# HEARING ON BIOSHIELD: COUNTERING THE BIOTERRORIST THREAT

## HEARING

BEFORE THE

## SELECT COMMITTEE ON HOMELAND SECURITY HOUSE OF REPRESENTATIVES

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# HEARING ON BIOSHIELD: COUNTERING THE BIOTERRORIST THREAT

**Thursday, May 15, 2003**

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON HOMELAND SECURITY,
WASHINGTON, DC.

The committee met, pursuant to call, at 1:15 p.m., in room 345, Cannon House Office Building, Honorable Christopher Cox [Chairman of the Committee] presiding.

Present: Representatives Cox, Dunn, Tauzin, Rogers, Shays, Camp, Linder Shaddegg, Thornberry, Gibbons, Sessions, Turner, Sanchez, Markey, Dicks, Frank, Slaughter, DeFazio, Lowey, Andrews, Lofgren, Jackson Lee, Pascrell, Christensen, Etheridge, Gonzalez, Lucas, Langevin, and Meek.

Chairman COX. Good afternoon. A quorum being present, the Select Committee on Homeland Security will come to order. The committee is meeting today to hear testimony on the administration proposed Project BioShield.

As members know, our rules permit any member to make a 3-minute opening statement. Alternatively, members who arrive within 5 minutes of the fall of the gavel and who waive their opening statement will at their election have that 3 minutes added to their time for questioning of the witnesses.

I will yield first for an opening statement to the ranking member of the full committee, Mr. Jim Turner of Texas.

You are recognized for 3 minutes.

Mr. TURNER. Mr. Chairman, if the chairman will indulge me for a minute, I want to speak to an issue unrelated to our hearing but very much related to our committee, a disturbing issue which has arisen concerning the Department of Homeland Security, which we have the responsibility of overseeing. Recent news reports have stated that an agency within the Department of Homeland Security, the Air and Marine Interdiction and Coordination Center based in Riverside, California, has used its domestic intelligence gathering capabilities for political purposes. It is reported by the media that the Center diverted Federal resources from homeland security purposes and used its intelligence gathering function to monitor and track down a private plane flown by the former Speaker of the Texas House of Representatives, Hon. Pete Laney. Former Speaker Laney was in public service for some 30 years. He is the gentleman who was asked by President Bush to introduce him to America for a prime time speech after the Supreme Court gave its verdict on the election of 2000.

Mr. Chairman, that domestic intelligence capabilities would be used for partisan political purposes should be deeply disturbing to this committee and to all Americans. We created the Department of Homeland Security to track down terrorists, not law abiding citizens. This new Department has been entrusted with an important mission, to protect and defend the American people. The Department must carry out its mission, and maintaining the trust of the American people is essential in carrying out this important task.

To those who suggest it is appropriate for Federal resources to be used to locate and arrest State legislators who have broken no law and have exercised a time-honored right to break a quorum, a practice used by a young Illinois State representative named Abraham Lincoln in 1840, reminds one of the days of Watergate when Federal resources were used for purely partisan political purposes, an act which brought a government down.

I am formally requesting, by letter to the Secretary, that an inquiry be conducted into this matter and that information be produced as soon as possible regarding persons responsible for this unacceptable action and the misuse of Department resources.

Thank you, Mr. Chairman.

Mr. Chairman, today we gather to deal with a very critical issue to this country, the threat of biological terror. The Defense Science Board has identified 67 diagnostic vaccines and therapeutic products which are priorities for defending against a biological attack. Right now we have only two, vaccines for anthrax and smallpox. Experts estimate it can take 8 to 10 years at a cost of as much as $800 million or more to develop a new vaccine from scratch, to put it through clinical trials and to bring it to market. These estimates assume that industry is fully engaged in actively pursuing the products.

Regrettably, that is not the case today. Last year the National Research Council reported that major pharmaceutical companies over the past 3 to 5 years have decreased their investment in drug discovery related to antibiotics, and few are exploring antiviral agents. Last year's shortage of numerous childhood vaccines revealed that a number of major drug companies have simply gotten out of the vaccine business altogether.

Against that troubling backdrop, today we are considering the administration's proposal, Project BioShield. This legislation is designed to stimulate private sector production of vaccines and other countermeasures for biological, chemical, radiological and nuclear attack. BioShield's purpose is to accomplish this protection by guaranteeing in advance that the government will purchase a large quantity of a drug or vaccine if the manufacturer produces an effective product that addresses a material national security threat. The administration has proposed $5.6 billion for this project over 10 years. The key question that we must consider today is whether Project BioShield is sufficiently bold in its response to this daunting challenge which faces our Nation.

The witnesses before us today will confirm what we all know to be true, and that is the threat to our Nation from bioterrorism, not to mention the natural development of new viruses like SARS and antibody resistant strains of disease, are deadly serious. We know there was a very active biological weapons program in the former

Soviet Union where they developed at least 30 deadly agents, but we do not know if the stockpiles created are secure. We know that Saddam Hussein had a biological warfare program that produced massive amounts of biological agents. Thus far, we have not been able to find them.

Moreover, we know that science may have progressed to such an advanced state that terrorists can engineer pathogens so that the drugs we develop will be ineffective. If that occurs, efforts to find vaccines and cures might not be able to be started until after we are attacked.

To address this grave concern to our Nation, we need to take bold action. We need to cast off our old ways of thinking and be open to new ideas and new ways of doing business. And we need to harness all of the energy and brilliance of our scientific community in a sustained, focused and massive effort.

I have some serious doubts as to whether Project BioShield meets this test. The most enthusiastic testimony provided by industry to date is that BioShield is a good first step. But many concerns have been expressed, both publicly and privately, as to whether the incentives in BioShield are strong enough to get the private sector to make the drugs we so badly need.

The former chief executive officer of Merck, Dr. Roy Vagelos, wrote me today that although the BioShield legislation should be tried, the proposals, and I quote from his letter, "will not accomplish what is needed, a reliable stream of bioterror measures."

I ask, Mr. Chairman, that this letter and Dr. Vagelos' biography be made a part of the record.

(*See* page 27.)

Mr. TURNER. To have a former CEO of one of the largest drug companies predict in essence that BioShield will not work is a frightening prospect, for if we pass BioShield with the expectation that drugs will be developed and they are not, we will lose valuable time in our race against the terrorists. I believe we will be making a mistake, and perhaps a tragic one, if our only approach is to incentivize the private sector.

We should simultaneously be building a capacity through a public-private partnership to develop these vaccines ourselves. We need to put out an all-points bulletin to our scientific community, and we need the best and brightest focusing on the problem. We need to appeal to their spirit of duty and citizenship to contribute their considerable skills toward the endeavor, even if greater financial rewards lie elsewhere. And we need our government to demonstrate leadership by developing a plan to get us from our current state of vulnerability to a level of protection that the American people expect as soon as possible.

While I look forward to the presentations of our witnesses today, I do not believe that Project BioShield is the complete solution we are seeking. It may be a positive first step, but I am confident that we will need to spend much more time and energy on this very compelling subject.

Thank you, Mr. Chairman.

Chairman COX. Thank you. I next recognize the gentlelady from Washington, the vice chairwoman of the full committee, Jennifer Dunn.

Ms. DUNN. Mr. Chairman, I am going to pass on my opening statement with the hope that we can get to our wonderful panel quickly, and add on to my question time.

Chairman COX. The gentleman from Louisiana, the chairman of the Committee on Energy and Commerce, Mr. Tauzin.

Mr. TAUZIN. Thank you. First of all, to my friend from Texas, I want to say that while we might have a legitimate debate over whether or not lawmakers ought to be finding another State to hide in at a Holiday Inn rather than doing their duties in the State Capitol, and while we can argue about the choice of venue where they landed, and I think the Holiday Inn in New Orleans would have been much more interesting and entertaining shelter for your legislators, none of us should argue about the misuse of funds dedicated to homeland security. I am anxious to learn those facts just as you are.

Let me just say that earlier today the Committee on Energy and Commerce reported out BioShield legislation. This hearing obviously is critical to further understand the issues as we move to the floor, but I want to make one simple point. To understand why this legislation is critical and why it does in fact advance us in the fight against the potential of a bioterrorism attack is a simple question of why would anybody in the country be interested in producing a vaccine against the black plague? Why would you invest money to do it unless you incentivize to do it when there is no market for a vaccine against the black plague, against diseases that we thought had been eradicated long ago, and no longer a threat to mankind?

When you consider that some of the potential bioterrorism attacks our country is beginning to receive might be possible, are not just threats to Americans, they are threats to human life on the planet, that is how critical and how immensely serious this debate is all about and why it is critical that the government assist in making sure that the companies that are good at producing vaccines and good at discovering cures and treatments, they be incentivized to do that.

The second question whether they ought to do it or government ought to do it ought to be a simple answer. We ought to incentivize and work with the companies that know how to do it and are good at it, and are the best in the world at producing health care treatments and vaccines and cures, and to incentivize them in a way that this bill attempts to do.

No, this is not going to be a perfect solution. We have worked carefully with the appropriators to make sure there is 10-year forward funding in the bill, and there is some guarantee that this is more likely to happen than not. But is it perfect yet? I guess not. I think we will be visiting it from time to time as we see it implemented, but I suspect this is a step, not just the right first step, it is a critical and unfortunately a necessary step that we must take to follow up on the great work of the bioterrorism bill that we passed in the House and Senate.

Senator Kennedy called me to talk about this and other matters. I complimented him once again on the extraordinary bipartisanship in which the Senate and the House worked on the bioterrorism bill last Congress. This is a complement to it, and a critical one. The

Vice President said to me last week that this could mean life on the planet, life or death for the whole human race on the planet. Thinking through what these evil people might intend for us and what they might be willing to do in their demented causes is an awful process, but one we cannot escape. We have to be prepared for the worst. This is not a perfect solution, I agree, but it is an essential step.

I commend the chairman and this committee for this hearing. I think it is going to advance the cause of understanding this process as we move forward. I thank the gentleman.

Ms. DUNN. [Presiding.] Mr. Chairman, we are going to consider this a rolling vote, so if you wish to go and vote and them come back, please do. We will continue the committee's business.

Ms. Sanchez.

Ms. SANCHEZ. Madam Chair, I reserve my time for questioning. Thank you.

Ms. DUNN. Mr. Rogers.

Mr. ROGERS. I will be brief, Madam Chair. The need for this kind of legislation is obvious and apparent, and we must deal with this forthwith. The question of how we incentivize the production of these antidotes while we also preserve the integrity of the congressional oversight of the expenditure of huge public sums is something we have to pay attention to. I think we can do that. We have had conversations with the select committee and the authorizing committee and myself on the appropriations subcommittee, and we think there is a way to do that and keep the integrity of the congressional oversight intact.

That is a concern that I have especially. We think there is a way to do that, much the same as we fund mass transit, FAA construction of runways at airports and the like, where there is a guaranteed stream of money but annually appropriated. We think that we can do that, and give the proper incentives to make production of these antidotes available to us. That is something that we will be exploring as the weeks wear on.

Thank you, Madam Chair.

Ms. DUNN. Thank you, Mr. Rogers.

Ms. Jackson Lee.

Ms. JACKSON LEE. Madam Chair, out of respect for the panel, let me simply associate myself with the comments of Ranking Member Turner on the issue of the use of Federal resources.

But I do want to say that I look forward to the hearing and presentation, and would simply suggest that there is an answer to the question of why the incentive process should not be the underlying and only basis of creating the necessary, if you will, bioprevention measures. It should be because it is the right thing to do. After 9/11 we turned the page of history in terms of responding to the threat against the United States, whether it is bioterrorism, whether it is a threat to our borders. I hope as we proceed in this hearing we will begin to establish the kind of homeland security plan that just says we should do it and we should do it no matter what it takes to get it done.

With that, I yield back the balance of my time.

Ms. DUNN. Thank you, Ms. Jackson Lee.

Mrs. Christensen.

Mrs. CHRISTENSEN. Thank you. Let me say at the outset that today's committee hearing is reassuring and I welcome the opportunity to get back to the many challenging issues that we have responsibility for on this select committee. I thank the chairman for calling us back to work to meet some of these challenges.

This is our second hearing on Project BioShield, and although the bill has undergone some slight changes, I still have reservations and concerns about it. Recognizing the importance of our universities and the pharmaceutical industry to this process, let me say nevertheless that some of my concerns remain very basic and relate to the open-ended funding and what appears to be another attempt to bypass congressional oversight. I have strong objections to both of those things.

The bill before us today is very important, not just because of what it seeks to accomplish, but also because how we deal with it will set the stage and be a precedent for everything else that follows in this important committee. I am going to listen very carefully to the testimony of all of our witnesses, but I am disappointed that there is not a public health expert on any of the panels. The burden as far as I am concerned is on the administration and the private industry to convince us that to be effective that competitive bidding has to be bypassed, that good science as the basis of decisions should be allowed to be compromised, the decision to obviate testing should be vested essentially in one person, and I am also concerned about how we are going to resolve the issues around indemnification and liability. An overriding concern is whether anyone can assure us if we pass this bill and Project BioShield, people of this country would be better protected in the case of bioterrrorist attacks, given all of the many, many possibilities, including the unknown. Of course, what good does all of this do if the public health infrastructure in so many of our communities remain in a state of severe disrepair?

I look forward to the testimony. I thank the panelists for coming to share their expertise with us this afternoon. I thank you, Madam Chair, for convening the hearing.

PREPARED STATEMENT OF THE HONORABLE CHRISTOPHER COX

I would like to welcome the Members in attendance this morning, and thank our witnesses for agreeing to appear before the Committee to testify on such short notice. This initiative has been moving very quickly. We have already had one hearing on BioShield; this is the second. A version of BioShield was marked up this morning by the Energy and Commerce Committee, and will be marked-up by this Committee in the immediate future.

But I also want this hearing to take a step back, to examine the unique nature of the bioterror threat, and the scientific and economic challenges that will need to be overcome to defeat it.

Each of us here has an understanding of the grave potential of bioterrorism. An attack on our population or our armed forces involving one ofthe numerous biological agents for which there is currently no effective treatment could be devastating.

This country is blessed to have the most vital and innovative healthcare system in the world. Our free markets and strong patent protections have led the American pharmaceutical and bio-tech industries to spend more on research and development of new products and treatments than all of Europe and Japan combined. This investment has led to incredible advances in the treatment of a wide variety of ailments.

At the same time, there have been few advances in the treatment of many of the diseases that pose the greatest bioterror threat. Diseases such as smallpox, Ebola,

and plague currently affect few Americans, and the reality is that manufacturers cannot afford to devote resources when there is no natural market.

The BioShield Act recognizes the great asset the American bio-tech and pharmaceutical industries represent. Rather than trying to create a parallel government bio-industry from scratch, BioShield seeks to draw on the expertise of the private sector by creating a "homeland security" market for bioterror countermeasures. It also recognizes the fact that we possess the strongest system of research unversities in the world, and gives us greater flexibility in working with them.

The proposal has three main sections. First, it gives the Secretary of Health and Human Services increased flexibility to conduct and support basic bioterror research. Second, it provides a stable source of funding for the purchase and stockpiling of bioterror countermeasures. It also recognizes the fact that we have the strongest academic research centers in the world, and gives us greater flexibility in working with then.

I look forward to hearing the witnesses thoughts on the provisions of BioShield. But more importantly, I look forward to hearing theft expert scientific opinions on the challenges we face in confronting the bioterror threat. We are privileged to live in a time that has been marked by remarkable progress in the biological sciences, particularly molecular biology and genetics.

Unfortunately, many of the same techniques that have allowed us to eradicate infectious disease as a major cause of death can also be used to manipulate infectious pathogens to create a bioweapon. As our world shrinks due to increased and rapid travel, an epidemic caused by the intentional use of a bioterror agent poses a threat of spreading world-wide with unprecedented speed.

The scientists that are with us today are world renowned for their work. They are experts in the treatment and diagnosis of infectious diseases, in how viruses spread in a population, and how to rapidly detect pathogenic organisms in the human population. They have been instrumental in developing new vaccines and treatments. And they have traveled the world, from the Ebola outbreak in Zaire to the sophisticated bioweapons labs secretly set up inthe former Soviet Union.

I hope the dialogue that will be generated today will help us to answer some basic questions such as: What is the value of stockpiling vaccines against pathogens that may naturally mutate or, more troublingly, may be purposely altered by terrorists? How easy is it for would terrorists to keep one step ahead in the race, and engineer agents that can defeat any new countermeasures I hope the witnesses will speak to these questions, and to the difficulties researchers and businesses confront in developing bioterror countermeasures.

## PREPARED STATEMENT OF THE HONORABLE LINCOLN DIAZ-BALART

Thank you Mr. Chairman. I would like to thank our distinguished panelists forjoining us today, and for your testimonies.

As with any measure to protect our population if terrorist attack, the key is preparation I applaud the Bush Administration for the proposed *Project BioShie1d*

We have seen the impact of a biological attack on our open society—and we have an idea of the price that it can bring. We have already witnessed many steps taken by our Federal, State, and local officials to protect our citizens I would like to particularly applaud Governor Jeb Bush and the Florida Department of Health for its efforts in carrying out Operation Vaccinate Florida.

I would also like to thank Director Fauci for his leadership at the NIH For years the National Institutes ofHealth has served as our Pentagon in the war against disease and Americans as well as people around the world have benefited, Now we must call upon the NIH to utilize the expertise and innovation of our scientists to guard against the horrors that a serious biological attack would mean.

The threat of biological weapons is real.

I look forward to working with my fellow committee members to ensure we take *all* steps possible to prepare for the possibility of such a threat.

## PREPARED STATEMENT OF THE HONORABLE NORM DICKS

Thank You, Mr. Chairman. This is a very important hearing this afternoon, as this Committee considers the new and serious threats of hioterrorism and our nation's ability to prevent and to respond to those threats.

Clearly we are late in recognizing the need to protect our population from the deadly biological agents that we know have been developed by nation's that support terrorism. In the past, we have worried about protecting our military personnel from the dangers of chemical and biological weapons that might be used in the battlefield, and thus the Defense Department has conducted its own research and development on various vaccines and antidotes. But today the threat is much more seri-

ous.. Since 9–11, and with the rise of terrorist actions directed at U.S.. citizens and facilities worldwide, we have more reason to believe that terrorists will attempt to use these new weapons of mass exposure on our citizens here inside the United States. There is no doubt there there is an urgency here.the urgent need to improve this nation's protection and response mechanisms. The urgency of our situation demands a bold response, and clearly Project BioShield as proposed by the President was a bold response, Mr. Chairman. The version of the BioShield legislation that has just been approved by the House Energy and Commerce represents an improvement on this concept, particularly with regard to the financing mechanism. But I know that many serious questions remain, and today's hearing will explore the implications of this particular bill as well as other concepts, including whether there are better harnessing the power and capabilities of the pharmaceutical industry to develop vaccines for the most serious of biological agents as well as for a broad array of other dangerous substances I have had some discussions with Mr. Rapoport, one of today's witnesses, about another method of jump starting the vaccine development process: namely, providing immediate incentives to industry—using private funds—to accomplish these objectives. I look forward to hearing from him today and from both of our panels of experts who are bringing their perspective and their insight to our committee Above all we must focus on actions that will be:

• Timely—recognizing that the threat is here and now;

• Complementary—avoiding unnecessary duplication of effort; and

• Cost-effective—because even though we will spend a considerable amount of federal funding on this bio-defense effort, there are still many other serious homeland security priorities to be addressed this year and in coming years.

Thank you Mr. Chairman and Mr. Turner for working to schedule this important hearing today and for keeping the Members of this Committee involved in the process.

## PREPARED STATEMENT OF THE HONORABLE JANE HARMAN

Thank you Mr. Chairman and Ranking Member Turner.

I'd like to put my remarks on Project BioShield in the context of the threat and the homeland security partnership between government and the private sector.

**Threat**

As the Ranking Member on the House Intelligence Committee, I am convinced that the United States faces a real bioterrorism threat TODAY. I made that statement at our subcommittee hearing on BioShield in March. Two significant events that have happened since then:

• SARS has killed at least 588 people worldwide, with more than 7,500 infected. While there's no particular reason to believe that this is a terrorist event, it shows the potential impact of an agent released into the global environment.

• Thousands of liters of enormously dangerous biological weapons from Iraq are missing.

So the threat is very real, immediate, and one for which we are not prepared.

While BioShield may be an important part of building our bio defense, other parts are also important:

• Identifying and safeguarding biological materials—from, for example, Iraq and Russia;

• Improving our intelligence on BW possession by other countries or groups and their intentions for use or proliferation; and

• Re-building the international taboo against use of biological weapons.

**Partnership**

BioShield depends on the partnership of the public and private sectors. There is a clear market failure to develop countermeasures for rare diseases, chemical weapons, and nuclear or radiological devices. At the same time, the government lacks the capacity and expertise to produce the countermeasures itself.

The Administration is requesting new authorities to get the private sector to do a fundamentally public sector job. It is for Congress to decide whether new authorities are in fact needed, and to determine what flexibilities are appropriate and in our best security interests.

I support, Mr. Chairman, doing what is necessary to produce the biodefenses to weapons we know are out there. But our action must take into account our dire budget situation, and the alternative possibility that we might be able to stimulate private investment for new breakthrough drugs without spending scarce federal dollars.

The private-public partnership in general is one of the most difficult issues for the Department of Homeland Security. As the most visible example of this partnership, it is especially important that we do this right.

PREPARED STATEMENT OF THE HONORABLE SHEILA JACKSON-LEE

Mr. Chairman and Mr. Ranking Member, I thank you for convening this vital hearing to hear testimony on the Project BioShield initiative.

The threat of bioterrorism must be one of our chief concerns as we continue our work of protecting our homelands from terrorist attacks. Biological weapons pose a particularly dangerous threat. Biological weapons are highly portable and difficult to detect. Positive strides have been made in securing our borders and preventing unwanted materials from entering our country, but it is unrealistic to expect no biological weapons to enter the United States. Last year alone 30 million tons of cocaine was smuggled into the United States. If we can't stop 30 million tons of cocaine from crossing our borders, how can we expect to stop a vile filled with anthrax, botulism, or small pox? A vile that could kill hundreds or possibly thousands.

Bioterrorism attacks not only pose a danger to human lives, they also have the ability to cripple the operation of our society and severly harm our economy. We all recall the primary and secondary impact of the anthrax attacks in 2001. The attacks involved a series of letters mailed in pre-stamped envelopes to media outlets in Florida and New York and to the offices of Senators Thomas Daschle and Patrick J. Leahy (D–Vt.). The anthrax attacks killed five Americans and left 13 others severely ill. The five people who died from inhalation anthrax included two postal workers at the Brentwood postal facility in Washington, a Florida photojournalist, a New York hospital worker and a 94-year-old woman in Connecticut. Thousands more were exposed to the lethal bacteria. The letters passed through various post offices and postal distribution centers along the East Coast leaving a trail of contamination. Buildings from the Brentwood mail facility, to the Congressional office buildings, to NBC headquarters had to cease operations.

The threat of bioterrorism did not end in September of 2001. As recently as April 22nd of this year in Tacoma, Washington we had a bioterrorism scare. a white powder was found in two envelopes, and 94 people had to be evacuated from a mail distribution facility. Initial tests of the powder tested positive for biotoxins that cause bubonic plague or botulism. Four people at the facility had to be decontaminated. The same day, a suspicious powder was found in a Federal Express cargo area at Southwest Florida International Airport, in Fort Myers, Florida. Six people were taken to a hospital for possible decontamination, including one who suffered burning eyes and nose.

We are presently faced with the threat of a worldwide SARS outbreak. The inability of many foreign countries to adequately deal with that outbreak raises questions about our own preparedness. What about other infectious diseases like tuberculosis? There are many ailments that our medical professionals are struggling to control. We must do better in the area of biological weapons.

The ease with which biological weapons can be manufactured is also a danger. The equipment and ingredients needed to manufacture many biological agents can be purchased over the Internet. Additionally, as our failure to apprehend those responsible for the 2001 anthrax attacks illustrates, biological terrorists can operate with more secrecy than traditional terrorists.

These are but a few concerns we face as we consider Project BioShield. The provisions of Project BioShield provide a good start to protecting Americans from a bioterrorist attack but work remains. Presently Project BioShield's provisions grant the National Institute of Health new powers, through grants and contract awards, to speed effective research and development efforts on bioterrorism countermeasures. Project BioShield also creates a long-term funding mechanism for the development of medical counter measures, and empowers the government to purchase safe and effective vaccines. Finally, Project BioShield authorizes the Food and Drug Administration to use promising, yet uncertified, biological treatments in the case of emergencies.

Mr. Chairman and Ranking Member, I believe these are good first steps in protecting Americans from biological attacks. However, I feel that many questions remain. I look forward to the testimony of our witnesses today, and I hope that there guidance can help us make all Americans less vulnerable to bioterrorism.

Ms. DUNN. We are expecting members to vote and return to our committee, but I think it is important to begin testimony in the time we have available since the last vote is going to be around 2:00 p.m., and we want to maintain as much membership here as possible. So we may interrupt you, depending on what the chairman wishes to do.

There being currently no further opening statements, I want to recognize the first panel of witnesses. Our first panel is a distinguished group of scientists who should all be able to speak directly to the challenges of conducting bioterror research.

We have Dr. Garry Adams, Associate Dean for Research from Texas A&M University; Dr. Ronald Crystal, Chairman of the Department of Genetic Medicine at Cornell University; Dr. C.J. Peters, Director for Biodefense and Emerging Infectious Diseases at the University of Texas Medical Branch. We also are very fortunate to have Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases.

Normally as a senior administration official, Dr. fauci would appear on a separate panel. Due to time constraints and scheduling issues, we have asked him to testify as part of our first panel, and he has accepted our invitation to do so. We are very interested in hearing his own research and scientific experience with bioterrorism.

In addition to being an administration official, Dr. Fauci is one of the world's most eminent research scientists. In fact, a recent survey found that in the period 1981 to 1994, of the more than 1 million scientists worldwide who published during that period, Dr. Fauci was the fifth most cited. So we are particularly appreciative for his willingness to provide his expert testimony alongside our other distinguished panelists.

We have your written testimony, and we would ask that each of you simply summarize in the 5 minutes you have your testimony. Dr. Fauci, we will begin with your opening statement, and work our way down the line.

**STATEMENT OF DR. ANTHONY FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

Dr. FAUCI. Thank you, Madam Chairman, and members of the committee. I want to thank you for calling this hearing and express my gratitude to Chairman Cox and other members of the committee for taking such an intense interest in this important subject.

September 11, 2001 changed forever the way we look upon the defense of our homeland, particularly followed soon thereafter with the anthrax attacks. Bioterrorism, be it microbes, chemicals, nuclear, or radiologic, are a clear and present danger, as articulated by Mr. Turner just a few minutes ago. So I need not spend more time on that.

What we can do to protect our citizens is developing and making available effective countermeasures against these agents of bioterror that are truly essential to protect the homeland. It is critical that we expedite and accelerate the development of countermeasures, for what we have been doing over decades, particularly in the arena of emerging and reemerging diseases, has positioned us quite well to accept the challenges of HIV/AIDS, West Nile virus and what have you, but we are now in a wartime mode of operation and we must adjust accordingly if we are to properly protect our citizens.

If you look here on this particular poster, that is the commonly used pathway of going from concept and basic research concerning a pathogen all of the way up to the development of a new product.

This need not be a pathogen, it could be a concept for the development of any product that is for the health of individuals. It is a complicated process that involves basic research and then identification of targets, preclinical development and clinical evaluation. There is a heavy dependence on industry and academia when one needs to come up with a product. We need to accelerate this and we need to do it rapidly. The reason is the incentives, for example, of industry to get involved in getting us to these products, particularly under exigent circumstances, must be considered.

If a product has great commercial value, it is easy. There are two parts to this. There is the push with the basic research and the pull or the incentive to industry. Let me give an example of that on this poster. If one looks at the situation with vaccines and why vaccines fail to compete with other agents because of the market appreciation of the need for it and the profit margin and incentives for industry to get involved, this particular poster shows the dollars in billions for all vaccines compared to a single drug like Lipitor, which is a lipid-lowering agent, and PRILOSEC, which is an acid blocker.

As you can see, the incentive of the marketplace puts vaccines at a great disadvantage. Vaccines are just one category of countermeasures that we need to develop, and so the problem is compounded in the arena of bioterrorism and biodefense research.

I would like to put these issues now into perspective in light of the President's proposal for Project BioShield as he has articulated in his January 28 State of the Union Address. The purpose of BioShield in the context of what I have just told you is to accelerate the process of research, development, purchase and ultimately availability of effective countermeasures against agents of bioterror.

It is a three-pronged program. It includes the push of research, and that includes making more flexible our capabilities to expedite the research and development process, which we do fundamentally at the NIH. When I say expedite, I mean very clearly not to compromise the tried-and-true mechanisms of peer review. I am talking about doing things on a much faster track while preserving the scientific integrity of what we do.

The second and an important component is related to the incentives associated with industry's involvement in the areas that I just mentioned, and that is to establish a secure funding source for the purchase of critical biomedical countermeasures and a funding source for deliverable products. It is very clear from our dealings with industry that they take risks when they get involved in developing any product. Most of them have no problem with taking the risk of failure when developing a product.

When you have great commercial value, the risk is certainly worth it. When you have a situation where there is no guarantee or at least at the present time no guarantee that there will be a market for the product and it might only go, for example, into a stockpile, we need to create incentives that make them feel secure and that is the secure funding capability which according to the BioShield proposal is a mandatory authority to allow money to be available when the companies, be they biotech or pharmaceutical

companies, deliver a product that is useful for the protection of the Nation.

Finally, the establishment of an FDA emergency use authorization for critical biomedical countermeasures, which means when there is a product which is absolutely needed to protect the Nation and the benefit clearly outweighs that risk, when a product that is on its way to being licensed or might be on a track showing it to be safe and effective but isn't licensed at this time, that under exigent circumstances the Secretary of the Department of Health and Human Services could allow the FDA to make that product available.

So in closing, Mr. Chairman and members of the committee, these are extraordinary times and we have extraordinary responsibilities. These responsibilities in turn call for extraordinary means to meet the challenge of protecting our Nation from the threats of terrorism, either by biological, chemical, radiological or nuclear weapons, and we can do this by developing and procuring and ultimately making available countermeasures to the citizens of our Nation that would be effective against such threats.

We believe that Project BioShield is a very important step in that direction.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF DR. ANTHONY S. FAUCI, M.D.

Mr. Chairman and Members of the Committee, I appreciate the opportunity to discuss the Administration's proposal, Project BioShield, with you today. The events of September 11, 2001, and the subsequent anthrax attacks, have changed forever how the biomedical research community responds to the emerging threat of terrorism. While the National Institutes of Health (NIH) and other Department of Health and Human Services (DHHS) agencies, including the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), have been preparing to address the threat of bioterrorism for several years, we have been called to accelerate our efforts vastly since the attacks of 2001.

*Overview*

Today, we know that there is a real threat to our nation, and one of the most important ways that we can respond to this threat is through the development of medical countermeasures to address potential agents of terrorism. We are now in a "wartime" mode and must modify the way we do business, while protecting the elements of our system that have made us so successful.

For decades, the NIH has led the biomedical research effort to improve the Nation's public health. The NIH research enterprise, fortified by a rigorous system for ensuring that only the best science is supported by Federal dollars, has served our country extraordinarily well. Through the traditional funding mechanisms of grants, contracts, cooperative agreements, and other partnerships, as well as time-tested personnel practices, this system has resulted in numerous major scientific advances that have improved the health of people around the globe, such as the development of interventions for emerging and re-emerging infectious diseases, including HIV/AIDS and Ebola.

With the unprecedented budget increases provided by Congress for biodefense research, NIH has hit the ground running with a comprehensive research agenda to address bioterrorism. However, there is an important issue that must be addressed: we must expedite and greatly accelerate the research, development, purchase, and availability of effective medical countermeasures against biological, chemical, radiologic, and nuclear terrorism. There is no time to wait.

When all Americans must confront the realities of terrorism directed at the United States, it is imperative that the Federal Government be prepared to protect its citizens from the scourge of terrorism. We are particularly challenged by the biological threats that are known to us or could be modified, as well as those that are unknown. To address these threats, we must build not only a strong biomedical research base, but we must create incentives for the companies upon whom we are reliant to produce the needed medical countermeasures to defend us.

NIH stands ready to push forward its biodefense research agenda to support the development of "proof of concept" for diagnostics, therapeutics, and vaccines to address agents of potential bioterror. However, without the expertise, resources, and proven capabilities of the pharmaceutical companies who develop these products and bring them to the market so efficiently and safely, we will not be able to meet the challenges set forth to us. Project BioShield would provide this needed incentive to industry, by giving it the necessary assurances that we will be reliable partners with them in meeting the challenge to develop the critical medical countermeasures to protect our citizens from acts of terror.

*Project BioShield*

Project BioShield would use the resources of NIH, FDA, and the DHHS Secretary to work together to accelerate the research, development, purchase and availability of effective medical countermeasures against chemical, biological, radiologic and nuclear terrorism. It takes a three-pronged approach. First, Project BioShield would increase authorities and flexibility for NIH, particularly the National Institute of Allergy and Infectious Diseases, to expedite research towards the development of critical medical countermeasures for biodefense, such as vaccines and therapeutics. Second, it would establish a secure funding source, via a mandatory authority, for the purchase of such countermeasures. And third, it would establish an FDA Emergency Use Authorization for critical countermeasures.

With regard to the first component of Project BioShield, the legislation would provide NIH with additional authorities to expedite the conduct of research and development in promising areas of medical countermeasures against potential agents of bioterrorism. This authority would provide NIH additional flexibility in awarding contracts, cooperative agreements, and grants for research and development of medical countermeasures including vaccines, drugs, biologics, and diagnostics. It also would streamline procurement authority, bolster authorities for acquisition and renovation of facilities, expedite personal services contracts and provide flexibility for certain personnel decisions to hire the necessary technical experts for biodefense research. Funding awards would remain subject to rigorous scientific peer review, but expedited peer review procedures could be used, when appropriate, without compromising scientific, technical, and programmatic standards. These new authorities would give NIH the tools it needs to expedite and push forward the pathway from basic research to effective biodefense countermeasures.

With regard to the second component of Project BioShield, the secure funding authority for procurement of countermeasures, it is worth noting that, historically, pharmaceutical research and development has focused on the development of products likely to attract significant commercial interest and a long-run market. We have found with experience, particularly in our numerous efforts to develop vaccines against some of the world's most devastating diseases, that uncertainties in the marketplace can create barriers to industry's willingness to invest resources and make long-term commitments to manufacture the needed products to prevent and treat disease. The recent shortages of vaccines for common and naturally occurring diseases are evidence of this problem. This lack of industry incentive is compounded with regard to the development of medical countermeasures to address bioterrorism, where the probability of a bioterrorist attack and the actual threats themselves remain unknown.

Our colleagues in the pharmaceutical industry—from small biotech firms to "Big Pharma,"—particularly those in the vaccine industry, have stressed that, they are willing and eager to help in the development of biodefense countermeasures. However, these companies are businesses, not non-profit organizations, and they need a tangible incentive to get involved in the critical effort to ensure adequate defense against bioterrorism.

When it is evident that a given pharmaceutical product has a potential to make a profit, no incentives are needed to engage industry. However, with the development of a product for which there is no guarantee of a return, or for which the market is uncertain, industry prefers some assurance that there would ultimately be a return on its investment. Without such assurances, companies likely will pursue the development of other products.

When NIH meets with industry, we hear that, first, companies already may be involved in the early stages of development of biodefense countermeasures at their own initiative and are willing to assume a degree of risk of failure. However, they would like assurances that a market would exist for their product if indeed they are successful in its development. Also, many state quite frankly that they do not want to be vulnerable to the vicissitudes of the cyclical appropriations process.

In the other case, when NIH tries to engage reluctant companies to get involved in biodefense research, we try to "push" them into action using discretionary research dollars. However, in many cases, this does not seem to be enough to convince

them to become engaged. With Project BioShield, we would be able to tell these companies that if they partner with us, meet certain milestones, and devise a licensable countermeasure, they will have our assurances that there will be money available to them for the purchase of that product. These are examples of the "pull" in the process: to the extent that the Federal Government can define its requirements and assure up-front that funds will be available to purchase critical countermeasures, regardless of the level of appropriations for the year in question, then industry will have a real incentive to meet the biodefense research challenge. We feel that such assurances can only be given by a mandatory funding authority.

With regard to the third component of Project BioShield, the FDA Emergency Use Authorization, it is worth noting that the FDA approval process for drugs, devices, and biological products is the gold standard for the world. The FDA's policies and regulations help ensure that products that get to market are safe and effective. In addition to animal studies, sponsors of new drugs and vaccines typically conduct three phases of clinical trials in humans to demonstrate the safety and efficacy of a product. This process, however, can take years.

In preparing for the challenges we face today, we may not always have a desirable amount of time to address the threat presented by agents of bioterrorism. While the FDA has several mechanisms in place to get products to market faster, these alone are not sufficient in an emergency.

Project BioShield would permit the Federal Government to make new and promising treatments that are still under development available quickly, if needed, for use in emergency situations where no effective approved or licensed products are available, potentially saving many lives. Specifically, Project BioShield would authorize the DHHS Secretary to grant an emergency authorization for the use of unapproved products in the event that the Secretary determines that there is no adequate and approved alternative available. This authorization would require the Secretary to determine that the benefits associated with using the countermeasure would outweigh the potential risks. Project BioShield would provide authority to the Secretary to apply conditions on the authorization, including limitations on distribution of the product, requirements to convey specific information to health care providers and patients, and requirements for recordkeeping, records access, and adverse event reporting. This authorization could be revoked by the Secretary and would be be limited in duration to the period of the emergency or not later than 1 year, unless renewed. It is important to note that the critical countermeasures would be tested for safety to the extent that the situation permits.

*Conclusion*

In summary, the need for medical countermeasures for biodefense is exigent and real, and we have a responsibility to the American people to make these products available now. The accelerated development of effective countermeasures against terrorism requires a new biomedical research paradigm, new ways to engage our industrial partners, and an ability to make promising products available for use during an emergency more quickly. Project BioShield would help us meet the challenges of terrorism effectively and expeditiously, improving our Nation's preparedness for and capability to respond to the threat of bioterrorism.

Thank you again for the opportunity to testify today about this important initiative to improve our homeland security. I would be pleased to answer your questions.

Chairman COX. [Presiding.] Thank you, Dr. Fauci. Since I was voting when you began, I didn't have the opportunity to welcome you personally and thank you for the outstanding leadership that you provide at NIH and the assistance you have provided to this committee in developing this legislative initiative.

Next is Dr. Garry Adams. We have copies of your testimony, and invite you to summarize your testimony in 5 minutes. I welcome you as well.

## STATMENT OF DR. L. GARRY ADAMS, ASSOCIATE DEAN FOR RESEARCH, BIODEFENSE AND INFECTIOUS DISEASES, COLLEGE OF VETERINARY MEDICINE, COLLEGE OF VETERINARY MEDICINE, TEXAS A&M UNIVERSITY

Dr. Adams. Thank you, Chairman Cox, and members of the committee. Thank you for an opportunity to give perhaps a different perspective from the veterinary profession and, as a member of the

public health community, to present what I hope is an informed and experienced perspective for the enthusiastic support for Project BioShield.

My name is Garry Adams. I am a veterinarian. I am a veterinary pathologist. I am also the Associate Dean for Research and Graduate Studies and I have my own research laboratory.

I have been actively engaged in these diseases, including category A, B and C diseases, for about 30 years. I have lived in foreign countries on four continents for 7 of those years and have worked with several of those pathogens. What is important on these pathogens is about 70 percent of them are transmitted from animals to man and vice versa, so the veterinary profession plays an important role in working with the entire medical community and a one medicine approach from a public health point of view to control these diseases, whether it is in man or animals.

Much of the work that I have done has been involved with several countries in South America, Africa, Europe, and Canada. I have also had personal experience in inspecting and now collaborating with former Soviet weapons bioscientists, particularly on the development and production of a vaccine against brucellosis, a pathogen that had been weaponized not just in the Soviet Union but also here in former years.

Thank goodness the U.S. government has invested in transforming former bioweapons laboratories into laboratories where they can now manufacture and produce vaccines and products for domestic and international consumption, but the point here is that I was able to see the mass scale production of manufacturing, distributing and arming missiles for deployment and what could be done and what was being done by some 60,000 scientists in some 14 laboratories. But that is hopefully now changing, and many of us are involved in that transformation.

So the other point that I would like to make is the relative ease of obtaining several of these pathogens, and for some of them the relative ease of transforming them into bioweapons. Right now in Texas we are probably having anthrax outbreaks in wildlife, or we will have in the very immediate future. The same can be said for a whole spectrum of pathogens on a worldwide basis. Or they are obtainable. While we close the cupboard here on much, and in fact all of the laboratories through the PATRIOT Act, those organisms are still available to those who would make them into weapons and use them against us.

I am convinced that they do pose a profound and real threat to the health of not just the U.S. human population but to livestock populations. In fact, I have heard it stated from a scientist, a political scientist from Lawrence Livermore, saying that should we be attacked by multiple pathogens of both man and animals, several different pathogens simultaneously in 100 different sites, some of those pathogens would cause disease, death, and loss of our economic viability as well as eroding the confidence of the people in the Federal Government, State government and local government to control these diseases to a point that we might not recover economically.

Also, I base part of my testimony on working with the foot and mouth disease in Yorkshire, England in 2001. As a veterinarian, I

worked there as a diagnostician under field conditions. And what I saw was a devastating impact, a psychologic epidemic among the people, much less the 11 million animals that were lost and the billions of English pounds that were lost. It was a psychological impact that I saw among the farmers, but not just the farmers, the postman, the person who delivered the milk, the person who ran the shop in the village, to the bed and breakfast where I stayed, a huge impact on the morale and on the future of that country. Plus the loss of breeding animals that have been bred for the last 500 years. One farm that I visited where the animals were destroyed, they had been bred since 1526, and all animals were destroyed by that night. That is what occurred in the animal population.

What could have been done was to have prevented this by preemptive diagnosis, preemptive vaccination, and preemptive therapeutics, perhaps not in the case of foot and mouth disease, but the concept embodied in Project BioShield is the sort of preemptive moves that this country needs to make for protection of human, animal and even plant viability because of our economy.

So the threat is real. I have seen it personally. Perhaps one could say at the animal level that biological systems are biological systems, whether it is animal, plant or man.

And as I have mentioned, many of those pathogens are transmitted. Up to 70 percent in category A, B and C pathogens, animals serve as a reservoir, so we need to think in terms of protecting the human and the animal population.

One other point is the ability to manipulate the organisms genetically and transform them from an organism that might be susceptible to current therapy to one that is not. The Brusella bacterium is one that I am familiar with where some of that work has, unfortunately, been done. However, there are strategies, and strategies that are proposed in BioShield, and strategies that are being proposed by federally funded projects now in several agencies to move in an anticipatory thinking and strategy to avoid that.

So the threats are real for inflicting loss on man and animals and eroding the national economy. I cannot overemphasize the economy and the impact it would have on our Nation, and the massive epidemiologic outbreak that we would see among the citizenry. What we saw in England in the foot and mouth was overwhelming the diagnostic capacity, the regulatory capacity. There were 25 diagnostic tests done in the first week, a thousand the second week, and the third week 10,000.

In summary, I am highly supportive of the Project BioShield and welcome the opportunity to speak to you today.

PREPARED STATEMENT OF L. GARRY ADAMS, DVM, PHD, DACVP ASSOCIATE DEAN FOR RESEARCH, BIODEFENSE & INFECTIOUS DISEASES, COLLEGE OF VETERINARY MEDICINE, TEXAS A&M UNIVERSITY

Chairman Cox and Members of the Committee, thank you for inviting me as a representative of the veterinary profession and as a member of the public health community to present an experienced and informed perspective for enthusiastic support for the concept, principles and implementation of the "Project BioShield" initiative. I am Dr. Garry Adams, associate dean for research and graduate studies, professor of veterinary pathology and a member of the faculty of the College of Veterinary Medicine, Texas A&M University, College Station, TX. I am and have been actively engaged in biodefense and infectious disease research for over three decades,

funded by the United States Department of Agriculture, National Institutes of Health, United States Agency for International Development and the Rockefeller Foundation. I am testifying based upon:

My personal experience as a research scientist developing diagnostic tests, therapeutics and vaccines to detect and prevent important high priority (NIH Category A, B and C pathogens) infectious disease pathogens transmitted from animals to man and vice versa (so called zoonotic diseases) either insect-borne or not while working for a total of 7 years on four continents and several other countries (Mexico, Colombia, Argentina, Ecuador, Peru, Brazil, Kenya, Republic of South Africa, Israel, Egypt, Germany, Canada).

On my personal inspection of former Soviet bio-weapons experimental production and aersol laboratories, and my current collaboration with former Soviet bio-weapons scientists that are now being transformed into civilian scientists and facilities for vaccine development and production for domestic and international markets, thanks to the US Government.

On my recent experience working as a veterinary inspector in Yorkshire, England with the Ministry of Agriculture, Fisheries and Forestry under the auspices of the Royal College of Veterinary Surgeons during the deadly, economically and psychologically devastating Foot-and-Mouth Disease outbreaks in the United Kingdom where pre-emptive diagnostic surveillance and tactical use of effective vaccines may have saved the lives of millions of animals, billions of English pounds, and loss of some of the world's best breeding livestock.

On my personal knowledge of the ease of obtaining and relative ease of weaponizing NIH Category A, B and C pathogens as well as public information that several of these pathogens have already been weaponized by nation states, rogue groups and defiant individuals with the malicious intent to use them as weapons of mass destruction, thus representing profound real threats to the health of US human and livestock populations, food safety, food security, national economy, and psychological well-being of our nation. Knowledgeable sources have stated that frequent serial or multiple simultaneous bioterrorist events with multiple pathogens in both human and animal populations could be so deadly and so economically devastating that our nation might never recover to the state of health or economy that we currently enjoy. While our system of transportation facilitates the rapid development of markets and accumulation of wealth, it also greatly enhances the spread of diseases in human and animal populations.

On the fact that approximately 70% of the NIH Category A, B and C pathogens are diseases transmitted from animals to man to contaminate our food supplies by entering our domestic livestock populations and food chains and even worse by spreading into our massive wildlife populations where eradication of certain of these diseases may be impossible.

On the basis that should these pathogens be genetically manipulated by bioterrorists for enhanced for infection and mortality, the magnitude of the threat and impact on US human and animal populations and could amplified exponentially.

Thus, as stated above from my personal experience and knowledge of these pathogens and their associated risks and threats to our nation, I am fully convinced of their real potential for use as Bioterroist Threat weapons of mass destruction for 1) inflicting loss of life of man and animals, 2) eroding the national economy, 3) creating a massive psychological epidemic among US citizens, and 4) overwhelming regulatory and control capacities at local, state and national levels as well as 5) undermining the confidence of American citizens in government organizations whose responsibility to prevent, control, contain and eradicate these diseases.

The old axiom of an (ounce of prevention is worth a pound of cure( does not apply in the case of intentional, well planned Bioterrorism, because the short and long term effects on the US society could well be hundreds or even thousands of times greater unless prevented, thus concerted, pre-emptive and fully functional programs, e.g. Project BioShield, are essential especially for prevention as well as for mitigation and recovery from small and large bioterrorist attacks. US scientists are especially well poised to address virtually all facets of malicious bioterrorism to produce 1) high quality, mass scale diagnostics, 2) large quantities of protective vaccines that avoid confusing diagnostic tests, and 3) new rationales of chemotherapies for treatment of these pathogens. Investment in US health-related research has paid great dividends to the US citizens in the form of improved health and longevity, safer food and water supplies, and prevention of many diseases causing high morbidity and mortality in other nations. Development of safe, effective countermeasures is obligatory for the prevention and recovery from bioterrorist attacks, but this will require large infusions of major resources, such as requested by Project BioShield, coupled with effective, transparent collaborations between and within academia, the biomedical industries and Federal agencies, under rigorous scientific review and scru-

tiny to develop and produce the diagnostics, vaccines and treatments required to protect our citizenry and food resources. Importantly in the absence of bioterrorist attacks, the investment in Project BioShield will have the greatest benefit that will be realized every day in the physician's and veterinarian's offices as well as in our super markets with improved health, safer foods, and confidence in the security, public health and well-being of our nation.

In summary, I sincerely thank the Chairman and all members of the Select Committee on Homeland Security for this opportunity to very enthusiastically encourage the appropriations essential for Project BioShield to protect the future of our nation's citizenry, livestock, public health, and economic viability as well applying the benefits of the Project BioShield in global populations. I strongly support the concept, principles and implementation of the "Project BioShield" initiative and urge that the necessary resources be made available soon to protect against not only the potentiality of bioterrorist attacks but also against new emerging diseases occurring globally, such as SARS, and mad cow disease (bovine spongioform encephalopathy). My profession has decades of experience with many of these diseases, and we look forward to becoming a full scientific partner in the development of improved diagnostics, vaccines and treatments as countermeasures for these devastating pathogens.

Chairman COX. Thank you very much for your testimony. Out next witness is Dr. Clarence Peters.

**STATEMENT OF DR. CLARENCE JAMES PETERS, UNIVERSITY OF TEXAS MEDICAL BRANCH, GALVESTON, TEXAS**

Dr. PETERS. Thank you for the opportunity to share some of the observations that I have made over the past 30 years with you. That is about how long I have spent working in the field of biodiseases, including both public health and biodefense. I have worked in the U.S., Africa, Latin America and Asia. In fact, I started my career in Panama where I was a NIH research associate. Most germane to this discussion, I was at USAMRIID, the DOD lead laboratory for biodefense for 13 years, including the time of the first Gulf War.

I then went to CDC, where I was head of the Special Pathogens Branch for 10 years. This is the branch which was charged with dealing with high hazard pathogens, and maintained the biosafety level for a laboratory there. During this time, we discovered the hantavirus pulmonary syndrome, we dealt with Ebola in Africa and Nipah virus in Asia.

Every single year we found examples of a virus that was new, that is new to science, previously unsuspected and undiscovered, or a virus doing something it was not supposed to be able to do, or a virus in a place it had never been known to occupy before.

I would like to leave the committee with one central idea about emerging infections and one about bioterrorism. First of all for bioterrorism, there are a limited number of different organisms that can truly cause mass casualties, but their threat is indeed quite real. During the Gulf War I had the occasion to examine the old classified data from our defensive program in depth and to consult with some of the experts who produced these weapons. This method of killing people can be successful, literally measured in the tens of thousands of casualties. The delivery is by an airborne aerosol, so it is stealthy and will go unnoticed initially, but later declares itself when humans sicken and die.

Now let us talk for a second about emerging infections. Why would I bring them up with bioterrorism? First of all, the organisms are often exactly the same as with bioterrorism only they

occur naturally. I would like to emphasize the central theme that I see in emerging infections. These microbes are on the move. The factors underlying emergence were put forth in an Institute of Medicine report 10 years ago. I had the privilege to be on an IOM committee and have a preliminary report from that committee that looked back over the revisited lessons. These conclusions set forth in Microbial Threats to Health were basically the news is not good. The factors in emergence are all working against us and these factors are interactive.

I believe the only way we will be able to deal with the full spectrum of these encroaching microbes is through an active program of vaccines and anti-infectives, just as we need to protect ourselves against bioterrorism. We can develop vaccines and therapeutics against these agents. Indeed, there have been some successes in the past. Unfortunately, these successes have not been carried forward for policy and funding reasons, but they do give us a road map and they can be surpassed with the fine technical base which has been built by NIH in the intervening years.

Let me share briefly an oversimplified model of how I think about dealing with diseases in the past. The physician recognizes the disease, the public health authorities count the disease, tell us how important it is, NIH research then builds a technical base and finally the private sector brings forth drugs and vaccines that we use to deal with these.

Well, neither an emerging infectious disease when it is on the march or a bioterrorism event when it has already been perpetrated will lend themselves to that model. They will come swiftly, and each element has to be in an accelerated mode. NIH training for the physicians who will be our infectious disease specialists must not be ignored by purchase of these other remedies. The public health infrastructure still could use some strengthening. NIH's current research agenda and their movement toward translational extension is going to be extremely important still, but Project BioShield may be what we need to give us the essential weapons that are going to be needed in this fight.

The fight will not work just with public health or physicians. We have to have vaccines and anti-infectives. We have already heard multiple times that there is insufficient incentive in the commercial sector.

I would just close by saying that I certainly support the goals of BioShield. I am not a sufficiently well-versed health economist to be able to help you with some of the other deliberations about the funding.

PREPARED STATEMENT OF DR. CLARENCE JAMES PETERS

Chairman Cox and distinguished members of the Committee, thank you very much for the opportunity to express the lessons that I have drawn from my experience in this area as they relate to the issue of Project BioShield. I was educated as a physician at Johns Hopkins Medical School in Baltimore, trained in Internal Medicine at the University of Texas Southwestern Medical School in Dallas, and did additional work in immunology at Scripps Foundation in La Jolla. My first introduction to research in infectious diseases was in Panama where I lived and worked for 5 years as a research scientist in an intramural NIH laboratory. Subsequently I spent 13 years at USAMRIID, the principal DoD laboratory in biodefense research; I began as a laboratory scientist and eventually became deputy commander, serving this role during Desert Storm. I then spent 10 years at CDC as head of their BSL–

4 laboratory, dealing with emerging infections including hantavirus pulmonary syndrome, Ebola, Marburg, Nipah, and other viruses. For the last two years I have been at the University of Texas Medical Branch at Galveston, TX where I am the John Sealy Distinguished University Chair in Tropical and Emerging Virology, the Director for Biodefense, Center for Biodefense and Emerging Infectious Diseases, and the director of the BSL–4 laboratory. This laboratory is the only such high containment laboratory in the US within an academic institution.

I would like to share with you reasoned conclusions drawn from that experience. I further believe that my impressions reflect those of a large number of my colleagues who are working in public health, infectious diseases, and epidemiology.

Bioterrorism is a real threat to our country and to our way of life. We have, of course seen the deep impact of 22 cases of inhalation anthrax with 5 deaths on our social and governmental fabric in 2001. During my work at USAMRIID I was deeply involved in biowarfare defense and as a part of our defensive posture had an opportunity to examine the offensive program that existed in the US prior to 1968. This convinced me beyond any shadow of a doubt of the practicality of biological attacks that could be small and focused with extreme disruptive effect or broad and lethal to tens to hundreds of thousands of citizens. The most dangerous of these attacks could be achieved with only a handful of agents, but defenses were woefully inadequate. The major route of dissemination for all except smallpox virus would be by small particle aerosols; smallpox virus could be spread initially by this route, but uniquely among the lethal agents of mass casualties would then be able to propagate itself by interhuman transmission.

USAMRIID, DoD's lead agency for biodefense, and related agencies worked intensively on medical countermeasures with considerable success given their resource limitations. When I became associated with the effort in 1977, a licensed anthrax vaccine existed but was not procured because of larger issues of DoD doctrine for its use and procurement; this is the same vaccine was used in the two Gulf wars. The licensed smallpox vaccine was given to troops explicitly for its importance as a deterrent for biological use of the smallpox virus; this was discontinued for a variety of reasons; incidentally, this coincides temporally with the increased efforts of the Soviet weaponization of smallpox described in Ken Alibek's book "Biohazard". USAMRIID had developed a number of prototype vaccines against other agents and before I departed in 1990 developed several more, including those against NIH/CDC category A agents Argentine hemorrhagic fever and Rift Valley fever. All these vaccines remained in investigational status even though they were used to protect investigators working with the agents in the laboratory as well as persons involved in epidemic disease control. There was simply no doctrine to drive their licensure and deployment nor was there a budget to support this. The antiviral drug ribavirin was also shown to have preclinical efficacy against several category A agents; and through contract CDC tested the drug in humans naturally infected with Lassa fever in West Africa to confirm this efficacy. Other potential products came out of this program, including botulinum antitoxins, a humanized monoclonal antibody to the virus of Argentine hemorrhagic fever, and other prototype vaccines that only now are being tested in humans. I thought it was important to bring these products to the committee's attention to show that these threats can be countered and to emphasize that the research base is not sufficient to actually bring products that have great promise to practical utility. I am not certain of the exact budget of USAMRIID during that period, but I would estimate $10–20 million annually as a reasonable figure; the results included the above-mentioned vaccines and drugs as well as a considerable knowledge base on expected behavior of agents and diagnostics.

We are facing an ever-increasing threat from emerging infections, as well. This is not irrelevant to the present discussion. Emerging infections arrive unexpectedly and can be equally or more lethal than bioterrorist events. In fact, in some ways they are even harder to prepare for. I would be willing to predict that we will suffer both bioterrorist attacks and significant depredations from emerging infections in the next decade. I can further predict that anthrax is the highest threat for a significant bioterrorist attack, followed by other agents in the category A and B lists developed by NIH and CDC. However, I have no idea what the next emerging infection will be, a problem exemplified by the recent surprising appearance of the SARS coronavirus as a serious threat to global health. Parenthetically, I would emphasize that among the emerging disease unknowns there is one established threat: the recurrence of pandemic influenza is virtually certain and should be a part of our planning.

Biothreats and emerging infections converge in two important ways: the agents are often the same and the remedies usually share significant elements, including the importance of vaccines and anti-infectives. I had the opportunity to observe emerging infections first-hand between 1991 and 2000 when I was head of the Spe-

cial Pathogens Branch at CDC. We were responsible for infectious diseases that required special containment for safe laboratory work and for field work. Our BSL–4 laboratory was the focus of the global struggle against high-hazard pathogens around the world. In that decade we dealt with new (new to science) viruses, returning viruses that had been thought to no longer pose a threat, and known viruses exhibiting behaviors not previously thought to be a feature of their behavior. The assessment and control of these agents was due to the dedicated and very capable staff of the branch as well as others at CDC, the strong scientific base laid by NIH, the work from USAMRIID, and the contributions of persons in the endemic areas. It is important for the committee to understand that we were not out looking for these agents: they came to us in the form of destructive and challenging epidemics.

Were these epidemics a phenomenon of the internet communications and the 24/7 news atmosphere? Emphatically, no! The Institute of Medicine in 1992 published a thoughtful analysis of the importance of infectious disease in the U.S.: Emerging Infections. Microbial Threats to Health in the United States, National Academy Press. This volume showed the importance of emerging infectious disease and antimicrobial resistance in the increasing role of lethal infectious diseases in our country, as well as the threat from microbes outside the US to our population. I was privileged to participate in a 10 year review of this report published in 2003: Microbial Threats to Health: Emergence, Detection, and Response, National Academy Press. Unfortunately, the findings of the committee were pessimistic. The factors originally identified as driving the emergence of infectious disease threats were correct and continued to operate, but at an ever-increasing force. The belief of the committee was that these factors plus the intrinsic adaptability of the microbes were driving us toward some very unpleasant consequences. Our major defenses against the adverse outcomes were in disarray. The initial investment in woefully undersupported basic public health deriving from our bioterrorism response was somewhat helpful in a general sense, but the modest new capacity was largely (and appropriately) utilized in bioterrorism planning and response enhancement. A particular national vulnerability to emerging infections was the lack of new industrial developmental efforts toward anti-infectives, vaccines, and pesticides.

Thus, the proposed BioShield initiative is particularly timely. It has the potential to improve our defensive posture toward bioterrorist threats utilizing weapons of mass destruction and to also enhance the ability to deal with major emerging infectious menaces. To explain this, I will use a greatly oversimplified model of how we have dealt with some past problems. This imaginary sequence goes something as follows:

1. Medical practitioners recognize the disease and make diagnoses
2. Public health authorities see the aggregate picture and analyze the importance of the infection in the community and the nation.
3. 1NIH sponsors research to understand the underlying scientific issues
4. 1Industry picks up on the above to produce a remedy, often a vaccine or perhaps an anti-infective

A novel infection, whether from a bioterrorist attack or from an emerging infection, will likely follow a similar sequence:

1. A medical practitioner recognized the 2001 anthrax attack and this has been the case for most of the emerging infections I have dealt with. I would urge the committee to recognize the needs for training of physicians and infectious disease practitioners as part of our front line defenses; this appears to be threatened by reduction of NIH infectious disease research grants to procure anthrax vaccine and initiatives such as BioShield would offset this cannibalism of resources.

2.Public health will be the first responders. Public health capabilities have been strengthened, but the over-all vigor of the public health establishment remains in doubt. We must be sure our quotidian public health needs are well-met with trained professionals who have the depth of staffing, organization, and resilience to recognize and deal with bioterrorist and emerging infectious disease emergencies.

3.We also have a great deficit in basic research on the important bioterrorist agents; NIH has recognized this and has launched excellent programs to remedy our gaps. These remedies inevitably are in the nature of "catch-up", but we are now on an accelerated track. Money for the research programs is not a sufficient response and NIH has recognized this. They have initiated programs for construction of the specialized laboratories that will be needed for the work in these diseases. I urge the committee to assure that these laboratories are constructed and supported. NIH has also recognized requirements for training in the diseases involved as well as in performing research in these highly specialized containment laboratories, and I would urge the continuing support of the committee for this aspect of biodefense.

4.The actual development of anti-infectives and vaccines for prevention and treatment of biothreat and emerging infectious diseases. This is a complicated and im-

portant area. It does little good to achieve 1–3 without having these remedies available.

Virtually every recent advance in drug and vaccine development has been due to the far-sighted and broadly supported research base evolving from NIH with its strong Congressional support. However, we also recognize that NIH has not usually been the actual product developer. The private sector has shouldered the initiative and responsibility of translating this research into a safe and effective armamentarium to protect our nation's health. I am convinced that this traditional model will not work in the case of biodefense and emerging infections. The financial incentive is not sufficient to draw the large pharmaceutical houses into the fray. This is not, in my opinion, inappropriate; they have responsibilities to their shareholders. The basic facts are fairly simple: I have worked with DoD and in the area of emerging infections for more than 30 years and have seen no movement or interest of the international pharmaceutical industry in the available markets. We must, however, overcome this lack of vaccines and anti-infectives, which is a major obstacle to the security of the Nation and its citizens.

Even more alarmingly, the DoD has suffered serious decrements in its capability to develop and produce vaccines. Although their programs were appropriately directed toward military problems, the severe cut-backs of in-house DoD vaccine development programs, the loss of the vaccine production capability at the Swiftwater facility, and the narrow approach taken by the Joint Vaccine Acquisitions Program documented in the "Top report" (Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military (2002), Medical Follow-Up Agency, Institute of Medicine) represent a significant national loss. This has changed our readiness landscape markedly. The ability to rapidly develop prototype vaccines, prepare modest-sized lots under suitable conditions for human use, and to test these in humans is vital to a flexible and forward looking biodefense and emerging infectious disease policy.

BioShield seems to provide an incentive to bring new initiatives into the arena of developing protective measures. The availability of targeted monies for actual procurement of the drugs and vaccines we need should draw entrepreneurs into the field and encourage the flowering of those already involved. This would be expected to synergize with the research that NIH has already shifted into the direction of diagnostics, therapeutics, and vaccines to lead to actual practical solutions to the problems we face. I see this as an important departure from what Dr. Fauci has described as "business as usual" and potentially a boon to humanity.

I believe that the significance of BioShield can only be realized if it is truly directed into the area intended. It must be used to insightfully develop the drugs we need in biodefense. There are some other considerations that I would list in closing:

1. It must take into account the dividends accruing from testing these drugs in populations that are at-risk for the different diseases that are simultaneously biodefense and emerging disease threats. This can provide proof or at least an indication of efficacy and may result in extensive local use that can enlarge the safety data base.

2. One of the areas that should be considered is the importance of anti-infectives over vaccines in the civilian population. Vaccines are supremely important for the military, but the difficulties of employing multiple vaccines in the face of uncertain threats are exemplified by the simple application of smallpox vaccine to hospital workers in the US. Thus, antiviral drugs for the category A threat agents become of particular interest.

3.Some of the vaccines and drugs that are in an investigational status would be of tremendous advantage for the researchers involved in these important studies of national defense importance. These protective measures should be made readily available to researchers. Vaccines formerly available for use under "Investigational New Drug Exemption" are increasingly difficult to obtain. Their use would decrease the risks of laboratory scientists, in some cases decrease the needs for expensive containment, and accelerate the development of definitive countermeasures for the agents.

4.The thrust of this effort must be protection of the civilian population from biothreats and from emerging infectious diseases. Military and civilian priorities will differ. However, the contributions of the military should not be forgotten and DoD biodefense work should be supported and the many complementary findings should be incorporated into the civilian effort.

Thank you very much for the opportunity to make these comments.

Chairman COX. Thank you, Dr. Peters.

Dr. Ronald Crystal.

**STATEMENT OF DR. RONALD CRYSTAL, PROFESSOR AND CHAIRMAN, DEPARTMENT OF GENETIC MEDICINE, WEILL MEDICAL COLLEGE OF CORNELL UNIVERSITY**

Dr. CRYSTAL. Thank you, Mr. Chairman. In addition to my role at Cornell Medical College as Chairman of the Department of Genetic Medicine, I am also a practicing physician and Chief of the Division of Pulmonary Critical Care Medicine, and I would like to give you the view of the academic/physician/scientist in regard to bioterrorism.

First, there is no question that these organisms are available. We, all of us on this panel, have trained many people over the years. There are thousands of people who know how to deal with these kinds of organisms, and the amount of resources that one needs to grow them up and reproduce are trivial. You can do them in 100 square feet with equipment that is readily available and not very expensive.

With regard to our care of patients who may be infected with these kinds of agents, despite the fact that my intensive care unit is as high tech as there is and our physicians are well-trained, we have a disaster plan and they know how to deal with these agents, if we had 10 to 100 individuals in New York City come to our hospital we would be overwhelmed, and so we have no choice as a Nation other than to protect ourselves, and clearly that is the goal of BioShield.

But the academic world cannot do it by itself, if we are going to produce these new therapies and vaccines. The academic community is capable of moving very quickly. We are capable of doing basic research, of doing experimental animal studies, and to a limited extent to do human studies. In our institution I have a facility available to me to produce vaccines that we can try on humans, but we cannot scale up to be able to treat and protect the Nation. We need the pharmaceutical industry and the biotech industry to be able to be part of that.

So there are several points I think that are critical. We as a Nation have to be very quick acting. We have to be able to move quickly in terms of response to these threats. Our defenses, our therapies in themselves have to be quick acting, particularly if we use a stockpile kind of strategy.

Second, the methodology and the technology to genetically modify these organisms is not very difficult. Our scientists who are training graduate students are capable of that kind of work. It is not that high tech. So we have to develop therapies that are versatile that can meet that change so that if an organism such as anthrax which has been modified so that it is resistant to antibiotics, that we can provide vaccines and therapies to meet that challenge.

In the context of the academic community not being able to do it itself, we need the industrial partnership, and clearly it has to be attractive as a commercial opportunity. Otherwise it seems to me that we are not going to be able to develop as a Nation these kinds of therapies.

Finally, as you have heard, we have to be able to get approval of these kind of therapies. You may have seen in the paper today there are new recommendations for the treatment of hypertension. If I was developing an anti-hypertensive drug, I would take the

group of people who had hypertension, treat them and another group, not treat them. You cannot do that with bioterrorism agents. You cannot try out your vaccine and then administer these organisms to human. We need other paradigms to be able to approve these drugs, and when we need them we have to do it quickly.

Thank you. I would be happy to answer questions.

PREPARED STATEMENT OF DR. RONALD CRYSTAL

Testimony of Dr. Ronald Crystal to the House Select Committee on Homeland Security

Chairman Cox, Ranking Member Turner and Members of the Committee, thank you for inviting me to present to the Committee a scientific assessment relating to "Project BioShield". I am Dr. Ronald Crystal, Professor of Medicine, Chairman of the Department of Genetic Medicine, and Chief of the Division of Pulmonary and Critical Care Medicine at Weill Medical College of Cornell University—New York-Presbyterian Hospitals in New York City. I will focus my remarks on the scientific aspects posed by the threat of the use of infectious agents for bioterrorism, the feasibility of preventing the spread of disease caused by these agents, and how the academic community can contribute to this effort.

We believe the threat is very real. While control of access to these agents will help, we cannot lower the risk to zero. If a group wanted to spread a bioterrorism agent in a populated area, it would not be difficult, particularly in the context where the perpetrators are willing to give up their lives to carry out an attack. As you know, there is a long list of bacteria, viruses, and other pathogens that, if introduced into a populated area, could quickly spread undetected through the population, with resulting morbidity and death and consequent social and economic disruption. These organisms are readily available and many are found in nature. Even most of the so-called class A select agents are not difficult to obtain.

**The 2002 Public Health Security and Bioterrorism Preparedness and Response Act requires Federal registration for possession and transfer of select agents.** All laboratories possessing and working with these agents are required to resister these pathogens, to identify the individuals that have access to these organisms, and to have in place a Select Agent Safety Plan for handling and accounting for all select agents. This is a positive step and will reduce the risk of these agents being available to potential bioterrorists. Even so, keep in mind that biologic agents by their very nature reproduce themselves. It is relatively easy, in a laboratory as small as 100 sq. ft. with equipment and reagents that are readily available and technology that is known to thousands of individuals in our country and around the world, to reproduce sufficient amounts of bioterrorism agents that, if released into the environment of a populated area, could result in massive disruption to society.

One of my responsibilities is to run the Medical Intensive Care Unit at the Weill Cornell Medical Center of New York-Presbyterian Hospitals. Our Intensive Care Unit is as modern and as high tech as any in the world, our physicians are trained to deal with the diseases that can be caused by the biologic agents of bioterror, and we have specific disaster plans in place to deal with a bioterrorist attack. Even so, the facilities of our hospital, and those of any of the medical facilities in our country, would be quickly overwhelmed if hundreds of patients with a highly infectious disease were to come to the hospital over a short period of time.

In the context of these realities, we have no choice other than to invest our resources to protect ourselves from the potential of bioterrorism in our country. This Committee's consideration of BioShield is central to that effort.

How can the resources of our country be mobilized to meet the challenge of BioShield? Between the academic community, guided by the efforts of Tony Fauci and the National Institute of Allergy and Infectious Disease and the pharmaceutical and biotech industries, we can get it done. Collectively we have the expertise and the infrastructure to create new generations of vaccines, monoclonal antibodies, and small molecule drugs to prevent and treat diseases caused by bioterror pathogens.

What should our strategy be? The list of potential bioterror agents is large, and it simply is not rational to believe that we could immunize everyone in our country against every possible agent. Not only is the list of possible agents too large, but inherent in any prophylactic therapy is the risk of adverse effects. While these risks may be small, when put in the context of the entire population, the risk-benefit analysis suggests the risk and cost for immunizing everyone against everything ar-

gues against this approach. I believe the strategy should be to leverage the exploding knowledge of the genetic revolution to develop new generations of vaccines and therapies against the most probable agents, and then stockpile the effective vaccines and therapies to be used in response to an attack.

The biomedical academic community in the US is unequaled in the world in regard to expertise, depth and infrastructure. It can be rapidly mobilized to focus on this challenge, and should be able to develop strategies to protect against and treat these disorders. With the information provided by the genetic revolution, the academic community can move quickly to develop safe, effective, and versatile platform technologies in which to provide the BioShield relevant to protect our population. In addition to being safe and effective, there are several features of new generations of vaccines and therapies that are specific to the bioterror threat.

First, if our defenses are going to be stockpiled and used in response to an attack, they must be rapidly acting.

Second, we must be cognizant that the technology is widely available to genetically modify potential bioterror agents to circumvent existing vaccines and therapies. For some agents, this has already been done, such as the creation of strains of anthrax that are resistant to conventional antibiotics. Thus, we have to develop "platform" vaccines and therapies that are sufficiently versatile to meet this potential threat.

Third, while our universities, institutes, and hospitals can develop the strategies for these vaccines and therapies and carry out proof-of-principle studies in experimental animals and in small human trials, the academic community does not have the infrastructure, expertise, or resources to turn these new generations of vaccines and therapies into large amounts of final products that would meet the necessary safety criteria for large scale human use. This final step is critical to the overall effort and will require a partnership of the academic community and the pharmaceutical and biotech industries. In this context, it will be important that strategies be developed to make working in this area attractive as a commercial opportunity for the pharmaceutical and biotech community.

Finally, because of the very nature of the threat, it is not possible to test the efficacy of these new bio-defenses in humans in terms of protecting against the actual bioterror pathogens. In this regard, the Food and Drug Administration will need to work with Congress to develop new paradigms for approval of BioShield products based on surrogate measures of efficacy, rather than the classic demonstration of efficacy in humans against the specific pathogen per se.

In closing, I thank the Chairman and the Members of the Committee for the opportunity to help you in your deliberations regarding BioShield, a national strategy that I and my colleagues in the academic biomedical community strongly support.

Chairman COX. Dr. Crystal, I will advise members because we moved forward with this hearing during the vote, that for all members under the rule who were here within 5 minutes of the fall of the gavel, if you have second thoughts about an opening statement you will have an opportunity to make one for 3 minutes at the beginning of the time during which you are recognized. Alternatively, you may take the full 8 minutes for questioning.

I will now recognize myself for 8 minutes.

I want to emphasize as I did a moment ago how grateful we are, first, Dr. Fauci, to you for the continuing work you have been doing on Project BioShield with the President for some months beginning when you and I and the President, Secretary Ridge and Secretary Thompson kicked it off on your campus; and next, to the other distinguished members of our panel, thank you so much for taking the time to be here with us and to help advise us. We have some scientific questions as well as economic questions that we cannot answer without your help.

I would like to begin with a very straightforward question that Dr. Fauci might answer in one way because of the classified information that rests behind part of the answer, but the rest of the panel can also address, and that is we have heard that biological organisms exist or can be manufactured which will not only wipe out tens of thousands of people if administered as a weapon, but

that conceivably could wipe out life on the planet. I want to know if that is an exaggeration or whether that is a real prospect, and I will begin with Dr. Fauci.

Dr. FAUCI. Mr. Chairman, I would not characterize the capability of literally wiping out life on the planet through biologics as something that is feasible. But within the same breath as I say that, I say clearly that engineered microbes in a number of categories could wreak destruction on our civilization measured in the millions and millions of people if you have a microbe that spreads from one person to another, and we know there are multiple different categories. We know the prototype for one that can be easily disseminated but does not spread from person to person: anthrax spores. The other type would be one that could be spread from person to person like smallpox.

When you have a situation where you can disseminate one or the other of those, I would have to say as a scientist it would be extraordinarily unlikely that you could wipe out civilization on the planet—but that is quite draconian,—but you could still do enough damage to make it a very, very horrible situation.

Chairman COX. Thank you. I would put the question to each member of our panel in turn.

Dr. ADAMS. Generally in challenge situations, there are always individuals who survive those challenges. I can use foot and mouth, anthrax, tuberculosis, and several others where there are natural resistance mechanisms which are yet unknown in engineering that pathogen to completely destroy all life on the face of the Earth. I have a lot of reservations about that statement.

On the other hand, the lateral impact, maybe not the direct impact, would have a huge impact on life as we know it. And so while wiping out all populations on the face of the Earth is I think an untenable statement, the impact on everyone else would be tremendous.

Dr. PETERS. I think we have one example of the movement of the Conquistadors to the New World. They brought measles, smallpox and a variety of other diseases with them. They did not wipe out the Indians, but they destroyed their civilization and were instrumental in the Spaniards being able to conquer the New World with relatively few people.

I think we have something going on right now with SARS that we do not know exactly what the end of it is going to be, but we already know that Asian economies are suffering tremendously. My prediction is they will not be able to control it in China. If that is true, we will be dealing with repeated introductions in this country for the indefinite future, so we may see a change in our way of life where we are taking temperatures in airports, in addition to taking our shoes off and putting them through the x-ray machines. And we may see emergency rooms rebuilt so if you have a cough, you go into one entrance. You would go into a negative pressure cubicle until your SARS test comes back.

So while I think wiping out human life is extremely unlikely, we have unengineered examples of bugs that have made great impacts on civilizations.

Chairman COX. Dr. Crystal.

Dr. CRYSTAL. The natural examples of what you suggest were, of course, hundreds of years ago with smallpox and the plague, which wiped out one-third of the population. We now have treatments for organisms like the plague, but if they were engineered to be resistant, but if they infected a number of people and had the capability of being spread rapidly from individual to individual, it would cause enormous havoc. I agree with the panel, I don't think it would wipe out civilization, but the consequences to our society would be enormous.

Chairman COX. Dr. Crystal, that leads to my next question. Given that engineered mutations represent a special threat, Project BioShield is designed to stockpile vaccines but obviously it can stockpile a vaccine only against something we already have in hand. What then of natural mutations that occur in organisms? The common cold changes from year to year, and what also of the fact that these stockpiled vaccines themselves will have a shelf-life? The prescription that I get has a date label on it which tells me it is good only for so long. There is a decomposition of any cure or antidote. Do we run the risk of investing billions of dollars in cures for the wrong thing because it is only what we now have in hand?

Dr. CRYSTAL. I don't think we have a choice because of the risk, but we have an example of that in influenza which changes from year to year and we effectively deal with that by developing new vaccines. What we have to do is a two-pronged approach. One is to develop the therapies and vaccines against what is out there, and then have versatile platforms, the development of these vaccines and therapies, so we can move very quickly, and the moving very quickly is a very important aspect of it, to develop the therapy if they are engineered to be different.

Chairman COX. Before a biological weapon is used, ought we to stockpile a vaccine for it; and if so, how do we know when to stop with the different possible threats against diseases?

Dr. CRYSTAL. You can prioritize the organisms, not only in terms of which ones are more deadly, but ones which can spread more. We can prioritize in terms of the vaccines and therapies that we already have, the ones that are getting close to development, and the ones further out. So I think one can make a rational plan about how to go about that problem without wasting resources.

Chairman COX. Do others on the panel wish to address either of those questions?

Dr. FAUCI. Mr. Chairman, just a brief comment about a word used by Dr. Crystal about what we call universal platforms, and by platform we mean if you can have a matrix vaccine to which you can insert the genes of whatever relevant microbe you are dealing with, even if it is a microbe that we do not have much experience with that we will ultimately identify.

A good example of doing this outside of the context of biodefense is what we are working on in our emerging diseases program where you can make a West Nile virus vaccine by taking a vaccine that we already have developed against dengue or yellow fever, and since it is the same class of virus as the West Nile virus, to essentially create what we call a chimera or a mixing of the vaccines where we insert the genes of the West Nile into the yellow fever backbone so you can have vaccines that allow you to then inter-

change these cassettes of genes. That is one of the things that we very much want to provide industry with incentives to get involved in because they can do that better than anyone else.

Chairman COX. My time for questioning is finished, but I would be happy to recognize Dr. Peters for further comment.

Dr. PETERS. In addition to the other comments, there are some parts of the microbe that are essential for its functioning, and in some cases you can develop vaccines against the essential part of the microbe which can't be circumvented.

Chairman COX. That is encouraging. Thank you.

I recognize Mr. Turner for 5 minutes of questioning.

Mr. TURNER. Mr. Chairman, I have no doubt that everyone of us on this committee and I am sure all of our witnesses agree that we face a very serious threat and we need to be very aggressive about dealing with it. The only question that I think is really open and perhaps unresolved regarding our legislative approach is will this get the job done?

I have been looking for someone with expertise who will tell me that if our goal is to find answers to five, 10, 12, whatever biological threats we want to address first, that within some period of time I can know that we will have addressed them.

Now Project BioShield and the administration's proposal attempted to accomplish that by basically providing a funding mechanism which says that the administration could just write a check to get some pharmaceutical company to proceed to try to develop a vaccine. Congress was very reluctant, and in the bill that was marked up today by the Committee on Energy and Commerce that blank check section of the proposal was eliminated.

I have a letter here and I want to read it into the record because I want some comment from anybody who feels this is an area that you have an expertise in. I know it is a specialty to know the economics of the pharmaceutical industry, but this is a letter from retired chairman and CEO of Merck & Company. I had the opportunity to talk to him on the telephone. I asked him to be here today but he had a conflict and could not appear. I understand that Dr. Fauci knows Dr. Roy Vagelos well, who is currently a resident of Bedminster, New Jersey. Here is his letter:

> Dear Congressman Turner: I have reviewed Project BioShield as you have requested. These are all good proposals and they should be tried. But I am afraid they will not accomplish what is needed: a reliable stream of bioterror countermeasures. The risk of failure with any R&D project aimed at a specific project is very high. That is true for products in the commercial marketplace as well as those that are aimed at the defined and limited market for a bioterror countermeasure. Although it would be useful to have many of the measures targeted by Project BioShield, these would help research organizations only if they succeed in discovering and developing a countermeasure. But most research aimed at specific product discovery and development fails. Long-term investments are required with great patience, waiting for the occasional success.
>
> Bioterrorism countermeasures will not be important targets for either large pharmaceutical companies or small biotech companies. Their priorities must be large commercial targets if they are to survive and prosper. For patriotic reasons some large pharmaceutical companies may take on a some of the bioterror targets. Small biotechs will rarely venture into this field unless they are motivated purely on patriotic grounds.
>
> In order to assure the Nation that significant bioterror countermeasure R&D aimed at product development will be undertaken, I believe an organization must be built that will dedicate its work to this field. The organiza-

tion must be contain top research and development people who know and practice state of the art research and development. To start such an organization, people experienced in drug vaccine research and development should be recruited from industry as well as inexperienced younger scientists who want to dedicate part of their careers to such work.

A fully equipped facility should be built, preferably close to the National Institutes of Health, so as to share the intellectual climate. People who work in this bioterror countermeasure laboratory could do this as a career, or they could spend several years in this environment either to gain experience in drug/vaccine R&D or to satisfy patriotic ambitions. The most important thing for succeeding in such an unusual venture is the identification and recruitment of an outstanding leader who understands the science and is willing to dedicated his career to the cause. I see no reason that people of similar quality as those working at NIH, Department of Defense, or the Center for Disease Control could not be recruited to such an important cause.

**P. Roy Vagelos**
Retired Chairman of the Board and Chief Executive Officer
Merck & Co., Inc.

Dr. Vagelos is Chairman of the Board of Trustees of the University of Pennsylvania, a post he accepted in October, 1994, having served as a trustee since 1988.

Dr. Vagelos served as Chief Executive Officer of Merck & Co., Inc., for nine years, from July 1985 to June 1994. He was first elected to the Board of Trustees in 1984 and served as its Chairman from April 1986 to November 1994. He was previously Executive Vice President of the worldwide health products company and, before that, President of its Research Division, which he joined in 1975.

Earlier, he served as Chairman of the Department of Biological Chemistry of the School of Medicine at Washington University in St. Louis and as Founding Director of the University's Division of Biology and Biomedical Sciences. He had previously held senior positions in cellular physiology and biochemistry at the National Heart Institute, after internship and residency at Massachusetts General Hospital.

The author of more than 100 scientific papers, Dr. Vagelos received the Enzyme Chemistry Award of the American Chemical Society in 1967. He is a member of the National Academy of Sciences, the American Academy of Arts and Sciences and the American Philosophical Society. He has received honorary Doctor of Science degrees from Washington University, Brown University, the University of Medicine and Dentistry of New Jersey, New York University, Columbia University, the New Jersey Institute of Technology, Mount Sinai Medical Center and the University of British Columbia; an honorary Doctor of Laws degree from Princeton University; and an honorary Doctor of Humane Letters from Rutgers University. He has received the Thomas Alva Edison from Thomas Kean, the Lawrence A. Wein Prize from Columbia University, the C. Walter Nichols Award from New York University's Stern School of Business and the National Academy of Science Award for Chemistry in Service to Society. Dr. Vagelos was awarded the Prince Mahidol Award in January 1998 by His Majesty the King in Bangkok, Thailand.

Dr. Vagelos is a Director of The Prudential Insurance Company of America, PepsiCo, Inc., and The Estee Lauder Companies, Inc. He is Chairman of the Board of Regeneron Pharmaceuticals, Inc. He is Co-Chairman of the New Jersey Performing Arts Center, a Trustee of the Danforth Foundation and Director of the Donald Danforth Plant Science Center.

Mr. TURNER. I would like to invite any of you to comment on Dr. Vagelos' recommendations who feel your expertise would allow you to make an assessment of whether or not we can be assured that the approach we are taking will get the job done.

Dr. FAUCI. Thank you, Mr. Turner, for reading that letter.

Certainly. Dr. Vagelos has put up an opposition that has been seriously discussed, not only with regard to biodefense but in the involvement of vaccines for things that are not related to biodefense. There are some good points that he makes. The problem I have with that is that I—what he is suggesting is essentially having a vaccine authority that is a megavaccine institute, where we, and I think he is talking about the Federal Government, fund an entity

that would be responsible for the developing of all countermeasures.

I don't reject that out-of-hand at all. But, what it misses is the fact that it doesn't allow us to call upon the extraordinary creativity and expertise of multiple, multiple biotech companies and "big Pharma" that can be enticed into using their capabilities to address problems that are imminent, or problems that might actually arise.

So it is not that it is a bad proposal at all, but the thing that BioShield does, and no program is perfect, Mr. Turner, but one of things that BioShield tries to do is embrace the extraordinary capabilities of something that this country has that is better than any country in the world, and that is a major, absolutely unparalleled pharmaceutical industry.

Mr. DICKS. Will the gentleman yield for a quick point?

Chairman COX. The gentleman's time has expired, but with unanimous consent the gentleman can have an additional minute to yield.

Mr. DICKS. You can take it out of my time. What if you had grants to the private sector and then grants to the universities like we do now, and you would have basically the kind of system that we operate today? Wouldn't that work around the model that has just been suggested?

Dr. FAUCI. Yes, Mr. Dicks. Actually, that is part of the underlying strategy of BioShield, as I mentioned. I don't think you were here because the vote was on. But, there are two major components to the development of countermeasures. One is what we call the push, namely the development of the proof of concepts at the research level. This is what the NIH and other Federal agencies that have research responsibilities are doing.

Trying to get the best of the minds to create the proof of concept, and to push the process through the early developmental stage. And then on the other side of the spectrum is what we call the pull, or the incentive to the industry which does this so well to get involved, to take risks, and perhaps even share risks with us, to the ultimate development of a product that they can do better than any other entity in the world.

So the point that you make is entirely compatible with the entire spectrum from proof of concept in basic research, up through and including the product, which is what we tried to do when we put BioShield together.

Mr. DICKS. Thank you.

Chairman COX. Mr. Turner.

Mr. TURNER. Dr. Fauci, I know you are well acquainted with Dr. Vagelos. I want to be sure the record is clear. I noticed in your response, in disagreeing with some of what he said, you left the implication that he did not approve of the things that were in the legislation. And the letter, and I am going to ask the chairman to make it part of our record. In the opening paragraph that I read, he said that these are good proposals, and they should be tried. But I am afraid they will not accomplish what is needed.

So it is not that he didn't approve of trying to utilize the private sector, after all he was Chairman/CEO of Merck, and I am sure

that he's more than willing to suggest that the private sector can be involved, it should.

The issue that he raises, and the one that I have concern about, is whether or not the goal is going to be accomplished. And I would suggest that perhaps utilizing what we have proposed, and also utilizing the establishment of a bioterrorism research laboratory along the lines suggested by Dr. Vagelos, may be our best insurance to be sure that this country is protected against biological attack.

Dr. FAUCI. Yes, sir. There are many good points that Dr. Vagelos has made. I hope I made it clear that I don't reject, at all, what he is saying. And I do recognize that he is saying that there are parts of BioShield that he feels are very important.

So I think it is just a question of the emphasis upon which you place your major thrust. I might also bring to your attention that Dr. Vagelos was also a colleague at the NIH before he went in to academia and became the Chair of Merck.

Mr. TURNER. Thank you. Mr. Chairman, I would like to offer the letter as part of the record from Dr. Vagelos.

Chairman COX. Without objection.

The gentlelady from Washington, Ms. Dunn, the vice-chair of the full committee is recognized for 8 minutes.

Ms. DUNN. Thank you. Welcome, gentlemen. This week Homeland Security Department is performing exercises in my hometown of Seattle, and also in Chicago, to evaluate our response to radiological or biological attacks.

We have learned certainly from the briefings we received in the Seattle exercise, and from your comments today also, about the rapid ability of these agents to spread throughout communities and throughout potentially nations and the world.

Assuming the existence of a national stockpile, do you believe that we have the rapid response team in place that we need to address such threats, any one of you?

Dr. FAUCI. We are getting better at it. TOPOFF II is an example of trying to get us on the road to being better than we are. We certainly are not at the peak of where we need to be.

But, considerable resources have been put in, are being put in, and will continue to be put in to revitalize a public health, local and State infrastructure that because of the successes of what we have been able to do with commonly occurring diseases, that infrastructure has, in fact, been neglected. And what Secretary Thompson is trying to do in the Department, and which last year he put $1.1 billion, this year $1.4 billion and we plan to put more in, is to try and revitalize what is somewhat decaying, but hopefully—being able to counter that and get it back to where it should be, a State and local health capability that would meet the needs of what we see as a threat to the health of the Nation.

Ms. DUNN. What I experienced in Seattle was very educational. And I think one of the points of this exercise, although it has been criticized for being expensive, is that what you practice, is what you produce in an emergency. And the ability to figure out the coordination and the decisionmaking ladders, I think, certainly made it apparent to me that this is an important sort of exercise.

You have indicated, all of you, in your testimony that there is a long list of bacteria, viruses, and other pathogens that, if intro-

duced into a populated area, could quickly spread undetected through our population.

Considering the large number of potential diseases that could be inflicted, and we talked earlier, other folks have asked the question about prioritizing dollars, do you think that Project BioShield at $6 billion is an effective use of our resources? Do you believe that this is going to help to prepare for the prevention, or at least the response if it does happen, of this problem, or is it your general, perhaps intuitive, sense that we ought to be using these dollars in some other way, focusing on prevention a little bit more, for example?

Dr. CRYSTAL. If I may. Keep in mind that we have there, for the bioterrorism agents, we have other than the antibiotics, we have very limited vaccines. We have basically smallpox that we can vaccinate against, and the others we can't do anything about.

Even the anthrax vaccine, which is used for our military, takes 18 months to reach full immunity and protection. And so essentially we are starting from almost scratch in terms of our response. And so I would suggest that any resource that is put into this is a start. It is something that we critically have to do.

Ms. DUNN. Dr. Peters.

Dr. PETERS. You know, I would agree wholeheartedly with Dr. Crystal. I would also point out that we can prioritize the agents. We do have some like anthrax and smallpox where anthrax will be back again and again. It is going to be like the nuclear threat in the Cold War. We will have to deal with anthrax for the foreseeable future. The next time it could be antibiotic-resistant to multiple antibiotics.

That is just a simple fact of life. The other issue about engineered organisms is that, certainly, there will come problems in the future. But, my guess is, for the next decade or perhaps longer, we will be dealing primarily with engineered antibiotic resistance in bacteria and not with super bugs.

So that we would be well-served, I think, to take care of the antipasto before we move on to the more complicated main dishes.

Dr. FAUCI. Could I make a brief comment on that?

Coming to the $5.6 to $6 billion number was based on the best estimate that we had of countermeasures that we could identify would either be imminent, in the process, or at least within reach. That is a number, when the President put that forth in the State of the Union Address, was a number that was based on material that was given vis-a-vis the background that I just mentioned to you of what kind of countermeasures could we project over a 10-year period. It was always felt that that number could be less than that, depending on the success, or more than that, which is one of the bases for the concept of a mandatory approach as opposed to a discretionary, so that you could have the flexibility of moving.

And I understand, as mentioned by Mr. Rogers, that this was marked up, and we respect and appreciate that. But, that was one of the reasons why the original proposal was brought forth as being a mandatory proposal to be able to have the flexibility of knowing that if indeed something came up, that the industry would know that there would be the secure funding source for something that we may not have accounted for in the original estimate.

Ms. DUNN. Thank you very much. The real goal of—

Yes. Go ahead.

Dr. ADAMS. Can I respond just a little bit to the TOPOFF II Exercise? Having been in three exercises now for Foot-and-Mouth and Rinderpest occurring in our State of Texas exercises, I want to emphasize that, what I think the real benefit there is the interaction of agencies, and who is in charge of the mission.

In the exercises that we have had, we have had up to 34 agencies working together. And the first one didn't go so well. But, as the agencies began to understand an incident command structure, and I think that is what they are testing. Resources, yes, you must have resources. And that is what I saw in UK, but it was the command structure that makes it work at the local level because all control starts locally and then goes nationally.

And so I think that these exercises are absolutely essential. Without those you won't know your deficiencies, and they have to be graded to find out where those deficiencies are.

And as far as supporting—BioShield supporting vaccine development, the limited numbers of vaccines available as tools is so few that this step must be taken to generate a spectrum of vaccines prioritized by risk assessment, which should be done first, second and third. Without that investment, I would say we would be derelict in our duties not to tell you that that needs to be done to protect the human population.

Ms. DUNN. Thank you very much, gentlemen. Thank you, Mr. Chairman.

Chairman COX. The gentlelady's timing is impeccable. You ran your time to precisely zero seconds.

The gentlelady from California, my colleague from Orange County, Ms. Sanchez.

Ms. SANCHEZ. Thank you, Mr. Chairman. It is nice to sit on a committee where the chairman is from Orange County.

Chairman COX. They should all be that way.

Ms. SANCHEZ. Well, if we turn to Congress around, I would get a chance. But, gentlemen, first of all, thank you for coming before us. And, you know, I am not—I will tell you—I'm am not an expert on this. Thank God you are scientists and I am not, but that is why we have you here. I guess I have a couple of directions of question that I have for you. And please feel free, any of you, to answer once I get through it.

You know, sitting on this committee our job, I think, is really to take a look at all of the threats to the American people here on our homeland, let's say, to try to figure out what is the tactical approach, what is it we need to take care of first? What is the long-term approach? What is it that will make us safer in the long run as an American public? It all comes down to, everybody comes to our door. Everybody wants money. Everybody has got an idea. Everybody has got something to protect.

Aside from the biological, we have all sorts of things happening, our borders, our ports, our airports, shoulder-to-air missiles to shoot down aircraft, what are we going to do with our nuclear power plants, our water, what about health crises, what about SARS in the United States? I mean, the list can go on and on and on.

My question is, first of all, the type of money that we are talking about to invest in these five known biological threats, is that really prudent in the sense that if I understand it, not only do they naturally change over time, sometimes short time, sometimes longer, but also couldn't terrorists genetically be changing them, all of the time with us, and how—how does trying to find a vaccination or antibiotic or whatever we would toward this, could we ever really keep up with what is going on?

And what about—I mean, why those five? Why are we taking a look at how they can affect our food, and you know why just people? I mean, I guess I am trying to ask you, is this really where we should be starting with these five?

Dr. FAUCI. These five are five of the six of the original, what we called, Category A Agents as determined by the CDC, which very closely mimics the high priority agents of the Department of Defense. And they are based on a number of criteria, with some degree of flexibility because it is empiric. And it has to do with known threat, known intelligence of nations such as the Soviet Union early on and Iraq and Iran and others that had the capability and were, in many respects, proven to have the capability to do that, as well as the ultimate impact, something that is easily made and easily disseminated like anthrax or something that is contagious and has a track record throughout civilization of wreaking havoc like smallpox, something that would strike terror in the population even if it were not efficiently spread, just the threat of having Ebola or the hemorrhagic fevers showing on CNN in our living rooms at night could disrupt our society greatly.

So it was a combination of known or suspected threat, efficiency of delivery and ultimate impact on the public health that brought things into the Category A Agents category.

Ms. SANCHEZ. But, Doctor, if we are telling the world that these are the five that we are researching and trying to find something for, wouldn't our opponents, whoever they may be, go off and start on something else that we are not taking a looking at?

Dr. FAUCI. Sure. You can never touch every base of the threat. But, there are some good bets that it makes sense to address for the reasons that I just gave you. To say that we are not going to cover every single option, therefore, we should not do our most likely, I don't think would be prudent. I think we should do the most likely, but be flexible enough to move for agents that could be genetically modified to circumvent the defenses that we already have. That is part of the program, is the degree of flexibility that would allow us to do that.

Ms. SANCHEZ. Yes, Doctor.

Dr. PETERS. A brief comment. These agents have sort of intrinsic properties that—the way they can become aerosol infectious or the way they spread and so on. When these properties are weighed, some of these are bad actors. And anthrax is a bad actor. And others are just not as bad. They are not as lethal, they have a higher dose, they are harder to grow, they are more difficult to work with and so on.

So I think the prioritization has been a very important issue. If we can take these off the table, I think we will be way ahead in terms of protecting against large numbers of casualties.

Ms. SANCHEZ. My second question is about, again comes back to these—I am actually thinking of these private companies, I guess they would be pharmaceutical companies. I am trying to think of where the profit incentive is. I mean if I am a company, I am a pharmaceutical company making the largest profits of any companies in the Nation by the way, and you know I am developing, and I am researching and developing, and we are actually giving them money to do this, which by the way, we do anyway because we give tax breaks and stuff for research and development, especially for pharmaceuticals, but the real payoff for these companies is to find a broad audience, and to actually be selling whatever it is that they come up with, that is the way that they make their profit.

Why would I taking my best and brightest and put them in a situation where they would be looking for the answers that you are looking for, only to not really have manufacturing base or to really have a base by which to sell it across, because hopefully we never use these. So where is the payoff to a pharmaceutical company to actually, even if we are paying for research and development to some extent, to actually put their best and brightest on this piece of work?

Dr. FAUCI. You have just articulated the rationale for Project BioShield, which is to create the incentives that they would not necessarily pursue because of the lack of the initiatives and the lack of the incentives that you just very well said.

Ms. SANCHEZ. So you have essentially articulated the fundamental rationale for why we need an incentive, a Project BioShield incentive, to get the industry to know that if they get involved, there will be a secure funding source to purchase their product, even if it is put in a stockpile. And the interactions, and you will hear from industry shortly, but in the interactions that I have had, a very common refrain or interaction would be, that they want to get involved, or they already are involved.

But, for them to go to the next step of the risk of investment on the part of the permission that they would need from their board of directors or from their stockholders to invest a considerable amount of money, they need assurances that if they are successful in developing a product, that their success would not be met with a lack of a commitment to buy that product.

So, in essence, that is the reason why Project BioShield was put forth.

Chairman COX. The gentlelady's time has expired. The gentleman from Kentucky, the Chairman of the Homeland Security Subcommittee on the Committee on Appropriations, Mr. Rogers.

Mr. ROGERS. Thank you, Mr. Chairman.

Dr. Fauci, let me address the last answer you just gave. How did we come up with this dollar figure of the amount of incentivization that the companies would need? I think it is what, $5 or $6 billion. How did we come up with that figure?

Dr. FAUCI. That was an estimate based on what we knew was already beginning to come into the pipeline, as well as our best scientific projection of what might be able to be pursued, either because a concept has already been established and proven, or we felt that the proof of concept was something that was imminently doable. All of those things, that is the point that I was trying to make

before, Mr. Rogers, that the number is a number that can be justified, based on the accounting of these five agents. But, depending upon the success or failure of these, as well as things that might, without our being able to predict, ultimately come up. And by predict, I mean either predict as a new threat, or predict as a scientific breakthrough, that that was the reason for the flexibility in saying that it could be less than that, or it could be more than that. But that was our best guesstimate based on our scientific information.

Mr. ROGERS. It would amount to about $900 million a year, if I am not incorrect?

Dr. FAUCI. The first year we estimated about $890 million in 2004.

Mr. ROGERS. Now, what is the size of the pharmaceutical industry in the country, in terms of annual sales?

Dr. FAUCI. Well, I don't think that I am qualified to give you an exact number. But you will soon hear from the pharmaceutical industry, who could give you a much more accurate number. But it is in billions and billions and billions.

Mr. ROGERS. It is hundreds of billions, is it not?

Dr. FAUCI. Yes.

Mr. ROGERS. So $800, $900 million a year is chicken feed, frankly, to this industry, is it not?

Dr. FAUCI. Well, I don't know if I would characterize it as chicken feed. I am not qualified to do economic cost accounting.

Mr. ROGERS. Isn't that a scientific term? But, nevertheless, the point I wanted to make was, the amount of money we are talking about here is not a huge amount of money in terms of the size of that industry.

Number two, you say in your statement with Project BioShield, quote, on Page 6, we would be able to tell these companies that if they partner with us, meet certain milestones, and devise a licensable countermeasure, they will have our assurances that there will be money available to them for the purchase of that product, end of quote.

That is not unlike the commitments that we make in any number of other governmental purchases, For example, or financing, for example, when we finance mass transit projects around the country, hundreds of billions of dollars worth. We do that by what is called full-funding grant agreements, where we sign, the Federal Government signs a contract with a local community on the funding amounts and process and procedures and the like. And then annually, we appropriate the funds to fulfill the commitments that we make under that multiyear commitment. Say it is 6 years, that full-funding grant agreement lasts for the full 6 years. We appropriate each year the annual installment for that contract.

What is different here? Why could that not work in this kind of a situation?

Dr. FAUCI. Well, sir, I certainly respect the analysis that you made about that. The experiences that we have had with what we would call the viscidities of the appropriation process, we feel, and this has been I think confirmed in discussions with the pharmaceutical companies, that although the intention of appropriating on a yearly basis might be there, there are many things that account

for the difference between an authorization and an actual appropriation.

The other issue is, that when funds are appropriated, there is, in some respects when the money is appropriated up there, as opposed to being available, that things can get earmarked—money might be spent for things that might not necessarily be the very, very best, whereas in this particular program that has been proposed, the company would get money for something that would ultimately be a deliverable product.

And the incentive, the incentive for them and again, sir, I say this with a great deal of respect for the process that you have gone through, the incentives to the company to rely on an appropriation process that we know from experience does not always proceed in a manner such that there are guarantees, that they will not necessarily be incentivized. And the whole rationale for the program is to get them involved in something that they may not otherwise be involved with.

Mr. ROGERS. I understand that. However, we have never failed to pass annual appropriations bills. And we have a Constitution that requires no moneys to be spent other than by an appropriation of the Congress. We frown very strongly on advance appropriations beyond our term of office.

We have too many programs now that are mandatory. It is slowly taking over the whole Federal budget. We only appropriate a third of the Federal budget now. So we have got to put some sort of a brake on the appropriations process which the Constitution guarantees.

Number two, those mass transit projects I talked to you about where we issue a full-funding grant agreement from the executive branch to the community to finance let's say a 6-year project, the community then goes out and sells bonds to finance the upfront money to build the project.

We pay off those bonds over the 6 years of that period with annual appropriations. We do the same thing with the FAA in building airports. They issue bonds to build the project. We pay off the bonds with appropriated moneys annually over the term of the contract. We are now doing the same thing with the modifications of airports to accommodate the new x-ray machines, it is hundreds of millions of dollars.

And the local authority will be selling bonds based on that commitment. I don't understand why if bonding companies and people that buy bonds on the market can't be—if they trust us to do what we say we will do by a written agreement, I don't understand why anybody else would want to question that. Have you got an answer for that one?

Dr. FAUCI. Well, I don't think there is a totally satisfactory answer to that. I might say, Mr. Rogers, again that we respect the rationale that you are putting forth on this. But, we realize, and the Administration realized that this is something extraordinary that we are asking for. But we believe that the circumstances within which we are asking this are extraordinary.

We often get asked a somewhat similar question of why not do it the way we do it when we make an authorization and ultimately an appropriation for things like battleships or different types of

bombers or what have you. And one of the—I wouldn't say arguments—but one of the rationales to counter that, is that people who make battleships and people who make airplanes don't really have any other arena to operate in than having the Federal Government be their customer.

We are trying to incentivize companies who really do not need us. We need them. That is the reason why we put that forth.

Mr. ROGERS. Well, I don't know whether Boeing would agree with you or not. Mr. Dicks might want to chime in on that one. But, Boeing I think sells commercial products other than to the U.S. Government as well as to the government. And yet, they are very anxious to get government contracts with no real assurance that the money is going to be there except by annual appropriations. Is that not correct?

Dr. FAUCI. I think the proportional relationship of the dependency of a company that makes aircraft carriers, their dependance on the Federal Government compared to an analogous situation of drug companies dependent upon vaccines or countermeasures that might not be used, I believe, sir, is a different story. They could just as easily go, and that is the reason why I put the slide up. Unfortunately, you all were out for a vote. When you look at all of the money that is made in vaccines, it equals one individual product that one drug company makes.

So that is getting back to the point that I was making with respect, sir, that they don't really need to make countermeasures for us. They can do just fine doing other things.

Mr. ROGERS. Perhaps we could, and I am finishing, Mr. Chairman, perhaps we could, as we do in the projects that I mentioned, issue bonds, sell them and get your money up front.

Dr. FAUCI. Thank you, sir.

Mr. ROGERS. Thank you, Mr. Chairman.

Chairman COX. Thank you.

I think it is very helpful to this process of the development of this legislation that the Homeland Security Chairman from the Appropriations Committee is also a member of this committee, and this discussion obviously needs to continue.

I next recognize the distinguished gentleman from the State of Washington, where TOPOFF II is still underway, Mr. Dicks.

Mr. DICKS. Well, thank you very much.

I appreciate your testimony. We are all trying to learn more about this subject. Chairman Rogers, of course, has the responsibility for the Homeland Security Subcommittee, newly created on the Appropriations Committee, and is the former Chairman of the Transportation Subcommittee.

Is it your understanding that—and the budget request that the President asked for, he wanted this—this would be an entitlement? In other words, he would have an open-ended source of funding that he can draw upon in order to pay for the work that is being done by the companies? Is that your understanding of it, Dr. Fauci?

Dr. FAUCI. Sir, I wouldn't call it an entitlement, because there are a lot of checks in that. First of all, money is not given for anything other than, essentially, a deliverable product, namely something that is ultimately licensed.

So it is not an entitlement for money to go somewhere without essentially knowing that you will get something for that. Also—

Mr. DICKS. But Medicare, and they are getting something for Medicare. They are getting something for Medicaid. Those are entitlements. We have to appropriate the amount that is actually utilized. And that makes it an entitlement. There are restrictions on all of those programs as well.

All I am trying to get to here, maybe this is the one of those situations where we may have to do that. I am waiting to hear all of the companies testify about their requirements.

And the idea is, that that is a better way to go than having the NIH, do these vaccines. And the reason for that is because you want to involve these private sector companies—you can't get there without having their expertise and their talent. It is just like the Defense Department. They can't build weapons systems. They have to go to the private sector to do that, because that is where the capability resides. Is that what you are basically saying?

Dr. FAUCI. What I am saying, sir, is that the NIH and other of the agencies of the government who do research, have an important role in feeding the basic concepts and the proof of concept that would allow you to ultimately make that transition into the advanced development of a product.

So there is clearly an important role of discretionary funding in that research arena that we already do now and have done since the beginning of the funding streams.

The point that I was trying to make is that we, for example, have a vaccine research center at the NIH that was originally developed for HIV/AIDS but now is getting involved in other arenas, which was part of the original mandate including biodefense.

What I am saying is that, that this is just one small component of the enormous capabilities that our pharmaceutical and biotech industry has. So we feel strongly that we need to embrace them and incentivize them, as opposed to trying to do it, essentially, all by ourselves. We want to be partners in it, but we don't want to exclude the enormous capabilities that these pharmaceutical companies have us to get us where we want to go.

Mr. DICKS. So the question is, how do you involve them? And how do you make it attractive for them to be involved?

Dr. FAUCI. Right. Well, I know you will get some good solid, well-thought-out answers from them.

But the way that we see it, sir, is that we show them that we have a secure funding source to be able to purchase their successes with them, and to share some of the risks, but make sure that they also take a risk.

We will pay for deliverable products if they do not have a true assurance that if they are successful, that someone will buy it. I have had CEOs tell me, we are not afraid of the risk of failure. What we are afraid of is the risk of succeeding and having no one assure us that they will buy the product.

Mr. DICKS. Let me ask you this hypothetical. Let's say you have got two companies doing something like a cure for anthrax. They are both incredibly positive ideas. They look good when they use animals for testing. And both of them are very attractive. At the end of the whole effort, one turns out to be just a whole lot better

than the other one. Are you going to pay for both of them? Are you going to compensate both of them, because both of them looked attractive enough to have entered into a contract, and then the one that is really good, you use that for a stockpile? How would you do that?

Dr. FAUCI. Well, again there are different scenarios. The one you gave, I am sure, could be modified defending upon the circumstances. But you would really pay essentially for the success, except if you contract for a certain amount of knowledge or even material that would get you here, the secondary and tertiary contract might ultimately get to one company, but you would pay the company for what it is they contributed to you.

Mr. DICKS. We do that in Defense a lot of times. We have two different companies do the R&D, and we get down and make a decision and procure one of the two products. But the company that did all of the work gets compensated. Would that help make this a better way of doing it? Or can that be done under the proposal?

Dr. FAUCI. That can be done under the proposal, if you look at it from a comprehensive standpoint of the fact that there are contracts for the actual procurement, which is what the specific issue that we are talking about. And there are research and development contracts that we get involved with now.

I can give you a real-life example of what we are trying to do right now with the recombinant protective antigen, anthrax, the second generation anthrax that we have R&D and ultimately some preadvanced and development contracts with a couple of companies. We are going to recompete the next RFP that would push us totally closer to procurement.

It is likely that one of those companies will be able to take it totally to procurement. But that doesn't mean that we are not, in our predevelopment contracts, paying the company to get us to the state of knowledge where we can then go to advanced development. But BioShield, as it is strictly laid out, will pay ultimately for the delivery of a product that can be used or put in our stockpile.

Mr. DICKS. Some people have looked at this proposal and say it is too timid. How do you react to that concern?

Dr. FAUCI. Well, I think it is an excellent start. If you don't take the ball guaranteed over the goal line, you can say it is too timid. You have to ask the question. There are constraints. We know that we need to live within a budget resolution. We have worked with members of this committee discussing that, although you would like to have X amount of money, the realties of a budget resolution would say that, in fact, you may not be able to spend over a certain amount in year 1 or year 5 or 10 year. So there are the realties of budget resolutions.

So if you were to say that you have an absolute, give me $20 billion and try and bring everyone in to do that, you probably can get some very good science and some good products. So, my answer to the people who say that this falls short is that we believe it is a very good start.

Mr. DICKS. Thank you.

Chairman COX. Thank you. The gentleman from Massachusetts for 8 minutes.

Mr. FRANK. Thank you, Mr. Chairman.

Let me just begin right there. I take it, Dr. Fauci, what you were telling Mr. Dicks is that if it weren't for budget constraints, you could spent more money usefully?

Dr. FAUCI. Well, yes and no, Mr. Frank.

Mr. FRANK. Yes, I understand. Explain no, please.

Dr. FAUCI. The reason, and it gets back to the question of mandatory versus discretionary appropriation, we feel that the incentive that we are talking about is the concept that if they come up with something that would work—

Mr. FRANK. So you have got enough as a starting point. The question is, you might need more later?

Dr. FAUCI. Right.

Mr. FRANK. By the way, on this little debate that you were having with the gentleman from Washington about whether entitlement means that you get something for nothing, that is really only true in agriculture. I just want to say that. That is where people are entitled to get something for nothing.

Chairman COX. Would the gentleman yield on my time?

Mr. FRANK. Yes.

Chairman COX. As you know, the Energy and Commerce Committee has marked up this bill. Both the Energy and Commerce Committee and this committee have an agreement with the White House now that we are not going to go the mandatory route.

So notwithstanding the importance of this discussion—

Mr. FRANK. I thank the gentleman. But can I ask you, you said this committee has an agreement. As a member of this committee, did I agree to that agreement? I am just wondering. What was the process by which this committee of which several of us are members agreed to the agreement?

Chairman COX. The leadership on both sides of the aisle were part of these discussions. But, of course, the member will have his opportunity during markup to—

Mr. FRANK. You mean—well, I mention that because that is the second question that I had. I was told that the representative from the Department of Homeland Security is not going to be here today. Is that accurate, Mr. Chairman?

Chairman COX. We have another panel next of industry, private industry.

Mr. FRANK. But there is nobody from the Department? We had someone listed from the Department of Homeland Security for that panel.

Chairman COX. That is correct.

Mr. FRANK. But he is not going to be here?

Chairman COX. These are science panels and commercial.

Mr. FRANK. Well, at least, maybe you weren't in on the agreement, because the listing, and, in fact, we have a statement from someone from what used to be FEMA, now Homeland Security, and I am told that he is not coming. I guess—here is the problem. I mean, we were talking about what happens if things get wiped out, et cetera.

At this point, I have got to be honest with you, I think if this committee got wiped out, nobody would notice. We are the Committee on Homeland Security. We are talking about legislation

which affects the Department of Homeland Security. We have a hearing with nobody from the Department of Homeland Security.

Chairman COX. If the gentleman would yield, this committee has already had such a hearing at which, I believe, the gentleman was not present, with the Department here.

Mr. FRANK. We had today—when was that hearing? I was at a hearing when we had a technical corrections hearing?

Chairman COX. No, this was a hearing on BioShield.

Mr. FRANK. When was that hearing?

Chairman COX. A couple of weeks ago.

Mr. FRANK. Was there a public hearing on BioShield? A subcommittee. Not being a member—that is why I wasn't at the hearing. But I do have—we were—I saw a statement in here from someone from the Department of Homeland Security. Maybe that directorate out in California ought to try to find him. Listen, the reason I say that is I had some questions, because the things that I am most concerned about, frankly, I am not a technical expert here, and I am not going to debate which paradigm is better for organizing the research. I am concerned about some of the local impacts.

And we have a statement from a Mr. Tolbert dated May 15th, 2003, which is today, and he isn't going to deliver that statement and can't be questioned about it. He is from the Department, about responsibility for a system that assists State and local governments.

I think we are doing a terrible job as the Federal Government in providing help to the State and local governments. I would have liked to have been able to talk about that.

Second, I do have a question about the legislation. I noticed that the Energy and Commerce Committee has already marked it up. Is there going to be a markup? Has it been recovered to this committee? Are we getting a sequential markup? What kind of markup?

I yield to Chairman.

Chairman COX. The markup will occur either next week or if we see the need for additional hearings after the break.

Mr. FRANK. So we are going to have a markup on this bill?

Chairman COX. Yes.

Mr. FRANK. Well, that is reassuring, because we had previously not—I was told by our staff—heard that.

Chairman COX. No, that is not correct. This committee has always intended to mark it up.

Mr. FRANK. Well, Mr. Chairman.

Chairman COX. That goes back to the very first—

Mr. FRANK. Excuse me, Mr. Chairman. I haven't yielded. You are supposed to enforce the rules. The fact is that we were told it hadn't been referred to us yet. And we inquired at the Parliamentarian's office, and we were told it hadn't been referred yet.

I am glad to know that, but I don't think we ought to be in the position of mind reading. I am glad to be reassured, but we had asked.

Chairman COX. The gentleman will suspend. The Chair will take the prerogative of—

Mr. FRANK. No. Under—point of order, Mr. Chairman. I don't recognize any right for you to order me to suspend on my time. Under what rule of the House is that appropriate?

Chairman COX. The gentleman will suspend. I am going to address the committee for a moment not on the gentleman's time.

This committee was asked, and both Mr. Turner and I were invited to the White House on Day 1 to discuss this legislation with the President, with the Secretary of Homeland Security, and with the Secretary of Health and Human Services.

The President and those Secretaries asked this committee to move this legislation on an urgent basis. We are doing everything that we can to accommodate that request.

But that has been in prospect since Day 1, and there has never been any question about that on either side of the aisle. I am sorry the gentleman had any mistake about it. And I yield back.

Mr. FRANK. Well, I disagree very sharply with that. I don't know when Day 1 was. I don't know what the holdup was. We have been in committee for several months and haven't done as much as we should. But I requested, today, information from the staff, was the—was the markup—was this going to come before us? Was it referred? I was told that the Parliamentarian said that it hadn't been referred to the committee yet. It wasn't clear that the Speaker was going to do that.

Now, the gentleman tells me, yes. But I can only go on the information that we were then given. If there was, in fact, a determination that it was going to be sent to us, apparently that information wasn't shared with the staff that asked about that.

I would also say, if we are going to mark it up, I am particularly troubled by the inability to get questions to Mr. Tolbert, because much of what we have here are problems about the adequacy of our interaction with State and local governments.

He says in the statement that he won't deliver, this system assists State and local governments by providing primary care, et cetera. It is to supplement State and local medical resources. I would be very interested as to what is involved with that. I don't know if, Dr. Fauci, is it something that you would know about? It doesn't come within your jurisdiction.

Dr. FAUCI. No, it doesn't. I am sorry, Mr. Frank.

Mr. FRANK. That seems to me a real hole in our ability to legislate on the subject. Let me just ask the other three witnesses then, because, obviously we have heard from Dr. Fauci representing the Administration's approach here, and I know there are alternative proposals. The ranking member read from Dr. Vagelos an alternative way to go about it. But within the framework that has been selected within this legislation, are there improvements, tweaks, changes you would make within this framework? I guess there is a broader question about a whole different framework, but within the framework that we are talking of here, I would ask any of the other three witnesses whether there are any specific proposals for changing in any way the financial system, the terms, the incentives, anybody have any proposals in that regard?

Dr. PETERS. I certainly don't have a proposal, but one of the things that Dr. Fauci has said that is implicit, but perhaps he has not made it explicit, is that vaccines making is not a guy in a white

coat who goes in a room and makes a vaccine. There are starts, failures. You make preliminary lots, you do testing. And the flexibility in this seems to me to be very advantageous. And being able to allow academia, small industry, NIH itself, to be able to make these starts and stops and have these failures and see the light at the end of the tunnel to go on.

Mr. FRANK. All right. I thank you for that.

Chairman COX. The gentleman's time has expired. I think the witnesses are free, however, to address the questions.

Dr. ADAMS. A point on scientific rigor in the process. And Dr. Fauci has implied that over and over is absolutely essential to produce the highest quality product possible.

And so the scientific rigor, while you might be building mass transit there is engineering rigor and we understand, but it is a bit more predictable than the biological systems that we are working in. And so the stop-start that Dr. Peters just mentioned, and the testing, coming back to animal testing, testing in test tubes and then in animals, that rigor has to be met to have a safe, effective product that can be used in mass populations.

And so, I think that scienctific rigor is a part that has to be upheld, and that is an absolute essential part of the BioShield Project.

Chairman COX. Thank you. The gentleman's time has expired.

The gentleman from Connecticut, Mr. Shays.

Mr. SHAYS. Thank you, Mr. Chairman. And I thank our panelists.

I have a sense that BioShield is basically to incentivize and accelerate research and development for vaccines and therapies, that is kind of what the—and I am—I would like the panel to tell me, how do we decide what vaccines and therapies we need? I would like to ask our three scientists not working for the government to walk us through that.

Dr. CRYSTAL. Well, Mr. Shays, one can prioritize based on two aspects. One is, what are the organisms, the pathogens that appear to be the most dangerous. That is the first. And the second are, what are the opportunities that we think that we have strategies that we can solve the problem.

And you can use those two priorities to make the list as to what you go after. So there may be a pathogen that is bad, but we have no idea, right now, how to go about it. And so it would not make sense to do anything other than basic research.

On the other hand, if you have a pathogen that is bad, but you have a strategy, you have to leverage the infrastructure of the pharmaceutical industry to be able to produce it so the public can access it.

Mr. SHAYS. Anyone else want to disagree with that or add to it or subtract from it? Dr. Peters.

Dr. PETERS. I think one of the important things is that this program be slanted towards civilian priorities. And I think in our current status of uncertainty as to what the threat is, this dictates that we not only look at vaccines, but we give an important look at drugs.

If you take, for example, the smallpox vaccine situation—

Mr. SHAYS. I think of drugs as being the therapies?

Dr. PETERS. Being therapies, especially anti-infectives, but possibly other ways to treat the condition that are not strictly anti-infectives.

Mr. SHAYS. Since this isn't a traditional marketplace, how do we know how much to order?

Dr. PETERS. We will have to make an estimate of the size of the event and the amount that we will need to treat, or at least to initiate treatment.

Mr. SHAYS. So we are basically having—it is basically—it is basically the concern of a human inducement of a disease, not a natural cause, primarily?

Dr. PETERS. Primarily.

Mr. SHAYS. So we have to understand the intent of the terrorist and the capability of the terrorist, and we also have to throw into that mix which things are—where we are most vulnerable, what can be the most fearsome and so on?

Dr. PETERS. Yes, sir.

Mr. SHAYS. How certain can we be of the shelf life of whatever vaccines we develop or therapies we develop?

Dr. PETERS. That will depend entirely on the chemical nature of the therapy or on the nature of the vaccines. We are still using smallpox vaccine that was made in the late 1970's.

Mr. SHAYS. How do we know what vaccines or therapies need financial inducement and which ones could technically be out there without needing to, you know, have the motivation of a profit margin in them? Are we saying there is none?

Dr. PETERS. Well, I think that the experience with emerging infections, is there is not a market that is big enough to drive any drug that is being developed for an emerging infection, up to and including Dengue Hemorrhagic Fever, in which there are hundreds of thousands cases every year in the third world.

So I think that almost all of this will have to be driven, it is my opinion, almost all of this will have to be driven by some other mode.

Mr. SHAYS. It doesn't just have to be Dr. Peters, but what I would love to understand is, will we—in my work in the National Security Subcommittee, I wrestle with this issue.

Do we publicize what we are going to be making, and let the world know that we have so much of this, or so much of that? And I think you can gather where I am going.

Dr. PETERS. Yes, sir. I think the exact nature of the stockpiles should be quiet. But, I think the nature of our society is that we have to publicize where we are going. That is the way science works, that is the way we get there, and we need the consent of the people to proceed in that direction.

Mr. SHAYS. The reason is, as you said, we would be prioritizing, because how many would we need if we needed everything?

Dr. PETERS. I am—

Mr. SHAYS. That is my point. The number would be large. So then we would prioritize. And then we have a list. And then the bottom line, and my time is up, but the bottom line is, they just do the one thing we don't have if they have any brains whatsoever.

Dr. PETERS. But I think, sir, that the—these bugs are of differential badness. They have different capabilities to kill large numbers of people.

Mr. SHAYS. Fair enough. So we do all of the bad ones, and we don't have to prioritize within that bad list. We do all the bad lists, and the terrorists know, so they have a choice of doing the bad list where we will have antedates, or they can do the not so bad list which we don't have an antidote.

Dr. PETERS. Yes, sir. To use an analogy. We are trying to get them down from a nuclear capability with anthrax, to cluster bombs with plague, and finally down to a car bomb.

Mr. SHAYS. Thank you.

Thank you, Mr. Chairman.

Chairman COX. Thank you very much.

The gentleman's time has expired. The gentlelady from New York.

Mrs. LOWEY. Thank you, Mr. Chairman.

Dr. Fauci, I would like to pursue an issue that was discussed previously, and you and I and Dr. Thompson, Secretary Thompson, have discussed this as well.

If BioShield is successful and new countermeasures are developed, the success of these projects will depend on a public health system's ability to distribute and deliver the serums to the general public in a timely, safe and orderly fashion.

Mrs. LOWEY. In the case of smallpox, the cost of vaccinating—roughly $200 per vaccination because of screening, testing, post-vaccination surveillance and treatment of adverse reaction—has been a significant impediment to the program. Thus, it seems to me the key to effective countermeasures depends on a lot of factors and costs other than buying these products and putting them in the strategic stockpile.

You mentioned before Secretary's Thompson commitment to putting—I think you mentioned $1.3 billion—and it happens to come from the Labor, Health, Human Services, Education Committee, but you and I know that basic health programs are really starved for cash for their core public health missions. In fact, there are a whole lot of reasons—the decrease in the reimbursement rate. So here we are asking them to take on greater responsibility in the terrorism preparedness area.

It seems from my perspective that we should seriously consider funding for our hospitals, for our public health network as part of our Project BioShield. I can remember a hearing we had in the committee with one of my colleagues sent a strong message to Secretary Thompson—I am not sure if you were there at the time—saying, now, remember, the money for homeland security cannot be taking the place of basic needs of hospitals, it seems to me, unless we have got to fund the basic needs of hospitals.

If someone is coming in—one of you gentlemen referred to cough. If someone is coming in, until they discern that it is SARS or it is something minor, they have to be prepared. In fact, the first tranche of money to the hospitals in New York State amounted to about $10,000 a hospital. Since then, more has come. As one hospital said to me in a meeting with all my chief financial officers, pay for a shower and my decontamination unit. They all have to

expand their emergency rooms. They are all cutting back on staffs. They are not prepared to handle this.

So my question is, do you believe this is an issue that should be seriously addressed in Project BioShield and not depend upon Secretary Thompson or anyone else pleading for an additional appropriation, or should we continue to fight about reimbursement rates for Medicare, or should we deal with this in Project BioShield?

Chairman COX. Would the gentlelady yield?

Mrs. LOWEY. I would be delighted.

Chairman COX. While you are all contemplating the best answer to that question, Dr. Crystal, I understand, needs to make an airplane. He alerted us early on that he needed to leave at 3:15. That time having approached, I wanted to excuse him and also give you the opportunity to leave us with final words if they are top of the mind. Either way, we are very pleased that you could join us today.

Dr. CRYSTAL. Thank you. I guess you are the closest congresswoman to where I live—

Mrs. LOWEY. And I am very grateful that you are here.

Dr. CRYSTAL. In response to your question, working in one of the large urban hospitals, I would love to see that, but that is response to these infections, and if we don't do something about preventing the patients from coming in, we will never solve it at the hospital level per se. We have to do both, but we have to do something in terms of preventing these kinds of attacks, and that is vaccines and therapies.

Mrs. LOWEY. Oh, I understand that. But is it realistic, given the knowledge that your hospital and others have shared with me—and I have met with many, many CFOs, CEOs of the hospitals. They are absolutely not prepared to deal with emergencies; and many of what may not seem like an emergency, if not handled correctly at their hospitals, could be an emergency.

If I remember correctly in talking to Sam Nunn of WTI and Peggy Hamburger, whom you know very well, the number that they gave me just this morning was, in World War I, 50 million people died of flu, more than any others dying of any other combat-related death.

So my question is, isn't this part of any solution? And if we are really going to fund BioShield at the rate that is requested to do the job, don't we have an obligation to consider delivery of services as part of that effort?

Dr. CRYSTAL. I can't comment as to what is best, but I agree absolutely with you that our hospitals are markedly underprepared for these kinds of problems.

Mrs. LOWEY. Thank you. Have a good flight.

Dr. CRYSTAL. Thank you.

Mrs. LOWEY. Dr. Fauci or any of the other gentlemen, one other question. We are living in a global world. I am not sure of the number, maybe a hundred million people enter somewhere between—I think I read 100, 200 million people enter the United States every year. People are travelling all over the world. Can this money—has this money or the prospect of this money served as an incentive? Are you in touch with others?

This is an international issue, an international crisis. Do you think that if we appropriate this money in an effective way the

President could be encouraging other nations who certainly will benefit—we are all in it together—to match the money or provide some important, significant dollars as well?

Dr. FAUCI. You asked two questions, Mrs. Lowey. The first one was, do I believe that the ability to shore up our capability of responding is important? It indeed is a very important issue. As you know, Project BioShield was formulated to expedite the process of the research concept development to the ultimate development and delivery of a product. That was the rationale for BioShield.

The addressing of the problem of our public health and hospital infrastructure is certainly a critical issue. Where that gets addressed, that is not for me to say, except to say that you put your finger on an important issue, our capacity to respond, which in fact is not what BioShield is about. BioShield is about getting the countermeasures that we need, which is part of the big picture of how we respond. One of them is the point that you made.

The other question that you mentioned is the international nature of it. I think if we incentivize the industry in this country, the pharmaceutical industry is also a global phenomenon, so there is no reason to believe that that won't, in fact, entice companies that are not just domestic companies but that have international interests. So we feel we will tap, if successful, the best of the pharmaceutical companies in a global fashion.

Mrs. LOWEY. Well, my time is probably up, but—

Chairman COX. It has indeed expired.

Mrs. LOWEY. Pardon me?

Chairman COX. It has indeed expired.

Mrs. LOWEY. I was thinking of other nations, not just of the pharmaceutical companies.

Dr. FAUCI. Well, I would hope so. I mean, we face the same issue in so many things where we take the initiative, because we have administrations—and the Congress have always been so supportive. We don't generally see that kind of support that we get from our own Congress from other countries; and, unfortunately, we have seen that with HIV/AIDS, where the vast majority of the burden of the funding, of the research, of the things that go into vaccine development are due to the generosity of our committees and our administrations who support it.

Mrs. LOWEY. To be continued, and thank you for your very important leadership.

Chairman COX. The gentleman from Massachusetts, Mr. Markey.

I would—before recognizing Mr. Markey, I would point out to all members we do have a second panel, and I leave it to you how you want to accumulate the time. It is entirely up to each member.

Mr. Markey is recognized for 8 minutes.

Mr. MARKEY. So if he wanted to, I could save it all for the second panel and then question Haseltine for 16 minutes.

Chairman COX. Thirteen minutes.

Mr. MARKEY. All right, 13 minutes for Bill Haseltine. No, I don't think I will do that.

How are you feeling down there, Dr. Peters?

Dr. PETERS. I am OK.

Mr. MARKEY. You can take a break, you know. If you want to go outside and—you know, you can come back in for a couple minutes.

Dr. PETERS. I think that would be helpful for—

Mr. MARKEY. Yeah. We can see that.

I am not going to ask Dr. Fauci all the questions, anyway.

So, first of all, we did mark up in the Energy and Commerce Committee today the bill; and, amongst other things, we changed it from an appropriations for an indefinite period of time, 5 years or 10 years—we don't do that even for the CIA or the FBI—to an authorization, so that it would have to compete for money each year and justify itself each year as a program, which I think is a good idea, and I am glad we were able to make that change.

Second, I was able to add in language that has a GAO evaluation of the various aspects of BioShield's effectiveness and to evaluate whether or not the money was spent well, which I think is important.

And, third, the committee did adopt my language, which instead of having no limit on what any outside expert could be paid and having an exemption to the Federal employee pay standards for anyone who would come in and consult and help us, I finally was able to, I think, persuade people that we should at least establish the limit as to salary of the President of the United States—although I would have preferred it to be your salary, Dr. Fauci, because there is no one who is going to consult with the government who is going to know more than you do. So for them to be paid two or three times as much as you get paid I think is in itself absurd, given the national importance, but nonetheless at least capping it at the President's salary is something that is a good start in terms of the overall legislation, but I do think we have to work on that even more.

The bill places no limits, however, Doctor, on what the companies can do with the countermeasures that they do develop with taxpayer money. So, for example, during this whole conflict with Iraq, we were afraid that they had developed a potent nerve gas vaccine which they could then immunize their troops so that they could use it against American troops.

So one of my concerns would be that we develop this series of vaccines at government expense and then the companies have no restrictions on which countries they can sell it to, which could then be used as a countermeasure against American forces. Do you think it makes sense that no company should be allowed to sell any of these vaccines to any country in the world that is on a terrorist list or any list that could endanger America without the express written consent of the U.S. Government?

Dr. FAUCI. Well, Mr. Markey, as a government witness, I don't think that I can speak authoritatively to represent the administration on this, but—except to say that it makes some common sense that if there is a countermeasure that is developed that might potentially ultimately lead to the harm of American citizens that you need to seriously consider how you can somehow put a process in place that would address that. So I essentially agree with the concept, but I am a little bit reluctant to make an official declaration of what administration policy would be on that.

Mr. MARKEY. Dr. Adams, does that make sense to you?

Dr. ADAMS. Well, it would make sense to me that any weapon that could be used against us shouldn't be given to our enemies, yes.

Mr. MARKEY. OK. Great. So North Korea, Iraq, Iran, do you agree a pharmaceutical company shouldn't in and of itself be able to make the decision to sell this vaccine then to those countries? I mean, in the absence of a smallpox breakout in their civilian population, which, of course, you know, would change the scenario, but, in the absence of that, you do agree that we shouldn't be selling this, that we shouldn't allow the pharmaceuticals to sell this stuff that can be used to protect their populations—

Dr. FAUCI. It makes sense.

Mr. MARKEY. Do you agree, Dr. Adams?

Dr. ADAMS. Yes, it makes sense. However, the products coming out of this will have global application for human health and well-being.

Mr. MARKEY. I appreciate all that, but I understand that in the hands of sociopathic leaders of countries that they actually view it a different way. I mean, a nuclear power plant that generates electricity in our country is viewed as a nuclear bomb factory in North Korea or Iran. So I don't know if we want to be selling nuclear power plants to North Korea or Iran. So that is my point. I do understand that.

Now, with regard to what the accountability should be—you know, when we engage a defense manufacturer in the process of making weapons we have very tight control over their books, access to their records to ensure that there is accountability. Now, do you believe that the same should now be true for pharmaceutical companies who are going to be enlisted in this effort in terms of our ability to have access to their books and records to guarantee the accountability so that we are not overpaying? Dr. Fauci.

Dr. FAUCI. Again, I hadn't seen that proposal before, since I was not—I didn't get the results of the markup this morning.

Mr. MARKEY. Oh, no, it is not in the bill. I am asking you, does that make sense to you that, given the fact that we are going to have this unprecedented government subsidy of an industry, that in all other industries, we do have—you know, we mandate access to the books and records so we can make sure that the government is not overpaying so that we get the best result for our dollar? Do you think that makes sense, that we ensure that the pharmaceutical companies give us the access to their books so that we can guarantee that there is no overpayment?

Dr. FAUCI. I think the fundamental principle of accountability for what the government pays for is something that I certainly would be in favor of. I hesitate to agree to issues in which I don't know the exact, specific details of access to books, because often I would say something, yes, you should, and then there is some technical issue that I did not consider because of my own lack of expertise.

But I would like to be able to be on the record to say that we certainly—if the Federal Government funds certain projects, that they should certainly be able to have the people who are the beneficiaries of the funding show responsibility and accountability to them.

Mr. MARKEY. Well, the pharmaceutical industry says that, on average, it costs about $800 million to develop a new drug. Is that what the U.S. Government should expect to spend for each one of the new antidotes that might be developed?

Dr. FAUCI. Approximately. But, again, Mr. Markey, when you talk about $500 million to $800 million, it sometimes is—the number is as high as that, is that that is the whole process from the proof of concept up through and including the advanced development and the production and the manufacture of it.

There will be other funding streams that will go into the process of the development of a countermeasure. For example, a lot of the discretionary money that we put into the research for the development of countermeasures will feed into what ultimately will be that. I am not so sure that the actual procurement of a particular product would be that $500 million. We feel when we calculated it that $500 million is a reasonable calculation on the part of the company. So if you are trying to figure out how much each would cost, that is not an unreasonable number to hold on to.

Mr. MARKEY. All right. You know, except for Jeff Skilling at Enron, most people think that $500 million is a lot of money to keep track of. That is why my question in terms of accountability and looking at the books are important, because, obviously, we are running huge deficits, maybe $500 billion this year in the U.S. Government. So we are going to have less and less flexibility as each year goes by, given the perhaps trillion dollar deficit we will have within another 5 to 8 years in the country here per year. So we have to get the maximum return, and as a result I think this accountability will be necessary.

Dr. FAUCI. When we let contracts typically, Mr. Markey, we build in accountability into that contract that we make.

Mr. MARKEY. Yeah. I—

Chairman COX. The gentleman's time has expired.

Mr. MARKEY. I thank you.

I just hope that the people who we bring in from the outside are as qualified as you are, Dr. Fauci; and I hope that would be the standard that we would establish if we are going to pay them twice what you get paid. Thank you.

Chairman COX. The gentlelady from Texas, Ms. Jackson-Lee, is recognized for 5 minutes.

Ms. JACKSON-LEE. Thank you very much, Mr. Chairman.

Out of a sense of humor, I thought I had heard 8 minutes, but I imagine—

Chairman COX. I was just checking to see if you made an opening statement, and I take it that you have.

Ms. JACKSON LEE. Next time I won't use those 30 seconds, but I thank you, Mr. Chairman, very much for the time, and the ranking member as well.

It is, I think, important to restate—this panel is obviously aware that this committee was appointed by the speaker and the leader of the House as an all-encompassing committee that includes expertise for many different of our jurisdictional committees, and I would expect and hope that in the course of our questioning that we do rise above—not just regard but do rise above some of the jurisdictional issues and really respond to what I hear often when I

travel around the Nation is the urgency that many Americans express in terms of their concern about what is transpiring, what is going on, what are we doing.

This hearing is particularly interesting in the backdrop of the 48-hour-ago tragedy in Saudi Arabia where we lost a number of Americans. I think we are fully aware of the fact that terrorism still very much exists, and it is very much alive. So I think this hearing couldn't be more timely, but I also am concerned about whether or not we are moving fast enough with the kind of respectful attention to detail that we should have.

I do want to acknowledge, if I might, two fellow Texans. Dr. Peters, we welcome you; and, Dr. Adams, we welcome you and are gratified that you are here; and, Dr. Fauci, we thank you very much for being here.

Let me just restate for the record what I understand the BioShield program to be—and that is that we can give NIH authorities to move quickly on research and development, on medical countermeasures. We know how thorough the NIH has typically been, and so that is to sort of jump-start and leap ahead to move us quickly.

The other is spending authority for the delivery of next-generation medical countermeasures, and that is, of course, the whole question of incentivizing or giving incentives to move people on quickly.

Then the other one is, of course, the FDA utilizing some form of emergency use authorization.

Might I just throw in a comment that everyone always remembers? I would be cautious on how we use fast-tracking, inasmuch as all of us either remember or have heard the history about the babies and the severe deformities that came about during the use of something that had not been so reviewed before the time that we were doing such, and so I know that we want to be cautious on that.

As I ask these questions, I am going to read them all off so that I can be mindful of the time. I want us to think not only of this mysterious concept of bioterrorism and mysterious diseases, and I want us to think of the impact of someone that is infected with tuberculosis going into a crowded school, someone who has SARS and going from one crowded place to another, as I understand the transmission there. These are familiar infectious diseases, SARS now becoming a household word, the ability of someone to take infected mosquitos and take them into an area and thereby putting in an epidemic of the West Nile.

So I would like us to realize that all of what may be dangerous or may be part of bioterrorism—and I may be reaching—may not be all of the unthought-of elements.

We have certainly begun immunizing on smallpox. We have heard that word over the centuries, but that has been considered one of the dangerous elements.

So let me quickly say to the panelists, the worst thing that could happen would be if we promised a billion dollars for a new vaccine and then find out in 5 years, for example, that nothing had happened. The whole idea of accountability when you go—and you talk about going into the private sector, how will we have that?

Also, if we implement the BioShield plan tomorrow, 6 months from now, how many companies do we predict would start new programs to develop such vaccines or drugs to combat bioterrorism? Where is the attractiveness, and why do we have to provide these incentives? As I started my opening remarks, why isn't it good to do just the right thing? And how many companies have already done—are involved in this business and already in the business will boost their programs?

Lastly, quickly, considering the relative lack of transparency in the private sector, how long will it take to realize that the mobilized industry is or is not getting the job done? Again, accountability. And considering that many pharmaceutical companies are publicly traded, do you expect them to be forthcoming about progress or the lack of progress?

I simply want to know, does it work or will it work? And I think that is our responsibility in this committee, is to look globally, not how many people we make happy but how many people we will help and whether or not it will work.

If you could begin, Dr. Fauci; and I would appreciate it very much.

Mr. Chairman, I ask your indulgence now for them to be able to answer that—

Chairman COX. By all means. The gentlelady's time has expired, but the panel may take as much time as you wish to answer those questions.

Ms. JACKSON LEE. Mr. Chairman, I am sorry. I may have been out of the room. Did you say we were going to mark this legislation up?

Chairman COX. Yes. We will have a markup on the legislation. The bill has not yet been introduced, which is one of the reasons that people—

Ms. JACKSON LEE. Thank you for enlightening me. I guess I was listening to someone saying that there had been a markup in another committee.

Chairman COX. There has been a markup in another committee; and, as I serve on that committee, I can report to you firsthand that even that bill had not been introduced at the time of the markup. It may well be introduced today.

Ms. JACKSON LEE. I thank you very much, Mr. Chairman. That shows how creative and forward-thinking we are in this body, and I hope that we will look forward to seeing that bill as it comes forward. Thank you.

Chairman COX. Would the gentlewoman yield?

Ms. JACKSON LEE. I would be happy to yield.

Chairman COX. In fact, yield to the time you don't have. The legislative language is available to all Members. It has been for some time.

Ms. JACKSON LEE. That would be helpful. Is it on our Web or—

Chairman COX. It is available by committee e-mail, yes.

Ms. JACKSON LEE. Great. We will make that happen. Thank you very much.

Dr. Fauci, if you would, and to the other two gentlemen, it is all about how it works and will it work.

Dr. FAUCI. You asked—and I will briefly answer three categories of questions.

What about other common diseases? We have a major emerging diseases program—a research program at the NIH that addresses things like tuberculosis, things like West Nile fever and things—ultimately, now we have a program that we are developing on SARS. We would consider these if, in fact, they fell under the category of being a threat to be used as bioterror agent and would have impact on our national security. They do not fall under the high categories for the reasons that were articulated by a number of us on the panel, particularly Dr. Peters. So although we are aware of them, they are not on our high priority, but we do address them in our emerging diseases program.

Second, how many companies? It is very difficult to tell. Right now, for example, there are four companies involved in vaccine research, just four entirely for the whole vaccine research—not research but vaccine development arena. We would like to get several more companies involved.

I can't give you the number. I would imagine it is not going to be a hundred, it is not going to be 50, but I think 15 to 20 companies involved, including Biotech and others, I would feel would be a very important step forward.

Also, the idea about accountability, the way the program has been proposed is that there will be some risk on the part of the companies, and I think you will hear some more about that when you discuss this with the pharmaceutical company panel, but Project BioShield as it now has been put forth would pay for a deliverable product. So there will be funds expended when the material of the product that has been contracted for is delivered.

Ms. JACKSON LEE. And not before?

Dr. FAUCI. There will likely be some modifications of some advances perhaps to get them going, but it is not going to be paid for something that would ultimately be an undeliverable product.

Ms. JACKSON LEE. Gentlemen, I am trying to get—if the two doctors could at least comment on how they think it might work in collaboration with the private sector and if you have one comment on using the less dangerous SARS in a dangerous way. I mean, someone could be infected and use it in a dangerous way.

Dr. PETERS. Well, I am not sure about the possibility of the SARS scenario, but one thing is important to recognize, is strengthening the public health infrastructure for bioterrorism strengthens it for SARS, for TB across the board, even though some of those resources will not be used on a daily basis for nonbioterror events.

Some of the issues that would revolve around a smallpox case introduced into this country would revolve around a SARS case introduced into this country. Isolation of the patient, quarantine, search for contacts, these types of things work with both of these agents. Hopefully, someday we will have a SARS vaccine and a smallpox vaccine, strategies which would then give us a basis for SARS vaccination strategies.

So I think that it is very important issues that we are not just working in isolation. Many of the agents that are bioterrorist agents are also natural threat agents. Smallpox, of course, is the exception, not existing as a natural disease. But we—to the extent

that we develop anti-infective vaccines and other treatments for these, they can be used in the Third World.

As a matter of fact, it is my contention that many of these will have to be tested overseas to assure safety and indeed, if they can find them, to assure efficacy, and indeed, if they can find a market, the usual market forces will dictate their use and determine their safety in an extended group of people who are actually at risk and who are not just chosen as experimental subjects. Thank you.

Chairman COX. I thank the panel. I thank the gentlelady. I am sorry.

Dr. ADAMS. No comment. These are both outside my area of expertise.

Chairman COX. The gentlelady from the Virgin Islands.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. I will try to be brief because several of my questions have been answered.

I want to say that, at the outset, I share the concern that was voiced by Congresswoman Lowey. Because what happened is we began the process not at the beginning, so we don't even have an overview of where the whole health piece is. We came in with BioShield. So a lot of the questions you are getting is because we don't have the whole picture, we don't know where our public health system is, the overall picture, so we are at a handicap.

I want to kind of follow up briefly, hopefully, on the issue, just using SARS as an example. We realize that we have been very lucky over in the United States, but had the Toronto experience happened here, if we had enacted Project BioShield, how would it have helped us to deal with a new disease coming in like SARS?

Dr. FAUCI. If you look at BioShield today—let's say we have an agreeable legislation that launches BioShield today and SARS came tomorrow. The impact of BioShield on how we handle SARS next week, the week after, the month after would be negligible, if not at all.

Mrs. CHRISTENSEN. And if it had been enacted 5 years before, say, and this was a new thing that we had never seen or heard of before.

Dr. FAUCI. Right. What Project BioShield does is the three things that Ms. Jackson had actually mentioned: expedite the research, develop secure funding capability and to make it available through, where appropriate, an emergency use.

That is to develop countermeasures against perceived or real threats. If something hits now, we are not going to be able to implement the BioShield mechanism to help us today, but what BioShield will do is it will create the incentives to get pharmaceutical companies involved in certain areas of development so that if we have an unknown attack on us that is delivered, it could be a SARS-like phenomenon, that we will be much better prepared to have countermeasures to hit the ground running.

The SARS—the response to SARS that you mentioned goes directly to our public health capability, and I think that is the point—

Mrs. CHRISTENSEN. That is the point—

Dr. FAUCI. That is exactly right, and that is the point that you are making, that we in this country did well for two reasons: One, we rapidly implemented infection control and public health meas-

ures; and I can tell you that we are much better off at it today because of the intensity of the effort that has been put in over the past year and a half following the anthrax attack on our awareness and ability to move rapidly to public health emergencies.

Mrs. CHRISTENSEN. But the disease doesn't really start here—

Dr. FAUCI. That is the point.

Mrs. CHRISTENSEN. It never got here. We—

Dr. FAUCI. Exactly.

My second point—if you will allow me, the second point is that we were pretty lucky, because we were a few days ahead of the curve. We knew what we needed to do with this new disease before it actually came here. Unfortunately, the people in Hong Kong and Vietnam did not know they were dealing with a disease that was transmissible the way it was and that—their health workers were vulnerable to it. So it was a combination of our rapidly moving but also being somewhat lucky.

Mrs. CHRISTENSEN. Can I just ask for clarification? At what point in that arrow do we start to pay the private sector out of that permanent, open-ended and definite authority?

Dr. FAUCI. Right from the advanced development till the actual procurement.

Mrs. CHRISTENSEN. Somewhere around the middle of that?

Dr. FAUCI. No, it is probably closer to the product. Because the concept to the preclinical, to the preadvance and then advanced development is probably closer to the advanced development and the actual procurement of the product.

Mrs. CHRISTENSEN. OK. Because just looking at one of the testimonies from PhRMA of 5,000 compound screen, 250 into preclinical testing. Will we be paying at the 5,000 or the 250?

Dr. FAUCI. No.

Mrs. CHRISTENSEN. Because out of that 250, maybe only one drug gets approved, and I realize we are talking about expedited approval, but—

Dr. FAUCI. Yeah. As I mentioned, essentially, on that, the monies that would come through for BioShield would be for the procurement of the product. Now, obviously—

Mrs. CHRISTENSEN. But there is some money to incentivize early on to even do the research, isn't there?

Dr. FAUCI. The research part of it on the far left of the slide, is what we do in discretionary research must be to prove the concept and get something into preclinical development. BioShield is talking about the far right-hand side, which is advanced development and procurement.

Mrs. CHRISTENSEN. One of the concerns, obviously, and I said it earlier, was this independent permanent contract authority and how do you actually price a fair contract without bidding? How do you decide—with not having bidding, this is going to be just going to a company that—the homeland security or—

Dr. FAUCI. No, there will be bidding.

Mrs. CHRISTENSEN. There will be bidding.

Dr. FAUCI. There will be bidding. For example, we will say that—or companies would come to us. It goes both ways. If we feel that we need to have a product, for example, to develop a monoclonal antibody for botulism toxin or, as you will hear from our industry

partners, other countermeasures, that we would put a request for a proposal to develop and deliver this product, and we would expect that hopefully we would have more than one company come in, because that would make the chances of getting to that goal line much greater.

Chairman COX. The gentlelady's time has expired.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

Chairman COX. The gentleman from Rhode Island, Mr. Langevin.

Mr. LANGEVIN. Thank you, Mr. Chairman; and I will probably have some additional questions that I would like to submit for the record, if that would be possible.

What I would like to ask are questions that might be a little more broad-based, and that is what do we as policymakers and perhaps even the executive branch need to know, what steps could be taken to better protect the population from either a bioattack or emerging pathogens that we are going to see come on the scene in the near future? Are there things that we should be more aware of, that we should be doing to better prepare ourselves and protect the population?

Dr. FAUCI. Well, yes, sir. As you know, some of these we have already discussed, but I will capsulize it very briefly.

It is a multi-facetted phenomenon. It is going to be one thing to do to cover all the bases, and it goes from everything—all we mentioned just a while ago to building up our public health infrastructure and capability to respond. That is one thing that we can do.

The other is a robust fundamental research base to feed into the concepts. As you know, the increase in biomedical research allocation to the NIH for biodefense in fiscal 2003 and continued into 2004 was the largest single increase in research endeavors in the history of the NIH in 1 year. So a robust research base. And now what we are trying to do with BioShield is to expedite the process, A, and, B, strongly create incentives for industry to partner with us so that we can use their considerable capabilities to ultimately develop the countermeasures. So it is public health, fundamental research and procurement.

Dr. PETERS. Dr. Fauci certainly reflects my views. I will leave these with you if you want to read more detail about the Institute of Medicine going into some of the factors of emergence.

Many of these are beyond my control. We can't control climate, development. Many of them are very contentious. Do we dam this river or not? And so I think it is a very complicated issue. If I may, I will leave these with you later.

Mr. LANGEVIN. Also, a second question, and my final one. About a year and a half ago, I held a forum back in my district on West Nile virus, and we had several experts come and testify as to what type of impact this was having on an area, what we could do to better protect our residents. And Dr. Bandy, who works in our Department of Health, suggested that we are going to see more and more of these types of pathogens coming on the scene that we need to protect ourselves from in the near future. And I just ask you if you could speculate about the types of things we need to be concerned about in the next ten years or so, where will we be, what type of timeline are we facing in terms of these various pathogens coming

on the scene that we need to be concerned about? How much time do we have, in other words, to prepare ourselves, as a best guess?

Dr. FAUCI. It is a continual dynamic, an infinite process. The relationship of emerging and reemerging microbes with the human species has been going on from the evolution of the human species and will be with us throughout the duration of the human species. We have the continuing emergence and re-emergence of microbes. Historically some of those have shaped civilization, like smallpox and measles. Some of them are little blips on the radar screen where they are interesting curiosities in their natural occurrence, but they don't have global health impact. Some of them do.

In the last century, in the 20th century, there were two major ones. One was the 1918 flu pandemic and the other was the HIV/AIDS epidemic. Right now in the 21st century, we have had some interesting forays into emerging and reemerging diseases. We have had the reemergence of West Nile Virus, because it was with us before, but it reemerged in an unusual location, namely the United States of America. And then we have had the emergence of a new disease that didn't exist before, namely SARS.

So the answer to your question, sir, is that this is a process that will continue. The best that we can do is to prepare ourselves by keeping our public health infrastructure able to respond at a public health level, and also create a robust research and development program that allows us to rapidly respond to these emerging diseases as, in fact, they do emerge.

Dr. PETERS. As a footnote to that very eloquent and complete statement, it is not just in the U.S. It is overseas. To the extent that we can deal with some of these issues overseas, enhanced surveillance and response overseas, then we are protected here.

Dr. ADAMS. I would like to also add on the point of surveillance and intelligence, modern diagnostics with large platforms to detect these before they become an issue is preemptive in nature, and that is something we need to be on the front end of as well as the vaccines and therapeutics, but the intelligence of what is going on in many places with modern diagnostic techniques will be essential for protecting ourselves.

Mr. LANGEVIN. Gentlemen, thank you for your time.

Chairman COX. I thank the panel. The gentleman's time has expired.

The gentleman from Florida Mr. Meek. I thank the gentleman from Florida and the gentleman from Rhode Island for your patience as well.

Mr. MEEK. Thank you, Mr. Chairman, and I want to thank all of our witnesses that are here today. I, too—I am from Miami, Florida, and I had a forum in my district and local health providers, first responders—I would like to—many of you are involved in front-line delivery or have some experience in it from reading your biographical information. A lot of our first responders are saying, especially with these exercises that we are having throughout the country—many of them are saying, well, that is fine what they are seeing on C–SPAN or the national news, but it is not necessarily reality if we were to see a full-scale bioexperience in our community.

As it relates to SARS and as it relates to other viruses that are moving around in our community, and as you know, terrorists, they look to economically cripple an economy, if they can, tourism, which is important to Florida and many other destinations in our country.

How do you feel as it relates to not only the vaccine movement but the communications with some of the front-line people that are not necessarily getting the message or the work that you are doing here or in your perspective locations towards bringing not only comfort but equipment, know-how, knowledge to them on the front line as it relates to health care workers?

Dr. FAUCI. As a Nation, we certainly have a ways to go to do that, and that is part of the multi-factorial and multi-facetted issue that I mentioned a little while ago with regard to emerging diseases there. The public health in the trenches infrastructure, the ability to be able to communicate with the citizens of this Nation in the case of an emergency, be it a naturally occurring or a deliberately perpetrated emergency is something that is a critical part of what we do, and we need to pay attention to that. That has been addressed and will continue to be addressed, because we are not where we want to be yet in part of the response to the biodefense initiative, which included the shoring up of the State and local health public capabilities as well as our communication capabilities.

So the point you make is right on.

Mr. MEEK. Well, let me just—furthermore, if I can—and maybe some—all of you want to chime in on this. They are very concerned not only in this field but also in the general application of homeland security. We have taken precautions in our water plants. Homeland Security has asked us to beef up security or buy a new filter or what have you, surveillance equipment, and as it relates to front line health providers, need it be in the hospital, need it be setting up an emergency triage situation in a bioterrorism situation, they feel that even though they are drilling, even though they are hearing a good game over television, they are not necessarily seeing it there. You say, yes we recollect do have a long way to go. I am asking you realistically, how long do you think it will take for us to get there, especially when it comes down to the training and—the training for those responders?

Dr. FAUCI. Again, if there is to be perfection, I don't think we will ever get there, but if there is getting better and better as opposed to staying static or getting worse, I think we are getting better and better. And I understand, because I too vat the local level have spoken to people who still feel that there is a lot of uncertainty. That is one of the reasons to have a TOPOFF II-like exercise as well as what the CDC is trying to do and is doing well, I think, over the past year and a half: partnering with the public health officials at the local and State level.

So we can't give total comfort and assurance that everything is going to get to where we want it to be very soon, but what we can say is that we are going in the right direction, and I think we can say that with some confidence.

Dr. ADAMS. I think the response in the—the exercises under way right now are where one really finds out where the deficiencies are,

and communication and education are certainly a big part of that. Within the organization, at the local level, all the way up to this level.

So I think education to the public may be one of the—the public itself may be one of the best weapons we have for the initial detection and initial reporting to public health authorities for the response.

I don't know how you find that out. In the first exercise we have done on foot and mouth in Brownsville, Texas, right on the tip, it was in Canada within the next day. The next exercise, much better, because of communications. And the next exercise even better than that. So there is hope for it, but will it ever be reduced to zero risk? No. But we can reduce it to a level where we can live with it and contain it and control it.

Mr. MEEK. Mr. Chairman, if I may, I understand that—I know what that is like in the perfect world, and I think we all know that, in all aspects, it is a reach to get there. The first responders, those individuals that will be—we know communications, communications as it relates to an incident, sometimes quarantine, sometimes paying attention to what you are doing so you don't want to spread, whatever the situation may be. That kind of training at the home front is very, very important. As we learn in these exercises that we are doing throughout the country and the one that is going on right now, the discussion amongst the first responders, they are saying when can we as a local community have that kind of exercise outside of what the sheriff is doing, what the police chief is doing, who may not have a great understanding as do all of you do on this panel of the—what needs to happen in a bioterrorism kind of situation.

So I will leave it at that in the interest of time. If any of you feel propelled that, the reason why I am glad that we are having this hearing here today, and I have rebooked my flight so that not only I would have a chance to be here to pose a question, but also hear the second panel.

Thank you, Mr. Chairman.

Chairman COX. The gentleman's time has expired.

Does anyone on the panel wish to address themselves to this?

Dr. PETERS. I hate to take up another minute, but let me just say there is such a dearth of microbiological understanding in the public and the press, that we I think are finding a real uphill battle. If we could get some kind of thorough briefing of reporters—and I work with this all the time—to get them up to a level where I can communicate to them in a relatively straightforward fashion, because when the balloon goes up, we are going to need a lot of help, and it will come mainly through the media.

Chairman COX. Well, I want to thank each of the members of the panel for contributing to a solution to that particular problem in your way today. You have shown both extraordinary patience and exceptional wisdom and good judgment. We appreciate your expertise that you shared with us today.

As you know in Congressional hearings we have essentially the opportunity for all members to ask questions. I think the reason that you have endured several hours here and the panel behind you as well, is that there is such member interest in this. This is

a very vital subject for our country, and so we appreciate very much your contribution.

I would like to dismiss this panel and welcome the next program. While our next panel is getting seated, I would like to thank my colleague Mr. Meek for rebooking his flight so that he could be here. Certainly, you are doing everything you can as a member of this committee to contribute, and we appreciate it.

Our second panel consists of representatives from the private sector, pharmaceutical and biotech industry experts who will be able to testify from the private sector point of view about some of the subjects that we have had under discussion this afternoon. I hope that this panel will be able to help us understand some of the factors that companies will consider when determining a line of research to pursue.

We have with us next Dr. William A. Haseltine, Chief Executive Officer of Human Genome Sciences; Alan A. Pemberton on behalf of the Pharmaceutical Research and Manufacturers of America, PhRMA; Robert J. Sutcliffe, Director, President and Chief Executive Officer of Digital Gene Technologies; and Frank M. Rapoport, a partner at McKenna, Long & Aldridge, who is an expert in public health procurement.

I very much appreciate the contribution that each of you have made in providing us your prepared testimony for today, the contribution that you have made in terms of your time and indeed the contribution that you have made by observing the first panel and being here with us here such a significant portion of the afternoon already.

Chairman COX. Without further delay, we will proceed from left to right, my left to right, with this panel.

Dr. Haseltine, your testimony, of course, has already been submitted for the record, and you have 5 minutes to summarize.

**STATEMENT OF WILLIAM A. HASELTINE, PHD, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, HUMAN GENOME SCIENCES, INC.**

Mr. HASELTINE. Thank you, Mr. Chairman.

Members of the Select Committee, thank you for the invitation to appear before you today on behalf of Human Genome Sciences.

My name is William A. Haseltine, and I am Chairman and Chief Executive Officer of Human Genome Sciences, the company I founded in 1992. Prior to that, I was a professor at the Dana-Farber Cancer Institute at Harvard Medical School and at the Harvard School of Public Health.

Human Genome Sciences is a biopharmaceutical company located in Rockville, Maryland that discovers, develops, and manufactures gene-based drugs to treat and cure disease. Currently we have eight drugs in human trials. The primary focus of Human Genome Sciences has not been the development of drugs to protect against attack by biological and chemical weapons. Nevertheless, just over 17 months ago, we realized that our company had the technology and capability to develop an effective near-term countermeasure against one of the Nation's most immediate and serious bioterrorism threats, anthrax.

As a company headquartered just outside Washington, D.C., we witnessed firsthand the potential devastating effects of the use of

anthrax as a terrorist weapon in 2001. Thus, while using private funds, Human Genome Sciences developed a fully human monoclonal antibody drug we call ABthrax that specifically binds a key anthrax toxin, thereby preventing or treating the lethal effects of the bacteria. The drug fills a gap that exists in our existing defenses against an anthrax attack and can be used alone or in conjunction with current vaccines and therapies.

In contrast to the anthrax vaccine, a single dose of ABthrax confers protection immediately. In contrast to antibiotics, the drug is effective against the lethal toxins released by the anthrax bacteria and may prevent and treat infections by antibiotic-resistant strains of anthrax, a subject you heard about earlier from the previous panel.

Moreover, the drug can be used both to prevent as well as to treat those exposed to anthrax. For example, ABthrax may be used to protect rescuers entering a contaminated building, soldiers in an infected environment or exposed individuals after an attack.

We have shown in animals that ABthrax is highly effective against many times the lethal dose of anthrax spores, and we are now ready to initiate human safety trials and to begin large-scale manufacture of the drug.

However, to move forward, we need commitment from the Federal Government to purchase the drug. With the necessary funding, ABthrax could be available for emergency use as early as the end of next year. A properly designed and implemented BioShield would provide the mechanism for this to happen.

Many companies have the capability and may be willing to develop new products to protect against attack by biological and chemical weapons. However, only a few firms such as Human Genome Sciences have actually already done so. The primary challenge we all face is the absence of a commercial market for such drugs. In most cases, the only viable market is the Federal Government and, potentially, the governments of our foreign allies.

Project BioShield, which aims to harness public and private resources, is an innovative effort to develop defenses against bioterror. It could create such a market.

While HES currently has—while HHS currently has the authority to purchase and stockpile drugs such as ABthrax, this specific framework created by Project BioShield would clarify and enhance that authority. A defined and transparent process with a clear path between threat evaluation, scientific validation and product procurement will go a long way toward giving companies the assurance they need to develop innovative new products to protect the public from chemical or biological attacks.

With respect to BioShield, I would like to urge the Select Committee to consider three broad points. First, in order to be as effective as possible, the program must be flexible. The vast differences between biological pathogens is mirrored by the diversity of potential treatments.

For example, small molecule drugs, such as Cipro, are manufactured by simple building blocks. In contrast, biologicals, such as ABthrax, are manufactured in genetically-engineered living organisms and require a process that is expensive, complex and time-consuming.

Thus, a one-size-fits-all procurement model will ultimately discourage the development of certain countermeasures. Project BioShield should provide not only for procurement of products that have already been developed, but also for late-stage development of promising drugs.

Second, Project BioShield should be an equal partnership between the Federal Government and those companies willing to commit their expertise and resources to defeat weapons of bioterror. A critical element of such partnership is the mutual willingness to take and share measured risks. Thus, provisions in BioShield legislation that allocate contract risk in an unbalanced manner could have a chilling effect on collaboration.

In particular, BioShield should provide for early funding of products in order to fairly allocate the risk between the parties.

Similarly, in the absence of a commercial market for drugs such as ABthrax, a permanent and secure source of funding is vital to encourage private investment. Pharmaceuticals and biological drugs in particular have enormous development costs that can only be recouped well into their procurement phase. Without guaranteed funding, companies will face substantial risks in development of these products and will likely choose instead to pursue other products.

The President's proposal for the creation of the funding authority will stimulate innovation, spur private investment and enable the government to purchase novel therapies without delay.

This brings me to my final point. Timing is critical. Agencies responsible for administering Project BioShield should take a proactive approach to identifying, evaluating and procuring effective drugs. Near-term delays in evaluating and securing the production of viable countermeasures can disproportionately prolong the procurement of such drugs.

In the case of ABthrax, Human Genome Sciences is ready to move the drug into production now, which will require significant investment to secure manufacturing facilities and to perfect the manufacturing process. Due to the demand for such specialized facilities, a delay of months now could postpone the delivery of a drug by over a year.

I thank you for this opportunity to testify and look forward to addressing your questions.

PREPARED STATEMENT OF WILLIAM A. HASELTINE, PHD

Mr. Chairman, members of the Select Committee, thank you for the invitation to appear before you today on behalf of Human Genome Sciences, Inc. My name is Dr. William Haseltine, and I am Chairman and Chief Executive Officer of Human Genome Sciences, which I founded in 1992. Prior to that, I was a professor at Dana-Farber Cancer Institute, Harvard Medical School and Harvard School of Public Health from 1976 to 1993.

Human Genome Sciences is a biopharmaceutical company located in Rockville, Maryland, that discovers, develops and manufactures gene-based drugs to treat and cure disease. Currently, we have eight drugs in clinical trials and a broad pipeline of preclinical compounds. These include novel human protein and antibody drugs discovered through our genomics-based research, as well as new, improved, long-acting versions of existing proteins created using our albumin fusion technology.

**ABthrax**

The primary focus of Human Genome Sciences has not been the development of drugs to protect against attack by biological and chemical weapons. Nevertheless,

just over seventeen months ago, we realized that our company had the technology and capability to develop an effective, near-term countermeasure against one of the nation's most immediate and serious bioterrorism threats—anthrax. As a company headquartered just outside Washington D.C., we witnessed first-hand the potentially devastating effects of the use of anthrax as a terrorist weapon in late 2001. Thus, using private funds, Human Genome Sciences developed a fully human monoclonal antibody drug—called ABthrax—that specifically binds to a key anthrax toxin, thereby preventing or treating the lethal effects of the bacteria.

The drug can be given prior to or after exposure; and it could be used alone or in conjunction with the current vaccine and antibiotics. We have shown, in animals, that ABthrax is effective against high doses of anthrax, and are now ready to begin manufacturing of this product and to initiate human safety trials. In order to move forward, however, we need a commitment from the Federal Government to purchase the drug. With proper funding, this product could be available for emergency use as early as the end of next year. A properly designed and implemented BioShield would provide the mechanism for this to happen.

Anthrax infection is caused by a spore-forming bacterium, Bacillus anthracis, which multiplies in the body and produces lethal toxins. Most anthrax fatalities are caused by the irreversible effects of the anthrax toxins. Research has shown that protective antigen is the key facilitator in the progression of anthrax infection at the cellular level.[1] After protective antigen and the other anthrax toxins are produced by the bacteria, protective antigen binds to the anthrax toxin receptor on cell surfaces and forms a protein-receptor complex that makes it possible for the anthrax toxins to enter the cells. ABthrax blocks the binding of protective antigen to cell surfaces and prevents the anthrax toxins from entering and killing the cells.

Currently, two options are available for the prevention or treatment of anthrax infections—a vaccine and antibiotics. Both are essential to dealing with anthrax, but both have limitations. The anthrax vaccine takes several weeks following the first doses before immunity is initially established. The vaccine also requires multiple injections over a period of eighteen months, in addition to annual boosters, to maintain its protective effect.[2] Antibiotics are effective in killing anthrax bacteria, but are not effective against the anthrax toxins once those toxins have been released into the blood. Antibiotics also may not be effective against antibiotic-resistant strains of anthrax.[3]

In ABthrax, Human Genome Sciences has discovered a third defense against anthrax infections. In contrast to the anthrax vaccine, a single dose of ABthrax confers protection immediately following the rapid achievement of appropriate blood levels of the antibody. In contrast to antibiotics, ABthrax is effective against the lethal toxins released by anthrax bacteria. It may also prevent and treat infections by antibiotic-resistant strains of anthrax.

Results from preclinical studies conducted to date demonstrate that a single dose of ABthrax administered prophylactically increases survival significantly in both rabbits and nonhuman primates exposed by inhaling many times the lethal dose of anthrax spores. In both models, we observed an absence of bacteria in the blood of all ABthrax-treated animals that survived. The rabbit and nonhuman primate models of inhalation anthrax are regarded as sufficient to demonstrate the efficacy of therapeutic and prophylactic agents in treating or preventing anthrax infection. A single dose of ABthrax also fully protected rats against a lethal challenge with the anthrax toxins. Full results of these studies will be disclosed in upcoming scientific meetings and publications as appropriate; they have already been shared with key government scientists.

Based on our preclinical results to date, we believe that ABthrax has the potential to be used both prophylactically and therapeutically. For example, ABthrax may be

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[1] Inglesby TV, O'Toole T, Henderson DA, et al. Anthrax as a Biological Weapon, 2002: Updated recommendations for Management. JAMA May, 2002. 287(17): 2236–2252

[2] The FDA-approved anthrax vaccine, known as Anthrax Vaccine Absorbed (AVA), is only administered to persons at high risk of exposure, like U.S. military personnel, but it is not recommended for the general population. BioPort, Inc. Anthrax Vaccine Adsorbed (BIOTHRAX??) Product Insert. Jan. 31, 2002. An improved version of the vaccine is currently under development, but its efficacy and suitability for civilian use are unknown, and it is not projected to be available until 2005 at the earliest.

[3] Bioengineered strains of anthrax that are resistant to multiple antibiotics, including Ciprofloxacin, have already been produced both domestically and overseas, and can be readily made using ordinary laboratory procedures. Friedlander A.M. Anthrax: clinical features, pathogenesis, and potential biological warfare threat. In: Remington J.S., Schwartz M.N., eds. Current clinical topics infections diseases. Vol. 20. Malden, Mass.: Blackwell Science, 2000:335–49. Brook et al. In vitro resistance of Bacillus anthracis Sterne to doxycycline, macrolides, and quinolones. Intl. J. Antimicrob. Agents. 2001; 18:559–562.

used to protect rescuers entering a contaminated building, soldiers in an infected environment, or exposed individuals after an attack. In addition, post-exposure treatment may lessen the natural progression of anthrax infection and increase survival. Human Genome Sciences plans to file an Investigational New Drug application in the near future, seeking clearance from the U.S. Food and Drug Administration (FDA) to begin clinical trials to evaluate the safety, tolerability, and pharmacology of ABthrax in healthy adults.

**Project BioShield**

Many companies have the capability and are willing to develop new products to protect against attack by biological and chemical weapons or other dangerous pathogens. A few firms, such as Human Genome Sciences, have already done so. The primary challenge we all face is the absence of a commercial market for such drugs. In most cases, the only viable market is the Federal Government and, potentially, our foreign allies.

Project BioShield, which aims to harness public and private resources in an innovative effort to develop defenses against bioterror, could potentially create such a market. While the Department of Health and Human Services currently has the authority to purchase and stockpile drugs such as ABthrax, the specific framework created by Project BioShield would clarify and enhance that authority. Indeed, overlapping jurisdictions between HHS and the Department of Homeland Security have complicated the picture, at least temporarily. A defined and transparent process—with a clear path between threat evaluation, scientific validation and product procurement—will go a long way toward giving companies the assurance they need to develop innovative new products to protect the public from chemical or biological attacks.

With respect to Project BioShield, I would urge to Select Committee to consider three broad points:

First, in order to be as effective as possible, the program must be flexible. President Bush recently stated that, "Project BioShield will give our scientific leaders greater authority and flexibility in decisions that may affect our security."[4] The vast differences between biological pathogens is mirrored by the diversity of potential treatments. For example, traditional small-molecule drugs, such as Ciprofloxacin, are manufactured from simple chemical building blocks or extracted from natural sources. In contrast, biologics such as ABthrax are manufactured in genetically engineered living organisms (bacteria or mammalian cells) and require a process that is more expensive, complex, and time consuming. The process of transitioning from an early-stage process to large-scale manufacture often can take anywhere from 12 to 16 months to complete. Thus, a (one size fits all( procurement model will ultimately discourage the development of certain countermeasures.[5] Project BioShield should provide not only for procurement of products that have already been developed, but also for late-stage development of promising drugs.

Second, Project BioShield should be an equal partnership between the Federal Government and those companies willing to commit their expertise and resources to defeat weapons of bioterror. As Secretary Tommy Thompson stated before the Select Committee's Subcommittee on Emergency Preparedness and Response:

"[Project BioShield] must be a public and private partnership. The pathway from idea to final product is complex. The best scientific approach to identifying the best drug and vaccine candidates must be based on laboratory studies. Testing must be performed in appropriate animal models to document safety and appropriate protective or treatment response, and to help determine dosing. Human studies must be carefully initiated to assure the basic safety of the product, and then appropriate dosing and response must be determined based on measurements of levels of drug or antibody predicted to have a protective effect. Steps must be taken to assure that the materials used to make the product and the final product itself can be manufactured safely, free of contaminants, and with reproducible and predictable purity, potency, and composition. Careful trials in humans, or where not possible, animal

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[4] Remarks by President George W. Bush on the BioShield Initiaitve (Feb. 3, 2003), at *http://www.whitehouse.gov/news/releses/2003/02/20030203–13.html.*

[5] Current versions of the Project BioShield authorizing legislation do not grant the Department of Health and Human Services the authority to engage in "other transactions" for R&D and prototype development, thereby limiting the agency's ability to engage in collaborative R&D arrangements. In contrast, the Department of Defense has such "other transactions" authority to make acquisitions through transactions other than contracts, grants or cooperative agreements, allowing the military to reap the benefits of research and development being done by non-defense contractors for commercial applications. The Department of Homeland Security was recently granted similar authority through the Homeland Security Act of 2002. See Pub. L. No. 107–296, 116 Stat. 2135, § 831 (2002)

models, must be performed to show that the product is safe and effective for the types of populations who might receive it and against the methods of infection or exposure that could be encountered. All of these steps require careful planning, experience, and ongoing management and scientific evaluation. Costs to develop and manufacture high quality biological products and perform and evaluate the needed animal and human studies are high. Grants and contract mechanisms may not always be sufficient or attract the most experienced manufacturers. Manufacturing capacity for biological products, particularly for vaccines, is not substantial. For all these reasons, the best possible support and public-private partnerships and teamwork are essential."[6]

A critical element of such a partnership is the mutual willingness to take and share measured risks. Thus, provisions in the BioShield legislation that allocate unfairly contract risk in a manner inconsistent with current Federal procurement policy and practice could have a chilling effect on collaboration with the private sector.[7] In particular, BioShield should provide for early funding of products in order to fairly allocate the risk between the parties.

Similarly, in the absence of a commercial market for drugs such as ABthrax, a permanent and secure source of funding is vital to encourage private investment in the development of medical countermeasures. Pharmaceuticals—and biologic drugs in particular—have enormous development costs that can only be recouped well into the procurement phase. Without guaranteed funding, companies will face substantial risk in developing these products and will likely choose instead to pursue more commercially viable projects. The President's proposal for the creation of a permanent indefinite funding authority will stimulate innovation, spur private investment, and enable the government to purchase novel therapies without delay.

This brings me to my final point: Timing is critical. Agencies responsible for administering Project BioShield should take a proactive approach to identifying, evaluating and procuring effective drugs. I applaud the Select Committee for acting expeditiously in considering the BioShield legislation and the Administration for making its enactment and implementation a priority. Near-term delays in evaluating and securing the production of viable countermeasures can disproportionately prolong the procurement such drugs. In the case of ABthrax, Human Genome Sciences is ready to move the drug into production, which will require significant investment to secure a manufacturing facility and perfect the manufacturing process. Due to the demand for such specialized facilities, a delay of months now could postpone delivery of the drug by over a year. We are also ready to begin clinical safety trials in humans, having already demonstrated the drug's efficacy.[8] To date, ABthrax has been developed entirely with private funds, but in order to move forward the company needs a commitment from the Federal Government to develop, manufacture and purchase the drug. With sufficient government support, Human Genome Sciences can begin producing significant quantities of ABthrax by the end of next year.

Thank you again for this opportunity to testify and I look forward to answering your questions.

Chairman COX. Thank you.

Mr. Pemberton, you are recognized for 5 minutes.

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[6] Statement by HHS Secretary Tommy G. Thompson on Project BioShield before the Committee on Energy and Commerce Subcommittee on Health and Committee on Homeland Security Subcommittee on Emergency Preparedness and Response (Mar. 27, 2003), at *http://www.hhs.gov/asl/testify/t030327.html.*

[7] Current versions of the Project BioShield authorizing legislation would preclude payment under a contract until delivery is made of a "substantial portion" of the product. In contrast, existing procurement laws and regulations provide for a variety of payment procedures that are negotiated by the parties based on the unique reqirements and risks of each contract. Similarly, the BioShield legislation permits the termination of a contract if a reasonable quantity of the product is not delivered within 3 years. In such a case, the contractor is not entitled to any payment.

[8] Under the Bioterrorism Act of 2002, the FDA specified the evidence required to demonstrate the efficacy of new drug and biological products used to counter biological agents, when traditional efficacy studies in humans are not feasible. Public Health Security And Bioterrorism Preparedness And Response Act Of 2002: Section 123. *http://www.fda.gov/oc/bioterrorism/PL107–188.html.* According to the guidelines set forth in the Act, successful studies in relevant animal models will be considered sufficient to establish efficacy for licensure and marketing approval. ABthrax is effective in preventing anthrax infection in two relevant models, rabbits and nonhuman primates. According to the guidelines, human clinical trials will be required to establish safety, tolerability, and pharmacology, but not efficacy.

**STATEMENT OF MR. ALAN PEMBERTON, PHARMACEUTICAL RESEARCH AND MANUFACTURES OF AMERICA**

Mr. PEMBERTON. Thank you, Mr. Chairman. Good afternoon members of the committee.

I am Alan Pemberton representing the Pharmaceutical Research and Manufacturers of America, PhRMA. I am a lawyer at the firm of Covington & Burling here in Washington, and I have been practicing government contracts law at the firm for 20 years. I head our firm's government contracts practice.

PhRMA appreciates the opportunity to share with this committee the views of the research-based pharmaceutical industry on the Project BioShield Initiative. We understand the seriousness of the threat of biological agents if used as weapons of war. At last count, PhRMA members were developing 256 new medicines for infectious diseases. The potential delivered use of infectious agents against targeted populations raises grave concerns. Numerous government reports make clear that a large number of countermeasures to bioterror agents must be developed.

PhRMA and its members are already working closely with Federal agencies and with academia on research about potential bioterror pathogens. A biosurveillance work group involving PhRMA, private companies, Federal agencies and the WHO is working to establish a global infectious disease surveillance network.

The President's BioShield Initiative is an important step to promote the timely and efficient development of modern effective countermeasures. We generally support the three main components of the President's proposal. One, permanent indefinite funding authority for purchase of countermeasures. Two, new authority for NIH to speed promising R&D through streamlined hiring and procurement mechanisms. And three, new FDA emergency use authorization for promising treatments still under development.

Any legislation to implement the President's initiative must take into account the significant technical and economic risks that will face companies that develop and produce bioterror countermeasures.

In addition to the normal uncertainties with commercial R&D and production, biothreat countermeasure research involves additional challenges, working with dangerous pathogens without a full picture of the risk of disease and without being able to test for efficacy in the normal manner because there may be no patients who currently have the disease.

Moreover, manufacturers that develop countermeasures may be exposed to potentially devastating product-liability suits. Private insurance could be unavailable or prohibitively expensive for such products.

In light of the special risks and obstacles of bioterrorism research and production, PhRMA has developed several legislative recommendations.

First, meaningful liability protection is essential. Provisions in current law, namely the SAFETY Act and the indemnification in Public Law 85–804, have too many uncertainties and may discourage participation by the industry. PhRMA supports liability protection modeled on either the Swine Flu legislation or the Homeland Security Act protections for smallpox vaccine manufacturers.

Second, the procurement process should be flexible and reliable and more like the private market. We have a number of suggestions in this regard. One, the Secretary of HHS should be given flexible "other transactions authority" similar to that given to the Department of Defense. The Homeland Security Act already gives such authority to DHS for other R&D, but not to countermeasure R&D through HHS.

Too, the legislation should recognize that contract pricing may take into account the actual cost of development, including costs incurred after contract execution.

Three, the Secretary should be permitted to enter into single contracts for both R&D and production.

Four, the Secretary should be able to purchase antibiotics and antiviral agents that have potential uses other than as countermeasures.

Five, the Secretary should be authorized to include performance based or milestone payments in procurement contracts.

Six, contracts should not be subject to termination for convenience or nondelivery within a fixed statutory period.

Seven, contracts should not be limited to countermeasures that can be developed within a fixed period of 5 years. We have been discussing these provisions with members of the administration and Congress, and we are hopeful they will be included in the final legislation.

Finally, within the model of competitive R&D, there may be instances where a narrowly tailored antitrust exemption would be appropriate in order to permit sharing of information among companies with careful government safeguards. America's pharmaceutical companies look forward to doing their part to protect the country against bioterror threats.

Thank you for your time, and I look forward to answering your questions.

PREPARED STATEMENT OF MR. ALAN PEMBERTON

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to share with this Committee the views of the research-based pharmaceutical industry on countering the bioterrorism threat and on the Project BioShield initiative.

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which invested an estimated $32 billion in 2002 in developing new medicines to help and heal patients. PhRMA member companies join others who are convinced that biological weapons present a serious and increasing danger to people around the world. The pharmaceutical industry is dedicated to the development of innovative therapies and vaccines to counter unmet medical needs. Because a substantial proportion of the unmet medical need in the United States and worldwide is both directly and indirectly related to infectious diseases, we understand the seriousness of the threat of biological agents if used as weapons of war.

The complexity of the problem of biological weapons is amply demonstrated by science's continuing difficulty in dealing with infectious agents as the cause of natural disease. The threat represented by infectious diseases—such as HIV, malaria, and tuberculosis—is real and all too well demonstrated by the deaths of over 5 million people annually from these three diseases alone. All together, infectious diseases claim more than 100,000 American lives each year and cost more than $30 billion annually in direct treatment expenses alone. At last count, PhRMA member companies were developing 256 new medicines to treat or prevent infectious diseases—medicines which include brand new classes of antibiotics, new vaccines (including edible vaccines), antifungals, antivirals, and immune enhancers.

Particularly in light of continuing difficulties in infectious agent research, the potential use of these agents in intentional concentrated exposures of targeted popu-

lations raises grave concerns. Reports from the National Academy of Sciences, the NIH Blue Ribbon Panel for Biodefense Research, and the US Defense Science Board make clear that a large number of countermeasures to biothreats must be developed. Indeed, existing medicines are not sufficient to combat the biological weapons already developed. Needed countermeasures will include vaccines, therapeutics, and diagnostics.

The basic science research required for countermeasure development has already been stimulated by funds appropriated to various Federal agencies including the Department of Health and Human Services and the Department of Defense. It is widely recognized, however, that a cooperative and collaborative research and development effort, which engages industry, government, and academia, will be essential to the development of a complete arsenal of countermeasures against bioterrorism agents.

PhRMA and its member companies are already working closely with Federal agencies and academia to move forward with this research. For example, PhRMA is working with CDC, DoD, NIH, FDA, and academia to support in vitro studies of five pathogens—B. anthracis (anthrax), Y. pestis (plague), Brucella spp. (brucellosis), F. tularensis (tularemia), and Burkholderia Spp. (Glanders)—for testing of existing antibiotics. Several companies are working with the National Institute of Allergy and Infectious Diseases (NIAID), the Department of Defense, and the FDA to test existing antibiotics against plague, and PhRMA will cosponsor a workshop with interested parties to determine how best to expand labeling of other existing antibiotics that may be effective against the top biothreat agents. PhRMA committees continue to work with FDA to clarify and improve existing regulations that pertain to biothreat countermeasure research, such as the "Spore Formers Rule," 21 C.F.R. Part 610, which imposes requirements on use of facilities or equipment that have been used with spore forming organisms, and the "Animal Rule," 21 C.F.R. § 314.610, which allows efficacy testing in animals where testing in humans would be impossible or unethical. We have prepared educational materials for the public on anthrax, smallpox, and vaccinia, and we are working on materials addressing tularemia and plague. Dr. Gail Cassell, PhRMA's Chief Scientific Officer for Emergency Preparedness and Vice President, Scientific Affairs at Eli Lilly & Co., sits on Secretary Thompson's Advisory Council on Public Health Preparedness. A Biosurveillance workgroup involving PhRMA, other private sector companies (TIGR, IBM, and Roche Diagnostics), Federal agencies (CDC, DoD, and NIH), and the World Health Organization is working to establish a global infectious disease electronic surveillance network.

Project BioShield, announced by President Bush in his 2003 State of the Union address, is an important step forward in the effort to ensure the development of modern, effective countermeasures and to ensure that these products become available in a timely and efficient manner. PhRMA generally supports the three main components of the President's proposal: first, the creation of a permanent indefinite funding authority to spur the development of medicines and vaccines by the private sector; second, new authority for NIH to speed promising R&D through streamlined hiring and procurement mechanisms and increased flexibility to award contracts and grants; and third, new FDA emergency use authorization for promising treatments still under development.

Any legislation to implement the President's initiative must—if it is to be successful—take into account the significant scientific, legal, and economic impediments to the research and development of biodefense products.

Research and development into new medicines is itself a lengthy, risky, and expensive endeavor. Bringing a drug from concept to market takes 10 to 15 years. The average cost to develop a new drug has grown from $138 million in 1975 to $802 million in 2000. The risks involved in the new drug development and approval process are substantial. Of every 5000 compounds screened, only 250 enter preclinical testing, and of every 250 drugs that enter preclinical testing, only one is approved by FDA. Only 3 of 10 marketed drugs produce revenues that match or exceed average R&D costs.

Moreover, research into biothreat countermeasures involves many challenges above and beyond those encountered in non-biodefense R&D. For example, biodefense R&D requires working with dangerous pathogens in highly specialized facilities, and developing countermeasures without a full picture of the risk of disease (because we cannot see into the mind of the terrorist) or the benefit of the treatment (because there are often no patients with the disease, which prevents clinical testing for efficacy).

The decision to divert resources from the research and development of medicines for serious illnesses like heart disease also can be financially risky, especially when a countermeasure may never be purchased or used, and especially for companies

with few products in the pipeline. (Diverting resources from research and development of these other medicines will also affect the future availability of treatments and cures for patients with other serious health conditions—especially since less than ten percent of all drugs that enter testing ever demonstrate sufficient safety and acceptable efficacy.)

Finally, manufacturers that develop countermeasures may be exposed to devastating product-liability suits. Some of these would arise out of adverse events that are unavoidable given the nature of the products, and some could arise simply because the products were made available without the usual battery of clinical trials required for FDA-approved products. Private insurance could be unavailable or prohibitively expensive for such products.

In light of the special obstacles to research and development in the bioterrorism context, PhRMA has developed recommendations for any legislation that would implement Project BioShield.

First, PhRMA believes that meaningful liability protection is an essential component of any legislation to encourage the development of bioterrorism countermeasures. Provisions in current law—namely the SAFETY Act, 6 U.S.C. §§ 441–444, and the indemnification available under Public Law 85–804—are associated with too many uncertainties, limitations, and conditions to make them effective in this unique context. Accordingly, PhRMA supports liability protection modeled on either the Swine Flu legislation or section 304 of the Homeland Security Act.

Second, in order to engage the private sector most efficiently and effectively in this research, the procurement process must be more flexible and reliable, and it must more closely resemble the private market. We have a number of suggestions in this regard, the most significant of which follow: (1) the Secretary of Health and Human Services should be given flexible "other transactions authority" similar to that given to the Department of Defense, particularly the Defense Advanced Research Projects Agency, under 10 U.S.C. § 2371; (2) the legislation should provide that procurement contracts may recognize that pricing should take into account the actual cost of development including costs incurred after contract execution; (3) it should expressly provide that the Secretary may enter into single contracts for both R&D and production; (4) it should permit the Secretary to purchase antibiotics and antiviral agents that have potential uses other than as countermeasures; (5) the Secretary should be authorized to include performance-based (milestone) payments in procurement contracts—rather than limited to repayable "advance payments" and payment conditioned on "substantial delivery"; (6) contracts should not be subject to termination at the convenience of the government or for non-delivery within a fixed statutory period; and (7) contracts should not be limited to countermeasures that can be developed within five years. We have been discussing these provisions with members of the Administration and members of Congress, and we look forward to continuing these discussions so as to work toward the inclusion of these provisions in the legislation.

Finally, although the overall model of bioterrorism countermeasure research and development should build on competition among private companies, the need for urgent development of medicines may require the sharing of information and cooperation among companies, which can raise antitrust concerns PhRMA therefore believes that it would be appropriate to provide a narrowly tailored antitrust exemption to facilitate certain meetings and activities, under careful governmental safeguards.

A strong commitment from all parties will be necessary in the months and years to come, as our nation seeks to protect itself against the terrible threats of biowarfare and bioterrorism. America's pharmaceutical companies look forward to doing our part.

We thank you for your time and look forward to answering your questions.

Chairman COX. Thank you very much. Mr. Rapoport, you have 5 minutes.

## STATEMENT OF MR. FRANK M. RAPOPORT, ESQUIRE PARTNER, McKENNA LONG & ALDRIDGE LLP

Mr. RAPOPORT. Mr. Chairman and members of the committee, it is an honor for me to testify with regard to Project BioShield, which we think is a superb start. We want to, however, offer four ideas if you are truly serious about jump-starting the creation of a new industry in America called the biodefense industry.

I appear before you today having represented 35 pharmaceutical companies in their dealings with the VA and the DOD, the largest hospital system in the world. I have also had the privilege of working on both the smallpox vaccine procurement out of CDC pre-9/11 based on Ken Alibek's information that we had pre-9/11, and more recently on NIH's anthrax procurement.

I am not going to be critical of NIH, but I want to point out that you must give procurement officials additional flexibility in trying to build this Department of Defense and Homeland Security biodefense industry. My four ideas that I offer are similar to my colleague next door who just gave you two or three of them, but I will just run through them quickly.

I am the president of a drug company. I am not interested in accepting R&D work from the Federal Government. I am not Lockheed, I am not Boeing. I don't want my books audited. I would rather do research to come up with the next Viagra or an antidepressant. Yes, I am patriotic, but I have shareholders. I will do business with you as the president of a large pharmaceutical company if you promise me if we build it, they come. If I am successful on the R&D under the same contract, and that is not what is crystal clear under BioShield, I want to be the one who does the production. I don't want to go through with what just happened in Dr. Fauci's anthrax procurement where you had the winning bidders were two very fine companies, but are not the companies that are one of the four large vaccine manufacturers. Why? Because the R&D was all that was offered in that contract. There was no production contract. In fact, any minute now the bid will come out of NIH for the production contract. It is going to be massive chaos and confusion about who owns the intellectual property under the original contract, whether the two contractors working on their own nickel get the R&D work and the proprietary data.

Second, in the same contract, you must allow the Secretary to make clear that corporate America has the worldwide intellectual property rights. I am going to share with you a story you have probably not heard elsewhere.

In Secretary Thompson's smallpox procurement, it was won by Acambis. Up to 250 million doses were allowed to be produced. There was an option clause for another 250 million doses. We asked the Secretary's people who is that for because there are only 300 million people in America and the answer we thought we got back was that the President wants to give away the vaccine that is developed under this contract to Tony Blair and his friends.

That may be a policy decision, but I am the president of the drug company, and I say, you have just destroyed my worldwide rights. I want to do business with you, I am willing to share my R&D costs, I don't want you to fund it all, as long as you give me the production contract, but don't negate my worldwide markets. I want to sell this same vaccine to the Japanese, the French and to the Brits.

We need to have a clear statement from Congress that the intellectual property rights will be respected. I don't have time to go through each, but that does not do it because right now the government could take the intellectual property rights of any of the contractors working under the cost contracts at NIH and give them to

Dr. Haseltine's company. I would argue that should not be done, but there must be clarity.

My second point, and I will echo the term "other transactions," which Mr. Pemberton referred to is a fancy way of saying don't make me adhere to all of the Federal acquisition regulations. Do a commercial deal with me, and then I will come forward and work on your behalf.

The Predator, which is an unmanned vehicle used in Afghanistan, was done on "other transactions."

Third, the Safety Act must be amended so that it applies to anything under BioShield. The protection the contractors get under the Safety Act is only triggered some say in the event of a terrorist attack. Dr. Haseltine is working on anthrax now. He should be able to have the protection of the Safety Act before that time.

Finally, I will leave with you one idea if you are clearly serious about jump-starting this industry. There is a law called the Defense Production Act. It is a very unusual law but allows the Secretary of the DOD to convene a meeting and put all of the bidders in one room, forget antitrust issues, and it can make allocations of market share and discussions between Merck and Human Genome. You can dispense with the bidding process and you jump-start the industry by using the Defense Production Act.

I will leave with you, if you care to have it in the record, an article which spells out how that is done.

[A copy of the article "Smallpox as a Biological Weapon", *JAMA*. June 9, 1999: Vol. 281. No. 22:, and the article "Plague as a Biological Wapon", *JAMA*, May 3, 2000, Vol. 283, No. 17, 2281, are maintained in the Committee files.]

Mr. RAPOPORT. Mr. Chairman, thank you very much for your time.

PREPARED STATEMENT OF MR. FRANK M. RAPOPORT

Mr. Chairman and members of the Committee, it is an honor for me to testify before you today regarding Project BioShield and how to jump-start the creation of a sustainable biodefense industry. Mr. Chairman, I applaud your immediate consideration of the steps necessary to incentivize the pharmaceutical and biotech industries to join as partners with the Department of Health and Human Services, the Department of Homeland Security and the Department of Defense to combat the evolving nature of agents of bioterrorism.

I appear before you today as a private attorney who has represented over thirty pharmaceuticals and biotechs in their contracting with the Department of Veterans Affairs, the Department of Defense, the Public Health Service, as well as directly representing companies in their individual bids to create a smallpox vaccine pre-9/11 from the CDC, a post-9/11 smallpox procurement by the Center for Disease Control and a recombinant protective antigen for anthrax issued by the National Institutes of Health.

Based on my view of how government agencies have operated in these procurements, as well as my intimate knowledge of what it will take to incentivize those to participate in a biodefense industry, I offer, with supporting analysis, four ideas for your immediate consideration.

1. Agency procurement officials should create for each needed drug and diagnostic a Master Agreement between a successful bidder(s) and HHS which identifies clearly who will pay or share in the research development phase of the agreement, clarify there is a linkage between successful R&D and a guaranteed production contract within the same Master Agreement, set forth the allocation of intellectual property rights including a private company's unfettered right to commercialize the product for worldwide sales, and that the Master Agreement will recognize payments sufficient to amortize investment, which would include return on capital and return of capital, particularly in the event of early termination should the needs of the agency be directed elsewhere due to changes in bioterror threats.

2. The procurement vehicle identified above as the Master Agreement should allow a Secretary to depart from the very stiff and burdensome Federal Acquisition Regulations which govern contracts, grants and cooperative agreements, and instead embrace "Other Transactions" which provide for commercial-like terms and conditions which are more likely to attract private industry, yet can also provide for protection of the Federal Treasury.

3. Provide a clear statement that participating industry will be protected from product liability law suits by invocation of Public Law 85–804 or direct statutory immunization. Since it appears that the Safety Act—which embraces the Government Contractor Defense—may be interpreted to apply on in the event of a terrorist attack—there should be a clarification that it, as well as Public Law 85–804, applies during the development and production phase of any counter measure under the Master Agreement.

4. Consider jump-starting the biodefense industry by seizing upon the express authority under the Defense Production Act ("DPA") of 1950, as amended to convene a meeting of all relevant companies competing for government contracts requesting the development and production of certain vaccines and counter measures for national defense purposes. Under such authority, the government may provide immunity from potential anti-trust liability to a company that participates in a process, the objective of which is to address issues of common concern to industry and the government. The government may, in exercising this authority, require a competitor to act in collaboration or share information that otherwise that could not be shared due to anti-trust laws and regulations.

I expand upon these four points below:

**I. Provide for Express Authority to Enter into a Single Agreement for Research, Development and Production, A/K/A, The Master Agreement**

We support strongly the need to provide for the possibility of the Federal Government entering into agreements (including contracts, grants, cooperative agreements, and "Other Transactions,") that permit a biodefense contractor to engage in research and development with the assurance of production under a single agreement. While this appears to be the intention of the BioShield legislation, the proposed legislation does not make this authority crystal clear. It is essential there exists a certainty that satisfactory completion of research and development will lead to a manufacturing agreement.

It is also my experience in order to stimulate private investment and biodefense counter measure research, development and production, private investors must be assured that they have the potential to receive a return on their investment, both in the price of the end product and in the event the government elects to terminate the agreement for its convenience. The proposed BioShield legislation does not account for the implications of using private investment to finance research, development, and production of biomedical counter measures.

I suggest language be included in the proposed legislation that permits the Secretary of Health and Human Services to enter into agreements that allow the end price of any biomedical counter measure to reflect the cost of private financing, including cost of capital and return on equity.

In addition, under the current Federal Acquisition Regulations ("FAR") when a contract is terminated for the convenience of the government, contractors may recover the cost of performance through the date of termination plus a reasonable profit on those costs in addition to settlement expenses associated with ceasing performance, negotiating termination liability, and disposing of equipment and materials. The terms vary slightly depending upon the specific language of the (Termination for Convenience( Clause used in the contract. However, one of the costs the FAR expressly prohibits—and one which very likely will apply to Project BioShield's contract—is capital financial cost.

Specifically, the program envisioned by the proposed BioShield legislation likely will be awarded via competitive negotiations. In such instances, the agency, here, HHS, negotiates proposals with one or more contractors. In such cases, the FAR expressly prohibits contractors from recovering as part of their contract price interest on borrowings (however represented) as well as cost of financing and refinance capital. See, FAR 31.205–20. Therefore, to recover return on equity costs and other capital financing arrangements, the existing regulations must be overridden.

In order to facilitate this change, I suggest language be included in the proposed legislation that requires the Secretary of Health and Human Services to include within an agreement a termination clause that requires costs of capital and return on equity to be included in any settlement in any event the government terminates the agreement for convenience.

Additionally, I propose that any Master Agreement[1] entered into between the government and the industry allocate clearly intellectual property rights. There is currently a problem, as discussed below, by reconciling the Bayh-Dole law with how the agencies have conducted their procurements for smallpox and anthrax.

In particular, the Bayh-Dole Act, in general, permits election by contractors to title of intellectual property made in performing federally funded R&D contracts. The government gets at a minimum a royalty free use called "government purpose license rights." The contractor's elections must include notification to the government of the invention, pursuant of the patent rights, or else the government has the right to march in and take over those rights or give them to a third-party. In a nutshell, the problem is that even in the event of a timely and successful election, the government's retention of government purpose license rights arguably allows the government to use these rights to meet "certain health and safety needs." It is unclear under this standard whether the intellectual property developed by one contract or could be given by the government to another for future R&D and production purposes in the event of a so-called health emergency.

An example of this confusion is found in both the recent smallpox and anthrax procurements. In the smallpox procurement for one hundred and fifty million doses, the successful bidder was to develop a new vaccine on a fixed-price per dose[2] It is unclear who will own the intellectual property rights for the newly developed vaccine.

Likewise, the anthrax procurement recently awarded by NIH was only for R&D (in two phases) and not production. Indeed, the solicitation issued April 22, 2002 provided that in the first phase (Phase One) (up to twelve months), the successful contractor was to develop a pilot lot and two thousand doses, as well as protocols for Phase One and Phase Two clinical trials. The contractor was also to produce a plan to produce twenty-five million doses. The contractors were to be notified that on or before the twelve-month period, HHS would convene a blue ribbon panel to select one or more of the Phase One contractors to be permitted to complete with government money clinical studies over the next six months, i.e., Phase Two. This was then to be an overall eighteen month development contract finishing in March 2004, eighteen months from the award date of September 2002.

Most interestingly, the RFP also stated that the production contract—not related to the R&D contract—would be assembled and put out for a bid by May 2003. It is certainly unclear how any intellectual property being developed over the eighteen month period from the award date of September 2002 through March 2004 will be allocated between the R&D contractor and those bidders interested in a production contract under a solicitation issued May 2003.

Based on the foregoing, the various Secretary should have the authority to "link" R&D with production so that there is certainty through this process. I am not suggesting—as discussed below under "Other Transactions"—that the government be the sole financier of the R&D phase, but instead announce clearly that the development of a successful counter measure will vest the contractor a long-term production contract (absent a change in "threat" "when a termination for convenience is appropriate). Indeed, the actual price of the items to be manufactured can be determined at the end of the R&D phase by negotiation in accordance with established government contracts procedures and other guidance negotiated in the initial contract award.

**II. OTHER TRANSACTIONS**

The term "other transactions" comes from legislation at 10 U.S.C. 2371 where Congress authorized DOD to enter into to "transactions... other than contracts, cooperative agreements and grants" to fund research and development efforts. It also covers efforts to develop "prototype" weapon systems under more recent legislation, namely Section 845 of the 1994 DOD authorization Act. Other transactions are viewed as being enormously helpful in expanding the field of companies that are willing to perform government contracts, specifically those companies that are predominately commercial like pharmaceuticals and biotech companies which are otherwise not willing to sign-up to the government's requirements regarding intellectual property, cost accounting, pricing and other circumstances which they consider unacceptable to the conduct for their business.

Under 10 U.S.C. 2371, the Department of Defense will pay no more than fifty percent of the total R&D costs, and this guideline could be used to allocate the respon-

[1] There is precedent for the term Master Agreement as by federal law pharmaceuticals which manufacture branded drugs enter into a Master Agreement with the Secretary of the VA to be eligible to participate in Medicaid and sales to the VA. 38 U.S.C. 8126.

[2] I note that fixed price development contracting has long been prohibited by Congress for DOD weapon system contacting and it appears the lesson has not been learned here.

sibility for R&D costs under the first phase of the Master Agreement. As stated previously, after the R&D phase, the government and industry can enter into a price determination for the cost of each production unit.

The added benefits of "other transactions" are that they depart from the very stiff Federal acquisition regulations which afford the government with almost unfettered discretion to terminate contracts, audit costs, eliminate foreign places of production, gain strong IP rights, and provide no indemnification. Under other transactions, several of these authorities could be minimized yet still give the government over the procurement. In particular, rather than terminating a contractor for default should it miss one deadline or determine the scope of the work is commercially impossible, the parties can agree to a termination at will that would allocate responsibility for costs incurred to date; also, the government can under other transactions minimize the amount of audit requiring review of contractors books and records; likewise, there could be a more clear allocation of intellectual property and patent rights than as provided under the Bayh-Dole Act now; and finally, Public Law 85–804 indemnification and coverage is clearly permitted under other transactions.

**III. PROVIDE FOR THE AUTHORITY TO INDEMNIFY AND/OR LIMIT THE EXTENT OF LIABILITY FOR ANY CONTRACTOR ENGAGING IN RESEARCH, DEVELOPMENT AND PRODUCTION IN BIO-DEFENSE COUNTERMEASURES**

The issue of the potential liability for any entity that provides, or performs research and development related to, biodefense countermeasures absolutely must be addressed in order to stimulate private sector interest in entering into agreements for such countermeasures. My experience was that the absence of liability protection was a major obstacle in the recent procurement for NIH for the development for the next generation anthrax vaccine, was a major obstacle in the pre-9/11 first CDC procurement for forty million doses of smallpox vaccine where the winning contractor was required to carry its own insurance, and continues to be a major hurdle today. Contractors will try to obtain commercial insurance, but the practical reality today is that it is unlikely to be available for these projects given their nature. The proposed legislation is silent with respect to addressing liability.

Both the Secretary of Health and Human Services and the Secretary of Homeland Security currently have the authority to provide for Federal indemnity to private entities engaging in research, development, and production of biomedical countermeasures under Public Law 85–804. However, use of such authorities are extremely rare. It is important to note that President Bush recently revised Executive Order 10, 789 governing use of the authority to provide for indemnity under Public Law 85–804. These revisions add two additional levels of coordination and approval for all agencies other than DOD before indemnification may be given to a contractor. I am also concerned that the use of the government contractor defense under the Safety Act only applies in the event of a terrorist act, and could be read to not apply to the development of vaccines and counter measures after 9/11 or until there is another similar incident.

Finally, while HHS is currently exercising its authority under Public Law 85–804 in very limited circumstances, it is my understanding the agency is not providing indemnity until a contract is awarded—and will not guarantee that the indemnity is forth coming as a part of the award process.

**IV. USE THE DEFENSE PRODUCTION ACT OF 1950 TO CONVENE A MEETING OF INTERESTED BIDDERS TO CONSIDER COLLABORATION AND ALLOCATION OF PROCUREMENT DOLLARS**

The DPA provides the government with authority to permit companies to enter into certain agreements that could include potential competitors and would have the effect of altering competitive behavior for the development of vaccines and countermeasures—activities which would otherwise violate anti-trust laws. Under the DPA, the government may convene a meeting with or some of the nation's vaccine and countermeasure manufacturers to discuss the government's procurement requirements. If the DPA statutory prescriptions are satisfied, the government's valid exercise of its DPA authority would provide complete protection against the operation of anti-trust laws for the private—entity participants in this process. Given the fifty or more bioterrorist agents identified by the Defense Science Board, it seems reasonable to consider using the Defense Production Act to stimulate and accelerate interest and investment by the new biodefense contractor.

Mr. Chairman, thank you for the opportunity to testify on this tremendously important issue. I will be pleased to respond to any questions from members of the Committee.

Chairman COX. Thank you. Mr. Sutcliffe, thank you for your written testimony. You have 5 minutes to summarize it.

**STATEMENT OF MR. ROBERT J. SUTCLIFFE, DIRECTOR, PRESIDENT AND CHIEF EXECUTIVE OFFICER, DIGITAL GENE TECHNOLOGIES, INC.**

Mr. SUTCLIFFE. Mr. Chairman, it is an honor for Digital Gene Technologies to be included on the panel, and to represent the hundreds of small, intensely science-driven biotech companies that are exploring the lessons which have been taught by the human genome.

It is also great to be on a panel with my friend Bill Haseltine, who has made a success of such a company but, more than that, was actually present at the creation of an entire scientific era that we now call genomics. And I think his insights from what it took to get from here to there are useful in trying to craft something that will take us through the next phase.

I have submitted my testimony and I come to this issue with a somewhat different background than most CEOs of biotech companies. I was a venture capital and corporate lawyer. Under the umbrella of no good deed going unpunished, I ended up running a client, and I think I have had an opportunity to look at the science from both ends.

I think the previous panel made some excellent points about the breadth and diversity of the risk that we face. They also made a point about the need for speed in responding. I think a number of the questions from the committee made it clear that the speed we are talking about on the customer side is a lot quicker than the speed we are talking about in developing particular antidotes to particular threats.

I think it also was clear from that discussion that a problem exists in the discussion about the customer and the market. It is clear that in connection with a number of these potential countermeasures the government is the customer in the future. But I don't think that means that there is any reason to suppose the government would not be a good customer. Our military may well be the user of some of these antidotes, and in the public health context a lot of them will only be used in situations that we would hope to prepare for but not need.

At the same time the market for some of the technologies that can answer this need can be very great, and I think it would be creating a perverse incentive for BioShield to immediately disqualify technologies that might actually have commercial promise as well as an answer for the government's own need.

In my submitted testimony, I actually make observations about three standards that we would hope the committee would apply in looking at something like BioShield and in biodefense generally.

The first relates to scientific merit. I think that you have heard an example today from Dr. Haseltine of a product that may well be both excellent science and an answer to something we have long needed. He and I have both, however, read a number of reports about failed biotech projects that are now being recast as bioterrorism defense projects, and as much as the need is great, we need to maintain the high scientific standards to make sure that we get an answer the public will accept.

Second, flexibility on two levels is important: Flexibility in the science that is pursued, and flexibility in the funding. Dr. Fauci

talked about the idea that the research element of biodefense is being taken care of as part of BioShield, but also as part of NIH's typical assignment.

Both Dr. Haseltine's solution and some of the research we have done at DGT to find new molecules that may more quickly and more accurately deliver pathogens and antigens to the immune system for response will come from basic research approaches rather than the development of specific antidotes to the known threats.

If we are going to get a handle on the threats that we can't predict exactly, it is going to have to be through the application of the science that particularly the biotech industry and the pharmaceutical industry have invested in over time.

I would suggest that the flexibility that is needed is flexibility in the kinds of solutions. Because we can only talk about five major known threats out of several hundred, it may well make greater sense, or at least equal sense, to look closely at the issue of delivery, absorption, how immunity is actually conferred on the recipient of a threat, and work on that angle such that our solutions and the results of the very considerable expenditure you are considering is something that can be used again and again to protect the patient rather than necessarily launch another development program.

Finally, accountability. I think that the original version of the BioShield proposal that was submitted suggests an opportunity to buy into a threat that we know, and yet what most of us are concerned about are the threats that we can't predict and can't know. There has been some good testimony about the potential for modification and mutation of the very agents we are worried about. So whatever program is adopted ought to continually reassess both the threat that we face as citizens and the response that industry is providing. I think the government stepping up to take its share of the market responsibility as customer will create any number of opportunities for the venture industry and our normal free capital markets to fund solutions as long as we are flexible and insist on scientific merit and keep both sides accountable.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF MR. ROBERT J. SUTCLIFFE

It is an honor for Digital Gene Technologies to be included on the panel today and in so doing to represent the hundreds of small, intensely science-driven biotechnology companies that are pursuing the newly-revealed lessons of the human genome in search of solutions to unmet medical needs.

It is also a pleasure to be in the distinguished company represented by my colleagues on this panel, including Dr. Bill Haseltine of Human Genome Sciences, who made a success of just such a science-driven company but also brings the insights of a researcher who was as they say (present at the creation(, and for whom the genomic science we take for granted today was just and truly a (vision(; I suspect his reflections on the blinding lights and blind alleys of that 30 year journey will be helpful to this committee's inquiry and to the proper structuring of a BioShield initiative.

The proposed BioShield program is an important and timely initiative, and I know each ofus on the panel approaches your inquiry as fellow Americans who share your alarm at the range of risks posed by the biological component of modern terrorism. As citizens it is our obligation to acknowledge those risks and also our much-less-than-perfect capacity to know their true dimension—let alone to answer them.

Only second do we approach your inquiry as industry participants and then—I believe—only to help determine which answers our industry can provide or contribute to, not which initiatives or decisions will benefit or burden some or all of us.

Indeed, our company, Digital Gene Technologies, approaches the issue of the Bio-Shield much like other Americans do: asking what we can do to help, based on what we know and do best. We are not a "biodefense" company nor do we focus our research specifically on "countermeasures". Our research platform has been developed and deployed over the past seven years to identify and characterize particular genes and groups of genes that explain the source and progress of human disease and suggest target points and pathways for medical intervention and cure. Our TOGA technology is unique in its capacity to simultaneously track all genes active in a cell and assess even the most subtle changes in their expression that might mark the onset of an affliction or a promising point for protective intervention.

In the course of our research, we have identified a number of previously unrecognized genes whose special function appears to be the constant surveillance of the human gut, lungs and nose for novel antigens—and the rapid delivery of those antigens to the immune systems for assessment and response.

These molecules, central to the human immune response mechanism, now may offer promising roles as direct transporters of new vaccines directly to the immune system, offering potential for more more robust and more reliable protections. As such, they may offer one—but only one of our future lines of defense to biological assault.

Interestingly, while these discoveries derive from research funded exclusively by a commercial partner with a commercial motive: the development of better delivery systems for oral and nasally administrable vaccines, the technology that made these discoveries possible—DGT's TOGA—Platform invented at The Scripps Research Institute in La Jolla—is the product of academic research funded by grants from the NIH, with additional basic research support from industry. Without both sources of funding, the technology—and these promising discoveries—might not exist.

Today, as you consider components of a national effort to combat bioterror, I'd like to suggest that three standards be scrupulously applied to scientific and monetary components alike regardless of the pressure, the fear, and the uncertainty that surround this threat.

Those three standards are MERIT, FLEXIBILITY, and ACCOUNTABILITY

Merit

The imperative of our defense must require merit in the science you fund and merit for the dollars delivered. It is axiomatic that medical need invites unworthy science parading as greater commitment.

Since September 11 we've seen too many failed projects retooled as "biodefense". Unworthy science wastes valuable resources and raises unrealistic and counterproductive hopes. The increase in funding contemplated for biodefense should not be an excuse for lowering of the threshold for peer review and peer respect. The prospect for this in a time of strained financing resources in the biotech industry should not be underestimated. Indeed the risk seems even greater if, as suggested, the absence of commercial viability becomes a positive qualification.

However, if the government—on behalf of its own use and the demands of the public—can speak for the existence of a market, the traditional combinationof peer-reviewed science and entrepreneurial financing represented in the venture markets ( should have no trouble promoting creative and prompt contributions whose scientific merit will insure their success.

Flexibility

The inherent unpredictability of the biological threats we face argues for maximum flexibility in the science we pursue and for flexibility in the funding mechanisms for biodefense you establish.

The potential for modification and mutation of threatening agents suggests we place emphasis on countermeasures that are adaptable and exchangeable. For example, focus on the mechanisms of absorption, resistance and immunity may provide us with a broader arsenal of useful protectants than would slavish pursuit of antidotes to individual agents whose creative modification or mutation could render our warehoused arsenal instantly obsolete. Similarly, research progress on speed and coverage of delivery of countermeasures may be a force multiplier for previously marginal defenses.

To support this flexibility of approach to the relevant science, an equally flexible allocation of biodefense dollars between basic research and product development may buy us more defense sooner.

Accountability

Finally, a word should be said about accountability.

For those of us who experience the scientific world as observers, its marvels include its constant reinvention, creativity and unscrupulous honesty about results. These marvels will also be our greatest assets in addressing the unknowable risks of tomorrow.

In structuring our national approach to biodefense, care should be taken to avoid creation of perverse incentives, absorption of an undue share of precious resources, or the diversion of creative scientific talent from its noble calling. Maintaining such a delicate balance will require supervision, continued reassessment of the threat as well as the effectiveness of the response, and a fair dose of candor, from scientists, government and industry alike.

As with any great effort, continued oversight of its goals and means will protect and preserve it.

With these observations in mind, I'd like to assure you that the people and the science of the biotechnology industry are ready for and capable of major contributions to the successful combat of bioterror: in articulating the range of risks, identifying the vulnerable targets, and generating an arsenal of countermeasures creatively broad and flexible enough to respond to the range of misapplied genius we will no doubt face in the years ahead.

Thirty years ago, the War on Cancer gave us a model of government stimulated science that has permitted measurable success against that scourge—but of even greater importance, that war trained a generation of research soldiers in new technologies and ways of thinking that are directly responsible for the leadership position U.S. science holds in the world and the capacity we've had to sustain and respond creatively to each new and horribly different health scourge of the intervening years.

Thoughtfully structured, funded and overseen, the BioShield initiative could again provide both immediate answers to a current threat and a new model for government stimulation of scientific progress that will insure our pursuit and perfection of technologies capable of meeting threats we can't yet know.

Thank you.

Chairman COX. Thank you, and I thank the entire panel. This panel has the benefit of having heard the first panel and the discussion that took place with members. As we write this BioShield legislation, we are concerned with the mechanisms for engaging the private sector. One of the ways that this might be accomplished, as Dr. Fauci outlined, is a contract relatively early in the process that anticipates work being done towards the achievement of a solution and then a commitment to purchase all that is necessary for the defense of the country in the event that a cure or an antidote is developed.

There are really two ways to go about this in principle. One is explicit contracts up front, the other is the reward model in which the government stands ready to buy what anyone successfully produces in answer to a generalized call to action. We send out the alarm, we need this, you provide it. Because we are going to be offering for this purpose, albeit in the billions a fixed amount of money, which direction you choose here matters significantly.

I wonder if I can ask each member of the panel to react to that point and help us with your suggestions about how to design this legislation.

First, Dr. Haseltine.

Mr. HASELTINE. Thank you. This is a very real issue for us because we are at that point where I as CEO have to make a decision as to whether to put a program on hold or to go forward with it based on our perception of what the reality is for government funding or potential funding. It is a very real issue. It is not a hypothetical for us.

I think it would be helpful if I gave the outlines for what that means. We did all of the R&D on our own based on years of research of understanding the anthrax vaccine organism to come up with a specific drug. As far as we can tell from discussions with HHS and DOD and others, this is a needed solution. This drug is

a very powerful addition to what already exists, and I think there is consensus that that is the case.

We are prepared to manufacture it for the first of two clinical trials. That is what is called the pharmacology phase. When it comes to finding a dedicated manufacturer for the second of the clinical trials and for the production phase, we cannot make that commitment absent a government commitment because it is simply too big. We have to go outside, find an outside manufacturer, compete on commercial terms for a long-term, multi-year contract to produce the material that will be needed to validate the safety of this particular drug. We are talking a minimum of $30 million the first year, 50 or $60 million the second year. Those are the numbers that we are talking about just to secure the facilities for the manufacturer. So it is vital how this legislation gets written.

It should support both the advance development and the procurement of that material because the material that is used for the advance development would actually be material that could also be stockpiled, in addition to the stockpile. It is very, very important to us how that decision gets made by your committee.

Chairman COX. Mr. Pemberton.

Mr. PEMBERTON. Mr. Chairman, I think it is important that the legislation as it develops be flexible because there are many different kinds of solutions and many different kinds of problems that are going to be addressed, and it is important that the Departments that are going to be actually applying and implementing this law will have as much flexibility as possible to see what works and to make sure that they have procurement mechanisms that they can respond to different sorts of industry needs and different sorts of industry problems.

That is why I think you want as the current bill has, it has an R&D portion, which I think is good. It also has a procurement portion. We believe it is important to tie the two together and to have a provision for the R&D to be linked to the ultimate procurement so that those who develop the original solution will naturally transition into production if that is desirable.

That will provide an additional incentive there to the R&D effort. It will be kind of both push and pull, as Dr. Fauci was saying.

It is important whatever mechanism is selected to maintain the maximum flexibility, but also maximum certainty for contractors in this area. It is extremely important to members of industry to know that the money will indeed be there when the process is done.

Chairman COX. Mr. Rapoport.

Mr. RAPOPORT. Mr. Chairman, I think we are very close. We just need to tweak the back portion of the BioShield bill to allow the Secretary to have authority not just to do procurement, but also have R&D money in there at the same time. We are very close. We have offered some language to a couple of other committees, and I have not seen the new draft that came out today from one of the committees, but we are very, very close.

The only other thing that I would also offer is Mr. Turner read a letter, and probably because I don't represent a pharmaceutical company I can be more candid and share what I have heard. Mr. Vagelos is one of the most respected people in the field. I can share

with you, though, that I think his views are not shared by the industry. They want a go at this as your partner. They do not want to have a government-owned, contractor-operated facility named a GOCO. They do not want to have a government think tank. They already have NIH, which is fantastic.

I think they are ready to come to the table with a little tweaking of the legislation, but they do not want some humongous government facility that is going to compete against them. Mr. Vagelos is so respected, but I am hearing that is not really right on message with the rest of the pharmaceutical industry.

Mr. SUTCLIFFE. Mr. Chairman, I think the issue that Dr. Haseltine raises about the initial production is a valid one and it is worth further investigation to ask whether it would be possible to finance that kind of risk in the private market on the reward basis, that there is a high reward left, and that will assume that the reward is still going to be high.

At the same time it would be disappointing I think to other companies attempting to solve the same problem to learn that the market actually had been foreclosed even for a better product. So the separation of the two, which was addressed in an earlier panel about what happens if the second best answer has the government contract, do we not get the first answer, do we get both or neither, I think the answer is we probably get the second because we have already identified that the major market is one that is controlled.

So I would think that the preservation of the reward opportunity would do a lot to spur private capital to invest in these kinds of projects.

At the same time, Dr. Haseltine is focused on an issue that is really pharmaceutical companies versus biotech companies. It is difficult for most biotech companies to imagine undertaking the kind of project that Dr. Haseltine has in mind, and his is not a small biotech company. He has been very successful at it. But still, I think, the pharmaceutical companies would have the resources to undertake that. So it would be worth investigating whether or not the reward model could in fact encourage private investment in the phase that Dr. Haseltine currently faces purely on a pot of gold at the end of the rainbow.

Chairman COX. I thank the panel for your help on that question. You have stimulated several more questions, but I will hold back and yield to the ranking member, Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman.

I think we all have the same objective here, and that is to figure out how to get the vaccines that we believe we need to address the threats that are there and get it quickly. I am not sure I have heard anybody say anything about the ability to accomplish this task in any given period of time.

Obviously the risks that we face in this endeavor is the same risk that the pharmaceutical industry faces in trying to develop product. Those risks, from what I understand, are greater in this field than any other. I think the reason we all have to be cautious about how we structure this is, number one, we want to be sure that we can assure the American people that the goal that we are after is going to be achieved. Number two, if we do it wrong, we obviously have the potential of wasting literally millions of tax-

payer money because we could, as I understand it, go down a lot of rabbit trails, spend a lot of money and get nothing.

I guess I was interested in the comment that was made a moment ago about the letter that I read because I think Dr. Vagelos had really not made any comment on this subject to my knowledge until we asked him to review the bill, which he did yesterday, and forwarded this letter to us today.

My fundamental question is, if we really are serious about getting this job done, what is wrong with trying to do it all? What is wrong with trying to do an incentive program in the form in which we have proposed, along with trying to mobilize a government research center, which we have plenty of examples of success with from our nuclear labs to our National Institutes of Health and others where we have successfully achieved some objectives by trying to mobilize the collective power of the Federal Government, to address the task? So explain to me why the two would be inconsistent with one another.

Dr. Haseltine?

Mr. HASELTINE. First of all, they are not inconsistent with one another. second, I don't think a special biodefense effort is required. I will give you two reasons for that. The first is you have generously funded NIH to do almost precisely what that government, super-government agency would propose to do; i.e. the broad scale research into new and emerging diseases. NIH has been very generously funded over the past 2 years, and it looks like it will continue to be funded. That research takes place at NIH and draws upon the very fine expertise in our best universities all over the country.

We are creating new generations of people who have the requisite expertise, and we are funding our current experts in that field. So many of the goals, and very laudable goals, are being met through the current biodefense initiatives.

I should say something we have not talked about is the admirable biodefense legislation that has already been enacted that does a number of very positive things for the creation of new biodefense agents, including allowing new pathways for rapid approval, speeding the time from concept to realization.

Let me give another example in a different field which I was deeply involved with as a university professor, and that was in the very early days of the AIDS epidemic trying to mobilize our government's efforts, as well as the private sector effort, to fight the problem of AIDS. That was done in a two-part program.

First, by generous funding from Congress of the NIH. Beginning in 1985, there was a steady ramp-up of funds. That money flowed first to NIH and then around the country and built a very powerful research organization. second, direct involvement of industry through transfer technology programs, not as big as the programs we are talking about here, but very definite transfer programs that led to the creation of the current generation of AIDS drugs.

Now there was one thing that allowed that to work which we don't have for many of these kinds of drugs, and that is there was a natural market for the AIDS drugs so we didn't need special government incentives.

Here we need that. But if you take the power of what exists at NIH, which you have already generously funded, and couple that to the power of industry, which is what BioShield can do, I think you will have achieved almost all if not all of the objectives that have been laid out.

Mr. TURNER. With regard to where you are in your efforts with anthrax, Dr. Haseltine, and to put it in context for me, I was reading Dr. Pemberton's statement about the risks involved in new drug development, and he said for every 5,000 compounds screened only 250 enter preclinical testing, and of every 250 drugs that enter preclinical testing, only one is approved by the FDA. Where are you in that chain with your anthrax product?

Mr. HASELTINE. We are down to 1 in 10. Probably even higher.

One of the things that biodefense did for us is it set a clear definition of what was required for approval. You have to demonstrate efficacy in two animal models of human disease. Our drug has already met that. You then have to test it for safety in human volunteers. That is what we are about to do. We are about to submit our drug to the FDA for safety testing. We presume, because we have done it many times before, that we will meet all of the government criteria, all of the FDA criteria, to allow us to do the safety testing.

Let me give one additional concern which has not yet been raised, but it is very important at an early stage. When you submit a drug for testing, it not only is reviewed by the FDA, it is reviewed by institutional review boards for ethical considerations. We are talking about exposing healthy people to a drug. Is it ethical to expose people to a drug for which there will never be a market? That is a question we are wrestling with today. Can we in all conscience go ahead with our phase 1 clinical trials before we get a green light from the government saying if you make it, we will buy it. That is an issue that has not been addressed, and it is why for some drugs it is really important to link the two, the advanced development and the procurement. I think my colleague to my left said it very well when he said what we need is flexibility.

Mr. TURNER. You gave us some numbers a minute ago. You mentioned to proceed from where you are you would need $30 million this year and $50 million next year. When you give those numbers, are you saying that is what you need from the Federal Government?

Mr. HASELTINE. That is what we need from the Federal Government. I would estimate in direct dollars we have invested about $15 million, and if you add in our facilities another $15 million, so a total of about $30 million we have already invested in this.

Mr. TURNER. At the end of that 2-year period, where are we then with regard to this project?

Mr. HASELTINE. You have approximately 150,000 doses or more stockpiled, perhaps more. I would have to check the numbers; but you already have a stockpile.

Mr. TURNER. So as part of that investment in the second year in production facilities, is that what—

Mr. HASELTINE. Even in the first year you are making materials that could be stockpiled. Both first and second year, the material you make could be stockpiled.

Mr. TURNER. So a large portion of the $80 million relates to production?

Mr. HASELTINE. Absolutely. It all relates to production. Some is technology transfer so it can be produced, and the rest is for production itself.

Mr. TURNER. When we are talking about production, are we talking about building a plant or facility?

Mr. HASELTINE. We are talking about contracting an existing plant that is already approved so we can get this product moving forward quickly. Eventually we would talk about building our own plant.

Mr. TURNER. That is after the $80 million?

Mr. HASELTINE. Yes. This would be a multi-year stockpile, and over time since the drug is relatively stable, we would build up a larger and larger stockpile over time.

Mr. TURNER. At what point in the expenditure of $80 millionp In other words, we could spend the $80 million and end up not achieving anything, or would you know that sooner?

Mr. HASELTINE. You would know it sooner. We have two efficacy trials, and the next trial is a safety trial. You will know after the safety trial whether you have something that is suitable for stockpile.

Mr. TURNER. How many million would that cost to get us to the point where we know whether we have a winner or not?

Mr. HASELTINE. About $30 million.

Mr. TURNER. If our intent is to have a program to develop, and the initial number I heard was 5 vaccines for various biological agents, then we might move to 10 or 12 and I heard somebody say there may be a hundred out there we need to be prepared for, is there any way the government can achieve some cost savings if we are going to make this investment in production facilities? You are going to lease a facility initially, but eventually you would want to build one, and since the bulk of these dollars are in production facilities, is there any way the government can say OK, we will do this and build such a facility, but then we want it to be able to be used for the next pharmaceutical company that we enter into an agreement with to produce something else?

Mr. HASELTINE. I would imagine that for most of these products you will have an ongoing stockpile requirement, and although these drugs may have a long shelf-life, it will not be indefinite so there would be a requirement for renewal. So at some point you will need dedicated facilities for manufacture of that drug for continual stockpile. There are such programs that currently exist for stockpile of certain materials today.

The simple answer is that I don't think that is a model that will work particularly well.

Mr. TURNER. In other words, you are thinking that for these vaccines that we hope over time to stockpile, that we would need for each vaccine to have a separate manufacturing production facility in order to accomplish that?

Mr. HASELTINE. I think the answer is more complicated than that, but to the first approximation, that is the answer.

Mr. TURNER. Maybe you can educate me a little more on that, but I am not sure I quite understand the logic of why a production

facility which in the private sector apparently is used for multiple production runs—I guess because you are initially going to lease one from somebody else—why that kind of facility could not be used for the production of more than one vaccine.

Mr. HASELTINE. It really depends on the size of the facility, it depends upon the materials that you are producing. For biologicals, it is very different from chemicals. A biological, which is a protein or antibody, which many of these products will be, you have dedicated manufacturing facilities for them, especially once you have an ongoing, recurrent need.

Let me just emphasize the dollars that I mentioned do not buy hardware. They are solely production costs. That is what these dollars are. They are not to buy and build factories.

Mr. TURNER. Mr. Rapoport, I think your comment earlier in response to Dr. Vagelos' suggestion was that you did not want the government to be in the business of having another agency to try to help solve this problem. Dr. Haseltine said those two approaches are not inconsistent. Do you believe they are inconsistent?

Mr. RAPOPORT. What I think the industry is concerned about is engaging down a slippery slope which ends up with the government taking over this business.

Again, these are not companies that have ever taken a cent of government R&D money. They are not Lockheed or Boeing. I think they want to keep a separateness working as partnerships, but they do not want to see their resources be drained off into a time and period down the road, and maybe we are getting ahead of ourselves, where the government says I can take over that business, you know. How about hepatitis A, hepatitis B, we have a platform now to take it all over. That was the only caution I was making. So perhaps they are not totally inconsistent that you would add to NIH's already sensational capabilities.

But I also wanted to share what happens if we go down this route and there is failure. I worked for the Reagan Justice Department, and I was assigned to represent the NIH. They are very skilled at handling contractors and terminating contracts that are not going anywhere. In this industry, you probably have to be a little more gentle than you would with a Boeing or Lockheed who does not perform and they are used to getting terminated for default. Here the government could terminate for convenience a contract where they have promised production contracts where the company simply wasn't getting there, or that solution wasn't the right solution any more.

But the point I want to leave with you is if you terminate those contracts for convenience, you have to recognize additional costs that are now unallowable such as financing costs and equity, costs of equity. So BioShield, one of the pieces we are trying to suggest is give the government the contracting officers' discretion. They are going to protect your purse, but make sure if they have to stop the deal in the middle of the procurement, they reimburse companies, not just for the widget to date or how far they have gone, but for a lot of their investor costs that traditionally would not be allowable under the FAR.

I have heard that the venture capitalists who obviously, look at the stock of biotechs now, it is very low. But the venture capital-

ists, and Leighton Read, who was the founder of Aviron testified before other committees that they are ready to participate and help co-fund the development, so this is not a handout. I don't think the pharmaceutical industry is looking for a handout. At least what I am hearing from the board rooms is we will share in the R&D, just as Dr. Haseltine's company has shared, but I need to know that there is a guaranteed market for some period of time.

Mr. TURNER. I have no doubt that what you are saying in that regard is true because every bit of information I have ever collected says it is going to be very hard to get the pharmaceutical industry to participate in this.

When we first had this presentation to the chairman and I, the big piece of this proposal was to have this unlimited power in the administration to write a check for whatever it cost without even going through the usual appropriations process. It seems pretty clear as this proposal has been vetted through the Congress that Congress is not likely to give up its power of the purse. If that was such a big part of this, I guess the question I would have for each of you, if that is not in the final bill that passes, is that a deal killer? In other words, are we wasting our time here talking about all of these other details like liability protection and other things, that if you don't eliminate the uncertainty of what has been described at least by Dr. Fauci as the "vicissitudes of the appropriations process," that this is all not going to work anyway? So can you live with the Congress still exercising its role in the appropriations process?

Chairman COX. If the gentleman would yield, this is a very important question. What is being proposed and what was in the bill as marked up by the Committee on Energy and Commerce today does not leave you subject to the vicissitudes of the appropriations process. It does, however, cap the total amount and it puts an end date on it of 10 years so that Congress would have to become involved at some point in increasing the amount beyond $5.6 billion or extending the program beyond 10 years. But within that period of time, the government would have complete flexibility and authority to disburse the entire amount of $5.6 billion and you would not need to come back to Congress between year 1 and year 10. The question is still the same question: How does that affect the real world?

Mr. TURNER. Mr. Chairman, I want to be sure that I understand the question. My impression is that there still would have to be an annual appropriation. They authorized in the bill, but the annual appropriation would still have to take place in the appropriations process. I see somebody shaking their head out there.

Chairman COX. The discussions we have had with Chairman Rogers, who was with us earlier, as well as the Committee on Energy and Commerce contemplates that we would make directed appropriations over a period of years. This is akin to no year money, the sort of thing we did after 9/11 with New York City with all of those billions, and there would be of course ongoing oversight, retained jurisdiction and so on by the Committee on Appropriations but the full amount of $5.6 billion would be appropriated up front in year 1.

Mr. TURNER. I may have misunderstood.

Mr. SHAYS. Would the gentleman yield? I am just curious when other members will be able to question witnesses.

Chairman COX. I appreciate the gentleman's comment.

Mr. SHAYS. They are very important questions, but there needs to be some framework.

Chairman COX. The gentleman's time has expired, and the other members are being very tolerant. The point is well taken.

Mr. TURNER. And I apologize if I overextended my time. I hadn't noticed.

Chairman COX. The bill passed today is styled as an authorizing bill, and so further action by the Committee on Appropriations needs to be taken. So you will not know from reading the four corners of the legislation what I have described to you, but that is the understanding that we have as of this moment.

Mr. TURNER. Let them answer as they see fit and then we will yield.

Mr. HASELTINE. Certainly permanent and definite funding authority would be desirable. But if we cannot have it, what we would like are multiyear contracts with firm commitments. That is extremely important, multi-year contracts with firm commitments.

Mr. PEMBERTON. The permanent and definite appropriation was a very important part of the bill to PhRMA, but that is not to say it is the only solution, and the multi-year money is certainly one that we will study and work with.

Mr. RAPOPORT. I will pass on that question.

Mr. SUTCLIFFE. My impression is the same as Mr. Turner indicated, and that is that the venture community is interested in this, and what they really wanted was a sign that the government recognized the problem and was prepared to stimulate, or assist in stimulating, both the science and the width that is required to get it moving. I think most companies that have an angle on a solution would find a government indication of a willingness to participate—or to be the customer and to step up to being the customer when the product is available—as a tremendous assistance to finding private capital to do the interim work.

Chairman COX. Next is the gentleman from Connecticut who is being rewarded for extraordinary patience by God, if not this committee.

Mr. SHAYS. I sense that this bill is incentivize and accelerated research and development for vaccines and therapies, and I am wrestling with a whole host of questions. I, for one, do not know the ethics of how you qualify a vaccine for a disease that does not really exist. I mean with polio, you got to try it on real people. How do we do that?

Mr. HASELTINE. The way the biodefense legislation handles that is to use two animal models of human disease followed by a safety study in humans of the drug, but these are humans that are obviously healthy.

Mr. SHAYS. So technically we do not know the efficacy of the drug on humans?

Mr. HASELTINE. That is true, and you cannot know it.

Mr. SHAYS. Fair enough. We are going to have to be making some tough choices. The legislation is basically going to speed up research and development for countermeasures. It is going to speed

up delivery for these countermeasures, and it is going to basically overrule FDA emergency authorization. It is going to provide for emergency authorization to bring out a drug that may not be fully tested. That is the world we are kind of living in.

Mr. HASELTINE. Already the Biodefense Act allows drugs to be registered which meet the two animals plus human safety. That is already existing.

What this would allow to happen is if a drug were in the process of being tested in humans but hadn't been finished and hadn't been registered, the FDA could decide.

Mr. SHAYS. I get that. I understand.

Mr. Rapoport, you are the most vocal on this end, and all of you are very effective in your presentation. I want to basically have a sense if we eliminate the risk and provide a promised revenue stream, what will we get beyond the product? Let me put it this way, would we get the product below at what would be a typical cost of a company that hopes to recoup research and investment?

Mr. RAPOPORT. The DOD and HHS are very sophisticated at price negotiations with government contractors. Obviously the more R&D money you take from the government, the less should be the price of the product. What we are suggesting is if you enter into one contract that has R&D in it and a commitment for production, at a certain point in time you enter into price negotiations and then the contractor and the government can decide what is a reasonable price.

Mr. SHAYS. And you recognize that?

Mr. RAPOPORT. I do. I don't think that Congress needs to go down into those details. I think the government is very good at this. I spend half my day fending off the government doing audits on contractors. I think there are many guidelines within the FAR that could be useful under other transactions to guide what is a reasonable price for the product.

Mr. SHAYS. Would any of you respond to what this world is going to look like, and first off when we do these top-off experiences and we see smallpox run amuck and we think how are we going to catch up, and we look at the plague and question how we are going to deal with that, the plague has been in both top-off 1 and top-off 2, and in both cases we don't have an antidote to the plague right now. Tell me, when will we?

Mr. HASELTINE. I think it could be available within several years, 2, 3. You asked a question, and the answer to your plague question actually is part of the answer to your previous question: What else do you get if you support these early programs? What you get is full involvement of the biotechnology and pharmaceutical industry to address a broad range of questions.

Many people, including ourselves for follow-up programs, are waiting to see what happens with these programs, because if these programs don't go very well, then other programs don't get developed. It could happen really quickly. There are plenty of technologies around that would allow relatively rapid development of ways to contain plague, for example.

Mr. SHAYS. It seems to me like it is a crapshoot. In my hearings, I have had 40-plus hearings in my National Security Committee, and the list is a long list of potential pathogens that we might

want to defend against. I realize the first panel said you are going to look at those that could be the most catastrophic and so on; but admittedly, this is a big list, true?

Mr. HASELTINE. The answer is yes and no. I think the first panel tried to address that question.

There are some big threats that are obvious that we know are major threats. Those include plague, anthrax, and smallpox.

Mr. SHAYS. The ones that tend to be the most contagious?

Mr. HASELTINE. Or already known to be weaponized.

Mr. SHAYS. Are we talking about five big ones?

Mr. HASELTINE. No more than 10.

Chairman COX. Mr. Dicks.

Mr. DICKS. Thank you, Mr. Chairman.

Mr. Haseltine, I wanted to ask you, what do you need to get this deal done? In other words, what is it that you would like to have to accelerate getting your product purchased by the government?

Mr. HASELTINE. Enactment of BioShield.

Mr. DICKS. All you need is BioShield?

Mr. HASELTINE. Then we are happy to compete. The money does not exist in any easy form. BioShield would allow us to move forward, and allow the government to move forward, because we have talked to every agency that we can talk to in government, and they all tell us the same thing. I hope it is true. If Project BioShield is passed, we can help you. Without Project BioShield, it is very difficult for us to help you.

Mr. DICKS. So we have to get the bill through and then we have to appropriate. I am on the Committee on Appropriations. Then we have to appropriate the money?

Mr. HASELTINE. That is right.

Mr. DICKS. If that is the way we are going to go?

Mr. HASELTINE. That is right.

Mr. DICKS. I hate to use the defense system because if it takes us 15 years to build a weapons system and it is not always a great one. But what about the idea of a situation where you would be reimbursed like they do in R&D where instead of you putting up $30 million, which is what you are doing here, you would be contracted by the government if they thought your idea was good enough, to pay for the R&D? What about that concept? You just don't think that is viable?

Mr. HASELTINE. I think that would buy you a lot more research from a lot more smaller companies. I think it would be very welcomed by certain segments of the biotechnology industry. I think it is a very interesting concept.

Mr. DICKS. That is basically what we do in defense. They use some of their money, companies do, and they obviously raise resources to do it, but then they get a contract to do the R&D if they have an idea that people think is worth doing. I bring that up so as we consider this legislation that is an alternative.

Mr. HASELTINE. Flexibility is the word. Part of that could be done through existing NIH mechanisms. Part of it could be done through other mechanisms as well. I think flexibility in the way this language is crafted is very important.

Mr. DICKS. How do you read the language on partnership as it is now? How do you decide who pays how much? Or what the shares are going to be? Is that defined in the legislation?

Dr. HASELTINE. I don't think it is defined. And I think it should be flexible.

Mr. DICKS. So they can enter a deal. So in other words, between the NIH, whoever is going to do the contracting, and your company, you can negotiate an agreement about how much is going to be done as a partnership.

We do that in some other areas too, so that concept is interesting. I kind of like the other idea, because I think you get more done sooner.

Let me ask Mr. Rapport about—Did you want to say something, Mr. Sutcliffe?

Mr. SUTCLIFFE. Yes. I think you are on the right track. In fact, what will happen under this legislation, except in the case of companies like Dr. Haseltine's, is that the large pharmaceutical companies will subcontract this work to biotech.

Most of the large pharmaceutical companies can't solve these problems the way that they will need to be solved with their existing research. They will subcontract the work by supporting the esearch, and will take the guaranteed contract.

The problem it presents is that the market will be tied up, and so it will—we really are using, in this case the government is using the large pharmaceutical companies to solve this problem by doing the subcontracting that you are suggesting could be done directly. I think you are right, under your approach, more answers would come forward without the government having made a commitment to any of them.

It would perhaps spend more in terms of initial R&D funding, but at much smaller dollars than we are talking about committing.

The numbers Dr. Haseltine is talking about in $30 and $50 million don't add up to $800 million a year. The number $800 million a year comes from the number of the total amount spent on research in the pharmaceutical industry divided by the number of successful profit-making drugs. That is what the average of what it costs to get a drug to market is.

But that is not actually what it costs to develop any particular answer. Some are obviously expensive and lose, some may be less expensive and win. So the more—the flexibility that we are talking about is, the more answers are sought out, the better the chances that the public will have the protection that they want at the end, which is not that we have made a good investment and got a pretty good antidote, but that we actually got something that works at the end.

Mr. DICKS. I appreciate your answer.

Mr. Rapport, let me ask you this, you talked about the Defense Production Act. Give me a little more on that. How would you see that operating? You could have a situation where we can say, if the President declares an emergency, you can use the Defense Production Act. That can be a paragraph in a this bill. So if we did get into a crisis like you are suggesting, and we really had to move, we would have this on the books.

Mr. RAPOPORT. I think what I would offer is that you can put in BioShield that the Secretary has authority to engage in a prototype plan, where they could—he could within his discretion use the Defense Production Act in a limited circumstance to see how it works. It has recently been used involving shipping lines in the Middle East, after the First World—after the First War, in that part of the world.

But it has not been used often. But it certainly could be helpful to jumpstart the industry. I wanted also to just address, I am trying to be as plain speaking as I can, because you are a leader on the defense issues, you understand this.

Lockheed and Boeing are used to having auditors roam their plants. I assure you that my clients, the thought of having government auditors audit the costs of an R&D contract, all of a sudden brings nightmares to them of toilet seats and overpriced widgets. And so I think at least from a big pharmaceutical company, they would be more inclined to at least try to go it on their own and not accept the R&D money, because they don't want to become part of that, you know, government contractor audit establishment that the FBI and prosecutors somehow get the money back at the end of the deal, in over zealous prosecutions. Some of them are obviously merit-based.

But that is what I am hearing, that I am the President of a multi-billion dollar vaccine company. The last thing I want to take is a hundred million dollars in government money, because then I have got to pay Ernst & Young and McKenna, Long and Aldridge and everyone else to come in and set up these cost accounting systems that your constituents have had for years.

Mr. DICKS. Thank you, Mr. Chairman.

Chairman COX. Thank you. Mr. Andrews.

Mr. ANDREWS. Thank you, Mr. Chairman. I wanted to thank the witnesses for their testimony. I regret not being able to hear it, but I read it.

I share with the author of the BioShield Act the basic premise that the way to prepare our country to deal with this problem is a combination of money, markets and immunity. I think the concept is exactly right.

I think there are—the question Mr. Turner was pursuing about the proper means of government oversight is one we have to explore. I would like to explore another one, which has to do with my amateur understanding of the future of scientific inquiry.

Some of the most impressive breakthroughs in the areas of biology and chemistry have occurred by accident, where there is a task that is different than the task that eventually winds up serving, where someone is involved in pursuing project A and they make some discoveries that are collateral to project A that lead to a new project B, which leads to a new project C and so forth. We do not want to foreclose that scientific dynamic.

My question to you is, how can we be sure that the umbrella of immunity and the financial reach of the subsidies that BioShield suggests, and the benefit of the guaranteed market that it suggests, would reach beyond the original stovepipe competitors in this field?

In other words, that is a bit theoretical. What I really mean is, if someone working in one of the outstanding pharmaceutical companies, all of which are in New Jersey I might add, is working on a cure for SARS, and in the process of that, makes some findings which are quite relevant to dealing with inhaled anthrax, I am not sure if that is an apt technical example, but you understand my point.

Does the BioShield legislation set up a sufficient mechanism so that that scientist's SARS-related discoveries can be sold, conveyed, shared, joint ventured with someone who is working on anthrax? If not, how do we do that?

Dr. HASELTINE. Thank you for the question.

It is a very interesting question about research and cross-fertilization. I think that that can happen. And the way it happens is, first of all you first create a market for these drugs. A market is extremely important in motivating researchers at all levels.

Once a market for a potential product exists, it is in people's minds that if I make a discovery, I have an outlet for it. If you don't have a market, they may never make that connection. I have been involved in creation of seven biotechnology companies myself, and overseen the creation of another 20 through involvement in venture capital advising, et cetera.

And that is a process that is fascinating to watch. The companies that I have started haven't come out directly of the research that I have done. They have come out of collateral ideas realizing that there might be a market. You create a market and people will come.

Mr. ANDREWS. Here is my follow-on question. Let's assume that because there is consciousness in the scientific community, that there is an effort to create an antidote to smallpox, that the scientists who comes across something on the SARS project says, my this has cross-applicability. He or she calls the person working on anthrax.

As a legal and policy proposition, let's assert for the moment that we want the ordinary drug laws and antitrust laws and intellectual property laws to apply to the pursuit of the SARS problems. But we want these special rules to apply to the production of antidotes to these national security problems. How do we sort the two out? How does a legal relationship get constructed that serves the public purpose of expediting and defending this defense venture, but does not create the unintended consequence of setting up a whole new set of rules and a special commercial marketplace that is not our intention? How do we do that?

Mr. PEMBERTON. The limited antitrust exemption with government supervision would permit technical collaboration among companies in ways that might currently be problematic. And creating a kind of opportunity for companies to collaborate on perhaps those kinds of cross-fertilization ideas would be one reason why you would want to have that.

Mr. ANDREWS. Let me say this. My own prejudice, I would rather err on the side of achieving the antidote for national security faster. If the cost of that is a perversion in the civilian market, much as I would not want that to occur, the cost of the attack on the

country is a lot greater, so I would want to err on the side of getting the antidote to the market.

Mr. SUTCLIFFE. Mr. Andrews, I am not sure that the cross-fertilization won't take care of most of the problem. I think that communication will take place. I mean, in the scientific world that information will cross.

The immunity problem comes in terms of doing the follow-on experiment, and that is a situation where it is the limitation of most institutions that would keep a researcher from performing the research, and you can be sure that you or the people who have the immunity under BioShield will get that call.

Mr. ANDREWS. Thank you. I see my time has expired. Thank you, Mr. Chairman.

Chairman COX. Thank you. Ms. Jackson-Lee. Thank you all also for your patience.

Ms. JACKSON LEE. Thank you very much, Mr. Chairman. And thank you, the ranking member.

And I would like to also associate myself with the remarks of Congressman Andrews with respect to having perused your remarks. I was in another meeting outside of the room, but I do appreciate your testimony.

Just for clarification, because it is a little difficult to see the names, and I wasn't sure whether Eric Tolbert was here.

Mr. Chairman, I just—let me just make a comment, and not specifically about Mr. Tolbert. But I do think it is crucial that we have a hearing that includes, or that we are able to cover the question of the threat assessment, which I assume might have been discussed from the perspective of this Director of the Response Division. And I hope that we will be able to, one of the—one, be able to secure that.

One of the points that we have been consistently making, some of us, is that a threat assessment is crucial. I know that one of our colleagues has been speaking eloquently about that, Ms. Harman from California.

So I hope that we can have that response. I am not sure why she was not here, Mr. Chairman.

Mr. Chairman, I would like to yield to you for a moment. I am not sure why the Director of the Response Division was not able to make it. I am concerned about the threat assessment issue, that hopefully we are going to address that.

Chairman COX. We are going to pursue that.

Ms. JACKSON LEE. Is it likely then that we will have witnesses that will be able to respond to some of those concerns in hearings to come?

Chairman COX. I will ensure that members of the minority and the majority have the opportunity to put questions to the Department, either at a subsequent hearing or in writing, and have them answered before we mark up.

Ms. JACKSON LEE. Thank you very much. Certainly it is not the fault of the panel that is here. But, in any event, I wanted to make that point.

I also want to associate myself with the remarks in a previous panel of Congresswoman Lowey, in terms of how all of this impacts the unpreparedness for the needs of our hospitals and emergency

rooms, and may have a question to you gentlemen along those lines. Because, as I said, if you have any thought on that, I would appreciate the oversaturation.

I had the opportunity to read some of the works of Professor Calabresi, formerly of Yale Law School, now on the Second Circuit. He makes a—I think a long-standing theory, he made it some many, many years ago about choices and cost. And that we ultimately wind up making choices on how many—what the loss will be, and if we lose one or two in the course of our research and work, we consider those lives expendable.

It is not his proposition that they are expendable, but he gives us sort of a model for how many decisions are made. I believe that a lot of his work was geared toward how insurance companies make determinations.

We know that we are in a crisis. We know that the last 2 days, that terror exists, by the tragedy in Saudi Arabia. I said that earlier, but I also asked the question in the earlier panel about accountability, and the answer was given that—it is paid only or moneys would be given only to the pharmaceutical companies and other research institutions on the basis of the deliverable.

So I would like to ask Dr. Haseltine and Alan Pemberton on the—how assured are we of that process working? And I would also like to pose the question, because as I said, we all bring a different perspective to this committee, of what kind of immunity from liability would you be looking for? So, would you be encountering the same problem with the first responders not being able to be protected by liability coverage out of this type of legislation?

I think that would be extremely important. And any of the gentlemen who would care to answer that, I would encourage you to do so.

Let me start with Dr. Haseltine on some of the questions that I posed.

Dr. HASELTINE. There are actually three questions that I can address briefly. The first is, certainly preparedness of our health care services is very important, part of our response. However, for many diseases, if there is no adequate drug, no matter how prepared you are, you can do little.

One of the key aspects for preparedness of health care systems is the appropriate drug for the appropriate threat. And I think we have seen, to some extent, that in SARS. There are some things you can do, but for some people you can unfortunately, at this point, do very little.

The second issue that you raised was the issue of guarantees, that if we had a product it would work. Is that your question?

Ms. JACKSON LEE. The question is—the answer was given to me before about accountability. And the answer I was seeing, give pharmaceuticals and other research institutions a billion dollars, how do you know they ever come back with anything? The answer was, you do it based upon what is delivered.

My question to you is, does that work?

Dr. HASELTINE. Yes.

Ms. JACKSON LEE. How does that guarantee that we will get a product?

Dr. HASELTINE. You give the money in relatively small chunks and based on very specific performance criteria, and if you don't meet these performances, you don't get the next installment. And if the quality of the product that you are delivering isn't up to the specified standards, then you don't get it renewed.

Ms. JACKSON LEE. You have the hammer—the nail by a hammer on the head. That is the quality of the product. And that is what I would be concerned about, is the quality of the product. That is what I would be concerned about as we move this legislation and look at what we are doing, quality of the product. Because I can always hand you a bowl of cherries; that may not be the answer, and that would be what I would be concerned about.

Dr. HASELTINE. The third issue you touched on was liability. I would say that liability should be looked at on a case-by-case basis. Many of the drugs that we will be developing may be FDA approved, and FDA approval provides you some measure of protection, as well as explicit legal liability. So I think that there should be case-by-case, perhaps not blanket liability protection.

Ms. JACKSON LEE. Before you answer, may I just throw this sort of curve in there, so that this could be included, and if anyone wanted to conclude on that, since I notice that the light is on.

The follow-up to all of that, where I am leading with this is, I sort of want to ensure that whatever we do is evenly distributed to all who are in need. And if we stockpile vaccines, the question becomes, how they will be distributed. We now know that we made a determination, we are doing first responders for smallpox. But what about the 40 million people in the United States that have no health insurance? Does that make them less able to secure access to protection from terror?

And I believe that the BioShield approach is good, but we may need to look at those aspects as well, because we know that we are a Nation with a huge amount of working individuals who are uninsured. If I can add that to the thought processes for anyone who wants to finally answer that. Yes, thank you.

Mr. PEMBERTON. The payment provisions in the current legislation, we believe, would be improved by adding flexibilities so that the payment, we agree that payment should be based on achievement of definite criteria. But whether those criteria, in all cases, are delivery of finished doses of medicine, should be left to the case-by-case determination.

There may be specific kinds of very long-range production projects or development projects that might warrant some other kind of milestone payments. And, in our view, it would be unwise to have the BioShield legislation tie the hands of the Administration in designing a system of payments for special cases.

As far as liability, liability from the point of view of the PhRMA members is an extremely important issue. And, if liability protection for potentially catastrophic tort suits is not provided, it will be a very significant disincentive to participation by many of the members of the industry.

We recommended that it be done along the model of the Swine Flu or the current—what is currently being done with the smallpox production contract.

Ms. JACKSON LEE. Yes, sir.

Mr. RAPOPORT. I think the issue is liability protection. During the anthrax solicitation, HHS took the position that when you were involved in Clinical 1 studies, you didn't need the government to give you liability protection. The industry, I think, probably feels differently.

What I have tried to suggest in my testimony is the Safety Act, which, I believe, Mr. Armey and others wrote, does give protection across-the-board to companies who are willing to participate in homeland security. That was the reason they wrote it, because a lot of companies were even talking about a mail-handling machine that could detect anthrax.

A defense contractor might not do this work if it could be found liable. What the Safety Act says very clearly, some say, is that it applies only in the event of a terrorist attack. So that if you fail, if your machine fails, we know that it was only used during a terrorist attack. But when I am developing a new drug, there is no terrorist attack.

So the Safety Act, we respectfully submit, ought to be amended slightly to say that it applies to any procurement under BioShield.

Chairman COX. The gentlelady's time has expired.

Ms. JACKSON LEE. Mr. Chairman, and I am not going to pursue it, but I would like to get in writing my question about the uninsured Americans access to such care. That was a question that I had asked, what happens if you don't have money, insurance and otherwise, are they going to be left out of the coverage against terrorism?

Chairman COX. I thank the gentlelady.

The gentleman from Florida, Mr. Meek.

Mr. MEEK. Thank you, Mr. Chairman.

I would definitely like to thank all of you for spending, not only your time here on this late Thursday evening with us, I know that there is no better place that you could be right now, but I definitely want to—I think this is very not only informative for me as a member of the committee, but as it relates to everyday Americans, because we are definitely out in the cold as it relates to having vaccines or preventative medicines to be able to protect many Americans and those friends abroad of bioterrorism.

Mr. Rapport, I hope I am pronouncing your name correctly, I can tell you that your testimony was just as good as the other panelists, but you define—it was kind of like a contract kind of thing, just cut and dry, let's don't sugarcoat it or put any icing on the cake as it relates to things that will prevent us from being able to achieve what we want to achieve through this piece of legislation.

And I think that when we start looking into intellectual property rights and cost of accounting and pricing and the government's nose being in the middle of R&D and things of that nature, that is something that would be—when we talked earlier with the first panel, about the ideal perfect world, unlike DOD, which I am on the Armed Services Committee, we meet here in this room. There are things that, historically that have taken place in the Department of Defense that people just kind of said, well, it is the defense of the country. Homeland Security new department, lot of attention, lot of concern about Americans, especially when it comes down to bioterrorism, or what have you.

You mentioned that you had language that you presented to the last committee for them to include in their markup. And I haven't seen their markup yet. I am pretty sure I will see it. I understand that they just passed it this morning. So, what are some of the things as relates to the cost accounting? I am sorry I stepped out for a minute myself.

Can you define further what could hinder, but also give us comfort as on Oversight Committee and as the Congress that through the Peer Review that I hear, see a lot in the literature of the R&D process of the—of making sure that we don't have cost overruns, things of that nature?

How does that work and how do we give Americans comfort in allowing that flexibility, because we do want all of you and your peers to participate in this process? Because this is something that we have to not only have an answer but a result.

Mr. RAPOPORT. Sure. Those are excellent questions. I think what Mr. Pemberton and I were suggesting is we deal with this world, as you do, of defense contractors who have regulations on top of regulations which Coopers and Lybrand, I think once did a study and said, for every dollar we spend there is 20 cents of it just to deal with the regulations.

What we have proposed is to give the authority to the Secretary to enter into transactions that don't come with stacks of regulations. And again, it has got a weird name, just other transactions. Came out of DARPA. It was a way to get a company like 3M who had never done business, but has a fantastic research capability, they wouldn't do business with the government, hypothetically. I think that it was perhaps 3M.

But they entered into a commercial-like deal. And I think what I am suggesting to you is, the contracting people at NIH are not going to allow the store to be given away. They are not going to enter into a one-page commercial deal, because even commercial contracts do have terms and conditions. But I think we can eliminate some of the ability to look at, you know, cost records down to the fine-toothed comb with months of auditing on every purchase order by saying in this commercial-like document that it is within the discretion of the contracting officials to go ahead and do some selective auditing, but they don't have to follow the Federal Acquisition Regulations.

Mr. MEEK. Quick question. What do you think would be—you have identified the Defense—I can't remember.

Mr. RAPOPORT. Production Act.

Mr. MEEK. Are you recommending that being the course outline as it relates to accounting and auditing? Because I am seeing in the backdrop the fact that you are pharmaceutical companies, and it is like some Members of Congress, you know, some people feel negative about that whole experience. I pay too much for my prescription drugs. So they are automatically thinking that there is some sort of deal that is going on somewhere, and we are not really getting the big bang for our buck, in that it is a blank check, even though as it relates to research and development.

And on the last panel, one of our panelists was really heavily into the AIDS/HIV research, and knowing that you have to spend millions of dollars, now a billion dollars almost to really get into

good research. How do you—I am trying to figure out, how do we get a level of comfort? Because this is not—this is something that all of the news stations, all of the writers are going to be focused on.

You start talking about individuals, appointees and pharmaceutical companies, kind of going off to the corner and saying, OK, we have the deal. I am not saying that that is a bad thing, because we have to move, and we have to move expeditiously. We don't have time, like you said, to be topping at every point because someone has to check the No. 2 pencil you bought last week.

Could you define more about a good example that is existing that we haven't had abuse? Because when we look at regulation, it is the reason why we have it, just like we have a stoplight in some intersections, a certain amount of casualties took place there.

Mr. RAPOPORT. Sure. I am certainly not the one to defend the pharmaceutical industry. I think they can do that on their own.

Mr. MEEK. Don't get me wrong. I am just saying, because we have to explain this.

Mr. RAPOPORT. Sure. I was just simply trying to build on what Dr. Fauci says, is that he needs this industry to bring their creativity.

All I was suggesting with the Defense Production Act, it in no way is a relaxation of any audit rights. It is simply a framework that allows you to avoid—the anthrax bid took 6 months before they even selected somebody who has got now 2 years to come up with R&D.

You could collapse that timeframe, and you could put, again, companies like Human Genome or Merck, they are not allowed to get in the same room now. But, under this Act, subject to supervision by the Defense Department, they cannot talk, absent someone from DOD or one of the other agencies in there, they can actually divide up the deck and decide, gee, you are going to take plague, you are going to take tularemia.

Is it going to work perfectly? No. But I am just suggesting if you want to get past all of the bidding stages that, you know, quite frankly the Mercks and the Human Genomes and the Glaxos, they are all very competent. They could all help. You don't necessarily need to decide and spend a year which one is going to get A and which is going to get B. Let's make that decision now and see their proposals and then hunker down and have a negotiation that protects the taxpayer, which I know that you are worried about.

Mr. MEEK. Thank you so very much.

Mr. Chairman, I just definitely want to state for the record that I appreciate all of the witnesses here and the work that you are doing.

And the work that you do want to do, not only on behalf of our companies but also on behalf of Americans, in making sure that we are safe in the effort against terrorism. Simply, you summed it up better than I could. On behalf of the taxpayers, I don't think there is anyone in this Congress that wants to abuse their trust that they put into us. And we appreciate all of you coming today.

Thank you, Mr. Chairman.

Chairman COX. Thank you, Mr. Meek.

I want to be as humane as possible with our panel. You have devoted many hours of your day here today. I am sure you can use a stretch if nothing else.

And so I have just one question I would like to put to you before, with the consent of the other members, we will certainly relieve you. It is the fulcrum of the discussion that we have been having thus far about what incentives are necessary in order to get this jump-started in the private sector, and what flexibility the Department should have.

I have reviewed, as carefully as I can, the legislation in its current forms. There are a couple of them extant. And I don't believe we have clearly stated in the bill as written, an authority for the Secretary of HHS or for the United States to make a public bonding commitment to purchase what we have defined as qualified countermeasures on such terms and conditions as the Secretary might specify in advance at the time of the publication of this binding commitment.

This is the reward model. And the question is, whether or not providing such authority as a supplement to what is already here, and Congress not tying the hands of the executive branch in their choice of which pitch to throw would be something that would make BioShield better or would compromise the effort in any way? And I would put it to the panel to help me with that.

Mr. PEMBERTON. I think if you can make the commitment binding and make it earlier, it would certainly encourage participation and would encourage more research earlier in the process.

Dr. HASELTINE. I am in concurrence with that.

Mr. RAPOPORT. As well.

Mr. SUTCLIFFE. It would increase the number of participants in the project, certainly from the biotech side and add them to the pharmaceutical companies that were already attracted to it.

Chairman COX. Well, given that unanimous view of this panel, what would you like to see in such a public call? What would resound most loudly in the private sector and get people spurred to action most successfully? Any essential elements to such a call, or to put it obversely, anything that the Federal Government could say or do in this model that would cause people to dismiss it?

Mr. PEMBERTON. I think the essentials are estimated within Minimum quantities of doses or other volumes be purchased and a guaranteed minimum price are going to be the two big items. Of course, you have to have standards of performance, you have to have some sort of measure of efficacy and safety.

Chairman COX. If the legislation were to leave those metrics up to the Secretary of HHS, would that be a flaw in the legislation or would that be admirable flexibility?

Mr. PEMBERTON. I think it has to be left to administrative discretion.

Dr. HASELTINE. I agree.

Chairman COX. What I mean is not the price and not the amount, but rather the legislation could say, for example, the Secretary shall, at the time that he makes the public building commitment, specify such details as will be necessary for people to qualify, which shall include the price, the quantity, what have you, and

some means that everybody could agree upon, in determining the efficacy of the countermeasure that is being purchased.

Mr. RAPOPORT. What I would add to the language is that the Secretary, in his discretion, shall negotiate a reasonable price which shall include recognition for the costs of capital and return on equity.

That is a piece that is not in BioShield that would announce clearly that there is a willingness on the government's part to reimburse the companies for their own sweat-equity costs that they have to go out and bring to the company, to the project, again on a reasonable basis.

Chairman COX. Let me just put a fine point on this. If we were to include such authority, and if we were to leave essentially all details of what would be in a public call, up to the discretion of the Secretary, would that be acceptable from your standpoint for the legislation, and would it be a good thing, or should we strive for some more specification, some more specificity such as, should we say things we ought to include—is your last comment, Mr. Rapoport rather advice for the Secretary, if and when he were to use this authority?

Mr. RAPOPORT. I think what I am suggesting is that you give him some parameters of issues that he should consider, that if you didn't say so, he wouldn't consider, because it would be Defense Department business as usual contracting, which is pretty much the way they did the smallpox and anthrax procurements, because they didn't have BioShield and not enough money.

Mr. SUTCLIFFE. I would also hope that such language would avoid predetermination that it is doses per dollar that is the solution, rather than, for example, some other form of protection that would allow him to encourage other solutions on the response side rather than on the drug side.

Chairman COX. All right. Mr. Turner.

Mr. TURNER. Just one question. I know the hour is late.

When, Mr. Rapport, you described the way you would like to see the process work, you talked about getting everybody in the room, all of the manufacturers and you decide who gets to work on plague, who gets to work on anthrax, that kind of thing. And earlier when Mr. Dicks was asking questions to the panel, I think Mr. Sutcliffe made a response to him that indicated that you thought, Mr. Sutcliffe, that it would be better to have more than one hook in the water. And I want to get clear, between the two of you, these two approaches and why each of you feel the way you do, and so that we completely have an understanding, because I think this is a critical issue.

I will tell you where I have been on this. I thought that the objective here ought to be to get more companies involved in this research and this effort. And that we would be best served in terms of achieving the goal of getting these vaccines out there in the shortest period of time if we did that. So the concept of simply sitting in the room and divide up the pie seems to me to be the wrong approach.

But if you disagree with that, let me know. But I want to hear the contrasting approaches that I think I heard from each of you two.

Mr. RAPOPORT. Mr. Turner, I think you rightly took my comments to the extreme. I am a big fan of something called dual sourcing or triple sourcing. And when I suggested that we make an award of one drug to one company, I was giving the example.

Again, this would be up to the Department of Defense and Homeland Security who actually would administer this. What we saw in the smallpox procurement that Secretary Thompson issued right after 9/11, they made an award to one company. In the years that I have been practicing government contract law on critical problems, critical programs, they never just source to one. They always have two or three, so hopefully at the end, somebody comes up with the answer.

But, Secretary Thompson had no money. He had to go with a very fine company, I think it is called Acambis. But, quite frankly, they were the low bidder. You didn't see Merck, you didn't Glaxo, you didn't Wyeth, or the fourth company in Mr. Andrew's District. The four big manufacturers have yet to participate. It is as if you fight the war in Iraq without Northrup Grumman, Boeing, you have a bunch of very qualified subcontractors.

But what I am suggesting is the Defense Production Act, I think can be a useful tool. A useful tool in areas where the President and his team feel we could get an edge in where maybe one company is raring to go and one isn't, that you consider that in the legislation.

Mr. SUTCLIFFE. I think you are correct to have perceived a difference in the point of view. My impression of the BioShield Initiative, as written, is that it is an assignment to a handful of companies to provide an already determined product.

The problem that has been brought out in this committee is we don't know what this product is, we are not sure how broad the threat is, and we would really like to have some answers to the threats we are going to find out about next week. There is no evidence that these particular companies have anything to offer in terms of the discovery side of answering those problems.

What we really ought to be doing is making sure that we get the best answer, more players certainly, and I think, different players. The production issue of the ultimate solution is probably the easiest part. There are many people who believe that the future of this combined industry is that the discovery side will be the biotech industry as we know it today, and the production and marketing element will be the pharmaceutical companies.

I think it makes a lot of sense to use the resources of the pharmaceuticals companies to deliver products when they are determined.

But, the BioShield Initiative is to find the products in the first place, or to find the countermeasures, I think that is the correct statement. The countermeasures may end up being things that are not drugs, that are not vaccines. And the way BioShield is written, it is really a one-off approach to each disease.

I think it was Mr. Dicks who asked, what will we get at the end? The answer is we are going to get, ultimately, a hundred individual vaccines produced under the same approach, as opposed to any chance at a global, "macro" solution to avoiding contact in the first place or moderating response to antigens and pathogens in a way

that draws upon the kind of science that Dr. Haseltine was working on 30 years ago, and now we think of as what we know about individual patient response.

So we can learn about that in the context of BioShield. I don't think that the existing NIH authority and approach is enough, because the urgency is not there. Indeed, in just talking with scientists in our company and elsewhere, the impression of BioShield is a lot of people are going to go into the vaccine production business for major pharmaceutical companies, because there will be jobs to do that.

I am not sure that gives us an answer. It will give us warehoused vaccines. Whether they will answer the need and anticipate the next threat is a bigger question. I believe they probably won't.

So if we can tweak the BioShield idea, use the urgency that is reflected in it and the government attention to bring as many solutions into play, we will get the right ones, and it may well be that that means not paying for them up front, not agreeing to pay for them up front, but agreeing to pay for them when they are delivered, then allowing private industry and the private capital markets to compete to give you a number of different solutions.

If we all get in one room and divide up the diseases, we will get a hundred thousand left shoes. I think that that is the giant risk of the way the structure is currently anticipated.

Dr. HASELTINE. I have a comment on your question. I think the notion of a priority of dividing up who gets what disease is a very bad idea. You don't know who is going to come up with the valid solution. On the other hand, at the other extreme, you can't have multiple people making products for the same purpose. We can't have say three or four vaccines for anthrax. That may work in the private sector where there is an open market, but it is very unlikely to work where you have the government.

So there should be something that allows diversity, a priority to come up with products that meet certain criteria, at which point there is a selection for which company does the production.

But, I think it would be an extremely bad idea to divide the world up before you had proof of efficacy.

Mr. TURNER. Thank you.

Mr. PEMBERTON. I think the basic model under the existing language is competitive R&D, and we are certainly comfortable with that. But there may be instances where there could be needless duplication of effort that could be discovered through a very limited process of meeting, where you would need an antitrust exemption to have those kinds of meetings, to discover where you are wasting effort, where two people are doing the same thing, that is not necessary.

Chairman COX. Well, I think you have surpassed yourselves in your contribution here this evening. I am sure that every one of our panelists is here beyond the hour that you expected depart. So you are very, very much appreciated we want you to know. You have helped this committee immensely in our task as we go forward.

We are very, very close to marking up this legislation. So your comments are both very timely and very consequential, I think,

and we appreciate your help a great deal. Thank you for traveling here, for being with us.

And with that the hearing is adjourned.

[Whereupon, at 6 p.m., the committee was adjourned.]

## APPENDIX

## ADDITIONAL MATERIAL SUBMITTED FOR THE HEARING RECORD

### QUESTIONS AND RESPONSES FOR THE RECORD FROM MR. ALAN PEMBERTON

Thank you for the opportunity to address further questions from Representative Jackson-Lee following the oversight hearing entitled "BioShield: Countering the Bioterrorist Threat" on Thursday, May 15, 2003.

Representative Jackson-Lee's first set of questions were as follows:

> I am concerned that we could promise about 1 billion dollars for creation of a new vaccine, sit back and think that we have taken care of the problem, and find out in five years that nothing has been accomplished. How will we monitor whether this Act is having the desired effect? How many companies do you think will start new programs to develop vaccines or drugs to combat bioterrorism? How many corn panics in the business will expand their programs? Is there some threshold level of new activity that you could see that might indicate that the industry is dedicating the appropriate resources?

She also inquired:

Considering the relative lack of transparency in the private sector, and the fact that many pharmaceutical companies are publicly traded—do you expect them to be forthcoming about their progress, or lack of progress, on this front? How long will it take us to figure out if the industry is not getting the job done, and that perhaps a federal effort is necessary.

On behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") on whose behalf I testified at your Committee's recent hearing, I am pleased to respond as follows:

First, while it is impossible to predict the specific research initiatives that will be undertaken if BioShield legislation is adopted, if the government does not remove significant disincentives to the development of such a market (including meaningful protections against liability exposure), the pharmaceutical industry is not likely to reallocate existing resources to developing countermeasures to bioterrorism. To stimulate private industry participation, it is imperative that Congress create a guaranteed market and address disincentives such as the liability exposure of participants. PhRImIA favors a liability protection system similar to that enacted currently for smallpox vaccine manufacture.

The transparency of research efforts will not be an issue. There will be (as there currently are) many ways to learn what research PhRMA member companies are performing. Information about the nature of the ongoing research and development is generally public. Public documents such as the PhRMA annual report, company press releases, and SEC filings provide such information. Additionally, government entities often are aware and involved in the research process—the NIH and CDC, particularly where infectious agents are concerned, and the FDA, once clinical trials are underway.

PhRMA would welcome the opportunity to work with Congress to construct a countermeasure contracting and procurement process that operates more like the commercial contracting process, which we believe will enhance its appeal to private companies. Pharmaceutical companies are accustomed to commercial contracting rather than government contracting and structure their research and development efforts differently from traditional defense contractors. For instance, authorization of "other transactions authority" would provide greater flexibility than is typically the case under federal acquisition regulations and would permit agreements that more closely resemble commercial transactions, thereby increasing the likelihood of research and development initiatives and product introductions in this area.

QUESTIONS FOR THE RECORD SUBMITTED FOR DR. FAUCI

QUESTIONS FROM REP. SHELIA JACKSON-LEE

Once vaccines or drugs are developed and we have them stockpiled, how will they be distributed? My concern is that we have about 40 million people in the United States who have no health insurance. Those without health insurance are less likely to go to see their physicians on a regular basis. Many do not even have a doctor of record, but instead only go to emergency rooms when extreme circumstances arise. If a situation arises where millions of people in an area need to go in for consultation, then inoculation, then follow up—and there are so many people without a good working relationship with a physician or clinic—we could have mass confusion.

What facilities will be in charge of distribution? Will people visit their own physicians or public health clinics? How will they know where to go? Do these facilities have the infrastructure to take the deluge of patients we expect? Do they have enough people to give appropriate education and advice? Will they be able to treat some of the side-effects or allergic reactions that may arise? We have a disparity in health and healthcare in the U.S. between the haves and the have-nots. I would hate to see a disparity in survival after a terrorist attack.

I am concerned that we could promise about 1 billion dollars for creation of a new vaccine, sit back and think that we have taken care of the problem, and find out in five years that nothing has been accomplished. How will we monitor whether this Act is having the desired effect? How many companies do you think will start new programs to develop vaccines or drugs to combat bioterrorism? How many companies in the business will expand their programs? Is there some threshold level of new activity that you could see that might indicate that the industry is dedicating the appropriate resources? Considering the relative lack of transparency in the private sector, and the fact that many pharmaceutical companies are publicly traded- - do you expect them to be forthcoming about their progress, or lack of progress, on this front? How long will it take us to figure out if the industry is not getting the job done, and that perhaps a federal effort is necessary?

No Response received by the Committee

Questions Submitted for the Record From The Honorable Peter DeFazio

1. With single-source procurement contracts for countermeasures, are the profit margin and rate of return pre-established in the contract?

2. As is customary in conventional government procurement, couldn't HHS simply expedite the RFP and awarding processes for developing countermeasures? Wouldn't a competitive bidding process serve the public interest and public health goals better?

3. Better still, why shouldn't DHS start contracting immediately to develop countermeasures for National Institute of Allergy and Infectious Disease High Threat List ("A List") toxins?

4. Much of the debate on preparedness revolves around biological toxins. Is there anything specifically that's being done to develop countermeasures for chemical agents?

No Response received by the Committee

RESPONSES FOR THE RECORD FROM WILLIAM A. HASELTINE, PH.D.

Thank you for the opportunity to testify last week before the Select Committee on Homeland Security. As I said in my statement and in response to questions from members of the Select Committee, Human Genome Sciences strongly supports the President's Project BioShield initiative. The program will go a long way toward giving companies the assurance they need to develop innovative new products to protect the public from chemical or biological attacks.

I also want to share with you some suggestions for improving the BioShield legislation that was approved last week by the House Energy and Commerce Committee. In some respects, the bill as currently drafted would offer less flexibility than under existing government procurement regulations. In order to be truly effective, the BioShield program must give Department of Health and Human Services the flexibility to craft development and procurement contracts that more closely resemble those in the private market and reflect a partnership between the federal government and companies willing to commit their expertise and resources to defeat weapons of bioterror.

I have attached three draft amendments, which I am hopeful you will consider as the Select Committee marks-up the BioShield legislation. In particular:

• Amendment 1 would (1) authorize the Secretary of HHS to include performance-based (milestone) payments in procurement contracts—rather than limit contracts

to repayable "advance payments" and payment conditioned on "substantial delivery"; (2) provide that the Secretary may enter into single contracts for research, development and production; and (3) ensure that procurement contracts may reflect the actual cost of development, including costs incurred before or after contract execution.

• Amendment 2 would further ensure that contracts may provide for both development and procurement.

• Amendment 3 would provide necessary liability protections identical to those included in the Homeland Security Act of 2002.

I believe that all three provisions would be strongly endorsed by the pharmaceutical and biotechnology industries and would be happy to discuss them further with you and your staff.

Thank you again, and I look forward to working with you and the administration to ensure that Project BioShield is a success.

Sincerely,

William A. Haseltine, Ph.D.Chairman and Chief Executive OfficerEnclosures

**AMENDMENT 1**

In section 31 9F–2 of part B of title III of the Public Health Service Act (as proposed to be added by section 3 of the bill), strike subclause (I) of subsection (c)(7)(C)(ii) and insert the following (and redesignate succeeding subclauses and references thereto accordingly):

"(I) PAYMENT CONDITIONED ON SUBSTANTIAL DELIVERY.—The contract may provide that no payment may be made until delivery has been made of a substantial portion (as determined by the Secretary) of the total number of units contracted for, unless the Secretary determines (in the Secretary's discretion) that advance, partial, progress or other payments consistent with section 305 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 255) are necessary to ensure the success of a project.

"(II) SECURITY COUNTERMEASURE DEVELOPMENT.—Notwithstanding any other provision of law, the contract may include the procurement of research, development, and production, and may reflect, in its terms and price, the actual cost of developing the security countermeasure, including any cost incurred either before or after the execution of the contract.".

**AMENDMENT 2**

In section 319F–2 of part B of title III of the Public Health Service Act (as proposed to be added by section 3 of the bill), insert ", including procurement of research, development, and production under a single agreement, as necessary," after "Secretary for procurement" in clause (i) of subsection (c)(7)(B).

**AMENDMENT 3**

In section 31 9F–2 of part B of title III of the Public Health Service Act (as proposed to be added by section 3 of the bill), at the end of subsection (c)(7)(C)(vii) add the following new clause: "(viii) LIABILITY.—Any product or service resulting from any agreement under this section for procurement, including research, development, and production, shall be designated as a "qualified anti-terrorism technology" as defined in section 865 of the Homeland Security Act of 2002 and, notwithstanding any other provision of law, shall be afforded any and all protections provided under subtitle G of Title VII of the Homeland Security Act of 2002 without regard to whether an "act of terrorism" as defined in Section 865 has occurred.".

QUESTIONS AND RESPONSES SUBMITTED FOR THE RECORD FROM L. GARRY ADAMS, DVM, PHD, DACVP

As requested in your letter of July 1, 2003 pertaining to my testimony before the Full Committee oversight hearing on "BioShield: Countering the Bioterrorist Threat," the following statements are my responses to the specific questions of U.S. Representative Shelia Jackson-Lee. I have responded from the context of my background over the last three decades as a veterinary medical research scientist participating in the development and implementation of new vaccines and diagnostic tests for two successful multi-billion dollar federal animal health regulatory programs, bovine brucellosis and bovine tuberculosis. For purposes of convenience, I have restated each of Representative Jackson-Lee's questions below.

Questions from Rep. Shelia Jackson-Lee: I am concerned that we could promise about 1 billion dollars for creation of a new vaccine, sit back and think that we have taken care of the problem, and find out in five years that nothing has been accomplished.

Question: How will we monitor whether this Act is having the desired effect?

Response: First, the specific federal-private enterprise contractual agreements must have clearly written time lines and due diligence clauses for completion of deliverables. Second, the contractual agreement between the federal government and private enterprise for vaccines, diagnostic tests and/or therapeutics must be written to have progressive milestones with due dates with demonstrable proof of deliverables meeting specific definitions of quantity and quality of products. Third, the US House Select Committee on Homeland Security will be expected to maintain rigid oversight of the entire process and the timeliness for the quality and quantity of deliverables, possibly functioning through single or multiple major federal agencies, e.g. Department of Homeland Security, Department of Health and Human Services, and/or Department of Defense.

An example from a national animal health perspective: For the last 60 years or more, the United States Department of Agriculture has been responsible for the implementation and oversight of contractual agreements with private enterprise for the timely production of the quality and quantity of vaccines and diagnostic tests required for the hundreds of millions of cattle involved in the successful federal brucellosis and tuberculosis regulatory programs.

Question: How many companies do you think will start new programs to develop vaccines or drugs to combat bioterrorism?

Response: This question is beyond my experience and background, however my impression is that current minor and major biologics and pharmaceutical companies would be responsive to the demand for vaccines, diagnostic test and therapeutics related to bioterrorism as long as the profit incentive remained viable for the firms.

Another example from a national animal health perspective: When the new bovine brucellosis vaccine was introduced in the mid-90s, the same USDA approved biologics manufacturer continued to produce the former vaccine and quickly expanded new manufacturing lines to produce the millions of doses of the new brucellosis vaccine required for the federal regulatory program.

Question: How many companies in the business will expand their programs?

Response: Again this question is beyond my experience and background, but as long as the profit incentive was viable for the biologics and pharmaceutical companies for several years, and the companies were able to meet the quality requirements for the products and had the capacity to expand production, U.S. enterprise would be expected to respond accordingly.

Question: Is there some threshold level of new activity that you could see that might indicate that the industry is dedicating the appropriate resources?

Response: The federal-private enterprise contractual agreements would need to be written with clear indicators that appropriate human resources and fiscal resources were invested to comply with the due diligence clauses for completion of deliverables.

Question: Considering the relative lack of transparency in the private sector, and the fact that many pharmaceutical companies are publicly traded—do you expect them to be forthcoming about their progress, or lack of progress, on this front?

Response: The federal government-biologics and pharmaceutical company contracts would need to be written such that timely milestone inspections and reports are obligatory in order to comply with the due diligence clauses for completion of deliverables.

Question: How long will it take us to figure out if the industry is not getting the job done, and that perhaps a federal effort is necessary?

Response: The frequency of the mandated milestone inspections and reports will be the determining factor for how quickly lack of compliance with due diligence might occur, i.e. the frequency of these inspections and reports would be expected to be no more than each six months throughout the contractual agreement.

Thank you, Chairman Cox, for the opportunity to respond to specific questions from the U.S. House of Representatives? Select Committee on Homeland Security hearing on "BioShield: Countering the Bioterrorist Threat." Should you require clarification for any of my responses, please contact me at your convenience.

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