available on its Website two additional draft guidance documents related to food and cosmetic security. The first, "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance," is designed to aid operators of food retail food stores and food service establishments. The second, "Cosmetic Processors and Transporters Cosmetic Security Preventive Measures Guidance," is designed to help operators of cosmetic establishments. Each document recommends the types of preventive measures that companies can consider to minimize the risk that food or cosmetics under their control will be subject to tampering or criminal or terrorist actions.

FDA developed and made available on July 11, 2003, an additional guidance document related to food security preventive measures for milk, "Guidance for Industry: Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors; Food Security Preventive Measures Guidance."

FDA, in collaboration with the Technical Support Working Group (TSWG) of the Department of Defense, is working with the John A. Volpe National Transportation Systems Center in Cambridge, Massachusetts on a project related to the security of domestic and overseas transport of food.

TSWG and FDA are also working with St. Joseph's University, Philadelphia, Pennsylvania, to develop an accredited modular food security and protection training curriculum for both academics and professionals that is capable of being delivered in a traditional classroom setting as well as via CD-ROM and though web-based delivery formats. Industry representatives at the first user's group meeting in June 2003 confirmed the value of the training.

TWSG and FDA are working with Sensor Research and Development, a small company in Orono, Maine, to develop a prototype of a food pathogen detector (MIPSTRIP).

Consumers play a critical role in preventing illness due to food tampering. FDA encourages consumers when shopping to carefully examine all food product packaging, check any anti-tampering devices on the packaging, not to purchase products if the packaging is open, torn, or damaged, not to buy products that are damaged or that look unusual and to check the "sell-by" dates. Consumers are also encouraged to carefully inspect products at home when opening the container and to never eat food from products that are damaged or that look unusual.

5. Vulnerability and Threat Assessments

Using the methodology called Operational Risk Management (ORM), FDA developed a vulnerability assessment for foods. The assessment evaluates the public health consequences of a range of product-agent scenarios associated with potential tampering, criminal, malicious, or terrorist activity. This relative risk ranking is designed to facilitate decision-making about the assignment of limited federal, state, and local public health resources to minimize such risks. It is also designed to assist the food industry in identifying areas where enhancements in preventive measures could increase the security of the food supply. This internal assessment identified a number of food/agent combinations that FDA is focusing on to implement shields for protecting those commodities. These shields will be implemented in partnership with our regulatory counterparts and industry.

FDA initiated and awarded a task order to the Institute of Food Technologists (IFT) to conduct an in-depth review of ORM and provide a critique on its application to Food Security. As part of this review, IFT was asked to apply ORM to food and to evaluate the relative public health consequences of a range of product-agent scenarios. This review validated FDA's vulnerability assessment process and provided additional information on the public health consequences of a range of product, agent, and process scenarios. This assessment affirmed the food/agent combinations identified in the FDA ORM assessment and identified additional commodities to consider for shield implementation.

As an additional step, on June 4, 2003, FDA awarded an additional task order to IFT, requesting that IFT conduct an in-depth review of preventive measures that food processors may take to reduce the risk of an intentional act of terrorism or contamination. The review will assess ways to prevent or reduce the risk of contamina-

tion of processed food and will provide information on various research needs related to elimination or reduction of the risks. IFT will provide information on various processing technologies that might be used for eliminating or reducing the risk of an intentional act of terrorism or contamination for several commodity, agent, and processing combinations.

FDA also contracted with Battelle Memorial Institute to conduct a "Food and Cosmetics, Chemical, Biological, and Radiological Threat Assessment". The assessment affirmed the findings of the FDA/CFSAN Operational Risk Management Assessment, provided an additional decision-making tool for performing risk assessments, incorporating a Hazard Analysis Critical Control Points (HACCP) type approach, and made a number of recommendations about research needs, the need for enhanced laboratory capability and capacity, and the need for enhanced partnerships between federal, state, and local governments to ensure food security.

FDA provides regular updates to Congress about threat assessments and vulnerabilities related to the safety and security of the U.S. food supply. FDA will be providing to Congress the threat assessments conducted by FDA, IFT and the Battelle Memorial Institute.

FDA is conducting additional assessments of the vulnerability of FDA-regulated foods to intentional contamination with biological, chemical and radiological agents. These assessments use processes adapted from techniques developed by the U.S. Department of Defense for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of the assessments will be used to develop countermeasures, identify research needs, and provide guidance to the private sector

6. Operation Liberty Shield: FDA Food Security Enhancements in Times of Heightened Alert

In March 2003, the United States government launched Operation Liberty Shield to increase security and readiness in the United States at a time of elevated risk for a terrorist attack. Operation Liberty Shield, a comprehensive national plan of action to protect many of America's critical infrastructures, was a unified operation coordinated by the Department of Homeland Security that integrated selected national protective measures with the involvement and support of federal, state, local, and private responders and authorities from around the country. Operation Liberty Shield was designed to provide increased protection for America's citizens and infrastructure while maintaining the free flow of goods and people across our border with minimal disruption to our economy and way of life. FDA has established protocols, trained staff and deployed supplies and equipment for future and similar elevated threat level actions. A key component of Operation Liberty Shield was increasing and targeting surveillance of both domestic and imported food. The Agency initiated the following activities;

FDA issued new industry guidance documents on security measures and encouraged industry to voluntarily assess their security measures in response to an increased threat level. These guidance documents were discussed earlier in the document.

FDA held a series of conference calls to brief state regulatory agencies, industry trade associations, consumer groups, and their federal counterparts, on Operation Liberty Shield and to request their assistance in distributing the food security guidance documents to domestic facilities and the portion of the import community that handles food products.

FDA increased its surveillance of the domestic food industry, during Operation Liberty Shield, by conducting 844 inspections of domestic firms based on risk/threat assessments with a focus on enhancing awareness of food security at these facilities by providing copies of appropriate food security guidance documents. These investigations targeted examinations of specific commodities based on risk/threat assessments and sampled specific commodities based on risk/threat.

FDA increased its monitoring of imported foods, during Operation Liberty Shield, by conducting increased examinations of specific imported commodities based on FDA's risk/threat assessments; enhancing the import communities' awareness of food security at ports by providing copies of FDA's food security guidance documents and sampling imported foods based on risk/threat assessments. FDA collected and analyzed 387 import samples for chemical and microbiological contaminants.

FDA conducted domestic and import reconciliation exams to confirm that regulated commodities were what they purported to be, exposed unexplained differences between associated documentation and the product, and uncovered signs of tampering or counterfeiting.

FDA increased joint activities with federal, state, and local partners to help ensure a safe and secure food supply, including working with the Centers for Disease

Control and Prevention to ensure that outbreaks or unusual patterns of illness or injury are quickly investigated.

Likewise, USDA undertook similar food security measures and activities for its regulated industries including meat, poultry and processed egg products. Thus, in combination, FDA and USDA comprehensively covered the U.S. food supply.

7. Emergency Preparedness and Response

FDA has established an Office of Crisis Management (OCM) to coordinate the preparedness and emergency response activities of the five FDA Centers, ORA and their Offices working with their federal, state and local counterparts that may be engaged in a variety of different emergencies involving FDA regulated products and/or the need to provide medical countermeasures. Within OCM, the FDA Emergency Operations Center serves as the chief communications node and point of contact within FDA.

Over the past two years, FDA has participated in and conducted multiple emergency response exercises. Frequently, these exercises are coordinated with other federal and state agencies. In both exercises and everyday issues, FDA's OCM works closely with the Department of Health and Human Services/Office of Public Health Emergency Preparedness (OPHEP) and the Secretary's Command Center (SCC). This relationship facilitates communication between all HHS Operating Divisions, the Department, and other federal agencies and Departments, including the Department of Homeland Security. In particular, FDA has focused on strengthening its working relationship with USDA by joint testing of several response plans in an exercise environment. In May 2003, FDA participated in the TOPOFF 2 terrorism exercise, a national, full scale, fully functional exercise intended to simulate two separate terrorist acts that had implications for food products (e.g., the possibility of food contamination by radiation), as well as the ensuing response by federal, state, and local governments.

FDA has also signed an Inter Agency Agreement (IAG) with the U.S. Army to design and develop two mobile laboratories to be deployed at borders, ports, or other locations, to provide timely and efficient analyses of samples being offered for import into the U.S. and/or in the event of terrorist activity. The mobile laboratories are expected to be ready for deployment in 2004.

Within current resources, FDA is assessing its ability to respond to high-risk product agent scenarios and for what sustained period. This includes a review of our current scientific capabilities that may be available for extramural sources (academia, DoD, etc.) and efforts to enhance the nation's food laboratory capacity at federal, state and local facilities to conduct rapid, accurate tests to determine quickly the precise extent of food contamination in the event of an actual or suspected terrorist attack.

8. Laboratory Enhancements—Methods Development

FDA has redirected laboratory staff to develop laboratory methods for priority biological and chemical agents in food. Methods have been developed for the highest priority select agents.

FDA has reviewed and modified current regulatory analytical methods for their applicability to terrorism related samples. Methods have been modified to provide more rapid analysis while maintaining practical sensitivity.

FDA is enhancing its capacity to develop methods that can be used for rapid analysis of suspect foods for select agents or toxins, including the development of rapid methods that can be deployed and used in a field setting.

FDA is working to adapt an FDA toxin screening method for application as a surveillance tool.

FDA has established an IAG with Edgewood Arsenal and a task order contract with Midwest Research Institute for the validation of methods for the detection of microbiological agents in foods.

FDA has partnered with the Department of Defense to develop and validate methods to detect agents most likely to be used in a terrorist attack on the food supply, and engaged in interagency agreements that would allow the Department of Defense to provide laboratory support in the event of an attack.

Under contract to FDA, the New Mexico State University (NMSU) Physical Science Laboratory (PSL) is evaluating rapid test methods for microbiological analyses of produce samples. NMSU's evaluation includes the assessment of rapid test methods for a particular analyte(s) or food commodity—which is required prior to the agency adoption of any kit for use in the regulatory arena.

Network Development

FDA has worked with CDC, USDA, EPA, DOE and the States to initiate development of a nationwide Food Emergency Response Network (FERN). FERN is a net-

work of state and federal laboratories that is committed to analyzing food samples in the event of a biological, chemical, or radiological terrorist event in this country. As of June 2003, there were 63 laboratories participating in the FERN network, representing 27 states and 5 federal agencies. Following the events of September 11, 2001, FDA took aggressive action to develop this network building on then-existing laboratory capabilities. FDA is working to add additional food laboratories to the FERN. Furthermore, FDA will work with CDC and the states to improve laboratory capacity to enhance response capability for food security concerns, With CDC grant funds, states are initiating additional activities to increase lab capacity for food-related emergencies.

FDA has made available methods for the isolation and detection of high-priority microorganisms and chemical agents not usually found in food that can be utilized by Laboratory Response Network (LRN) and FERN laboratories on a password protected website.

FDA has used emergency funding to purchase rapid method test kits for chemical and microbiological agents and has distributed the materials to laboratories within FERN.

Ninety five laboratories representing 48 states are participating in the Electronic Laboratory Exchange Network (eLEXNET), the nation's first seamless, integrated, webbased data exchange system for food testing information. eLEXNET allows health officials at multiple government agencies engaged in food safety activities to compare, share, and coordinate laboratory analysis findings on food products. At its inception in 2000, eLEXNET included a mere 8 labs from 7 states and was capable of tracking a sole analyte. Whereas FERN laboratories are involved in the actual analysis of food samples, eLEXNET provides a forum for the exchange of laboratory data. FDA is continuing efforts to expand eLEXNET to provide better nationwide data on food product analyses by regulatory agencies.

Staff Development and Training

FDA has trained its staff as well as staff from USDA, state food laboratories and the CDC Laboratory Response Network public health laboratories in the analysis of foods for several microorganisms.

9. Research

HHS Secretary Tommy Thompson and FDA Commissioner Dr. Mark McClellan announced the commitment of $5M in supplemental funding from the Office of Management and Budget (OMB) to support FDA's food security research initiative. The FDA plans to focus this new food security research thrust on three broad areas: (1) development of prevention and mitigation technologies/strategies, (2) the elucidation of agent characteristics needed to develop these prevention technologies, and (3) the development of means for continuously assessing foods (raw or finished product) for contamination with chemical, microbiological, and radiological agents. This integrated program will draw upon all three components of FDA's research infrastructure: its intramural research capabilities, its collaborative Centers of Excellence (e.g., National Center for Food Safety and Technology, Joint Institute for Food Safety and Applied Nutrition, National Center for Natural Products Research), and extramural research programs that provides competitive research contracts and grants. Specific projects will involve: determining the stability of select chemical threat agents in foods and the impact of processing operations; the development of enrichment techniques for the isolation of select microbial agents from high priority foods; the development of prevention/mitigation strategies for intentional contamination of animal feed used for food-producing animals; the development of risk assessment tools for assessing critical control points within a food security/safety system; the development of methods for decontaminating food processing facilities, retail establishments, and transportation equipment that have been exposed to microbiological, chemical, or radiological agents as a result of a terrorism incident involving foods; the acceleration of the development of rapid, field deployable analytical methods for detecting select agents in foods; and the development of a PC-based Analytical Modeling Tool to facilitate rapid response to food security and safety emergencies.

Intramural Program

Although modern technology has considerable potential to improve our ability to keep the nation's food supply secure, research on food security is a relatively new concept. To take advantage of the opportunities for making foods safer and more secure through research and development of new technologies, FDA, HHS, and the Administration are taking unprecedented steps to develop this new area of research. In particular, FDA has already redirected existing research staff to ensure that ap-

propriate resources are focused on key priority food safety and security issues. FDA has over 25 intramural research projects ongoing related to food security.

Steps Toward Establishment of Extramural Food Security Research Program

On June 25, 2003, FDA published in the Federal Register a Request for Applications (RFA) entitled "Food Safety, Nutrition, Bioterrorism, Agricultural Research, Medical, Analytical Methods and Risk Assessment." The RFA requested applications to support collaborative research efforts and to complement and accelerate ongoing research in four project areas: (1) development and rapid analytical screening methods for the detection of pathogens that are not usually associated with food and foodborne illness at a contamination level of 100 to 10,000 microbial pathogens/gram of food without pregrowth or selective enrichment; (2) development of PCR-based methods for rapid confirmatory identification of pathogens that are not usually associated food and foodborne illness; (3) development of rapid screening methods capable of detecting a broad range of non-traditional chemical and toxin adulterants; and (4) development of improved equipment, software, procedures, and/or methods for determining radionuclide contamination in foods.

New Research Collaborations

FDA is collaborating with the National Institutes of Health (NIH) on a joint project to fund critical research on the thermal stability of key select agent(s) in high risk food(s).

FDA has initiated cooperative research programs with the National Center for Food Safety and Technology (NCFST) on the impact of food processing on the stability of microbiological and chemical agents in foods under conditions that would occur in commercial operations.

FDA participates in the Technical Support Working Group (TSWG), the U.S. national forum that identifies, prioritizes and coordinates interagency and international research and development requirements for combating terrorism.

The Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a public-private partnership established between FDA and the University of Maryland in 1996, in collaboration with the US-Israel Binational Agricultural Research and Development (BARD) Fund held a food security conference, "Science and Technology Based Countermeasures to Foodborne Terrorism," on June 29—July 2, 2003. The conference provided a forum to discuss the current state of knowledge about foodborne terrorism, including threat assessment methods, methods of detection, tracking, tracing, authenticating and anti-tampering technologies and hazard mitigation.

Establishing Broader Research Agenda

FDA is developing a broader research agenda to address critical research needs to aggressively meet food security challenges. The research would focus on three broad areas: (1) development of prevention and mitigation technologies/strategies, (2) the elucidation of agent characteristics needed to develop prevention technologies, and (3) the development of means for continuously assessing foods (raw or finished product) for contamination with chemical, microbiological, and radiological agents. These research needs are being prioritized into short, medium, and longer-term phases: (1) technological assessment and critical data deficiencies that can be addressed in the short-term (12 months), (2) critical knowledge deficiencies or technology applications that can be addressed with targeted research and development projects lasting 12-24 months, and (3) research and development that will require elucidation of new technologies or substantial extension of existing scientific knowledge (24—60 months). Such research is being planned as an integrated program that will draw upon all three components of FDA research infrastructure: its intramural capabilities, its collaborative Centers of Excellence (e.g., National Center for Food Safety and Technology, Joint Institute for Food Safety and Applied Nutrition, and National Center for Natural Products Research), and extramural research program that provides competitive research contracts. FDA will also actively collaborate with other federal government research organizations, including NIH, USDA, and DoD.

10. Interagency and International Communication and Collaboration

Food security, like other aspects of protecting our Nation's critical infrastructures, requires effective and enhanced coordination across many government agencies at the federal, state, and local level. FDA's activities in public health security are coordinated through the Department of Health and Human Services (DHHS) Secretary's Command Center. This relationship facilitates communication between all HHS Operating Divisions, the Department, and other federal agencies and Departments, including Homeland Security. Some of these security steps facilitated by this coordination are outlined below.

FDA holds regularly scheduled interagency conference calls with representatives from USDA [Animal and Plant Health Inspection Service (APHIS) and FSIS], CDC, Environmental Protection Agency (EPA), DoD, Department of Commerce, Tax and Trade Bureau, and the Bureau of Customs and Border Protection (CBP). FDA also regularly consults with its interagency partners.

On February 4, 2003, FDA, in conjunction with the National Association of State Departments of Agriculture (NASDA), the Association of State and Territorial Health Officials, USDA, and CDC, sponsored a one day executive level meeting with the Secretaries of State Departments of Agriculture and the State Departments of Health titled "Homeland Security—Protecting Agriculture, the Food Supply and Public Health—The Role of the States."

FDA is also actively promoting the commissioning by FDA of State secretaries of agriculture and health so they can receive and review food safety and security documents from FDA. This helps promote information sharing between States and FDA.

FDA is also represented on the White House Homeland Security Council's Interagency Food Working Group (IFWG). The IFWG includes representation from DHHS/FDA, USDA/FSIS, Department of Defense, Environmental Protection Agency, Department of Transportation, Central Intelligence Agency, Federal Bureau of Investigation, Department of Treasury, Federal Emergency Management Agency, and a variety of White House representatives. FDA is developing plans for improved laboratory preparedness, and product security, and is drafting a National Interagency Food Response Plan in coordination with states, industry, and food trade associations. FDA is represented on three IFWG subgroups: Laboratory Subgroup, Shields Subgroup, and Incident Command Subgroup.

As part of the Department-wide collaboration and effort to improve nationwide capacity, the Centers for Disease Control and Prevention (CDC) has initiated a cooperative agreement program and has made funds available to upgrade state and local jurisdictions' public health preparedness for and in response to bioterrorism, other outbreaks of infectious disease, and other public health threats and emergencies. CDC is making available $870 million this fiscal year. Awards will be made to address needs in seven focus areas: (1) Preparedness Planning and Readiness Assessment, (2) Surveillance and Epidemiology Capacity, (3) Laboratory Capacity—Biologic Agents, (4) Laboratory Capacity—Chemical Agents, (5) Health Alert Network/Communications and Information Technology, (6) Communicating Health Risks and Health Information Dissemination, and (7) Education and Training. Improving laboratory capacity, including for food analysis, is an integral part of this effort.

FDA is working very closely with the Department of Homeland Security and the White House Homeland Security Council on a variety of issues. We are consulting with DHS and HSC on research initiatives, shield implementation, and seeking security clearances for appropriate individuals within the food industry in order to share classified information.

FDA has conducted numerous emergency response exercises with our federal counterparts to strengthen the federal response to a food incident. The Department of Health and Human Services has participated in several Deputy Secretary level exercises with USDA, DoD, EPA, CIA, and FBI to test our emergency response capabilities. TOPOFF 2 was an excellent example of interagency cooperation by USDA/FSIS sending representatives to the DHHS/Command Center and the FDA Emergency Operations Center.

Despite the comprehensive work that FDA has accomplished to date, there are additional steps that are being contemplated. These future projects are discussed below.

FDA is working with the Department of Homeland Security and USDA, to establish a Food Sector and a Food Information Sharing and Analysis Center (ISAC) to facilitate the overall protection of the food sector's critical infrastructure and to share information about vulnerabilities, threats, and incidents.

FDA is working closely with Canada and Mexico in an effort to assess and strengthen our public health and food security systems and infrastructure at our mutual borders. FDA and USDA are working with our Canadian and Mexican counterparts through bilateral workgroups to enhance existing partnerships, e.g. Global Health Security Action Group, forge new and improved food and agriculture security measures and systems covering prevention and preparedness; response to and recovery from potential threats.

FDA is collaborating with the Department of Homeland Security and USDA (Food Safety and Inspection Service) and has proposed projects for the prevention of and response to an intentional threat to the food supply.

SUMMARY

FDA thorough it's aggressive program, has made significant progress in strengthening the safety and security of the Nation's food supply.

Nearly 20% of all imports into the U.S. are food and food products. FDA anticipates that we will receive over 8 million food shipments from over 200,000 foreign manufacturers this year-a huge volume that continues to grow rapidly. To meet this challenge, FDA is providing a greater import presence. FDA has placed an additional 300 field personnel at U.S. ports of entry. FDA now has a presence at 90 ports of entry and quintupled the number of food import examinations it performed this year compared to 2001-FDA has exceeded its year-end goal of 48,000 by 14,000 food import examinations.

FDA is using risk-based strategies to provide better information and in its collaborative efforts with other entities. This includes working with foreign authorities and manufacturers to improve production and shipping practices abroad as an alternative to detailed inspections at the boarder. FDA is using better information on imports to focus border checks on products that present significant potential risks and is working with producers to improve checks on the integrity of ingredients and to implement commonsense steps to reduce security risks.

FDA is on schedule to publish four major new regulations in accordance with provisions of the Bioterrorism Act that provide the agency with most significant enhancements to FDA's statutory authority to keep food imports secure. The agency intends to publish two final rules in October of this year and two additional final rules by the end of this year.

FDA has taken unprecedented steps to develop food security research, FDA has received $5 million in supplemental funding from OMB to support FDA's food security research initiative. FDA is using this supplemental funding to focus on three broad areas: development of prevention and mitigation technologies and strategies, elucidation of agent characteristics, and development of means for continuously assessing foods for contamination. FDA has redirected existing research staff to focus on key priority issues and has over 25 intramural research projects ongoing related to food security. FDA is developing a broader research agenda to address critical research needs to aggressively meet food security challenges including development of prevention and mitigation technologies/strategies, elucidation of agent characteristics needed to develop prevention technologies, and development of means for continuously assessing foods for contamination.

FDA remains dedicated to ensuring the safety and security of the nation's food supply, Americans depend on FDA to keep food safe and secure, and FDA will keep doing all we can to fulfill this critical mission.

PREPARED STATEMENT OF MARK B. MCCLELLAN, M.D.

Good morning, Mr. Chairman and other Members of the Committee. I am Dr. Mark B. McClellan, Commissioner of Food and Drugs in the Department of Health and Human Services (HHS). I am pleased to he here today with my colleagues from two of our sister agencies, Dr. Julie Gerberding of the Centers for Disease Control and Prevention (CDC) and Dr. Elias Zerhouni of the National Institutes of Health (NIH). The Food and Drug Administration (FDA or the Agency) appreciates the opportunity to discuss some of FDA's counterterrorism activities and to discuss the biodefense workforce issues raised in the recent report by the Partnership for Public Service entitled. Homeland Insecurity: Building the Expertise to Defend America from Bioterrorism.

In my testimony today, I will first briefly describe FDA's role in counterterrorism activities. Second, I will address a significant omission in the report and describe the food safety and food security responsibilities of the FDA. Third, I will discuss the development and availability of countermeasures and the Administration's Project BioShield initiative. Finally, I will describe FDA's actions to improve our ability to recruit and retain the types and numbers of staff necessary to defend against terrorist attacks.

FDA'S ROLE IN COUNTERTERRORISM ACTIVITIES

FDA is the Federal agency that is responsible for ensuring that 80 percent of the food supply, all foods except meat, poultry, and certain egg products, are safe and sanitary; that human and veterinary drugs, biological products, medical devices, and radiological products are safe and effective; and that cosmetics are safe. With more opportunities but more costs and complexity than ever in the development of better medicines and foods, FDA must increasingly focus on ways to reduce the cost, time, and uncertainty of the process of translating scientific breakthroughs into safe and

effective products that can be produced reliably. FDA is also responsible for assuring that the health consequences of foods and medicines are accurately and honestly represented to the public, so that they can be used as effectively as possible to protect and improve the public health.

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. FDA plays a central role in the nations defense against terrorism. First, terrorists could use an FDA-regulated product, such as food, as a vehicle for biological chemical, or radiological agents. Second, FDA-regulated products, such as human and animal drugs, vaccines, tissues, blood, and blood products, will play a central role in countering or preventing the effects of terrorism. It is FDA's responsibility, working closely within HHS and with other Federal agencies, state, and local governments, industry, and the public, to reduce the chance that an FDA-regulated product is misused to terrorize Americans and to help ensure that the nation's public health system is prepared to deter a potential threat and is ready to respond to an act of terrorism.

FDA'S FOOD SAFETY AND SECURITY RESPONSIBILITIES AND ACTIVITIES

Now, I would like to address a significant omission in the Partnership's report and describe FDA's food safety and food security programs.

The section in the Partnership's report entitled "The Threat to Our Food Supply" fails to mention the FDA's significant responsibilities for safeguarding the food supply.

FDA regulates 80 percent of the national food supply—practically everything we eat except for meat, poultry, and certain egg products, which are regulated by our colleagues at the U.S. Department of Agriculture (USDA) FDA's responsibility also extends to live food animals and animal feed.

Food safety and food security continue to be top priorities for this administration. The events of September 11, the discovery of terrorist cells in Europe, the potential threat of a terrorist attack on the nation's critical infrastructure—all of this means that our mission must include protecting Americans from those who would harm us through our food supply. A terrorist attack on the food supply could pose both severe public health and economic impacts, while damaging the public's confidence in the food we eat.

And so FDA's mission today is not only about food safety—it is fundamentally about food security as well. The changes in food security that we are implementing now amount to the most fundamental enhancements in our food safety activities in many years. Yesterday, Secretary Thompson and I issued a report entitled "Ensuring the Safety and Security of the Nation's Food Supply." The report outlines a clear and comprehensive approach to protecting the safety and security of our food supply.

In these new efforts, FDA has many partners. We are working closely with our Federal partners such as the U.S. Department of Agriculture (USDA), the new Department of Homeland Security, and the Homeland Security Council at the White House. I would like to call special attention to our close working relationships with CDC, our sister public health agency, Customs and Border Protection in the Department of Homeland Security, and USDA's Food Safety and Inspection Service, our counterpart agency responsible meat, poultry, and certain egg products. Some of our other Federal partners include USDA's Animal and Plant Health Inspection Service, USDA's Foreign Agriculture Service, Army Veterinary Services, Department of Commerce's National Oceanic and Atmospheric Administration, the Environmental Protection Agency, and the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau.

IMPLEMENTATION OF THE BIOTERRORISM ACT

As you know, Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) provided the Secretary of Health and Human Services with new authority to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. FDA is responsible for implementing these food security provisions. Let me commend you, Mr. Chairman, for your leadership, as well as that of the Ranking Member and other Members of the Committee, in enacting this landmark legislation.

The Agency is working hard to implement this law effectively and efficiently. We have already published four proposed regulations to implement some of the provisions of the Bioterrorism Act. These regulations address four provisions of the law: registration of domestic and foreign food facilities, prior notice of imported food shipments, the establishment and maintenance of records, and administrative detention. We intend to publish final regulations on two of these provisions in October of this

year and the remaining two in December. These new authorities will enable FDA to act quickly in responding to a threatened or actual terrorist attack.

VULNERABILITY AND THREAT ASSESSMENTS

In addition to implementation of the Bioterrorism Act, FDA has been engaged in numerous other food security activities. As part of our efforts to anticipate threats to the food supply, we have conducted a scientific vulnerability assessment of different categories of food, determining the most serious risks of intentional contamination during various stages of food production and distribution. This assessment utilized an analytical framework called Operational Risk Management (ORM) that considers both the severity of the public health and economic impacts of a potential attack on our food supply and the likelihood of such an event taking place.

FDA also awarded a task order to the Institute of Food Technologists (IFT) to conduct an indepth review of ORAI and provide a critique of its application to food security. This review validated FDA's vulnerability assessment and provided additional information on the public health consequences of a range of scenarios involving various products, agents, and processes. FDA also contracted with Battelle Memorial Institute to conduct a "Food and Cosmetics, Chemical, Biological, and Radiological Threat Assessment," The assessment affirmed the findings of the ORM assessment. It also provided an additional decision-making tool for performing risk assessments, Further, the Battelle assessment made a number of recommendations that addressed research needs, the need for enhanced laboratory capability and capacity, and the need for enhanced partnerships between Federal, state, and local governments to ensure food security.

FDA is conducting additional assessments regarding the vulnerability of FDA-regulated foods to intentional contamination with biological, chemical, and radiological agents. These assessments use processes adapted from techniques developed by the U.S. Department of Defense for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of the assessments will be used to develop countermeasures, identify research needs, and provide guidance to the private sector.

EMERGENCY PREPAREDNESS AND RESPONSE

FDA has established an Office of Crisis Management to coordinate the preparedness and emergency response activities within FDA and with our Federal, state, and local counterparts. Over the past two years, FDA has participated in and conducted multiple emergency response activities.

Frequently, these exercises are coordinated with other Federal and state agencies. For example, FDA and USDA's Food Safety and Inspection Service have focused on strengthening their working relationships by the joint testing of several response plans in an exercise environment.

In May of this year, FDA participated in the TOPOFF2 counterterrorism exercise. This was a national, full-scale, fully functional exercise intended to simulate two separate terrorist attacks: detonation of a "dirty bomb" in Seattle and aerosol release of plague in Chicago. The ensuing response involved participation from 17 Federal Departments and Agencies, the state governments of Washington and Illinois, the local governments of the affected cities, and the Canadian Government.

FDA's response was coordinated from our Emergency Operations Center on an around-the-clock basis throughout the exercise. FDA performed duties as if this were a real event. At the Seattle venue, FDA's Center for Devices and Radiological Health (CDRH) monitored the dispersion of the radioactivity from the blast site. The Center for Food Safety and Applied Nutrition (CFSAN), in conjunction with other Federal and state officials, formulated a plan for sampling contaminated sites and developed recommendations regarding the shipment and consumption of potentially contaminated foods. In addition, the Center for Drug Evaluation and Research (CDER) provided guidance on the availability of medical countermeasures that would have been effective in this situation. The Center for Biologics Evaluation and Research (CBER) developed draft guidance on blood and tissue donor deferral for radiation exposure.

In the TOPOFF2 Chicago venue, representatives from CBER and CDER worked with CDC to provide guidance on medical countermeasures and their availability. CDRH provided information on diagnostic kits for plague in addition to ventilator inventory information. FDA's Center for Veterinary Medicine (CVM) issued guidance on animal species susceptible to plague and worked with USDA's Animal and Plant Health Inspection Service to develop an emergency vaccine to prevent continued transmission of the disease.

In September 2002, FDA led an exercise to test our draft biological and chemical agent response plan and to test our Agency's coordination and communication. In

January 2002, FDA led another emergency response exercise with representatives from CDC, USDA, the Federal Bureau of Investigation, the Department of Defense, state agencies, and others. The purpose of this exercise was to improve coordination of responses among various agencies, so that those responses are smooth and appropriate and so that all needed parties are involved. Other exercises are being planned. We have also reviewed food security and rapid response and recovery procedures with industry groups and trade associations.

LABORATORY ENHANCEMENTS

An additional step in enhancing our response capability is to improve our laboratory capacity. A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for a broad array of biological, chemical, and radiological agents. We have been working with CDC to augment our "surge capacity" by working to expand the nationwide Laboratory Response Network and the Food Emergency Response Network (FERN) to include a substantial number of counterterrorism laboratories capable of analyzing foods. We are accomplishing this expansion in capacity through agreements with other Federal and state laboratories. As of June 2003, there were 63 laboratories representing 27 states participating in FERN, including five Federal laboratories. Participation continues to grow. By working together with our Federal and State partners, we will have the ability to test a much higher than normal volume of samples. With CDC, we recently announced grants that states can use to buy special laboratory equipment and reagents and to develop skills to ensure there is a national network of laboratories that are ready to assess and respond to a food security emergency.

We also are expanding Federal, state, and local involvement in our eLEXNET system by increasing the number of laboratories around the country that participate in this electronic data system. eLEXNET is a seamless, integrated network that allows multiple agencies engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. It enables health officials to assess risks and analyze trends, and it provides the necessary infrastructure for an early warning system that identifies potentially hazardous foods. At present, there are 95 laboratories representing 48 states that are part of the eLEXNET system. We are continuing to increase the number of participating laboratories.

RESEARCH

We have embarked on an ambitious research agenda throughout the Agency to address potential terrorist threats. To enhance food security, FDA has significantly redirected existing research staff to ensure that appropriate resources are focused on priority food safety and security issues. For example, research sponsored by FDA's CFSAN is aimed at developing the tools essential for testing a broad array of food products for a multiple number of biological and chemical agents. We are actively working with our partners in government, industry, and academia to develop such methods. FDA's work with the Association of Official Analytical Chemists on validating analytical methods for the detection of biological, chemical, and radiological agents in foods is considered the "gold standard" against which other validations programs are judged. Likewise, the FDA's research on microbial genomics and analytical chemistry is widely recognized for its importance to other Federal agencies charged with forensic investigations of terrorism events. In compliance with Section 302 of the Bioterrorism Act, we will soon be submitting a report to this Committee that will provide additional details about the research that is underway.

OPERATION LIBERTY SHIELD AND INDUSTRY GUIDANCE

In March 2003, the Federal government launched Operation Liberty Shield to increase security and readiness at a time of elevated risk for terrorist attack. Operation Liberty Shield is a comprehensive national plan designed to increase protections for America's citizens and infrastructure while maintaining the free flow of goods and people across our border with minimal disruption to our economy and way of FDA's Office of Regulatory Affairs (ORA) conducted a number of targeted inspections of domestic and imported products as part of this initiative. ORA also increased joint activities with Federal, state, and local partners. Also as part of Operation Liberty Shield, we issued guidance documents for the food industry on the security measures it may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. We have issued such guidance for food producers, processors, and transporters, for importers and filers, for retail food stores and food service establishments, and for cosmetic

processors and transporters. In addition, we just recently issued specific security guidance for the milk industry.

ADDITIONAL COUNTERTERRORISM EMPLOYEES

The Fiscal Year 2002 supplemental counterterrorism funds enabled FDA to hire about 800 employees. Most of these additional employees were hired by ORA to address food safety and security issues, primarily at the border. With these additional employees, we have expanded FDA's presence at ports of entry, increased surveillance of imported foods, increased domestic inspections, and enhanced our laboratory analysis capacity. More specifically, within the last two years, we have more than doubled the number of ports that have an FDA presence from 40 to 90 ports. We have more than quintupled the number of food examinations at the border. So far this year, we have performed 62,000 food import examinations compared to 12,000 two years ago. We surpassed our goal of 48,000 import examinations this year due to increased surveillance of imported food products during Operation Liberty Shield when the nation was at a heightened security alert status.

MEDICAL COUNTERMEASURES AND PROJECT BIOSHIELD

Today, the U.S. is better prepared than ever to meet the threat of terrorist attack with a biological, chemical, radiological, or nuclear agent. FDA plays a critical role in the response to a terrorist act. A primary responsibility is the expeditious development and licensing of products to diagnose, treat, or prevent outbreaks from exposure to bioterrorist agents.

FDA scientists guide the products through the development and marketing application review processes, which include review of the manufacturing process, preclinical testing, clinical trials, and the licensing and approval process.

FDA has been engaged in an accelerated effort to help to develop and make available better countermeasures. For example, in recent months, FDA has taken major steps to make available safe and effective treatments for certain nerve gases and radiological agents, and the Government has enhanced the national stockpiles of vaccines and treatments for smallpox and other possible agents of biowarfare. FDA also has sought data to provide the regulatory basis for defining the safety and efficacy of medical countermeasures. In addition, FDA has initiated collaborations with industry to utilize any additional data it may possess.

In effect, FDA's actions eliminate preliminary steps in the approval process for certain medical countermeasures. For example, during the anthrax crisis in 2001, FDA reviewed available data and safety information to conclude that two approved drugs not typically considered indicated for treatment of anthrax exposure, doxycycline and procaine penicillin G, could be safely used to treat anthrax exposure without and additional clinical trials. More recently, FDA reviewed the data on treatments for radiation exposure and determined that Prussian Blue was safe and effective in treating people exposed to radioactive elements such as cesium-137. After a review of the published literature, FDA determined that 500 mg Prussian Blue capsules would be safe and effective for the treatment of patients with known or suspected internal contamination with radioactive thallium, non-radioactive thallium, or radioactive cesium. FDA's guidance to industry and approved labeling for Prussian Blue products gives manufacturers critical information necessary for producing an FDA-approved product that will be an important medical countermeasure.

In reviewing the lessons learned after the anthrax attacks, we identified the need for additional mechanisms for healthcare providers and the general public to report their outcomes or product-related adverse events to the FDA. To address this need, FDA and CDC have created a working group to define mechanisms, processes, and training needed to integrate Federal, state, and local follow-up activities. In addition, FDA participates in a number of interagency working groups to address laboratory surge capacity, prophylactic countermeasures, and novel pathogens.

CBER is working closely with industry and other government agencies in an effort to assure an adequate supply of products for immunization against anthrax, smallpox, and other substances that might be used by terrorists and to evaluate adverse experiences reported after administration of anthrax vaccine in order to optimize its safe use. With the FY 2002 supplemental counterterrorism funds, CBER was able to hire 97 full-time equivalent (FTEs) employees to assist in the regulation of the development and licensure of new biological products including vaccines, blood, and blood products. Current workforce data indicate that CBER has approximately 200 FTEs dedicated toward counterterrorism activities.

CDER has created a specific counterterrorism office to facilitate the product development of medical countermeasures. In addition to the numerous Center review

staff, more than 30 employees are dedicated full-time to facilitating the identification of promising products.

These employees assist both external and internal groups in defining and developing the science and databases necessary to move products toward full approval as a medical countermeasure.

CDER has leveraged its science-based regulator mission by pooling its resources with other Federal agencies to fund homeland defense research to develop medical countermeasures. This research has addressed the need for drugs to treat plague, the safety of long-term antibiotic use, and the use of medical countermeasures in special populations, such as children, the elderly, and pregnant women. The research has also included the development of animal models to test drugs for biological threats. For example, working with other Federal agencies such as the Department of Defense, NIH, and CDC, FDA has developed the following research activities:

Monkey studies involving numerous antibiotics for the treatment of plague;

Human trials in plague-endemic areas; and

Small animal models in viral hemorrhagic fevers.

The pro-active approaches described above have facilitated the development and availability of safe and effective treatments. The national stockpile of medical countermeasures is large, and getting more extensive all the time, but more needs to be done.

Earlier this year, President Bush proposed Project BioShield to enable the government to develop, procure, and make available countermeasures to chemical, biological, radiological, and nuclear agents for use in a public health emergence that affects national security. Enactment of the Project BioShield legislation is a priority for the Administration.

Unfortunately, the medical treatments available for many pathogens have improved little in decades. For example, some treatments for radiation and chemical exposure have not changed much since the 1970's and some diseases, such as Ebola, have never had an effective medical countermeasure.

Some diseases lack effective or modern treatment in part because there are no clear financial rewards for developing valuable new treatments that can save and improve lives. By contrast, the treatment of the vast majority of common, naturally occurring illnesses has improved dramatically as a result of continuing innovations from biomedical research and development. Heart attacks were often fatal in the 1970s, but they are much less likely to be fatal today. And better detection and therapeutic options have significantly improved survival rates for many kinds of cancer over the last 20 years. We must bring that sort of progress to the rare yet deadly threats posed by bioterrorists.

Pharmaceutical research and development historically have focused on development of products likely to attract significant commercial interest. Many countermeasures for potential agents of terrorism realistically have no market other than the government and thus have not generated a great deal of manufacturer interest. Because the market for developing countermeasures is speculative, without government interest, private companies have not invested and engaged in developing the countermeasures that may he needed. However, in the vaccine development area, representatives of the pharmaceutical industry have stressed that they will meet the challenge if the Federal government can define its vaccine requirements and assure up front that the requisite funds will be available to purchase the vaccines.

Project BioShield would speed up research and approval of vaccines and treatments and ensure a guaranteed funding source for their purpose. More specifically, the BioShield legislation would:

Ensure that sufficient resources are available to procure the next generation of countermeasures;

Accelerate NIH research and development by providing more flexibility in the contracting process, procurement authorities, and the issuance of grants for critical biodefense work; and

Make promising treatments available more quickly for use in emergencies by establishing new emergency use authorization procedures at the FDA.

FDA'S WORKFORCE

Now, I would like to respond to workforce issues raised in the recent report by the Partnership for Public Service. A key component of FDA's strategic plan is to assure a high-quality professional workforce. Capable personnel with the appropriate expertise are critical for the success of FDA and for the Agency's ability to maintain a high level of public trust in its activities. FDA's responsibilities require a very special workforce, one that can keep up with rapid changes in the industries

that it regulates and that is capable of developing and implementing effective and innovative public health measures. Our workforce includes a solid cadre of experienced physicians, toxicologists, chemists, microbiologists, statisticians, mathematicians, biologists, pharmaeologists, veterinarians, and other highly qualified and dedicated professionals. FDA currently has 10,695 employees. Of these, there are almost 1,500 professionals with Ph.D.'s and well over 400 with medical degrees. As FDA Commissioner, one of my foremost goals is to make sure that FDA's working environment attracts and retains top-quality scientists and encourages creativity, efficiency, and superior performance.

Through training and education, FDA has expanded the scientific knowledge of its staff. For example, FDA has acquired and made available to its staff information on the characteristics of a wide range of biological, chemical, and radiological agents. FDA has hired additional personnel with specific expertise to assist us in our counterterrorism efforts. These areas of expertise include, but are not limited to, the use of select agents, law enforcement, intelligence, security, and risk assessment, FDA also has cross-trained existing scientists and consumer safety officers to meet the new challenges of food security and medical countermeasures. We have had to revise, expand and re-engineer investigation, laboratory, and compliance procedures and policies to bring them in line classified information gathering, facility and procedure security, and personnel security to accommplish these tasks. This new direction has also required the acquisition of secure storage and secure workstations. Further, FDA has redoubled its collaboration with Federal intelligence partners through our own Office of Criminal Investigations so that we are better prepared, are working on consistent priorities, and have regular and effective lines of communication with other law enforcement and intelligence agencies in the event of a biodefense situation.

FDA began an Agency-wide strategic workforce alarming initiative in 2001 to examine the workforce challenges of the future. In 2002, we expanded the initiative to identify the types and numbers of positions needed to enhance our counterterrorism readiness. The initiative also looked at the aging of the workforce, the attrition rate, succession planning, and leadership development. We identified ways to recruit, develop, and retain personnel. Two key outcomes of this initiative have been a heightened awareness among the FDA leadership of the importance of workforce planning and integration of workforce planning into the Agency's strategic planning process.

For your information, our data indicate that 26 percent of our total workforce will be eligible to retire in the next five years. For some of our key occupations, 20 percent of our medical officers, 24 percent of our microbiologists, and 16 percent of our chemists are eligible to retire in the next five years. Our data seem to conflict with the Partnership's report data that indicate 52 percent of medical field employees and 51 percent of employees in the biological sciences will be eligible for retirement in the next five years.

FDA has created many new human resources policies to attract and keep high-caliber employees. I'd like to mention a few of these initiatives to recruit and retain staff:

FDA has created a national program that allows academic and esteemed individuals to spend time at FDA to inject innovative thinking into the current regulatory science and review process.

FDA has established partnerships with universities and colleges. These partnerships provide opportunities for joint research, for recruitment of students, and for sabbaticals for FDA employees.

FDA has established occupational retention allowances for hard-to-fill and hard-to-retain positions such as medical officers, clinical pharmacologists, and mathematical statisticians. We are able to pay employees in these categories an additional 10% of their salary.

FDA has created a student loan repayment program. We can pay up to $6,000 a calendar year with a career maximum of $40,000 per employee.

FDA has created a recruitment referral award for an employee who helps the Agency recruit new talent by referring external applicants. The cash awards range from $500 to $1,000 per referral for hard-to-fill positions.

FDA has created a pay banding schedule for scientific, supervisory, and managerial positions. Using the flexibility offered by Title 42 of the U.S. Code, we are allowed to set salaries of up to $200,000 per year for our scientific workforce.

In addition, employees can take advantage of flexible work schedules, including an "any-80" program that enables employees to work any 80-hour schedule over the two-week pay period so they may better balance their professional lives with their family lives. About one-fifth of our employees take advantage of our flexi-place program, which permits telecommuting. We also have a child-care subsidy program for

lower-grade employees. We offer transit subsidies for employees who use public transportation.

These measures seem to be working. In a recent survey conducted by the Office of Personnel Management to gauge how Federal employees feel about their jobs, FDA did very well compared to other agencies and the private sector. About 73 percent said they found FDA a friendly place to work, 82 percent said their supervisor supports their need to balance work and family issues, and 65 percent said they would recommend FDA as a place to work.

In addition, a November 2001 report by the National Academy of Public Administration entitled "A Work Experience Second to None: Impelling the Best to Serve" cited FDA's flexible work environment as a successful employee retention practice in the competition for talent.

To further assist in our recruitment efforts, FDA has taken steps to expedite the hiring process. FDA piloted the automated application system called Quick Hire. HHS has now adopted Quick Hire for the human resources consolidation effort. Quick Hire is a web-based on-line application system. The computer automatically rates and ranks the applicants based on pre-determined weighted questions developed by managers. In the past, we used a manual process of reviewing applications. Due to the pilot, we were able to hire 673 Consumer Safety Officers within the last fiscal year. We rated and ranked over 5,000 applications for 90 different field locations and had the lists of the best-qualified candidates to the managers within two weeks; one month after the initial advertisement. Under the old manual system, this task would have taken several months to complete. Management officials have reported that they have been pleased with the quality of the applicants.

FDA recently demonstrated its ability to hire, train, and utilize counterterrorism personnel quickly. The FY 2002 supplemental funding that Congress provided for counterterrorism activities enabled us to hire 800 additional personnel. Of these employees, 655 were hired by FDA's ORA. The remaining employees were hired by CDER, CBER, and the Office of the Commissioner to handle counterterrorism issues. Of the employees hired by ORA, 612 were hired as investigators and analysts, 33 were hired as Special Agents in the Office of Criminal Investigations, and 10 were hired as supervisors and compliance officers. The majority of these were allocated for food safety and security activities. Using the Quick Hire automated system and other innovations, ORA was able to bring these additional employees on board in a short amount of time, less than a year. Through a new, more efficient, training program we were able to have the new hires doing "basic" work within three months of employment and becoming fully operational within 12 months. These additional employees have improved our ability to detect and respond to terrorist threats and attacks.

CONCLUSION

FDA plays a critical role in the nations defense against terrorism. Although we are better prepared than ever before, we are continuously working to improve our ability to detect and respond to terrorist threats.

As part of this preparedness, we're building a strong workforce, and we intend to do even better. FDA has made significant progress in improving staffing for biological and medical sciences, and we will continue to do so. FDA has already implemented many of the suggestions in the Partnership report, we will continue to find additional innovative ways to support our workforce.

Thank you for this opportunity to discuss some of FDA's counterterrorism activities and our efforts to attract and retain high-quality personnel. I look forward to continuing to work with the Committee on security and workforce issues. I would be pleased to respond to any questions.

PREPARED STATEMENT OF ELIAS A. ZERHOUNI, M.D.

Mr. Chairman and Members of the Committee, thank you for inviting me to discuss how the National Institutes of Health (NIH) is helping to increase national preparedness against terrorist threats. The events of September 11, 2001, and the anthrax attacks that followed changed forever our collective thinking about the Nation's vulnerability to terrorist attacks. In response, the NIH and our sister agencies in the Department of Health and Human Services (DHHS), the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), have strengthened and expanded programs that will markedly enhance our ability to protect the American people against a broad range of potentially deadly terrorist threats. Indeed, many of these efforts have already borne fruit, and bioterrorism readiness stands at an all-time high. Nonetheless, we have more to do to develop

the full complement of medical countermeasures and procedures that homeland security requires.

Today, I will address how the NIH is contributing to the nation's capacity to counter bioterrorist threats. In Fiscal Years 2002 and 2003, the NIH greatly accelerated and expanded its research program on dangerous microbes and their toxins, an emphasis that reflects the lead role of the NIH, and particularly the National Institute of Allergy and Infectious Diseases (NIAID), in federally supported research on human infectious diseases. For Fiscal Year 2003, the NIH received a budget appropriation of over $1.5 billion for biodefense research, an unprecedented amount for any single program in the history of NIH.

More recently, the NIH has begun to identify next steps to implements its responsibility to develop a research agenda to address chemical and nuclear/radiological threats, as well as interventions to address the mental health impact of terrorism on individuals and society. The ultimate goal of these efforts is to develop an armamentarium of vaccines, therapeutics, and diagnostics that can protect the people of the United States against dangerous pathogens, toxins; chemicals, and radiological agents. Our bioterrorism-related research and development efforts are closely intertwined with the activities of the CDC, the FDA, and the Department of Defense (DoD).

The success of our efforts to develop safe and effective biomedical countermeasures against terrorist threats depends on a balance of basic and product-driven research, sufficient infrastructure and resources, and the outstanding men and women whose expertise and commitment make the entire enterprise possible. With this emphasis in mind, my remarks today will focus on NIH's efforts to: (1) develop a broad range of medical countermeasures. including vaccines, against terrorist threats and emerging infectious diseases; (2) develop the necessary research infrastructure, including specialized laboratory facilities and equipment; (3) enhance collaborations with other federal agencies and the private sector, and (4) develop and sustain the human capital that is central to all our activities.

DEVELOPING MEDICAL COUNTERMEASURES TO TERRORIST AGENTS

As the United States confronts the threat of terrorism, it is imperative that the Federal government develop the means by which to protect its citizens. The NIH response to this challenge has been unprecedented in its swiftness and scope. Aggressively managed, milestone-driven, interagency-coordinated efforts, and enhanced partnerships with industry have already resulted in important progress in basic research and in the development of biodefense countermeasures.

Last year, the NIH devised an intensive strategic planning process to shape its biodefense research program. These efforts resulted in the development of the NIAID Strategic Plan for Biodefense Research, as well as comprehensive research agendas for Category A agents, and Category B and C priority pathogens. Prepared in consultation with blue ribbon panels of experts, the research agendas delineate immediate, intermediate, and long-range plans for basic research and the development of vaccines, drugs, and diagnostics. Category A agents are considered to be the most serious bioterrorist threats. They include smallpox, anthrax, botulinum toxin. plague, tularemia, and hemorrhagic fever viruses such as Ebola. Category B and C priority pathogens include many food and Waterborne microbes such as those that cause cholera, typhoid fever, encephalitis, and certain forms of dysentery. In accord with the priorities outlined in its research agendas. NIAID developed a total of 46 biodefense initiatives in Fiscal Years 2002 and 2003. The response from the scientific community was swift and strong; NIAID has seen a 30 percent increase in the number of grant applications, the vast majority of which are for biodefense.

NIH has already advanced the development of vaccines and therapies for smallpox and anthrax. Last year, for example. NIH-supported scientists demonstrated that the existing U.S. supply of smallpox vaccine was still potent and could be diluted five-fold and retain the ability to stimulate the skin lesion "take" considered an indication of the vaccine's effectiveness. The discovery made it possible to Greatly expand the number of doses of smallpox vaccine in the United States. NIH is now developing and testing next-generation, attenuated smallpox vaccines such as modified vaccinia Ankara (MVA) that can be used safely in people whose immune systems are compromised, in pregnant women, in people with skin conditions such as eczema and atopic dermatitis, and in other vulnerable populations for whom the existing vaccine is not recommended. NIH is also testing antiviral compounds as potential therapies for smallpox, developing antibodies that could be used to treat complications caused by the current smallpox vaccine, and sequencing the genomes of smallpox and related poxviruses to identify potential molecular targets for new drug and vaccine development.

Progress on anthrax is following a similar pattern of success. Last year, NIH-funded scientists identified the site on a human cell that binds the anthrax toxin and developed a compound that may block its lethal effects. The information gained through these and other studies will likely hasten the development of new drugs to treat anthrax. In May 2003, NIH-supported investigators at The Institute of Genomic Research in Rockville, MD, determined the complete genetic sequence of the strain of the anthrax microbe used in the 2001 mail attacks. In addition to providing valuable forensic information, this achievement may give scientists valuable clues about designing drugs and vaccines that capitalize on the bacterium's vulnerabilities. And as of July 2003, four clinical trials of a next-generation, DNA-based vaccine for anthrax called recombinant Protective Antigen (rPA) are underway.

Future NIH biodefense research will reveal more about the basic biology of these and other microbes, identify the mechanisms by which they cause disease, identify factors in the human innate and adaptive immune response to these microbes, and develop new and improved interventions that can prevent and treat diseases caused by Category A, B, and C agents. For example, NIH is developing and testing candidate vaccines for Ebola and is currently in the planning stages for initiation of a Phase I clinical trial to evaluate a candidate DNA vaccine for Ebola. Over a dozen more research initiatives are planned for Fiscal Year 2004, all of which will help accelerate the development of medical countermeasures against biological agents that could be used as weapons of terrorism.

Over the past several months, NIH has also begun to examine several other areas of concern: nuclear/radiological terrorism, chemical terrorism, and the psychosocial impact of traumatic events. Earlier this year, we convened panels of experts in radiobiology and medical chemical defense to identify research opportunities in medical countermeasures. On February 26, 2003, NIH convened a meeting that included scientists of the NIAID, National Cancer Institute (NCI), the Armed Forces Radiobiology Research Institute, the National Academy of Sciences (NAS), other government agencies, and academia, to identify priorities in the development of medical countermeasures against nuclear/radiological terrorism. This meeting was a logical sequel to two NCI-sponsored workshops held in 2000 and 2002 that reviewed information on tissue damage from ionizing radiation and possible mechanisms of protection. On March 19, we convened a panel of experts that included representatives of the NAS, academia, industry, other federal agencies, including the DoD and the Army Medical Research Institute of Chemical Defense, the newly created Department of Homeland Security, and NIH Institutes and Centers. The panel was charged to identify gaps in scientific knowledge about chemical injury and repair, and to identify priorities for the research and development of medical countermeasures. These meetings have provided an excellent framework for new medical product development and greater homeland security.

The National Institute of Mental Health (NIMH) has a program committed to research on mass casualties and trauma. Within several months of the attacks on the World Trade Center and Pentagon and the anthrax mailings, the NINTH expedited the award of grants to assess the mental health impact of these terrorist actions. The institute also convened, with other agencies, a major national workshop on mental health needs in disaster response. The NIMH is exploring additional behavioral/mental health research aimed at two problems, the treatment of trauma in individuals, and communication with the public during disasters and other traumatic events.

DEVELOPING THE RESEARCH INFRASTRUCTURE

Continuing progress in our efforts to develop medical countermeasures against a broad range of terrorist agents also depends on the availability of specialized resources that enhance the NIH research infrastructure. hey among these resources is a nationwide network of Regional Centers of Excellence for Biodefense and Emerging Infectious Disease Research and the construction of the Regional and National Biocontainment Laboratories, all of which are being launched in Fiscal Year 2003. These facilities will serve as national resources for biodefense research and product development, as well as for the study of other infectious diseases such as SARS and the West Nile virus. which require specialized biocontainment laboratories for research. The new centers and laboratories will include a small number of Biosafety Level (BSL)-3 and BSL-4 laboratories, which have the containment safeguards necessary to study highly pathogenic organisms. Only four BSL-4 laboratories exist in the United States today, which limits the ability to conduct safe and efficient biodefense research; the new facilities will substantially increase our country's biodefense research capacity. Review of applications for the Regional Centers

of Excellence and the Regional and National Biocontainment Laboratories programs is occurring now, and awards will be made this fall. In addition to these extramural facilities. NIH is planning the construction of new intramural facilities, which will include BSL-3 and 4 laboratories at Fort Detrick and Rocky Mountain Laboratories, and BSL-3 laboratories at the NIH campus in Bethesda.

NIH is also investing in other research resources necessary for meeting our biodefense goals. These include expanding our capacity for large-scale genome sequencing, developing new technologies to mine the wealth of data generated from genomic research, and establishing a national biodefense research reagent repository.

ENHANCING COLLABORATIONS

Collaborations with other federal agencies, private industry, and academia have always been a cornerstone of NIH's programs of research and development to promote public health. For the past two years, we have expanded these collaborations in many directions to bring together the multidisciplinary expertise and make possible the rapid response required to address terrorist threats. These partnerships have contributed greatly to the progress in the biodefense enterprise to which I have already alluded. For example, our ability to initiate clinical trials to test the next-generation rPA vaccine for anthrax resulted largely from collaboration between NIH and DoD. NIH has also developed an interagency agreement with the U.S. Army Medical Research Institute of Infectious Diseases that allows for cross-utilization of resources and joint research projects of high national importance, such as next-generation vaccines against smallpox. NIH is also working closely with the FDA and DoD in the evaluation of antimicrobial drugs against high-threat agents such as plague and tularemia.

Also critical to our continued success are partnerships with private industry. Unfortunately, many biodefense products provide insufficient incentive for private-sector engagement because there may be no viable commercial market. Within the limits of current statutory authority. NIH continues to develop new and innovative approaches to public-private partnerships to overcome such obstacles. The Project BioShield legislation now under consideration would provide significant funding for countermeasures against the highest priority threat agents. It would also greatly strengthen our ability to respond to the many challenges associated with biodefense research and development by providing streamlined authority, increased flexibility in awarding grants and cooperative agreements, expedited peer review procedures, bolstered authority for acquisition, construction, and renovation of facilities, and greater flexibility in hiring technical experts.

Our plan is to work closely with colleagues elsewhere in government, including the Departments of Homeland Security, Defense, and Energy and the NAS to ensure that our efforts to develop chemical, biological, radiological, and nuclear countermeasures are successful.

DEVELOPING AND SUSTAINING HUMAN CAPITAL

A fundamental element in our ability to protect the American people against terrorist threats is personnel. We must hire, train, and retain the most highly qualified and dedicated men and women to form the core of the NIH research enterprise. Our current personnel levels have been sufficient to foster the progress in biodefense research that I have described.

NIH is committed to the education and training of biomedical research scientists to meet future challenges. Recently, NIH initiated a number of programs to provide research training and career development opportunities in the area of biodefense. These opportunities, in the form of institutional training grants, individual pre- and postdoctoral fellowships, and career development awards in both basic and clinical research, will ensure a continuum of highly qualified men and women in this crucial area of research.

We believe that the talent exists to conduct the necessary research. Our challenge across the federal government is to find more effective ways to attract, hire, nurture, and retain qualified, committed people into national service.

CONCLUSION

Today, the United States faces a challenge that demands a rapid and coordinated scientific response. This challenge appears new and sinister because it arises from the deliberate use of deadly microbes, toxins, chemicals, and ionizing radiation as weapons against citizens. However, the tools and processes we need to combat these forms of terrorism are familiar to us. They include fundamental research to discover the mechanisms of injury and disease, investigations that lead us to a better understanding of how humans respond to these potential weapons, and the translation

of that fundamental knowledge into safe and effective countermeasures. Indeed, the experience and expertise of the NIH places us in a unique position to accelerate the development of countermeasures needed by Americans and people around the world to protect them against the threat of terrorism in the 21st century.

Mr. Chairman, this concludes my statement. I will be happy to answer any questions you and the other Members of the Committee might have.

[Whereupon, at 11:31 a.m., the committee was adjourned.]

○