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BIOLOGICAL THREATS: IS THE CURRENT U.S. VACCINE PRODUCTION SYSTEM PREPARED?

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

SPECIAL HEARING

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FRIDAY, AUGUST 21, 2009

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Pittsburgh, PA.

The subcommittee met at 10:30 a.m., in Courtroom 6A, Pittsburgh Federal Courthouse, 700 Grant Street, Hon. Arlen Specter presiding.

Present: Senator Specter.

Also present: Representative Jason Altmire.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. It is 10:30 a.m., time to proceed with the hearing of the Appropriations Subcommittee on Labor, Health and Human Services, and Education to take up the subject of 21 CB, 21st century biodefense.

The subcommittee is pleased to welcome Congressman Jason Altmire to join us in this hearing. Congressman Altmire's district encompasses some of UPMC.

Our hearing today will focus on a very serious problem facing the United States and facing the world and that is the problem of swine flu and the problem of biodefense against other items where we need vaccines, some of which implicates the threat of terrorist attack.

As to swine flu, for which we are looking for a vaccine of H1N1, as of August 13, a week ago yesterday, in the United States 7,511 people have been hospitalized, 477 deaths in the United States from swine flu; worldwide, 1,799 deaths. And we have been looking for a vaccine of H1N1 where the expectation had been to have some 120 million doses as of October 15, and the Department of Health and Human Services (HHS) announced last Monday that instead of the 120 million doses previously forecast, we only have 45 million doses.

A number of problems have been created, which we will hear detailed in our hearing. One company in Australia was taking care of Australia first, not taking care of the United States first. We would expect UPMC not to ignore Australia, but look at the United States first.

Another company had to take care of their regular accommodations.

I do not know what happened to the other three companies. The witness, the distinguished Dr. Bruce Gellin, Director of the National Vaccine Program Office, can tell us about what those problems were there. But it is obvious that we have a significant problem in meeting a problem which could be enormously serious—enormously serious.

We are looking at the limitations of availability of vaccines which have quite a number of other potential fronts such as smallpox, anthrax, ebola virus, botulism, and another long list, some of which are susceptible to terrorist attacks, for example, if the smallpox virus were unleashed in the United States. What we want to do is to avoid having the Government come up short on something like what happened with Katrina where we are unprepared for the eventuality.

Since 2004, when I chaired this subcommittee, with the joinder of Senator Harkin, who is now the chair, we appropriated $6.4 billion to deal with the vaccine problem, and in the supplemental recently we added $5.8 billion for the discretion of the President to call up the funding. So you can see that we are talking about very substantial funds to meet a very substantial problem.

What we are looking for on the project, which has been worked on by UPMC, is an $830 million project, $580 million from the United States and $250 million from a public/private partnership, which is directed to give the United States control, not to have it in the hands of Australia or companies which may or may not be reliable.

UPMC has come forth with a very important program where their CEO, Jeff Romoff, has played an active part. We have had a series of top level meetings, one in the office of Vice President Biden on March 31, an old train pal of mine. Early in his work as Vice President, I said to Joe we need a meeting with some people here to tackle an important problem, and he promptly opened his office and brought in key people. He is in charge of the funding on the stimulus package, $787 billion, and on May 20, asked Secretary Sebelius to be present at a meeting which was in my office. Again, CEO Romoff came, and on June 15 when Secretary of Homeland Security Janet Napolitano was in Philadelphia on another matter, we had a third meeting to acquaint the key people who are involved in this important matter.

One witness today from General Electric (GE) will testify about GE's involvement on some matters and technology which they have exclusive control. They have the patents. Smaller companies, to change all the production of vaccines, have to go to different equipment and clean steel which takes a long time. GE has a disposable plastic apparatus.

So you can see a lot of thought has been given to this issue, and the general approach is to recognize the primacy of competitive bidding. John Myers, my able deputy, is now drafting authorizing legislation to move ahead on this project so we do not get caught like we got caught on Katrina, do not get caught with a problem with swine flu or any of these other kinds of problems.

Now I am pleased to yield to my distinguished colleague, Congressman Jason Altmire. Jason.

STATEMENT OF HON. JASON ALTMIRE, U.S. REPRESENTATIVE FROM PENNSYLVANIA

Mr. ALTMIRE. Thank you, Senator, and thank you for allowing me to participate as part of this very important——

Senator SPECTER. Jason, you may want to wait just a minute. The TV cameras are being set up.

Mr. ALTMIRE. I think they are probably here to see you, Senator.

Senator SPECTER. I am not going to begin my presentation at the start, although I probably should, but I will rely on PCN, Pennsylvania Cable Network, to carry it.

Mr. ALTMIRE. Well, I would just say very briefly thank you, Dr. Gellin, for being here. There are few, if anyone, in the country who knows more about this and has a level of expertise about this subject matter than you, and we very much appreciate you being here today.

This is an issue that is very important to many in the Congress, both in the House and the Senate. We feel that we need to have some advice from you on whether or not we are prepared as a Nation because it appears often—we saw it with H1N1—that we are in a reactionary mode rather than a preparedness mode. We are always reacting to what we see. And I know you cannot predict the future. You cannot predict what is coming down the road, but we believe that the Nation would benefit from having a better prepared system.

We strongly believe here in western Pennsylvania that we have assets that we can bring to the table that would be of great national interest. We have strength of organization here that is unmatched anywhere else with regard to this issue. We believe we have the expertise and the planning to put this together in a way that is unmatched anywhere in the country. We have the strengths of infrastructure and in financing that we feel like are unmatched anywhere in the country. Regardless of what the conclusion is on that, we believe that the first step has to be an acknowledgement that we could do better with regard to preparedness with our vaccination program.

So we greatly appreciate you being here and look forward to your remarks on this issue, and we look forward to hearing the second panel as well. Thank you.

Senator SPECTER. Thank you, Congressman Altmire.

Just one additional note. With the kind of a proposal for UPMC, it would create 1,000 jobs, 6,000 indirect jobs, and there is a major concern in Washington, DC, about stimulating the economy. We are not going to spend any money which is not really necessary as a matter of public policy and public welfare, but in an area which has been hard hit by an economic decline, this is something which the President has in mind and I know the Vice President does as do the Secretaries of HHS and Homeland Security.

Dr. Gellin is the Director of the National Vaccine Program Office within HHS. He has held positions at the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the two premier Federal agencies dealing with health, also the Rockefeller Foundation and the Johns Hopkins University School of Public Health, quite a prestigious background.

Under our subcommittee procedures, Dr. Gellin, you have testified many times. So you know it is 5 minutes. To stay within the limit, to the extent you can, would be appreciated. Please proceed.

STATEMENT OF BRUCE G. GELLIN, M.D., M.P.H., DIRECTOR, NATIONAL VACCINE PROGRAM OFFICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. GELLIN. Thank you very much, Senator Specter. It is a pleasure to be with you here today to discuss this important topic, particularly what you have highlighted in terms of our ongoing challenges related to the H1N1 influenza outbreak and in terms of lessons that we have learned in our preparedness planning for an influenza pandemic. Vaccines are an important part of our public health system and our medical countermeasure armamentarium particularly against biological weapons. But we also need to recognize—and my role at HHS is in vaccines at the National Vaccine Program Office, but what we are talking is the range of countermeasures of which vaccines are one. So it is in addition to the preventive aspects or some of the treatment aspects for chemical, biological, radiological, and nuclear threats.

In the interest of time, I am going to focus my brief remarks this morning specifically on medical countermeasure advanced development, recognizing it is just one step in the larger process.

In July 2008, Dr. Bob Kadlec, then the Special Assistant to the President for Biodefense and Senior Director for Biodefense at the Homeland Security Council, requested that HHS and the Department of Defense (DOD) conduct an analysis of alternatives to identify the optimal facilities and operating models to address the gaps in the production and manufacturing of medical countermeasures against weapons of mass destruction threats in a manner that provides the best long-term value to the Government. Again, that highlights what Congressman Altmire was talking about, just the relative degree to which we are looking at preparedness rather than just reacting to things and just recognizing that we need to be moving forward on this.

To accomplish this analysis, HHS and DOD commissioned an independent third-party study of manufacturing facility alternatives that should be considered. Because the commercial market for these products is small and the pathways long and the complexities are many—I think that is evidenced with what you discussed, Senator Specter, about the complexities of just the reliability of producing the influenza vaccine by the manufacturers that make vaccine.

For these reasons, the industry as a whole has not been particularly interested in these kind of products, and there is a perception that large gaps exist in the manufacturing and production facilities. The recent history shows that both HHS and DOD have successfully contracted with biotechnology innovators and contract manufacturers for advanced development and procurement of medical countermeasures. Moreover, some of these contractors are investing heavily in production facilities, and the majority in the United States, to further address these gaps.

The independent third-party analysis, which I mentioned, suggests that the Government should increase our capabilities to oversee the advanced manufacturing process development and supply

programs to ensure that the needed medical countermeasures achieve FDA approval, there is an ongoing supply of the product, and there is an ability to surge production should a need be there.

Three alternative scenarios for the development, approval, manufacturing, and the sustained replenishment of large molecule medical countermeasures were examined in this analysis using both quantitative and qualitative criteria.

The first of the three examined the continuation of the existing process of contracting the development and manufacture of medical countermeasures.

The second alternative examined was continuing the existing process of contracting for the development but, in addition to that, strengthening the technical, quality/regulatory, and sourcing and supply capabilities in addition to contracting with additional manufacturers for bulk ingredients, as well as additional manufacturers for final formulation and filling. This approach also provides for enhanced access to process development and manufacturing capabilities.

The third alternative is one that has been proposed in previous studies, and it calls for the Government to manufacture all needed medical countermeasures. This approach includes establishing a new public/private partnership that would include the need for a fully dedicated manufacturing facility for all medical countermeasures under control of the U.S. Government.

HHS is committed to protecting the health and safety of American citizens from both CBRN biodefense threats and emerging infectious diseases and, as we talked about, assuring the Nation's preparedness. Along with our colleagues at DOD, HHS is committed to a full examination and discussion of all viable options for the manufacture of vaccines and other medical countermeasures against these identified threats.

PREPARED STATEMENT

There have been numerous conversations at the technical level about the needs that have been identified and this gap that is being discussed, as well as the range of possible solutions. Given the importance of this topic, all options are on the table right now. And HHS and DOD leadership will be meeting soon to discuss the findings of this report and determine the path forward.

We appreciate your support on this very important topic and your continuing interest in this area. I am happy to answer any questions you have.

[The statement follows:]

PREPARED STATEMENT OF BRUCE GELLIN

INTRODUCTION

Good morning, Senator Specter and Representative Altmire. I am Dr. Bruce Gellin, Director of the National Vaccine Program Office within the Department of Health and Human Services (HHS). I am honored to be here today to discuss this important topic, particularly in light of our ongoing challenges related to the 2009-H1N1 influenza outbreak. Vaccines are an important piece of our public health system and our medical countermeasure armamentarium, particularly against biological weapons. This morning I will provide a brief overview of HHS responsibilities for medical countermeasures development for chemical, biological, radiological, and

nuclear threats and then will focus more specifically on the topic of medical countermeasure manufacturing.

MEDICAL COUNTERMEASURES—DEVELOPMENT AND ACQUISITION

Our progress in securing medical countermeasures begins with and depends on effective planning. The central framework for medical countermeasures planning and implementation in the Federal Government is the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), established in July 2006. This coordinated interagency group is led by the Assistant Secretary for Preparedness and Response (ASPR), and includes my office, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH) as well as our partners from the Department of Defense (DOD), Department of Homeland Security (DHS), and Department of Veterans Affairs (VA). Through this Enterprise-wide effort, we are able to ensure that Federal activities with respect to needed medical countermeasures are effectively coordinated from research and development to acquisition and, ultimately, deployment. This supports a range of programs that I will briefly summarize for developing and acquiring medical countermeasures for man-made and naturally occurring public health threats while building domestic manufacturing infrastructure.

The Biomedical Advanced Research and Development Authority (BARDA) within HHS's ASPR directs and coordinates the Department's countermeasure and product advanced research and development activities. BARDA establishes systems that encourage and facilitate the development and acquisition of medical countermeasures such as vaccines, therapeutics, and diagnostics, as well as innovative approaches to meet the threat of chemical, biological, radiological and nuclear (CBRN) agents and emerging infectious diseases, including 2009-H1N1 influenza. BARDA provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies and diagnostic tools for public health emergencies. It directs and coordinates the Department's countermeasure and product advanced development activities and medical countermeasure domestic manufacturing infrastructure building, including strategic planning for medical countermeasure research, development, and procurement. This coordinated approach is critical to achieving success in the area of bioterrorism preparedness and has been proven through the recent H1N1 effort.

Specifically with respect to vaccines, HHS has a number of efforts underway. These efforts supported the first U.S. licensure of an avian influenza-based H5N1 vaccine in April 2007, which was highlighted by Time Magazine as the number one medical breakthrough of 2007. By the end of 2007, HHS had stockpiled 12 million courses of pre-pandemic H5N1 vaccine. However, maintaining a domestic production capability for these priority countermeasures is also an essential component of the pandemic influenza preparedness strategy. In May 2006, HHS awarded five contracts for more than $1 billion to GlaxoSmithKline, MedImmune, Novartis (formerly Chiron), Solvay, and Dynport (with Baxter) for support of advanced development of cell-based influenza vaccines toward U.S. licensure and expanded domestic vaccine manufacturing surge capacity. In June 2007, we awarded two contracts for the retrofitting of existing domestic biological manufacturing facilities to produce egg-based influenza vaccines and included warm base operations for up to 5 years. Additionally, contract awards were made in 2008 for the construction of new domestic facilities for manufacturing cell-based influenza vaccines that is expected to quadruple the domestic pandemic vaccine manufacturing surge capacity by 2012.

A robust and groundbreaking advanced development program has led to the rapid maturation of modernized cell-based influenza vaccine production and antigen-sparing technologies. New combinations of adjuvants and products provided by multiple manufacturers are currently supported by performance-driven milestone contracts. More rapid vaccine production may be afforded by the development of next generation recombinant influenza vaccines, which HHS will support.

These investments enhanced our current capabilities to respond to the urgent needs for development and manufacturing of vaccine for use against 2009 H1N1 influenza. Currently, HHS has contracted with five companies that are now producing and conducting clinical trials or 2009 H1N1 vaccine for U.S. supply (GSK, Sanofi, Novartis, CSL, and MedImmune).

MEDICAL COUNTERMEASURE ANALYSIS OF ALTERNATIVES

In July 2008, Dr. Robert Kadlec, the then-Special Assistant to the President for Biodefense and Senior Director for Biodefense at the Homeland Security Council, requested that HHS and DOD conduct an Analysis of Alternatives:

> "to identify the optimal facilities and operating model for addressing the gap in production and manufacturing of medical countermeasures against WMD [Weapons of Mass Destruction] threats in a manner that provides the best long-term value to the U.S. Government."

It is important to highlight that the inspiration behind the development of such a biofacility is consistent with many of the broad goals articulated in the draft National Vaccine Plan (November 2008), especially regarding the objectives of

—Fostering advanced research and development toward new and/or improved vaccines that prevent diseases, including those that protect against emerging, reemerging, and important Biodefense-related pathogens, and

—Improving access to appropriately designed pilot lot manufacturing facilities that produce clinical grade material for promising vaccine candidates.

As Dr. Kadlec noted, the timely availability of sufficient quantities of medical countermeasures "is essential for saving the lives of civilians and warfighters following a WMD attack."

A principal mission of HHS and DOD is to provide medical countermeasures—drugs, vaccines, and therapeutics—to protect civilian and military populations, respectively, from attack with CBRN agents. Developing sustainable medical countermeasures that are effective and readily available is an enormously complex task from a technical and organizational perspective.

Such medical countermeasures require:

—Discovery and early research;

—Development and testing in surrogate animal models;

—Advanced development through clinical trials;

—FDA regulatory approval;

—Production and manufacturing;

—Stockpile supply management;

—Distribution and dispensing strategies; and

—Stockpile replenishment.

To accomplish the requested analysis, HHS and DOD commissioned an independent, third-party study of vaccine manufacturing facility alternatives that should be considered. We will soon meet with our colleagues at DOD to discuss the findings and determine any recommendations that will be made in response to the request. But permit me to briefly share some general findings with you.

The focus of the analysis was on the advanced development, FDA approval and sustainment phases of the medical countermeasure lifecycle. Within the advanced development phase, the focus was only on advanced manufacturing process development. Sustainment refers to the storage, maintenance and replenishment of the active pharmaceutical ingredients and the dosage forms of medical countermeasures, as well as procurement, storage, and maintenance of required ancillary supplies needed to administer the countermeasure.

To date, the United States Government (USG) has successfully procured small molecule medical countermeasures (e.g., drugs) from established contractors, and the analysis determined that there is excess industry capacity available for manufacturing these types of products. Thus, the current process of contracting with industry to produce 'small molecule' medical countermeasures appears to be viable now and in the future.

Together, HHS and DOD have stated requirements for a collective portfolio of 23 large molecule CBRN medical countermeasures that are biologically based products. Past analyses have recommended that the USG own and manage a production facility for the manufacture of large molecule products (e.g., vaccines, monoclonal antibodies) to increase control of the approval and supply processes in order to minimize risk of supply disruption.

Since the biopharmaceutical industry, as a whole, has not traditionally developed medical countermeasures for the USG, there is a perception that large gaps exist in manufacturing and production facilities. However, recent history shows that both HHS and DOD have successfully contracted with emerging biotechnology innovators and contract manufacturers for advanced development and procurement of medical countermeasures. Moreover, some USG contractors are investing heavily in production facilities, the majority in the United States, further addressing the facilities gap.

The analysis suggests that the USG should increase its capabilities to oversee the advanced manufacturing process development and supply programs to ensure that,

—Needed medical countermeasures achieve FDA approval, and

—There is an ongoing supply of the product.

ALTERNATIVE SCENARIOS EXAMINED

Three alternative scenarios for the development, approval, manufacturing, and sustained replenishment of large molecule medical countermeasures were examined using both quantitative and qualitative criteria.

—The first alternative examined was continuing the existing process of contracting the development and manufacture of medical countermeasures.

—The second alternative examined was continuing the existing process while strengthening technical, quality/regulatory, and sourcing/supply capabilities; and contracting with additional manufacturers of bulk active product ingredients and formulation, filling, and finishing. This alternative also provides for enhanced access to process development and manufacturing capabilities.

—The third alternative is one that has been proposed in previous studies. It calls for the Government to manufacture all needed medical countermeasures. This approach, which includes establishing a new public-private partnership, anticipates a fully dedicated manufacturing facility for all medical countermeasures under control of the USG.

The first alternative only satisfies the need of the USG to a limited degree because, although the USG has been successful in developing and manufacturing some medical countermeasures, it does not provide the USG with the most effective and efficient processes for managing the potential growing number of highly complex medical countermeasures. While this alternative is the least costly of the three alternatives, it provides the fewest capabilities and carries the risk of less than optimal oversight to ensure the manufacturing capability for the growing medical countermeasure supply chain.

The second alternative builds on the successful current USG medical countermeasure contractual approach and enables flexible decision making for advanced manufacturing process development, stockpiling, backup, and surge. It expands current capabilities to meet the complexity and urgency of medical countermeasures yet to be developed and scaled to manufacturing requirements. This alternative offers the lowest operational risk to achieve current requirements of all the alternatives by creating a collaboration of USG and a network of incentivized, highly specialized, and knowledgeable industry suppliers. It enables future operations to be enhanced most efficiently by incorporating dedicated technology, quality and regulatory compliance, and sourcing and supply functions. In addition, contract manufacturing is less costly and timelier than constructing and operating a dedicated facility.

Of all alternatives examined, the third alternative potentially has the highest risk of supply chain failure and, compared to the two other alternatives, carries the highest cost. In addition, the time required to develop reliable systems for long-term, full-scale manufacture of biologics (large molecules) could impede progress toward needed FDA approval. This alternative also does not provide sufficient surge or backup capabilities. Finally, only a few, if any, biopharmaceutical companies have clustered the production of so many products in a single facility. An adverse regulatory decision or a catastrophic event could shut down the single facility. A single facility with many products is more complex to manage, and is more likely to trigger an adverse regulatory decision than a network of specialized manufacturers.

CONCLUSION

HHS is committed to protecting the health and safety of American citizens from CBRN threats. Along with our colleagues at DOD, HHS is committed to a full examination and discussion of all viable options for the manufacture of vaccines and other medical countermeasures against identified threats.

We appreciate your support and continuing interests in this important area. I am happy to answer any questions.

Senator SPECTER. Well, thank you, Dr. Gellin, for that opening statement.

Dr. Gellin, in looking at the statistics as of 1 week ago yesterday with 7,511 hospitalized cases of swine flu in the United States and 477 deaths in the United States and 1,799 deaths worldwide and the prospect of having serious problems of additional cases of swine flu, I was very concerned to see the report on Monday of this week that the companies were only able to produce 45 million doses of vaccine for swine flu when the expectation had been for 120 million vaccine doses.

Now, is there not really a very substantial public risk when there has been that shortfall on the number of vaccines available for this very serious problem?

Dr. GELLIN. You are right. We were dismayed to learn that as well. We have been working with the manufacturers to try to determine what the expected number of doses would be. This to me, as I said, highlights how complicated this kind of manufacturing is.

Senator SPECTER. And are there not major problems in looking for manufacturers because the big companies do not want to undertake manufacturing these kinds of vaccines because compared to their other business where they have enormous sales and very substantial sums of money, that these are relatively small and not attractive for other big companies?

Dr. GELLIN. Exactly. I think we should put separately the influenza discussion because those vaccines are being made by the same manufacturers that make influenza vaccine around the world. What we are focusing on here is exactly as you say, Senator, looking at the manufacturing for products that do not have a large commercial market.

Senator SPECTER. So what are we talking about is smallpox, anthrax, ebola virus, botulism, and others where there could be a very serious public health problem if terrorists, for example, were to unleash smallpox germs on the community.

Dr. GELLIN. It is exactly the same. There is a list of those threats and there is a need to make sure that we can have the products that we need should we have to face a threat like that.

Senator SPECTER. Dr. Gellin, when you testify, as you did, about Federal Government oversight, is that sufficient? If you do not have a controlling voice in what the company is going to do and you deal with somebody in Australia, it is understandable that the Australian company wants to look after Australia first. I do not like it, but you have to expect that. Or if you find a company that you have contracted with is going to take care of their regular business first and their interests, not in the public interest, I do not like that either, but that is to be expected.

But does there not have to be something more than governmental oversight? Does there not really have to be something like a public/private partnership where the Government is able to control what the producers are going to do, looking out after U.S. health interests?

Dr. GELLIN. I think you are exactly right. And the situation you describe really underscores at least our approach with influenza, as you have mentioned, and the generous support the Congress has provided to develop domestic-based facilities. I think that is clearly a part of this. I think there is a range of possible solutions to this problem, of which the public/private partnership is clearly one.

Senator SPECTER. And when you have a need to change equipment on vaccines and the standard equipment on stainless steel requires a good bit of cleaning and down time and delay, isn't GE in a unique position having the patent on the plastic so that they are in a position to move from one production of vaccine to another?

Dr. GELLIN. I cannot speak to GE specifically, but——

Senator SPECTER. Well, we will hear from them this morning.

Dr. GELLIN. But GE—like many—I think—we are encouraged that a number of companies are taking this seriously and are trying to move us into the 21st century with some of these production techniques.

Senator SPECTER. Has any entity as prominent as UPMC with its very prestigious, very effective operation been as innovative and thoughtful in coming up with a proposal to deal with this very serious national problem?

Dr. GELLIN. I am certainly impressed by the UPMC group proposal, and again, coming into Pittsburgh, it is hard to not see the footprint that UPMC has here. What they have put together, as the Congressman has highlighted, really represents the range of the strengths that they bring to it.

Senator SPECTER. Well, my red light is on the red line, but I will ask you in addition to being impressed, which you testified to, my question was, has anybody like UPMC come forward to tackle this problem in this imaginative, innovative comprehensive way. I want to hear more than whether you are impressed with them. I want to know if anybody else is doing what they are doing.

Dr. GELLIN. There are a lot of discussions about this from a procurement standpoint. So I am not aware of other offers like this. There may be——

Senator SPECTER. Okay. The answer is none that you are aware of.

Dr. GELLIN. Correct.

Senator SPECTER. Well, you are the witness.

Dr. GELLIN. I am the witness and——

Senator SPECTER. Congressman Altmire.

Mr. ALTMIRE. Thank you, Senator, and thank you, Dr. Gellin.

I read your written remarks which, of course, in 5 minutes you cannot go into everything, and you were very thorough. And I wanted to ask you a couple questions that you address in there.

You outlined the options in your oral statement right now that people are talking about, but without picking a favorite option, what is your opinion about the need to restructure the process in a way that maybe better adapts to modern technology and modern threats so that we are not constantly being in that responsiveness frame of mind that we have talked about?

But when you do have to respond quickly, is it fair to say—I am not going to put words in your mouth. I am asking for your opinion—that we need to do a comprehensive restructuring of the process or that we just need to keep doing what we are doing and maybe just refine it a little bit?

Dr. GELLIN. To pick up where you left off, I think we need to take a fresh look at the way we are approaching this. What is comprehensive is, I think, in some ways in the eye of the beholder, but I think that we have identified that there are some substantial gaps. We need more flexibility in our approach, and we need to be more fluid. In my assessment of the assessment of the variety of alternatives, that is what they are looking at as a way to be able to close some of these gaps.

Mr. ALTMIRE. With regard to the American role, public/private partnerships in this process, I think the Senator has accurately said some things that are of concern to the Congress generally,

that when you have foreign entities involved, even though they are allies, they are going to look out for themselves first. So when we talk about the idea of putting forward large sums of money, $600 million or more, toward this effort, would it be your opinion that that would be money well spent if we were to look at the idea of having one leading center in the country that would have the expertise and all the assets that we talked about, regardless of where in the country that is located, versus having—I think you referred to this as an option—a bunch of co-equal centers around the country that do the same thing, but maybe the coordination, in my opinion, may not be what we would like if we had to respond very quickly?

Dr. GELLIN. Yes. I cannot speak to that directly. I think that people make an argument on both sides of that. And my experience with the NIH on the research side is they have a number of Centers of Excellence and they are able to tap into the expertise of different places on common problems. So again, I think there are a number of approaches to this, and I think that that is where the discussions between the leadership of HHS and DOD I think will be quite helpful in trying to figure out what is the right balance and what is the right structure.

Mr. ALTMIRE. Thank you. I have no further questions, Senator. I have a couple of minutes left. I would be happy to yield to you if you had one more, or just yield back.

Senator SPECTER. Well, we are not going to let any time go unused. So thank you.

Dr. Gellin, how do you see the matter progressing? I believe that there will be considerable support in the Congress for the authorization and then ultimately for the appropriation. What next steps do you see in the consideration of this issue? And I ask that in the context that I want to see us move ahead promptly. I do not want to see the bureaucracy slow it down. To what extent will the Office of Management and Budget be a block to getting the necessary funding?

Dr. GELLIN. So I think it is clear, as I mentioned, that this now—the analysis has been done. The discussions have occurred at the technical level and it has got to be briefed up the chain of the respective Secretaries. That then because of the importance of this contract is going to obviously include White House conversation in which, at least in my experience, OMB is always a part of those conversations.

Senator SPECTER. Can you give us some insights as to what the report has shown? I realize it has not been made public, but I know there is tremendous interest in knowing. Describe at least the parameters of the report and what it has been designed to seek.

Dr. GELLIN. Well, you have actually highlighted the broad strokes of what that report has shown. I tried to emphasize some of that in my testimony. Do we continue similarly to what we are doing now? Do we have a little bit more of a hybrid approach of doing what we are doing now but having additional ability to add more control? And then the third possibility is the possibility of having a place where this goes on. So I think that is what is out there for discussion. The analysis has been done. The analysis has

to go up to the leadership to try and figure out the best route forward.

Senator SPECTER. Does the executive share the sense of urgency, which the subcommittee feels on this subject? A sense of urgency to move ahead and get something done?

Dr. GELLIN. Merely because we are in the middle of the H1N1 problem does not mean that everything else is not a problem right now. We recognize that a range of problems exist. The gaps that have been identified exist, and we need to try to close those gaps.

Senator SPECTER. Thank you very much, Dr. Gellin. The red light is on and we will move now to panel two. We would appreciate it if you would stand by because there may be some questions which will arise from the testimony of our distinguished panel which you could shed some additional light on.

We now call CEO and President of UPMC, Mr. Jeffrey A. Romoff, retired Major General Philip K. Russell, Dr. Philip Gomez, Dr. Donald Burke, and Dr. Nigel Darby.

Thank you very much for coming, gentlemen. As noted a moment or two ago, in accordance with our general practice, the subcommittee allocates 5 minutes for opening statements to give a maximum amount of time for questioning and answers.

We turn now to our first witness, Mr. Jeffrey A. Romoff, President and CEO of UPMC, one of the leading nonprofit health systems in the United States. He began his distinguished career at the University of Pittsburgh in 1973 as Director of the Office of Education and Regional Programming at Western Psychiatric Institute and Clinic. In 1992, he was elevated to the presidency of UPMC, and in 2006 became UPMC's President and CEO. A master degree in philosophy with a specialty in political science at Yale University, recipient of the honorary Doctorate of Public Service from Chatham College, and an honorary Doctorate of Science and Technology from Carnegie Mellon University. Welcome, Mr. Romoff, and we look forward to your testimony.

STATEMENT OF JEFFREY A. ROMOFF, PRESIDENT AND CHIEF OPERATING OFFICER, UNIVERSITY OF PITTSBURGH MEDICAL CENTER, PITTSBURGH, PENNSYLVANIA

Mr. ROMOFF. Thank you very, very much, Senator Specter. Thank you, Congressman Altmire, for being here.

I have submitted testimony that provides an overview of UPMC's perspective on this problem, and we have also submitted a summary of the 21st century biodefense project.

Senator SPECTER. All of that will be made part of the record, as will all of the formal statements.

Mr. ROMOFF. Also, I am privileged here to be a member of a panel with far more distinguished and knowledgeable scientists and chem specialists. So I will seek to address issues as you would address issues rather than get into many of the details.

The first issue that is so absolutely essential here is the issue of preparedness, which you, Senator, highlighted in the previous testimony. It is our view and I think it is the view of most commentators and most observers that when it comes to the protection of the national security from a bioterrorist attack, all of the protection of the national security and the national well-being from various naturally occurring infectious diseases, this country and virtually all

countries in the world are relatively defenseless. We can talk about why and how, but this is a very, very grave problem and one that we do not often realize regrettably until after the fact.

It is not just a problem of finding the right medical countermeasures or vaccines to address the problem, should there be a natural accident, as we already saw, or should there be SARS, as we already saw. It is even a more serious problem because the public psyche is highly vulnerable. It is always vulnerable. It was vulnerable after 9/11. It was certainly vulnerable after Katrina, and now coming out of, hopefully, the recession, we see that something that happens unexpectedly, something that shocks like a bioterrorist attack or a lot of what happened with the subprime causes ripple effects that are even more profound than the initial occurrence.

The most serious harm for this country that will come from even a small bioterrorist attack would likely not be the casualties that occurred initially, but the harm will come in the school systems, in the workplace, in the economy, in all the aspects of our daily living because when we do not have the confidence that our Government or that our corporations or that our society is well-prepared to deal with something that is unknown and frightening, we lose confidence completely.

I find it fascinating that yesterday there were statistics that only, if you will forgive the expression, 15 percent of the subprime mortgages actually went into foreclosure. Now, this country reacted extraordinarily to the fact that subprime mortgages were very, very vulnerable. Now, the facts now come out that it was a limited damage in itself, but the damage to the economy, the fact that the credit system came to a screeching halt is profound.

We are now watching the H1N1 situation, and that is a situation where I believe, despite this last finding that they were not making enough vaccine as anticipated, the Government deserves kudos because as soon as the H1N1 emerged, Secretary Sebelius, Secretary Napolitano, the CDC got in front of the public and said we are on top of this or we are learning about it. This is what we are doing, and it calmed the public and it raised the expectations. Now, of course, if the expectations are not completely met, then we have a secondary set of problems.

PREPARED STATEMENT

If this Government, if there is a bioterrorist attack or there is a new infectious disease, cannot stand before the public and say straightforwardly we anticipated this—and it is anticipated. It was anticipated in the Weapons of Mass Destruction Commission report which says there is a reasonable chance that in 5 years—that is, 5 years from a year or 2 ago—that there will be a bioterrorist attack. If the Government cannot stand before the people and simply state we anticipated this, we knew about it, and this is what we did, we caused these things to happen, not that we caused these studies and analysis to happen, but that we caused these concrete approaches, just like we caused new—about H1N1 for now, then I believe beyond whatever attack occurs, there will be a significant, significant diminution in the confidence of the Government and a

diminution in the competence of the Government. This, of course, is what we saw after Katrina.

So in conclusion, I thank you once again for caring about these very, very important issues, and UPMC stands absolutely ready to do everything we can if we have the opportunity.

[The statement follows:]

PREPARED STATEMENT OF JEFFREY A. ROMOFF

Thank you, Senator Specter, for the opportunity to provide testimony on the vital issue of improving the Nation's capacity to develop and manufacture countermeasures critical to national and homeland security. I'd also like to recognize and thank Congressman Jason Altmire (and Congressman Mike Doyle).

I am here today in my capacity as president and CEO of the University of Pittsburgh Medical Center (UPMC), the University of Pittsburgh Medical Center. UPMC is a unique organization that has, over the past two decades, evolved from an outstanding academic medical center into an $8 billion integrated global health enterprise. We have 50,000 employees and are the largest employer in western Pennsylvania. We act as a major health resource for residents of the western Pennsylvania, and contribute more than $500 million annually in community benefits. UPMC is closely affiliated with the University of Pittsburgh, which ranks fifth in National Institutes of Health (NIH) research funding.

One of the key roles that UPMC plays is revitalizing the economy of western Pennsylvania by nurturing new capabilities derived from our intellectual capital and based on medicine, science, and technology.

UPMC's core expertise in this regard is vividly demonstrated by the new $622 million, state-of-the-art Children's Hospital of Pittsburgh of UPMC, where we have deployed a fully integrated electronic health record, developed in collaboration with and for the doctors, nurses, pharmacists, and infection control practitioners at the hospital. Children's is among the only 1.5 percent of the Nation's hospitals that use a comprehensive electronic record, and the care provided is among the finest, safest, and most cost-effective available today.

Our expertise and capacity for innovation are also evident in the Hillman Cancer Center, which acts as the hub of a network of cancer centers throughout western Pennsylvania. These centers are connected through sophisticated linkages that enable the most advanced forms of radiation therapy to be delivered to patients here and abroad.

In a similar vein, one of the telemedicine programs that we have implemented now provides the expertise of stroke specialty consultants to physicians and patients in distant community hospital emergency departments without the risks attendant in spending valuable time in transit to larger hospitals.

In Italy, a decade ago, in collaboration with two hospitals and the Region of Sicily, we brought transplantation and other specialty surgical care to Palermo at a level never before available in the region. The hospital we built, which is known as ISMETT, has become a leader in transplantation in Italy. Building on the success of ISMETT, UPMC is now working with the Italian Government on plans to create a new biomedical and biotechnology center in Sicily, in collaboration with the University of Pittsburgh, the Italian Council of Ministers, the Region of Sicily, and the Italian National Research Council.

Obviously, we are proud of each of these accomplishments, but what do they have to do today's topic, "Advanced Development and Manufacturing for U.S. Biodefense?" I would submit that these seemingly unrelated initiatives share a number of common threads.

First, each of these examples demonstrates that extraordinary achievements can be brought about through out-of the-box creativity and innovation. This creativity should be applied to the challenge of protecting this Nation from bioterrorism. My colleagues on this panel will speak to this issue in greater detail.

Let me just say that UPMC has had a long-standing commitment to serving the Nation and advancing our readiness in the area of biosecurity. In 2003, we founded the Center for Biosecurity of UPMC, an independent, academic think tank dedicated to providing research, analysis, and policy solutions to address national and international biosecurity challenges. We have been at the table in a wide array of regional readiness efforts, and most recently have been conducting comprehensive analysis, in collaboration with DARPA, to assess the U.S. Government's biodefense countermeasure requirements and the Nation's infrastructure in place to meet those requirements.

The second theme that our experience illustrates is that by departing from traditional paradigms, one can develop new and effective solutions. This is as true in biodefense as in electronic health records or telemedicine.

We are already seeing growing recognition that biological weapons and naturally occurring pandemics represent a grave risk to the health of the populace and to the continued economic recovery of this Nation.

Over the past decade, we have all seen official Government report after report cite biological weapons as being among the top national security threats to the Nation. A recent Weapons of Mass Destruction Commission report concluded that a biologic or nuclear attack somewhere in the world is more likely than not in the next 5 years. President Obama recognized biological threats as a major national security issue during his campaign and has committed to improving U.S. biosecurity since taking office. Congress also has worked to improve the state of U.S. biosecurity.

In particular, the central importance of countermeasures—medicines and vaccines—to U.S. biosecurity has been recognized. The Obama administration has expressly committed to "accelerate the development of new medicines, vaccines, and production capabilities."

It is also recognized that the traditional platforms for developing solutions have not yielded the biologics, vaccines, and countermeasures that are required.

It is not because the Nation lacks great scientific knowledge or new ideas—our universities are brimming with new leads and new directions, but they lack the ability to bring these great ideas to market.

It is not for lack of superb pharmaceutical companies that have the top-level industry knowledge and experience to develop, license, and manufacture biodefense countermeasures. There is no commercial market for these products outside the Government, there are substantial opportunity costs for these companies, and they have largely not seen the Government as a predictable partner in this enterprise.

As a consequence, the current U.S. approach to biodefense medicine and vaccine development relies almost completely on small biotech companies. These companies are innovative and focused, but few have demonstrated the capability to produce licensed vaccines or medicines, and few have in house the technical expertise and/or regulatory experience needed to do this work. These companies must raise money to build dedicated factories to make these products. They must have the plans and capacity to manufacture a batch of their products annually to maintain their FDA license, with the result that many of these manufacturing plants will be idle most of the year, with a very limited ability to surge production.

It is in this context that I would strongly urge this subcommittee to initiate a new public-private partnership within HHS BARDA, the mission of which would be to establish and run flexible, multiproduct medical countermeasure development and manufacturing facilities that would address these issues and challenges.

This public-private partnership would make maximal use of flexible technologies that do not require building highly capital-intensive facilities. It would be capable of developing and manufacturing multiple products concurrently in different suites, using disposable technology that can easily be changed depending on the needs and requirements of the Government. In time of national crisis, such as after a substantial bioattack on a U.S. city, all suites of the multiple-suite vaccine plant could be converted to the manufacture of a single drug, providing critical surge capacity not now available.

Another key feature of this public-private partnership would be that it would provide and concentrate "big pharma" development expertise—high-level expertise that is not easy to find for the biotechnology companies now working to develop these products. This would not only increase the odds of success substantially, but also would reduce risk of failure midway through a complex product development life cycle.

In this partnership, key responsibilities of the Government would include setting requirements for medicines and vaccines, making decisions about procurement, and providing part of the funding. The private sector partner would provide the remainder of funding and bring pharmaceutical and technological know-how, and would provide workforce training and education. A range of professional backgrounds and educational levels would be required to operate this facility, from top scientific and professional training to high-school-educated workers. The design, construction, and operation of this facility would provide thousands of jobs.

An economic analysis undertaken by UPMC demonstrates that this approach would save the U.S. Government—that is, American taxpayers—$28 billion over the next 25 years, an estimated 80 percent of the development costs for making the current DOD/HHS requirements for vaccines and medicines. In addition, adoption of such an approach to this challenge would help maintain the U.S. industry in bio-

manufacturing, an industry that has provided excellent jobs, but that has been steadily moving overseas and will continue to do so unless U.S. policy changes.

Finally, this public-private partnership model can and should be used to develop noncommercial medicines and vaccines for emerging infectious diseases—a group of diseases that is of great importance to the world, but for which many of the same market conditions and risks have prevented progress.

We fully anticipate that a project of this importance and scope would be competitively bid. In all likelihood, UPMC and its partners would participate in this competition. We have a proven track record of superb execution and success, but we would anticipate top-level competition from others as well.

In closing, let me again thank you for the subcommittee's leadership on these issues. These are critical issues for the country. The nature and seriousness of the biological threats have been clearly stated for years. The importance of making medicines and vaccines to counter these threats has been similarly recognized for quite some time. There are concrete and innovative steps the country can and should be taking to deal with these vulnerabilities and challenges that will make us far better prepared for a range of crises. We can make new medicines and vaccines for these threats more quickly, more reliably, with less risk and at less cost to the Government. The private sector is capable of being a much more active and effective partner with BARDA and the U.S. Government on these efforts. In the last year, there has been growing discussion in Washington about the vital importance of establishing new public-private partnerships to solve problems that neither the Government nor the private sector can solve alone. My judgment is that countermeasure development and production is the archetype of such a problem, and that the elements of the public-private partnership I have described in this testimony are central to addressing it.

Senator SPECTER. Thank you, Mr. Romoff.

We turn now to Dr. Philip K. Russell, Trustee and Senior Scientific Advisor to the Sabin Vaccine Institute in Washington. He served in the U.S. Army Medical Corps from 1959 to 1990, some extended period of time. Following the anthrax attacks in 2001, Dr. Russell led an HHS effort to develop and stockpile vaccines and other medical countermeasures against bioterrorism agents. Thank you for coming in today, Dr. Russell, and we look forward to your testimony.

STATEMENT OF PHILIP K. RUSSELL, M.D., RETIRED MAJOR GENERAL, ARMY MEDICAL CORPS; BOARD OF TRUSTEES AND SENIOR SCIENTIFIC ADVISOR, SABIN VACCINE INSTITUTE, WASHINGTON, DC

Dr. RUSSELL. Good morning, Senator, Congressman. Thank you very much for the opportunity to be here today and provide my views on the urgent need for a major improvement in the capability of the U.S. Government to develop and acquire biomedical countermeasures that are needed to protect our citizens against bioterrorism.

The experiences that I have more than 40 years of research and development in infectious diseases, including senior leadership positions in both the U.S. Army and HHS medical biodefense programs, has provided me with some insight into the deficiencies of our current programs and the urgent need for change.

The successful development and licensure and utilization of several vaccines by the Walter Reed Army Institute of Research, including meningitis type C and type A—vaccines, unattenuated adenovirus type 4 and 7 vaccines, and hepatitis A vaccines, were made possible by several critical factors. First, a recognized need and adequate funding. Second, a strong internal research base including scientists capable of process development. An associated availability of a pilot-scale GMP manufacturing capability. Partner-

ships with large vaccine manufacturers, and clinical trial capability.

Without these elements, those complex vaccine development programs would not have succeeded.

Another vaccine, the leading malaria vaccine, now undergoing a final phase III trial in Africa, and a similar product—development program in partnership with GSK. Industrial partnership plus adequate funding from the Gates Foundation is critical to this important vaccine.

The success of the military in developing vaccines against recruit camp diseases and natural disease threats has not been matched by success in developing medical countermeasures against biologic threat agents, although we have made enormous investments in basic research, notably in DARPA, and the NIH program, and the Centers of Excellence. We have not been able to translate the results of that research into new products licensed for use. This is in spite of the magnitude of the threat of bioterrorism and its potential devastating impacts on our Nation.

The deficiencies of the DOD biodefense program, as well as regulative changes that have been outlined by several independent studies and reports over the past 2 decades beginning with the Tri-Service Task Force report in 1990. It included an independent study known as the—Report in 2001 and two Institute of Medicine studies, the last in 2004. The common themes of the recommendations in the reports were manufacturing capacity and the need for industrial capability.

In HHS there is a similar problem. The gap between basic research and industrial development and manufacturing, is only partly felt by BARDA funding, that is dependent on an increasingly reluctant and fragile biotechnology industry. The very impressive results that HHS has had with influenza vaccines underlines two issues: capability that exists within the vaccine industry if properly utilized and the fact that vaccine manufacturing is increasingly moving overseas.

The success of HHS's biodefense field is the very rapid development and licensure of ACAM 2000 smallpox vaccine. That was made possible by very solid funding from Congress, a partnership of the small developer with a large pharmaceutical manufacturer with bulk manufacturing capability in Europe and a strong capability in process development and regulatory affairs. Process development capability, as well as manufacturing capability and surge capacity, are necessary to provide the biologic products needed to counter the very real threat of bioterrorism. The best way to provide that capability within the context of a biodefense program is a facility designed and managed to be responsive to Government needs.

PREPARED STATEMENT

A very important additional benefit would be the capability to develop and manufacture vaccines against emerging infectious diseases such as Rift Valley Fever, chikungunya, and hemorrhagic fever. That would be a very valuable contribution to global health and to medical diplomacy, as well as meet the response to something like the next SARS epidemic.

Thank you for your time. I will be happy to answer questions. [The statement follows:]

PREPARED STATEMENT OF PHILIP K. RUSSELL

Good morning Senator Specter, thank you for the opportunity to appear here today and provide my views on the urgent need for improvement in the capability of the U.S. Government to develop and acquire biologic medical countermeasures needed to protect our citizens against bioterrorism. I am Dr. Philip Russell, a retired Army Medical Corps Major General. My medical specialty is infectious diseases and I have been involved in research and development for my entire medical career. For 2½ years following September 11, 2001, I served as a senior advisor to the Department of Health and Human Services (HHS). In that capacity I was deeply involved in the acquisition of medical countermeasures against smallpox, botulism, and anthrax, as well as the experimental H5N1 avian influenza vaccine. As Acting Director of the Office of Research and Development Coordination within the Office of the Assistant Secretary for Public Health Emergency Preparedness I was responsible for coordination of the initial purchases made under Project BioShield.

During my military service, I served as Director of Walter Reed Army Institute of Research (WRAIR) and later as Commander of the U.S. Army Medical Research and Development Command. I was responsible for the management of the biodefense research and development program from 1985 until 1990. As a research scientist and R&D manger, I was involved in the successful development of several licensed vaccines including meningitis, adenovirus and hepatitis A vaccines by the U.S. Army as well as the development of the ACAM 2000 smallpox vaccine. Through this experience I learned what is needed to move a potential new medical product from the laboratory through the development process to licensure, manufacturing and utilization.

The successful development of several vaccines by WRAIR was made possible because of several critical factors:

—A recognized need and adequate funding;
—A strong internal research base including scientists capable of process development;
—Pilot-scale GMP manufacturing capability;
—Partnerships with large vaccine manufacturers; and
—Clinical trial capability.

The success of the military in developing vaccines against recruit camp diseases and other natural disease threats, however, has not been matched by success in developing medical countermeasures against biological threat agents.

The investment in basic science by the Department of Defense (DOD) through the service laboratories, notably the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), by contractors, as well as the immense investment by NIH through its university Centers of Excellence, has produced a wealth of new technical opportunities for development of new and improved vaccines and therapeutics to counter the very real threat of bioterrorism. Yet in spite of the magnitude of the bioterror threat, neither DOD nor HHS has been very successful in moving potential products from the research laboratory to the field or to the national stockpile. We still mainly depend on products developed in the 1950's and 1960's for prevention of casualties while the results of research efforts by both the basic scientists and the biotechnology companies go largely undeveloped.

Both DOD and HHS depend on product development through contracts with contractors that lack the experience, capabilities and resources of the large vaccine manufacturers. The large manufacturers have shown little interest in the high-risk, low-volume, and low-profit medical countermeasures needed to combat bioterrorism.

Several studies of the DOD program have detailed the weaknesses inherent in the current approach. In 1990, a DOD task force entitled Project Badger ("Tri-Service Task Force for the Expansion of the Industrial Base for Production of Biological Defense Vaccines") analyzed the shortage of medical countermeasures for anticipated threats.[1] Continuing concerns over the lack of a stable pipeline of medical countermeasures to protect troops led to the creation of another task force to focus on assessing the need for a Vaccine Production Facility (VPF). This additional task force was to determine a solution for DOD biodefense medical countermeasure manufacturing.

[1] Chronology of Project Badger (Long Term). October 24, 1990. CMAT Control # 1998337–0000036.

In 1993, this VPF task force recommended a Government-owned, contractor-operated (GOCO) facility that could manufacture a variety of medicines and could surge production in times of crisis.[2] The task force recommendation reflected the view that the private sector lacked the means to provide medical countermeasures to the military on its own without adequate incentives. The choice of a GOCO model also reflected a then common DOD acquisition strategy to procure military equipment (e.g., ammunition, tanks) from GOCO facilities. A high-level conceptual design of the facility proposed by the task force was also completed.[3] At the time of the recommendation DOD concluded that the VPF concept was too costly to implement.

DOD vaccine acquisition strategy then evolved to a prime systems contractor approach, one in which a single contractor is dedicated to the development and licensure of biologic products. This was executed in anticipation of the biopharmaceutical industry ultimately supporting DOD production requirements. Over time, however, very little commercial interest in producing biodefense medical countermeasures emerged, thus DOD still had no assurance that existing producers would provide vaccines and novel medical countermeasures.

Consequently, the prime systems contractor approach proved insufficient. Biopharmaceutical companies were discouraged from medical countermeasure development by such factors as low profit margins, the risk of liability for adverse reactions to the products, marginal Federal funding for medical countermeasure programs, and inconsistent U.S. Government priorities for product acquisition. Examples of that troubled process include the loss of availability of Wyeth Laboratories' adenovirus vaccine in 1996, which caused an increase of respiratory disease in military trainees; the loss of the Greer Laboratories' plague vaccine in 1997, which had proven extremely effective in Vietnam against bubonic plague; and temporary loss of Bioport's (now Emergent Biosolutions) anthrax vaccine in 1997.

In July 2001, a study by an independent panel of experts provided the Report on Biological Warfare Defense Vaccine Research and Development Programs to the Deputy Secretary of Defense.[4] The report recommended the overhaul of DOD biodefense program management and the construction of a GOCO VPF, advising integration with the industry and the national scientific community. The recommendations in the report were not implemented.

In 2004, the Institute of Medicine and National Research Council of the National Academies completed a report critical of DOD's efforts in developing drugs and vaccines against biological agents.[5] This report, entitled Giving Full Measure to Countermeasures describes the substantial efforts to develop new drugs, vaccines, and other medical interventions against biological agents and made recommendations for major revisions in the structure of the DOD effort including the creation of a new agency within the Office of the Secretary of DOD. This subcommittee recognized the problems inherent in developing and manufacturing medical countermeasures and the need for major changes.

Major progress has been made in recent years by HHS' Biomedical Advanced Research and Development Authority (BARDA) through the use of the special appropriations for Project Bioshield and for influenza preparedness. The success of the influenza vaccine program managed by BARDA underlines the critical importance of industrial partners with vaccine development and manufacturing experience. Influenza, however, is a special case with significant market incentives due to an expanding annual market.

It is very clear from reviewing the progress made in the past two decades and the several pertinent reports from independent reviews that major changes are needed to provide the protection the country needs from a bioterrorist attack. It is also very clear that the threat is very real and the countermeasures currently in the stockpile will be insufficient to provide the protection that would be made possible by an effective product development effort making maximum use of recent and future scientific advances in the field.

A Government-funded capability to carry out process development, pilot manufacturing as well as surge manufacturing capacity would be immensely valuable and would remove the present bottleneck in development of medical countermeasures.

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[2] DOD Vaccine Production Facility Task Force Final Report, U.S. Department of Defense, 1991 (draft), 1993.

[3] DOD Vaccine Production Facility. LF–0445.00. *Conceptual Design Submittal*. Life Sciences International. November 27, 1993.

[4] Report on Biological Warfare Defense Vaccine Research and Development Programs.

[5] Giving Full Measure to Countermeasures: Addressing Problems in the DoD Program to Develop Medical Countermeasures Against Biological Warfare Agents. Authors: Lois M. Joellenbeck, Jane S. Durch, and Leslie Z. Benet, Editors, Committee on Accelerating the Research, Development, and Acquisition of Medical Countermeasures Against Biological Warfare Agents, National Research Council.

Industrial experience in process development and biomanufacturing must be incorporated into any proposed facility. In addition, a proposed facility should take advantage of advances in manufacturing technology to achieve maximum flexibility and surge production capability.

A Government-controlled capability to develop and manufacture biologics for defense against bioterrorism could also provide a very important capacity to make vaccines against emerging infectious diseases such as Rift Valley Fever, chikungunya and hemorrhagic fevers for both emergency use and as an important medical diplomacy option. This could be a very important ancillary role.

I appreciate the invitation to discuss these issues and will be happy to take questions.

Senator SPECTER. Thank you very much, Dr. Russell.

Our next witness is Dr. Philip Gomez, the Director of PRTM Management Consultants and President of the 21st Century Biodefense Industry. He holds a bachelor degree from Dartmouth, a master of science and doctor of philosophy from Lehigh, and an MBA from the University of Maryland. We appreciate your joining us here today, Dr. Gomez, and we look forward to your testimony.

STATEMENT OF PHILIP GOMEZ, Ph.D., DIRECTOR, BIODEFENSE AND PUBLIC HEALTH PRACTICE, PRTM MANAGEMENT CONSULTANTS, WASHINGTON, DC

Dr. GOMEZ. Thank you, Senator Specter, and thank you, Congressman Altmire, for the opportunity to speak here today. As I described in my written testimony, I had the privilege of working in the private sector for nearly 10 years and then working at the NIH on vaccine development for nearly 7 years. So I hope my perspectives will be helpful in this discussion today.

I have been working with UPMC for almost 2 years now in examining this problem and greatly have been impressed and thank UPMC for taking the leadership on this important issue.

What I will describe today is my support of a study that was sponsored in a cooperative agreement with the Defense Advanced Research Projects Agency, DARPA, which UPMC conducted with a variety of experts on that team to perform that study.

The current U.S. Government procurement model relies on industry to development biodefense countermeasures through the Food and Drug Administration (FDA) licensure, followed by procurement on a product-by-product basis as products become available. This is an incremental approach, whereby the Government identifies the highest priority threats and then issues an RFP to purchase doses. History has shown, however, that in lieu of the participation of large, well-established pharmaceutical companies, the advanced development and manufacture falls on the academic laboratories and innovative small biotech companies that perform the initial research and development of the product. Lacking extensive experience, infrastructure, and resources, these laboratories and smaller companies face extraordinary challenges moving candidate medical countermeasures successfully through advanced development that includes both clinical trials and the complex time-consuming and costly licensure process. Because of the limited investment in advanced development, the current Government approach in biodefense has yielded few successes of novel drugs or vaccines.

The UPMC study analyzed the feasibility and potential technical and economic advantages of building capabilities for advanced de-

velopment and manufacture of biologics for the Government. A key finding was that the Government demand does exist for these countermeasures that have yet to be developed. Although some countermeasures have substantial requirements that have already been procured, for example, anthrax vaccine, therapeutics, and the smallpox vaccine discussed, most of the countermeasures needed for national security require much smaller quantities, especially when compared with the demand needed for commercial drugs or vaccines that you highlighted, Senator. Because these lower volume countermeasures have no viable commercial market, unlike flu, as Dr. Gellin reported, it is left to these smaller biotechnology companies to license and produce them over the long term.

Although the Government has had a need for many different biologics, there is only a limited number of core suitable manufacturing technologies to actually produce them. This now, for the first time, technologically allows us to incorporate these core technologies in flexible, multi-product development and manufacturing capability. And we believe in the study this would greatly reduce the cost and other constraints, enabling the manufacture of medical countermeasures for both stockpiling and, most importantly, surge production.

Implementation of this approach can be pursued via one of many options for structuring and operating the capability. These options range from a wholly private sector approach, a contractor-owned and operated entity, to a wholly public sector approach; i.e., the Government could own and operate an entity. Our study concluded that combining the Government and private sector resources would significantly reduce the long-term costs and the technical and strategic risks commonly associated with licensing and producing required medical countermeasures in a dedicated capability.

The UPMC study included an industry outreach to determine the factors necessary to encourage industry participation in medical countermeasure development. The results of this outreach indicated a preference for operating models that enhance collaboration among all stakeholders, with the most support aligned behind those models that include elements of collocation of advanced development with manufacturing. This is a very important point. Our study started with manufacturing but quickly realized that advanced development, the process of getting ready for FDA licensure, was a very critical aspect that could not be ignored and only from the analysis.

Successful procurement requires the participation of both biodefense innovators and experienced biopharmaceutical firms. Biopharmaceutical firms have the experience, but have avoided the U.S. Government medical countermeasure market because of its perceived low profitability and high risk. They also cite a critical shortage of scientists and engineers to work in this field and that they cannot afford to assign these valuable individuals to noncommercial projects. Therefore, a successful dedicated capability would leverage the development expertise of experienced biopharma while retaining the innovation of small biotech companies and other innovators. It must also focus on training the next generation of scientists and engineers to develop the new drugs that NIH research so capably supports. To succeed, it is critical

that the U.S. Government demonstrate a long-term fiscal commitment to medical countermeasure development and procurement so all industry partners have the economic incentive to become and remain engaged.

The major conclusion of the study was that a flexible, multi-product capability to accomplish advanced development and production of biologic countermeasures would offer numerous scientific, technical, economic, and strategic benefits not provided by the current system. Operated as a public/private partnership, a capability supporting both advanced development and manufacturing would provide the Nation with a much-needed expansion of its domestic industrial base for vaccines and therapeutics. In addition, it would streamline the effectiveness of advanced development while simultaneously reducing technological risk. Analysis suggests that such a capability would also significantly lower the Government's costs of acquisition while enabling the Nation's first domestic flexible surge production capability for both CBRN and noncommercial public health threats.

PREPARED STATEMENT

Finally, in my view, it is important that the job of executing this concept be awarded through a competitive process. This will ensure the best-qualified coalition of private sector partners is brought to bear in helping the U.S. Government meet this important challenge.

Thank you for your support in highlighting these national security and public health needs at this time. I would be pleased to answer any questions you may have.

[The statement follows:]

PREPARED STATEMENT OF PHILIP GOMEZ

Mr. Chairman, Ranking Member, Senator Specter and other distinguished members of the subcommittee, I thank you for the opportunity to discuss the Nation's capabilities in the area of biologics development and manufacturing. Senator Specter, I appreciate your leadership and focus on this issue, and hope my testimony will be informative.

I have been fortunate to work for more than 15 years as a biochemical engineer bringing drugs and biologics to market, both in industry and the U.S. Government. I hold a Bachelor of Arts from Dartmouth College in Engineering Science, a Master of Science and Doctor of Philosophy in Chemical Engineering from Lehigh University, and a Master of Business Administration from the Smith School of Business at the University of Maryland.

I am currently a Director at PRTM Management Consultants, where I work in the field of drug development, helping clients develop operational strategies for successfully developing and manufacturing biologics. Previously, I was employed at the Vaccine Research Center at NIAID/National Institutes of Health (NIH), where I established the Vaccine Production Program Laboratory in 2001. My laboratory developed the Vaccine Pilot Plant for production of vaccines for clinical trials. During my 6 years at NIH, my laboratory oversaw the manufacturing of more than 40 bulk pharmaceutical compounds and more than 15 candidate vaccines utilizing innovative collaborations with industry to advance the development of vaccines against HIV, Ebola, Marburg, West Nile Virus, SARS, and influenza. In 2007, I was awarded the NIH Director's Award for the establishment of the Vaccine Pilot Plant and rapid production of a pandemic influenza vaccine.

Prior to NIH, I spent nearly a decade in the pharmaceutical industry at Abbott Laboratories, Sanofi Pasteur, and Baxter Healthcare in positions of increasing responsibility, leading process/product development organizations and project teams for multiple biologics.

In industry, I saw first-hand the enormous benefits that can flow when the public and private sectors collaborate to address the need for vaccines like meningitis and

influenza, and I believe in areas like biodefense, these partnerships can play a critical role in enabling the development and production of new vaccines and drugs. I believe this combination of NIH and industry experience qualifies me to participate in this hearing and contribute uniquely to this discussion.

For nearly 2 years, I have been working under contract for UPMC as it has examined the challenge of vaccine and biologics development and procurement for biodefense, and as it has sought to identify options for addressing that challenge. Medical countermeasures are needed to protect military and civilian populations against chemical, biological, radiological, and nuclear (CBRN) attacks and naturally occurring emerging infectious diseases. As part of my work, I was assigned to assist UPMC in conducting a Defense Advanced Research Projects Agency (DARPA) sponsored study, which examined the U.S. Government's ability to rapidly develop, license, and manufacture biologics required by the Department of Health and Human Services and the Department of Defense. The study was performed under a Cooperative Agreement with UPMC and DARPA. DARPA is currently reviewing the final report and has therefore not yet released the full report to the public. However, I am pleased to provide a high-level overview of the scope and findings of the study as submitted. Please keep in mind that the study content does not necessarily represent the position or the policy of the U.S. Government, and no Government endorsement should be inferred.

The current U.S. Government procurement model relies on industry to develop biodefense countermeasures through Food and Drug Administration (FDA) licensure, followed by procurement on a product-by-product basis as products become available. This is an incremental approach, whereby the Government identifies the highest priority threats and then issues a request for proposal to purchase doses. History has shown, however, that in lieu of the participation of large well-established pharmaceutical companies, the advanced development and manufacture falls on the academic laboratories and innovative small biotech companies that performed the initial research and development of the product. Lacking extensive experience, infrastructure, and resources, these laboratories and smaller companies face extraordinary challenges moving candidate medical countermeasures successfully through advanced development that includes both clinical trials and the complex, time-consuming, and costly licensure process. Because of limited investment in advanced development, the current Government approach in biodefense has yielded few successes for novel drugs or vaccines.

The UPMC study analyzed the feasibility and potential technical and economic advantages of building capabilities for advanced development and manufacture of biologics for the Government. A key finding was that Government demand exists for CBRN biologic countermeasures that have yet to be developed. Although some countermeasures have substantial requirements that have already been procured (e.g., anthrax vaccine and therapies, smallpox vaccine), most countermeasures needed for national security require small quantities when compared to quantities needed to fulfill the demand for a commercial drug or vaccine.

Because these lower volume countermeasures have no viable commercial market, it is left to the small biotech companies to develop, license, and produce them over the long term.

Although the Government has a need for many different biologics, there is only a limited number of core technologies suitable for manufacturing them. Incorporation of these core technologies in a flexible, multi-product, development and manufacturing capability would reduce cost and other constraints, enabling the manufacture of medical countermeasures for both stockpiling and surge production purposes. Recent technological advances in disposable manufacturing equipment and associated changes in the regulatory environment have greatly enhanced prospects for a multi-product capability by both reducing the overall capital costs and the time necessary to change over from producing one biologic to another. It also provides additional production capacity with reduced technical and strategic risks.

Implementation of this approach can be pursued via one of many options for structuring and operating the capability. These options range from a wholly private sector approach (i.e., a contractor-owned and -operated entity) to a wholly public sector approach (i.e., a Government-owned and operated entity). The study concluded that combining Government and private sector resources would significantly reduce long-term costs and the technical and strategic risks commonly associated with licensing and producing required medical countermeasures in a dedicated capability.

The UPMC study included an industry outreach to determine the factors necessary to encourage industry participation in medical countermeasure development. The results of this outreach indicated a preference for operating models that enhance collaboration among all stakeholders, with the most support aligned behind those models that include the element of co-location of advanced development with

manufacturing. Successful procurement requires the participation of both biodefense innovators and experienced biopharmaceutical firms.

Biodefense innovators have researched promising early stage medical countermeasure candidates, yet they often lack the advanced development expertise to produce FDA-approved products. Biopharmaceutical firms have this expertise, but have avoided the U.S. Government medical countermeasure market because of perceived low profitability and high risk. They also cite a critical shortage in scientists and engineers to work in this field, and that they cannot afford to assign these valuable individuals to noncommercial projects. Therefore, a successful dedicated capability would leverage the development expertise of experienced biopharma interests, while retaining the innovation of small biotech companies and other innovators. It must also focus on training the next generation of scientists and engineers to develop the new drugs that NIH research so capably supports. To succeed, it is critical that the U.S. Government demonstrate a long-term fiscal commitment to medical countermeasure development and procurement so all industry partners have the economic incentive to become and remain engaged.

The major conclusion of the study was that a flexible, multi-product capability to accomplish advanced development and production of biologic countermeasures would offer numerous scientific, technological, economic and strategic benefits not provided by the current system. Operated as a public-private partnership, a capability supporting both advanced development and manufacturing would provide the Nation with a much-needed expansion of its domestic industrial base for vaccines and therapeutics. In addition, it would streamline the effectiveness of advanced development while simultaneously reducing technological risk.

Analysis suggests that such a capability would also significantly lower the Government's cost of acquisition while establishing the Nation's first domestic, flexible, surge production capability for both CBRN and noncommercial public health threats.

Finally, in my view, it is important that the job of executing this concept be awarded through a competitive process. This will ensure the best-qualified coalition of private sector partners is brought to bear in helping the U.S. Government meet this important challenge.

Thank you for your support in highlighting these national security and public health needs at this time. I would be pleased to answer any questions you may have.

Senator SPECTER. Thank you, Dr. Gomez.

We now turn to Dr. Donald S. Burke, Dean of the Graduate School of Public Health, and Director of the Center for Vaccine Research, and Associate Vice Chancellor for Global Health at the University of Pittsburgh. First occupant of the UPMC Jonas Salk Chair in Global Health. Bachelor degree from Western Reserve University and M.D. from Harvard Medical School.

Thank you for coming in today, Dr. Burke, and the floor is yours.

STATEMENT OF DONALD S. BURKE, M.D., DEAN, GRADUATE SCHOOL OF PUBLIC HEALTH; ASSOCIATE SENIOR VICE CHANCELLOR FOR GLOBAL HEALTH; DIRECTOR, CENTER FOR VACCINE RESEARCH, UNIVERSITY OF PITTSBURGH, PITTSBURGH, PENNSYLVANIA

Dr. BURKE. Senator Specter and Congressman Altmire, thank you for the opportunity to discuss the pressing needs of the U.S. Government to find a better way to develop and produce countermeasures for our country's health security.

And Senator Specter, on behalf of health scientists and patients here in Pittsburgh and around the Nation, I also thank you for your extraordinary efforts to provide increased funding for biomedical research through the NIH.

Senator SPECTER. Thank you.

Dr. BURKE. I currently serve as the UPMC Jonas Salk Chair on Global Health and work at the Center for Vaccine Research. In every research setting in which I have worked, I have witnessed

personally the difficulty of translation of advances in basic scientific research into medical products.

The University of Pittsburgh is committed to joining with UPMC and other partners in developing a flexible, multi-product vaccine facility, and indeed, the university could bring exceptional strengths to this partnership. As you know, the University of Pittsburgh has a long and proud tradition of vaccine research, dating back to Jonas Salk's extraordinary achievements in development of the polio vaccine.

The Center for Vaccine Research that I direct is evidence of the university's resurgent excellence in the field of vaccines. The establishment of the center was made possible by a $10 million contribution by UPMC, a visionary step toward this process we are engaged in now. It is housed on two floors of the new, state-of-the-art biomedical science tower. We have 31 full-time and affiliate doctoral-level research academics and occupy 32,000 square feet of laboratory space. We also have a regional biocontainment laboratory, a high containment facility that was constructed with NIH support. This lab is designed to permit research on vaccine development for avian influenza and swine influenza, tuberculosis, dengue, tularemia, and other highly infectious disease threats.

The Pittsburgh Regional Biocontainment Laboratory at our university also serves as a core laboratory for the NIH-supported Regional Centers of Excellence for Biodefense. This laboratory houses the animal model core for the Mid-Atlantic Regional Center of Excellence and Biosafety Level 3 laboratories in one facility and supports a full spectrum of investigations from basic microbiological and immunological manipulations to animal challenge studies.

Another strength here in Pittsburgh is our leadership in developing and using computational modeling simulations to optimize vaccine development and deployment strategies. Recently the university was recognized as one of two NIH National Centers of Excellence for modeling of infectious diseases to serve the country.

We also serve as the home to the Vaccine Modeling Initiative which is supported by the Bill and Melinda Gates Foundation.

Pitt also has an excellent research and training collaboration between the School of Medicine and the School of Engineering, especially as related to the design and production of medical devices and more recently the development of novel biomanufacturing processes. These interdisciplinary medical-engineering programs create a unique environment for academic consultations and training of biotechnology personnel related to vaccine design and manufacturing.

Thus, the University of Pittsburgh today demonstrates excellence in many disciplines that are critical in vaccine research. However, university professors who conduct early preclinical and clinical stage research are not able to bring the candidate product all the way to licensure on their own. Product development, as opposed to basic discovery, requires a different set of skills and expertise, and this product development expertise resides primarily within large biopharmaceutical companies whose business it is to bring drugs and vaccine discoveries from the lab to the consumer market.

PREPARED STATEMENT

The formation of a public/private partnership such as UPMC is proposing is the only real alternative that has the possibility of success in fixing the critical problem that has faced our Nation for many years. The University of Pittsburgh with its outstanding research and training capacities stands ready to support these public/private partnerships.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DONALD S. BURKE

Mr. Chairman, Ranking Member, Senator Specter, and other esteemed subcommittee members and staff, thank you for the opportunity to discuss the pressing need for the U.S. Government to find a better way to develop and produce biologic medical countermeasures for our country's health security. This endeavor represents a key component in the larger biodefense and public health framework and will certainly help ensure a safer and more resilient America. And on behalf of health scientists here in Pittsburgh and around the Nation, I also thank you for your extraordinary efforts to provide increased funding for biomedical research through the National Institutes of Health (NIH).

I am a physician, an infectious disease expert, an epidemiologist, and vaccine researcher. I have worked on prevention and control of epidemic infectious diseases for my entire career. Previously, I served 23 years on active duty in the U.S. Army, including service as the Associate Director for Emerging Threats and Biotechnology at Walter Reed Institute of Research (WRAIR). I currently serve as the Director of the University of Pittsburgh's Center for Vaccine Research. In every research setting, I have witnessed the difficulty in translation of advances in basic scientific research into medical products to protect people from serious health threats. I am here today to discuss the exciting idea of a new facility to solve this pressing national problem.

As you are aware, the first step in producing any effective drug to counter a bioweapon or epidemic begins in the research lab. Initial research and testing, if successful, then requires the crucial step of applied research. Translational research is a term used to describe the process by which a drug or vaccine candidate moves from early basic research, through the various stages of development, and eventually into a licensed product.

Both the NIH and Department of Defense (DOD) have made tremendous investments in basic research, with significant progress achieved in understanding disease threats, and identifying potential drugs and vaccines to mitigate their impact. Although there have been remarkable advances in the diagnosis and treatment of many medical conditions, infectious diseases remain the leading cause of deaths worldwide. Few discoveries in biomedical research are as important as those that revolve around vaccines for infectious agents that pose risks to global public health and global security.

The University of Pittsburgh is committed to joining with UPMC and other partners in developing a flexible multi-product vaccine facility, and indeed the University brings exceptional strengths to that partnership. Out of more than 3,000 institutions nationwide, Pitt now ranks fifth in NIH funding and fifth in the number of individual grants received. Last year the University and its affiliates received more than $450 million in NIH support.

The Center for Vaccine Research (CVR) that I direct is evidence of the University's growing excellence in the field of vaccines. The Center is housed on two floors of the new, state-of-the-art biomedical science tower. The CVR consists of the research teams of 31 full-time and affiliate doctoral level researchers, and occupies 32,000 square feet of laboratory space. A key component is the Pittsburgh Regional Biocontainment Lab, a high-containment facility that was constructed with NIH support. This lab is designed to permit research on vaccine development for avian influenza and swine influenza, tuberculosis, dengue, tularemia, and other highly infectious disease threats.

The Pittsburgh Regional Biocontaiment Lab (RBL) also serves as a core laboratory for the NIH-supported Regional Centers of Excellence for Biodefense. The RBL houses the nonhuman primate core of Mid-Atlantic RCE and Biosafety Level 3 (BSL3) research labs on a single floor, thus supporting a full spectrum of investiga-

tions from basic microbiological and immunological manipulations to animal challenge studies.

We have also gained national recognition for our exceptional collaborations between the School of Medicine and the School of Engineering, especially as related to the design and production of medical devices and more recently to the development of novel bio-manufacturing processes. These internal collaboration have been further enhanced by inclusion of engineering faculty from Carnegie Mellon University. We have NIH training grants for the Medical Scientist Training Program (MD/Ph.D.) and for biotechnology, the latter focused on vaccine development with the CVR. These interdisciplinary medical-engineering programs create a unique environment for academic consultations and training of biotechnology personnel related to vaccine design and manufacturing.

Those performing early clinical stage research such as is done in the CVR are typically not able to bring a product candidate all the way to licensure on their own. Discovery and development require different expertise. Product development expertise resides primarily with large biopharmaceutical companies whose business it is to bring drugs and vaccines all the way from lab to the consumer market. However, because most biodefense products are noncommercial by nature, there is no market-based incentive for biopharmaceutical companies to pursue their development and they have accordingly been reluctant to engage.

As products are developed and brought into early human clinical testing by the NIH or DOD there currently is not a clear path to licensure and procurement for the U.S. Government. Despite attempts by the U.S. Government to attract experienced biopharmaceutical companies to the process, few have entered.

For this reason, commercial partnering with the U.S. Government is essential to bringing biologic medical countermeasure candidates to full licensure. Without such a partnership, only the biopharmaceutical industry retains the ability and know-how for scaling production levels of biologics up to required levels. Larger biopharmaceutical companies possessing this experience and expertise in advanced development must be incentivized to engage if the U.S. Government wants to fulfill its biodefense requirements.

It is clear that given the lack of commercial incentives for these products, we cannot expect industry to enter alone. The formation of a public-private partnership between industry and the USG is the only alternative that has the real possibility of success in fixing a challenges that has been at the DOD and HHS for many years, one that I have personally encountered. I encourage the subcommittee and the Government to continue to develop this concept, and ultimately compete it implementation to ensure the best and most current ideas are incorporated.

Senator SPECTER. Thank you very much, Dr. Burke.

Our final witness is Dr. Nigel Darby, Vice President, Biotechnologies and Chief Technology Officer at GE Life Sciences. These products are used in the manufacturing of more than 90 percent of registered biopharmaceutical products. He has been the Vice President for Chemistry Technology at Astra Zeneca, 16 years in academic research in medicine and molecular biology. He has a master's degree in natural science from the University of Cambridge, UK, in 1981 and a Ph.D. in biochemistry from the University of Kent in 1985.

Thank you for coming in today, Dr. Darby, and we look forward to your testimony.

STATEMENT OF NIGEL DARBY, Ph.D., VICE PRESIDENT, BIOTECHNOLOGIES, LIFE SCIENCES, GE HEALTHCARE BIO-SCIENCES AB, UPPSALA, SWEDEN

Dr. DARBY. Thank you. Senator Specter, Congressman Altmire, firstly, thank you for the opportunity to testify today.

GE Healthcare provides much of the technology which is used in the discovery and manufacturing of lifesaving pharmaceuticals. Relevant to the testimony today, as you just mentioned, GE provides the technology which is used in the manufacturing of more than 90 percent of registered biopharmaceuticals and many vaccines.

Now, we have heard today from our colleagues about the importance of manufacturing biological countermeasures such as vaccines in response to biological threats. I am here today to outline the current state of the technologies used to manufacture these countermeasures and the importance in developing a partnership between the public and the private sector to deploy these technologies to provide an effective response to future biological threats.

Any manufacturing solution addressing biological threats needs to address four key issues which relate to the development of countermeasures: quality, safety, flexibility, and speed. I will briefly address the primary considerations about each of these areas.

Traditional manufacturing facilities for biopharmaceuticals and vaccines are, indeed, expensive. There are often constructed from "hard-plumbed," permanent, stainless steel technology and they are dedicated to a single product. They can cost up to $1 billion to construct and take up to 5 years to build and validate. Between manufacturing runs in these facilities, the equipment must be extensively cleaned and tested to ensure that there is no contamination, a time-consuming and costly process reducing productivity but ensuring the safety of the final end product.

So how do you go about achieving some more flexibility? Clearly, a $1 billion biological countermeasure production facility dedicated to a single biological threat is not a viable response to a threat which is as yet not well-defined. Recent advances in developments in biomanufacturing, however, mean that we can design more flexible facilities that can manufacture a number of medicines and still retain the quality and safety profiles of traditional facilities and, in addition, achieve this at a lower cost and with improved efficiency.

New developments are allowing us to replace the traditional stainless steel manufacturing technology with disposable plastic technologies. These allow us to rapidly reconfigure the manufacturing process, using off-the-shelf, ready-to-use components. After a manufacturing run, components are simply discarded and a new set installed for the next manufacturing cycle. Expensive cleaning and validation processes required in traditional facilities are significantly reduced, improving the facility productivity substantially, but retaining the overall level of safety in manufacturing.

The use of this disposable technology improves manufacturing safety. It reduces contamination risk and increases the outputs of the facility, and that adds the crucial element of flexibility. It also reduces the capital expenditure and lowers the start-up costs.

If we turn to speed, in a pandemic or biological attack, reaction time inevitably must be short. Preparedness, therefore, should focus on solutions that deliver a significantly more likely response. Disposable, ready-to-use manufacturing technologies bring unprecedented speed to both the development and manufacturing of biopharmaceuticals and vaccines. In collaboration with the vaccine developer, we have demonstrated that disposable technologies can reduce the time it takes to get a flu vaccine into production by up to 60 percent.

In summary, then our four critical manufacturing challenges—safety, quality, flexibility, and speed—can be addressed by implementation of the new disposable manufacturing technologies being

developed by GE and our industry peers. Virtually all manufacturing steps required can be carried out with disposables.

While currently not capable of achieving the manufacturing scales of the largest fixed stainless steel installations, the technology is evolving rapidly enough to deliver significant volumes of therapeutic agents and vaccines in a safe and timely manner.

PREPARED STATEMENT

In conclusion, biopharmaceutical and vaccine manufacturing technology is at an exciting and important point in its development. What we now need at this point is a commitment from Government to help bring these technologies to the forefront at a time when we have the capacity to do so and when the need has never been greater. We believe this presents a unique opportunity for the public and the private sector to come together and ensure that these critical technologies can be in place to deal with the threats of biological agents which we face potentially in the near future.

That concludes the testimony that I have. Once more, thank you for allowing me to participate today, and I welcome any questions that you have. Thank you.

[The statement follows:]

PREPARED STATEMENT OF NIGEL DARBY

Chairman Specter, distinguished guests, thank you for your attention to the important issue before us today. My name is Dr. Nigel Darby. I am the Vice President for BioTechnologies of GE Healthcare's Life Sciences division and have worked extensively in the pharmaceutical and biotechnology industries, both as an executive and in research and development. Today I manage a large product portfolio of tools and technologies that support research, discovery and drug and biopharmaceutical manufacturing.

Prior to entering industry, I spent 16 years in academic research in medicine and molecular biology at the National Institute for Medical Research in London, the M.R.C. Laboratory of Molecular Biology, Cambridge and at the European Molecular Biology Laboratory in Heidelberg, Germany. I have an M.A. in Natural Sciences from the University of Cambridge and a Ph.D. in biochemistry from the University of Kent in the UK.

GE Healthcare provides much of the technology used in the discovery and manufacturing of pharmaceuticals. Most relevant today is our expertise in manufacturing of biopharmaceuticals and vaccines. Biopharmaceuticals are drugs such as insulin and monoclonal antibodies, often based on proteins, and are among the most rapidly growing groups of medicines today. More than 90 percent of registered biopharmaceuticals and many vaccines rely on GE-developed technologies or processes for their manufacture.

We have heard a lot today about the risk and the threats biological weapons and pandemics pose to national security and the necessity to develop and manufacture biological countermeasures. I am here to outline the current state of the relevant manufacturing technology that can be brought to bear on these threats, the key issues that need to be addressed, and how that technology is evolving.

Any technological solution addressing biological threats, whether natural outbreaks or terrorist actions, needs to address four key issues in manufacturing biological countermeasures: quality and safety, flexibility, and speed.

QUALITY AND SAFETY

For reasons of patient safety, quality and consistency in pharmaceutical manufacturing is critical and this is particularly the case for biopharmaceuticals and vaccines. These are complex medicines, usually produced in biological systems, such as cell culture, and they require a series of purification steps to deliver a safe end product. The quality and safety of the end product is assured by robust control and validation of the manufacturing process. The aim is to deliver as reproducible a process as possible and to exclude all possible sources of contamination.

Biopharmaceutical and vaccine manufacturing requires established, validated equipment and highly skilled, fully trained individuals to perform the procedures. Production must meet standards as set out by FDA approval guidelines and ISO standards, including complying with cGMP biocontainment requirements for aseptic production, and biosafety regulations. These standards must be maintained throughout all stages of the development process to ensure that the product remains the same and retains high quality. Development of systems and standard operating procedures are vital to promote stability, reduce costs, and ensure quality.

Traditional manufacturing facilities for biopharmaceuticals and vaccines are expensive, partly, and rightly, because of the time and effort spent controlling the facility's environment, the cleaning and maintenance required to avoid contamination of the end product. These are often 'hard-plumbed' stainless steel facilities, dedicated to a single product, and can cost up to $1 billion and take 5 years to build and validate. Between manufacturing runs, the equipment must be extensively cleaned and tested to ensure there is no contamination; a time-consuming and expensive process.

While reasonable for mainstream commercial pharmaceuticals and vaccines, where volumes are high and demand is predictable, a billion dollar biological countermeasure production facility dedicated to a single biological threat is not a viable response to an as-yet nonspecific threat. Recent developments in bio-manufacturing mean we can design flexible facilities that can manufacture a number of medicines and vaccines and yet retain the quality and safety profiles of traditional facilities.

FLEXIBILITY

To achieve this flexibility, manufacturing must move beyond the dedicated "hard-plumbed" stainless steel plants focused on a specific product. Ideally, we should be able to rapidly manufacture different products in a single facility, and do this without compromising product safety.

New developments are allowing us to replace much of this stainless steel technology with disposable plastic technologies. These allow us to rapidly reconfigure the manufacturing process, using off-the-shelf ready-to-use components, for example pre-sterilized where appropriate. After a manufacturing run, components are simply disposed of, with a new set brought in to manufacture the next batch, or even a different medicine or vaccine.

The use of this disposable technology improves manufacturing safety, reduces contamination risk and increases the throughput of the facility, and adds that crucial element of flexibility. They also reduce capital expenditure and lower start-up costs.

When compared with traditional stainless steel production facilities, the "ready-to-use" system combines the advantages of single-use technology—at its simplest, offering plug-and-play ease of use—with cost-efficiency and additional safety aspects. In the event of an emergency, a flexible and modular production approach would facilitate rapid capacity deployment in a cost-effective and robust manner.

Additional benefits of ready-to-use and single-use technology are numerous. By eliminating many of the time-consuming steps from initial set-up, cleaning, analysis and documentation—downtime can be turned into uptime and production capacity within such a facility increased. In cases where rapid facility change-over is demanded, single-use products will be especially useful eliminating the risk for cross-contamination and operator exposure, especially important when manufacturing processes are based on the production of biological pathogens.

Adaptability is a key advantage of ready-to-use systems. Many of our customers are switching to systems with these components as a more flexible option, allowing the user to quickly change the target molecule, and providing some flexibility in batch volume.

In summary, single-use components offer many benefits beyond speed and flexibility, including reduced risk of contamination, minimized downtime for cleaning, sterilization and corresponding validation procedures, reduced operation costs and minimal maintenance.

SPEED

In the event of an incident such as an outbreak of an influenza pandemic or other pathogen, reaction time is inevitably short. Therefore preparedness efforts should be directed at implementing solutions that will facilitate a rapid response. Simplifying development and accelerating manufacture of a biological countermeasure are critical challenges, and GE Healthcare has allocated significant investment to lead technological progress in this area.

To effectively protect a target population, a biological countermeasure must be developed in such a way that it can be produced and delivered in large volumes. For

example, when faced with the threat of seasonal and pandemic influenza, vaccine manufacturers face the challenge of scaling up production to deliver large batches of product in the shortest possible time. Currently, in the event of a pandemic, existing global manufacturing capacity would provide sufficient influenza vaccine for only around 4.6 percent of the world's population.[1]

Understanding both the biological and production hurdles, much of our focus has been on developing more cost-effective, quicker, modular ready-to-use manufacturing solutions, to both help traditional manufacturers gain efficiencies, but also to meet the growing need for flexibility in development, as governments search for solutions that would enable production capabilities to be implemented at speed and low cost.

Take the current influenza epidemic as an example: Traditionally many vaccines such as flu vaccines, rely on an inactivated or weakened attenuated pathogen that is produced in eggs and purified. With normal seasonal lead-times, flu vaccine demands can be met, however in a crisis situation, even if all the current manufacturing plants were to concentrate on producing a "pandemic" vaccine, a serious capacity gap would still exist.

Responsible health planners around the world are looking to increase manufacturing speed and capacity and vaccine stockpiles to counter the threat of a flu pandemic: the global demand for pandemic influenza vaccine has been reported as possibly approaching 7 billion doses, and according to the WHO with current world capacity, the potential vaccine supply would fall several billion doses short of the amount needed to provide protection to the global population.

Disposable and ready-to-use manufacturing technologies bring unprecedented speed to both the development and manufacturing of biopharmaceuticals and vaccines. As an example, working with a vaccine developer as a partner, we have shown that it is possible, with disposable technologies, to reduce the time it takes to get a flu vaccine into production, after the isolation of the relevant viral strain, by up to 60 percent.

Safety and quality, flexibility, and speed—all three of these critical elements can be addressed by the advent of new disposable and ready-to-use manufacturing technologies being developed by GE and our industry peers. Virtually all manufacturing steps can be carried out with disposables, from cell culture to purification steps such as chromatography and filtration.

While currently not capable of achieving the manufacturing scales of the largest fixed stainless steel installations, the technology is evolving rapidly enough to be able to deliver significant volumes of therapeutic agents and vaccines. This is aided as the flexibility of disposable technology allows the economic and rapid set up of multiple production lines in parallel.

In conclusion, biopharmaceutical and vaccine manufacturing technology is at an exciting point of development, increasing speed and flexibility in manufacturing, while assuring product safety and quality. Interest in these developments is high, as pharmaceutical companies, governments, and their national health and security organizations recognize the new capabilities that this technology can deliver in the challenging circumstances of an emerging infectious disease or other biological threat.

Mr. Chairman, thank you for the leadership you've shown and for calling attention to this important issue.

Senator SPECTER. Thank you very much, Dr. Darby.

We will now proceed with 5-minute rounds of questions from the panel.

I begin with a statement made by Dr. Gomez commenting that they started with manufacturing and then quickly moved to advanced development, emphasizing the need not only for manufacturing capabilities but also to keep abreast on technological development. UPMC, the University of Pittsburgh Medical Center, has the advantage of having the University of Pittsburgh research at its side, and the University of Pittsburgh has the advantage of having UPMC as well. There is a little mutuality.

Dr. Burke had testified of his appreciation for the increase in funding by the NIH, and just a comment about that. When I was elected to the Senate in 1980, the first committee I chose was Ap-

[1] Heuer A., Editor's Note. *The Bridge*. 2006 Fall: 36(3):3.

propriations because of its power, candidly, in bringing money back to the State. And the first subcommittee was the Subcommittee on Labor, Health and Human Services, and Education, which is the subcommittee with this hearing. In my first year in the Senate, the NIH budget was $3.6 billion, but when I became chairman, in collaboration with Senator Harkin, now the chairman—he was then the ranking minority member—the NIH budget was $12 billion, and we took the lead in increasing it to $30 billion, some years as much as $3.5 billion added. And during those years, there was a marked decrease in fatalities or morbidity due to stroke and many other maladies.

I have taken a look here at the funding for the University of Pittsburgh from NIH, which has been considerable. In 1998, it was $169 million, and then with the increases, it went as high as $386 million. A lot of money. And in the span from 1998 to 2007, it was—I want to be sure these figures are right. It is $3,020,000,000, which has really been—well, how would you characterize it, Dr. Burke? What has that done for the University of Pittsburgh?

Why should I characterize it when I have a witness at hand?

Dr. BURKE. I would characterize it as a lot of money, sir.

Senator SPECTER. Well, what has it enabled you to do?

Dr. BURKE. During this time, there has been the explosion in biotechnology is probably the most important change in——

Senator SPECTER. And it was not only the University of Pittsburgh. It happened across the country.

Dr. BURKE. That is correct. The entire country has had this explosion of biotechnology that now allows us to move some of these vaccine technologies into the advanced development that would permit this kind of facility to be useful where previously we relied on the traditional steel technologies, the larger-scale technologies, and here I think we now have flexible, fast-moving technologies. So it not only affects these. It is across the board. There has been an incredible impact on biomedicine.

Senator SPECTER. And in recent years, it has been cut back as a result of budget constraints, no cost-of-living adjustments, across-the-board cuts so that there was a decline on NIH in real dollars of $5.2 billion. But then with the stimulus package, the amendment, which I offered, got into the bill for $10 billion extra. What has that done in terms of reawakening a whole generation of research scientists?

Dr. BURKE. As you point out, in the last 2 or 3 years, we have had a flattening and an actual decline, and it has been very difficult to sustain first-rate biomedical research, and the additional funding that was provided in the last year, the additional $10 billion, has allowed us now to take up some of those projects that otherwise would not have been funded and carried forward. So it has been an incredible stimulus. The money is being well-spent and being spent quickly.

Senator SPECTER. I am going to move through the 5-minute round, if it is okay with you, Congressman Altmire.

Mr. ALTMIRE. Yes, sir.

Senator SPECTER. You will have equal time. But I am on a line of questioning which I want to pursue further with Mr. Romoff.

Comment on the relationship between the University of Pittsburgh Medical Center and the University of Pittsburgh. You are separate but how do you interact?

Mr. ROMOFF. We are two separate, independent organizations but intimately joined at the hip. I think using the 21st century biodefense project as an example, as Dr. Burke stated before, we contributed $10 billion—$10 million—excuse me——

Senator SPECTER. You are getting your zeroes mixed up, Mr. Romoff.

Mr. ROMOFF. These days it is too easy, I am sorry to say.

We contributed $10 million to develop, under Dr. Burke's leadership, the Center for Vaccine Research, and Dr. Burke and his colleagues bring the scientific underpinnings, both the basic science and political science, to figuring out and solving——

Senator SPECTER. So tell me why is it that UPMC undertakes this kind of a project as opposed to having the University of Pittsburgh do it?

Mr. ROMOFF. Because UPMC has the capacity to take science and translate that science into products and then to, say, a vaccine factory or to translate into patient care innovations. The university does a good deal of the science and research. We take the research and translate it into things that work for patients, work for society in general.

Senator SPECTER. Well, that is the unique opportunity which I wanted Dr. Gellin to hear in detail. May the record show he saluted and raised his hand and acknowledged the information. Well, that is what hearings are about. Dr. Gellin is going to play a key role in what is going to be done here in his position.

The joinder of the University of Pittsburgh and UPMC is very unique. I look for a competitive bidding at the end of the rainbow, and I am going to be pushing hard to land it for Pittsburgh in the 7,000 jobs, which I commented about earlier, and also the expertise to really contribute to the national welfare. There are two edges of the sword. We are not going to spend the money foolishly, but when you can produce this kind of a product, you produce the jobs to an area which needs them, there is a lot to be said for that. And the synergy between the University of Pittsburgh and UPMC to get the job done I think is really significant.

Mr. ROMOFF. Can I just add one point, Senator? In addition to thanking you once again not only for—or $10 billion in NIH funding which produced the science, but for your extraordinary efforts on behalf of this project here.

But to focus in on the economic development aspect, this project, if done, would bring 1,000 jobs directly and 6,000 jobs indirectly, but that is really just the beginning. As is clear from testimony here, we are talking about creating an industry and an industry without significant bounds, and that is, if we were able to, through competitive bidding, land this public/private partnership with your assistance here in Pittsburgh, I have no doubt that we would then be able to attract around that other private biotechnology companies to come to Pittsburgh who would set up laboratories——

Senator SPECTER. Do you have any idea as to what the dollar figure would be or the employment opportunity figure would be?

Mr. ROMOFF. It is all speculation, but I think——

Senator SPECTER. Go ahead. Speculate a little.

Mr. ROMOFF. Well, I think we are talking about multiplier effects of at least 10 times what the initial investment is.

Senator SPECTER. So something like 70,000 jobs and——

Mr. ROMOFF. I think you can certainly imagine that because everyone understands that these small biotechnology companies do not have the resources, do not have a place to turn to develop—do not have a flexible facility that is able to produce small batches, not just large batches, of different kinds of vaccines and other kinds of drugs that they need to go to clinical trials and to develop things that become commercially viable. A facility like this serves not only the Government's needs, but it serves an enormous amount of proprietary needs, and that is where you get the influx into the region of this kind of money, energy, people, and jobs.

Senator SPECTER. Dr. Russell, you said in 1993 that the task force recommended a Government-owned, contractor-operated facility for manufacturing medical countermeasures, and that kind of an organization would avoid the kind of the problem that we have with Australian manufacturers for vaccines. They look out for Australia not for the United States. But the DOD determined that it was too expensive.

Now, I commented earlier about the kind of funding which has been produced here, that in 2004, when I chaired the subcommittee, we put up $6.4 billion and the President now has additional discretion from further appropriations for $5.8 billion. And considering the severity of the problem, would you continue to recommend, as you did in 1993, that it be a Government-owned facility or at least a public/private partnership where the Government could have a determinative voice in manufacturing for the welfare of the United States in light of the kind of threat we face now after 9/11, the kind of money which the Congress has already been willing to put up?

Dr. RUSSELL. At the time that decision was made by the DOD, I disagreed with it. I was in support of the Government-owned, contractor-operated. The technology at the time was more expensive and the methodology required dedicated facilities. It was not as efficient as we can do today with today's technology. I would argue very strongly that the decision by the DOD to move to a prime contractor method of operation basically failed to produce the product effectively.

Senator SPECTER. So the old system failed, and you stand by your approach for Government participation?

Dr. RUSSELL. I think it definitely requires that we have a facility that the Government has sufficient control over to meet its needs when it is required and it has the flexibility to develop new products as they come out of the research base in the universities.

Senator SPECTER. Dr. Darby, I have run a little long on time, but Congressman Altmire will have equal time.

GE has a patent on an operation on plastics which enables to shift from one vaccine to another very promptly, contrasted with having stainless steel equipment which takes an amount of time to clean. May the record show the witness is upward nodding in the affirmative. That is true, is it not?

Dr. DARBY. Yes.

Senator SPECTER. I am asking you a leading question, but I want to move forward with some speed here so we can conclude in a reasonable time.

Senator SPECTER. But GE does have that patent. Right?

Dr. DARBY. Yes. GE has technology which is surrounded by patents.

Senator SPECTER. And that enables GE's participation to move from one vaccine to another with disposable plastic as opposed to a lengthy cleaning process.

Dr. DARBY. Yes, sir.

Senator SPECTER. And you have been working with UPMC to bring that technology to bear in the kind of an operation which they have proposed.

Dr. DARBY. Yes. All the studies that UPMC has been putting, which have been mentioned, we have been involved in those studies with the technology knowledge that we have today. So I think we are reasonably satisfied that it can be made to work.

Senator SPECTER. Congressman Altmire, you are entitled to equal time, and that is 14 minutes and 16 seconds.

Mr. ALTMIRE. Thank you, Senator, and I do not plan to use all that time, but I appreciate it.

Very quickly to begin with, Dr. Gomez, you spoke at length about the study that you conducted, and as a management consultant at the firm, you obviously have a financial relationship with people that commissioned the studies. I am making no implication, but just for the public record, what is your relationship with UPMC as a consulting organization, and do you feel that that impacted that study and the results in any way?

Dr. GOMEZ. So PRTM was under contract to support that study, so we certainly provided what we believed was the best advice and analysis of part of that study.

Mr. ALTMIRE. But do you believe that the outcome and the conclusions that you testified about today and that the study showed were in any way impacted by that relationship?

Dr. GOMEZ. No. I certainly believe that we provided the best analysis of the industry based on certainly my experience, having been in industry for a long time, as well as being within the U.S. Government.

Mr. ALTMIRE. Thank you.

Mr. Romoff, you spoke at length in your initial testimony about the need for this type of center, a national vaccination center, and in response to Senator Specter's question, about the assets that UPMC has to the region with its relationship with the University of Pittsburgh. And Dr. Burke spoke about their specific interest in the vaccination center and the long history going back to Dr. Salk that they have with that issue. I want to give you the opportunity to close the loop on these things because you talked about the benefit western Pennsylvania has, you talked about the need that exists, University of Pittsburgh's role in it. What are UPMC's assets specific to the vaccination center, and why is western Pennsylvania a good location, and why is UPMC a good organization to do this?

Mr. ROMOFF. Well, thank you for the softball question.

UPMC, as you know so well, Congressman, is an $8 billion organization with 50,000 employees and that does not include the enor-

mous assets at the University of Pittsburgh. We manage 20 hospitals, hundreds of clinics. We do a great deal of things. We have laboratories and we do international consultations with hospitals in Ireland and Italy. UPMC has developed an intellectual managerial power fundamentally in the health care sector and in the health research sector to get things done, to take the brilliance of the scientists and the consultants and convert it into things that happen and grow and develop, treat patients, come up with new products, and then they bring economic value. We have been very successful at doing that, and we have been enormously comfortable with—here in western Pennsylvania, with the workforce that is here, with—that is here, and when it came to this project, it was first and foremost needed in a way that I think was obvious for everyone.

And secondly, western Pennsylvania just has such extraordinary natural resources and such a good climate for productivity and a good workforce that this became a natural thing for UPMC to do here.

Mr. ALTMIRE. Thank you.

Dr. Darby, I was very impressed by your talking about the leadership that GE has in this issue and the expertise that you have. My question is, with regard to this project in specific, which is more important to GE? Is it the dollars, the Federal investment of $600 million or more, or is it the commitment that the Federal Government brings that this is an important project? And I ask it in the context of the obvious question is GE a company that historically has done very well. You have leadership on this issue. You have obviously made a substantial investment through the company. Why do you need public money? Is it a Federal commitment that you need that this is important? Is this something you can do yourself, or is this something that you really believe the public needs to play a role in financing?

Dr. DARBY. Well, I think one of the major elements of this is, of course, we bring the manufacturing technology, which is at the heart of the puzzle. I think we need Federal backing behind this to bring the different players together, GE, organizations such as UPMC, to create the whole structure that is required to make this actually happen. So we bring a part of the puzzle, but there is no way that we could provide a countermeasure solution simply by ourselves. We need to work in partnership with the Government and other players to help to deliver this to you.

Mr. ALTMIRE. And you feel that the players at this table, others in the country who are interested in these types of programs, universities, private companies, that there is not an ability to make this happen without a substantial Federal investment?

Dr. DARBY. I think the Federal investment puts a certain level of imperative behind it. One cannot say it will never happen without the Federal investment, but I think the Federal investment and sponsorship serves as a rallying point to make this happen. So it will happen far more quickly.

Mr. ALTMIRE. Thank you.

Lastly, for Dr. Russell, you spoke about the industrial development in the United States for these types of centers. I wanted you to talk about the risk that exists if we do not do this, if we do not

move forward. What are we putting ourselves—and I am not asking you a leading question. Perhaps you would say there is no risk, but I would suspect you would say that there is if that is the case. What is the cost of doing nothing? What is the cost of inaction?

Dr. RUSSELL. I think that the structure of cost of doing nothing is going to be the products that come out of the research community, potential products, will not be developed and we will not have the vaccines and other pharmaceuticals that are necessary to counter a bioterrorism attack or another emerging infectious disease situation. I think the current system has proven to be inadequate. It is slow, cumbersome. It is inefficient.

And this concept that is being talked about today is a means of really streamlining the advanced development and the manufacturing and a means of providing the countermeasures that could be available based on our current scientific knowledge if we move ahead with this. If we do not, we are going to have a much longer period of vulnerability.

Mr. ALTMIRE. Thank you.

No further questions, Senator.

Senator SPECTER. Thank you very much, Congressman Altmire.

Dr. Gellin, why do you not step forward and have a chair at the end? Just a question or two.

What do you think about the proposal? You said earlier you did not have too much idea. I will not ask you a leading question. I will just ask you what do you think of it?

Dr. GELLIN. Well, I think I told you in a meeting—it was not in front of the microphone when we were speaking before—that I was impressed with this proposal. I am also impressed that in a 45-minute period you can assemble this panel to tell you about the details of their proposal.

You also heard in this period that there is a need to move forward. Dr. Russell has often told me that when things are more than 10 years away, they are going to stay 10 years away unless we begin to move them. So I think that there is a commitment clearly by the U.S. Government, as I mentioned before, by both HHS and DOD to begin to explore a path forward to fill some of the gaps that we recognize.

Senator SPECTER. And what do you think of the synergy that you find here with the research capabilities of the University of Pittsburgh and the implementation capabilities of UPMC?

Dr. GELLIN. Well, in his opening remarks, the Congressman spelled out the attributes that this project brings forward and you were able to assemble the people to tell us all about that and just to really scratch the surface of what I know at least of some of the things that are going on here. So I think that what they presented to you is clearly an interesting proposal and is one that we are obviously aware of and need to move forward to make a decision on how to fill these gaps.

Senator SPECTER. Especially with the joinder of GE and their capability with plastic disposables to expedite the production of vaccines?

Dr. GELLIN. It is clear, as Dr. Darby commented, that this requires a multitude of talents to be able to solve this problem, and I think that this is clearly an opportunity to show how different

elements that come to a table in partnership are needed to do something like that.

Senator SPECTER. I thank Senator Harkin, chairman of the subcommittee, and Senator Inouye, chairman of the full committee, and Ms. Ellen Murray, who has contributed mightily and done so much work in arranging for this hearing. She has the benefit of coming to her hometown. So thank you, Ms. Murray, and thank you, John Myers, for the work you have done.

I think this has been a very important hearing to put a lot of pieces together, and my colleagues in Washington on the subcommittee and the full committee and the full Congress will be reviewing it. Congressman Altmire will carry the words in the House of Representatives because this is a matter of urgency for the country. I, obviously, have been explicit before in promoting this as a Senator from Pennsylvania, and I am authorized to say that Senator Casey joins me in this effort. But there is a very important national interest in public health and very important interests in economic development, which we have specified.

And as I said, we are going to be introducing authorizing legislation, and I will be working with it on the Appropriations Committee where I serve. We will be coordinating with the DOD and HHS, which we have talked about. Secretary Sebelius is well aware of the program. I had a chance to talk to her about it a little more. We did have a quiet moment, believe it or not, 2 weeks ago in Philadelphia with the first of the public demonstrations. And I look forward to a chance to talk to Secretary Gates. One small personal, not irrelevant note. Secretary Gates and I went to the same grade school in Wichita, Kansas.

CONCLUSION OF HEARING

Thank you all for coming, and that concludes our hearing.

[Whereupon, at 11:57 a.m., Wednesday, August 21, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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