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OUTSIDE VIEWS ON BIODEFENSE FOR THE DEPARTMENT OF DEFENSE

HEARING

BEFORE THE

SUBCOMMITTEE ON EMERGING THREATS AND CAPABILITIES

OF THE

COMMITTEE ON ARMED SERVICES
HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

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OUTSIDE VIEWS ON BIODEFENSE FOR THE DEPARTMENT OF DEFENSE

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ARMED SERVICES,
SUBCOMMITTEE ON EMERGING THREATS AND CAPABILITIES,
Washington, DC, Wednesday, February 3, 2016.

The subcommittee met, pursuant to call, at 3:31 p.m., in room 2118, Rayburn House Office Building, Hon. Joe Wilson (chairman of the subcommittee) presiding.

OPENING STATEMENT OF HON. JOE WILSON, A REPRESENTATIVE FROM SOUTH CAROLINA, CHAIRMAN, SUBCOMMITTEE ON EMERGING THREATS AND CAPABILITIES

Mr. WILSON. Ladies and gentlemen, I call this hearing of the Emerging Threats and Capabilities Subcommittee of the House Armed Services Committee to order. I am pleased to welcome everyone here today for today's hearing on outside views of biodefense for the Department of Defense [DOD]. This hearing will provide an overview of the findings and recommendations from the recent bipartisan report of the Blue Ribbon Study Panel on Biodefense.

It is critical that the United States maintain a dynamic national defense against the growing threat posed by biological weapons and naturally occurring diseases. The Department of Defense plays a large role in the U.S. biodefense enterprise, contributing biodetection tools, medical countermeasures and protection, and decontamination technologies. The recent response to the Ebola outbreak illustrates the importance of the Department of Defense's biodefense contributions to broader government and global efforts.

This hearing is especially timely in preparing for our subcommittee hearing next week with the Department of Defense on countering weapons of mass destruction policy and programs for the fiscal year 2017. The findings and recommendations discussed today will be important aspects of our review of the fiscal year 2017 Department of Defense biodefense enterprise.

Our witnesses before us today are the Honorable Ken Wainstein. He is the Blue Ribbon Study Panel on Biodefense panel member. Additionally, Dr. Gerald Parker, the Blue Ribbon Study Panel on Biodefense Panel ex officio member.

I would like now to turn, but he is not here, to Mr. Jim Langevin, but Lindsay has assured us that he will be here soon, and we will proceed. And so we would like to begin right this moment. Thank you.

[The prepared statement of Mr. Wilson can be found in the Appendix on page 19.]

STATEMENT OF HON. KENNETH L. WAINSTEIN, BLUE RIBBON STUDY PANEL ON BIODEFENSE PANEL MEMBER

Mr. WAINSTEIN. Thank you very much, Chairman Wilson. It is a real pleasure to be here today on behalf of the Blue Ribbon Study Panel on Biodefense and to represent our co-chairs, Governor Tom Ridge and Senator Joe Lieberman, as well as the rest of our colleagues who worked with us on the Study Panel.

As you mentioned, last October we released our bipartisan report in which we provided an assessment of our national biodefense, and offered 33 recommendations that we believe will improve our ability to defend against biological threats of all types—against those that are intentionally and maliciously introduced, against those that are naturally occurring, and also against those that result from accidental release.

Before highlighting a couple of these recommendations, I would like to briefly discuss the biological threat that we currently face. I will start with the anthrax attacks of 2001.

We don't need to remind you up here on Capitol Hill about those attacks and about how they were a tragic wakeup call to the Nation about the possible consequences of deadly biological agents falling into the wrong hands.

As tragic as those attacks were, however, there is good reason to believe that future attacks could be much more devastating. For one, we know that are there are stockpiles of biological weapons throughout the world that may now be or may become accessible to our enemies. When the U.S. discontinued its offensive biological weapons program in 1969, other nations, including the former Soviet Union, continued to produce stockpiles of biological agents, stockpiles that represent an appealing opportunity for rogue nations and those terrorist groups, like ISIS [Islamic State in Iraq and Syria], that are intent on inflicting the maximum possible damage against our Nation and against our people.

As we on the panel heard from a number of experts who appeared before us, including former Senator Jim Talent, former Representative Mike Rogers, and others, our enemies are currently taking specific steps to develop, or to procure, biological weapons for use against us. Intelligence indicates that they are actively trying to recruit scientific experts; they are seeking control of laboratory, manufacturing, and other infrastructure for biological weapon production and development; they are talking about how best to deploy biological weapons; and they are making concrete plans for the use of these weapons.

In light of this information, we believe that it is not a matter of if, but rather when and how soon a biological attack will be launched against our Nation, our people, or our allies; and the fundamental question is whether we are equipped and prepared to handle this imminent threat. And sadly, our panel found that the answer to that question is no. Despite a number of important strides taken in the past 14 years since the anthrax attacks, we have failed to develop the coordinated and comprehensive biodefense that is necessary to meet and defeat this threat.

To address this failing, our panel made 33 recommendations that we believe will improve our Nation's overall ability to prevent, deter, detect, respond to, recover from, and mitigate biological

threats. And if I may, I would like to highlight just a couple of those recommendations.

First, recognizing that leadership is the key to success for any such effort, our initial recommendation is that the White House take point in coordinating the national biodefense, and specifically that the Vice President take charge of that effort; that he establish and operate through a Biodefense Coordination Council comprised of representatives of the responsible agencies, and that as a first step he and the Coordination Council jointly develop a national biodefense strategy to replace the current piecemeal strategies, directives, and policies with a comprehensive strategy that contains both the overarching vision and the specific policy and operational objectives that are necessary to drive the construction of a viable national biodefense.

In conjunction with this and the other recommendations that are directed primarily to the executive branch and its State, local, tribal, and corporate partners, we also recommend that Congress take steps to contribute to this effort. Specifically, we recommend that Congress follow the lead of this committee and enhance the level and the intensity of its oversight in the biodefense area.

Progress in this biodefense area will require strong encouragement and strong oversight from Congress. And while we applaud this committee for taking the step of having this hearing, we recognize that it is only a first step; a first step of what will be a long-term national effort to build an effective and enduring defense system to protect against the biological threat.

It is important to remember that after the terrorist attacks of 9/11, 2001, we succeeded in doing exactly that, and we built a defense system that has largely protected us against the more general traditional terrorist threat. With commitment and with support from both the executive and legislative branches, I am confident that we can do that again, that we can build a defense system that will protect us against the specific threat of biological attack and infection.

I want to thank you, sir, for holding this very important hearing and for having me here today, and I look forward to any questions that you may have.

[The joint prepared statement of Mr. Wainstein and Dr. Parker can be found in the Appendix on page 20.]

Mr. WILSON. And, Mr. Wainstein, thank you very much. And it is ironic that you would reference anthrax. I was elected in a special election right at that time, December 2001. What an introduction to Washington.

Dr. Parker.

STATEMENT OF DR. GERALD W. PARKER, JR., D.V.M., PH.D., BLUE RIBBON STUDY PANEL ON BIODEFENSE PANEL EX OFFICIO MEMBER

Dr. PARKER. Good afternoon, Chairman Wilson, Ranking Member Langevin, and members of the subcommittee. Thank you for the invitation to appear before you today. It is an honor to be here with Honorable Ken Wainstein representing the Biodefense Blue Ribbon Panel.

Mr. Wainstein covered the threat and the need for a biodefense strategy. For my part, I would like to bring a few programmatic issues to your attention.

As a retired member of the Armed Forces, I spent many years working to protect the Nation, our soldiers, and their families. I am proud to tell you that the Department of Defense institutions, such as USAMRID [U.S. Army Medical Research Institute of Infectious Diseases], which I once commanded, contribute significantly to U.S. biodefense alone and in concert with our civilian and international partners. These organizations have dedicated scientists, they conduct cutting-edge research, they discover new countermeasures, and they provide science-based knowledge to operations. In summary, they are the go-to scientists to counter biothreats for the DOD.

While this is commendable, it does not mean that these human institutions are infallible, as has been recently seen in both military and civilian labs in the DOD and HHS [U.S. Department of Health and Human Services]. They have made mistakes, and if left uncorrected will contribute to the Nation's biological risk.

The recent laboratory safety and security breaches at Dugway illustrate this point. As you know, despite following protocols, viable anthrax spores were inadvertently sent to other labs over an extended period of time. As it turns out, there is an incomplete scientific understanding of the inactivation process, there are no standardized protocols for inactivation, and the checks that Dugway had in place were insufficient.

It is important to note that DOD's risk assessment concluded that this incident posed little risk to public health; but we must assume that without continued focus on smart improvements in biosecurity and biosafety, this will happen again somewhere in the Nation's laboratory network with a worse outcome. We cannot afford institutional failures.

One of the basic tenets of DOD is that we must protect the warfighter. No other agency can do that for DOD. This is a top priority. In the case of biodefense, it means addressing a number of vulnerabilities.

Military personnel are the most likely to be exposed to infectious disease threats, some which the world has never seen before, and some which do not have any treatments. Ebola is a good example of this, but there are worse examples. This means that we have to protect our soldiers. We need trained and equipped medical teams with logistical support ready to respond to outbreaks or bioterror attack. We have to have rapid diagnostics, effective biodetection, as well as global biosituational awareness.

These and other issues drive a number of DOD programs, to include the Chemical and Biological Defense Program, the Military Infectious Disease Program, the Cooperative Bio Engagement Program, GEIS [Global Emerging Infections Surveillance and Response System], DARPA [Defense Advanced Research Projects Agency], and others, who have broadly followed either AT&L [Acquisition, Technology, and Logistics], Health Affairs, and OSD [Office of the Secretary of Defense].

I want to emphasize there are many hardworking, dedicated professionals working in these programs, but we need to better pre-

pare for the eventual use of biological weapons. We believe that DOD needs to clarify parameters for military support to civilian authorities in response to a domestic biological attack, update and implement military biodefense doctrine, hopefully tiered to a new national strategy as recommended by the panel.

Let me provide one programmatic example of the need to include military-civilian collaboration. There is a longstanding need for effective biodetectors on and off the battlefield. Mr. Langevin and others that serve on the House Committee on Homeland Security are well aware of the DHS [Department of Homeland Security] experience with BioWatch, a biodetection system that a number of experts believe is insufficient to the needs of the Nation. DOD also has a separate biodetection program and it's had one for years. And although DOD and DHS are communicating better than ever on these programs, this is just an example where we need an integrated program, in this case biodetection, driven by strong centralized leadership, guided by a national biodefense strategy, that we can field effective and affordable solutions in a timely manner for our soldiers and citizens.

DOD and the interagency face a number of other challenges. These include the need to establish effective BW [biological weapons] intelligence, authoritative microbial forensics and attribution, and decontamination and remediation.

I can go into detail about these later, but before closing I would like to add that the lines between BW and infectious diseases have blurred, and DOD's positive contributions to global health security through our OCONUS [outside the contiguous United States] laboratories, our global biosurveillance programs, and cooperative bioengagement cannot be overstated.

In closing, I would like to thank the members of the subcommittee again for this opportunity to appear before you today. Thank you.

[The joint prepared statement of Dr. Parker and Mr. Wainstein can be found in the Appendix on page 20.]

Mr. WILSON. I thank both of you. And we are going to begin now. And Katie Sutton is going to maintain a strict 5-minute rule for all persons, including me, on questions.

And so right away, one of the recommendations, Mr. Wainstein, of the report is to improve the intelligence community efforts to address the biological threat. Can you further elaborate on the specific measures that could be taken to indeed achieve better estimates of biological threats?

And then, specifically, you had indicated that scientists were recruited, that their facilities could be used. A concern that I have had is a major city in Iraq, being Mosul, that with the capture by ISIL [Islamic State of Iraq and the Levant], that there would be hospitals, there would be medical facilities, there would be universities that might have the facilities that could facilitate the development of weapons to attack the American people.

Mr. WAINSTEIN. Yes, Mr. Chairman, I think you have put your finger on one of the big risks here.

Look, the bio threat has always been one that has caused people in the government to lie awake and worry about at night, and especially since the anthrax attacks.

But I think what is new now is what you just identified, which is the primary adversary, it used to be Al Qaeda, we were concerned about Al Qaeda generating weaponized anthrax, probably in caves or in pretty primitive facilities. We now have ISIS that is infinitely better funded, infinitely better resourced, more people of all types, not just fighters, but people of educational backgrounds, scientists and the like. And, as you indicated, they have facilities, they have the footprint where they can put together a program like this and have the continuity and the protection to do that, but they also have hospitals and labs and that kind of thing right there in their territory.

So the threat, I think, has always been there, and we have heard about it from a number of different commissions and panels. But this, I think, it is a new threat, a newly enhanced threat.

In terms of the intelligence and what the intelligence community can do, look, this was an unclassified exercise, we didn't get a classified briefing from the intelligence community, but we did learn about sort of the general state of intelligence. And it is clear to us that the intelligence community would be doing a much better job if they were linked in with a more centralized, coordinated, all-of-government effort. Then their requirements and their intelligence collection can be more focused in order to enhance the overall effort to identify the bio threat, think of best ways of dealing with it, and then taking those steps.

So I think that the intelligence community is going to be a major player in this, what we present as a potential overhaul of the biodefense bureaucracy, and it is going to require some direction from the top.

Mr. WILSON. Well, thank you again for your efforts bringing this to the attention of the American people, both of you.

In the report, the panel noted that work dealing with cyber threats to pathogen security is nascent and that the United States is not yet well positioned to address cyber threats that affect the biological science and technology sectors. Could you further describe the cyber threat identified by the panel? What role could the Department of Defense play in responding to this biological security cyber threat?

Dr. PARKER. Thank you, Mr. Chairman. I will try to address that for you.

We are in the age of biology, and biology is all about information, from the genetics, the proteomics, and so forth, as well as our medical records. And so it is all about information. And much of our information now, it is all digital. And we are also in the era of synthetic biology where in the not too distant future new and dangerous pathogens can actually be synthesized.

So the ability to protect this information and make sure the information does not get misused is actually a very critical step. And I believe there are things being put in place to help protect that information, but I think this is an area that is going to require increasing focus as we move forward so that this information doesn't get hacked and misused.

Mr. WILSON. And has there been proper public-private cooperation, including universities, with the government to address this?

Dr. PARKER. I think it is still, I would say, a work in progress to begin to address how we make sure and protect. And it is a dual-edged sword. On the one hand, we have to be able to share information to collaborate for solutions, but on the other hand, we have to make sure that we can protect the information so it is not being used for nefarious purposes by bad people.

So we do have to be able to work it both ways, but it is a work in progress. And I think more attention will need to be put in place here so that we can have the appropriate security, but also be able to share in the scientific discoveries and work that needs to take place in collaboration across that space that you mentioned.

Mr. WILSON. Well, with both of you, we look forward to working with you in the future.

I now shift to Congressman Pete Aguilar of California.

Mr. AGUILAR. Thank you, gentlemen. I appreciate the report and the work that you are doing.

Dr. Parker, you touched on this a little bit, and the chairman mentioned it, the coordination between DHS and DOD. Can you talk a little bit about that and the role within the biomedical advanced research groups and DOD as well, what more we can do to foster that? The chairman mentioned obviously the potential to have events abroad and here nationally as well. I represent the city of San Bernardino where the incident was last month, and obviously it could have gone a different way.

And so making sure that the coordination between local law enforcement agencies also exists within a DHS interface or DOD interface is something that I think our communities also want to see us take serious.

Dr. PARKER. Thanks for the question, and absolutely. I think you know I spent a lot of my career in government and was a major proponent, cheerleader, whatever word, for interagency coordination. And there are a lot of people working very hard at trying to drive interagency collaboration and communication, and I would say they are doing a good job. But on the other hand, we can do better.

And it really comes back to the central tenet of the findings of the report that the need for having strong centralized leadership, driven by a solid strategy, and then tied to the budget, and department, agency accountability, with clear leads and supporting roles identified, timelines, metrics, et cetera, et cetera, et cetera. It really comes down to that leadership and strategy is going to be necessary to improve our collaborative interactions across the departments and agencies.

People are working, they are trying to work very closely together, but sometimes process can be more important than the outcome. And the only way to get above that, again, strong leadership, strategy, accountability, tied to the budget, and somebody willing to make some hard decisions. But I do not want to give you the impression that people aren't working hard to collaborate and communicate, because they are.

Mr. AGUILAR. No, no, absolutely, and we wouldn't indicate that. But areas, specific ways that we can use the committee and use the work that we are doing to highlight those positive examples as well

as areas of deficiency where we can continue to improve, I think is important.

Dr. PARKER. And I think this is also critical too, because in the report we are not recommending increases in the budget, but it really comes down to how can we best use the budget available.

Mr. AGUILAR. Sure.

Dr. PARKER. And it comes down, again, to that leadership, accountability, and the strategy to enhance that collaboration across the interagency space.

Mr. AGUILAR. Mr. Wainstein, anything to add?

Mr. WAINSTEIN. No, thank you.

Mr. AGUILAR. Mr. Chairman, I will yield back. Thank you.

Mr. WILSON. Thank you, Congressman.

We now proceed to Congresswoman Elise Stefanik of New York.

Ms. STEFANIK. Thank you, Mr. Chairman. And thank you, Dr. Parker, for your testimony. Mr. Wainstein, good to see you again. You and I served in the White House together.

Mr. WAINSTEIN. Great to see you.

Ms. STEFANIK. I am excited to be able to connect with you.

I wanted to talk about the report's comments on the rapid development and employment of developmental Ebola vaccines, which was, quote, "a remarkable achievement." But the report also noted that the general medical countermeasurement development is very risk averse and is not focused on innovation. Can you talk about what some of the lessons learned from the development of the Ebola vaccination and how we can improve how our MCM [medical countermeasures] development, how we can improve that?

Dr. PARKER. Yes. First, like the report says, medical countermeasures development, acquisition, procurement, it is really hard. There is risk for everybody involved. It is hard for the government, it is hard for industry.

I will say, echo as it was reported, it was an amazing achievement, how the Federal Government, industry surged to try to produce an Ebola vaccine very quickly. But we still don't have an Ebola vaccine.

What is really critical is what we do between outbreaks, between attacks. If we don't have something available in the stockpile or soon to be licensed, it is going to be very hard to have it and surge.

I think that is really one of the big lessons with the Ebola outbreak. What is critical is between epidemics, not in a crisis situation. And it comes back, then, to leadership, strategy, and accountability; then down at the lower level on what can we do to improve our medical countermeasure development.

We have got to be willing to take risk in that in between outbreaks. We have got to bring more innovation to that. Tried and true past technologies aren't going to necessarily work. We have to also think about the regulatory pathways, how can we improve that. And the FDA [Food and Drug Administration] is thinking about those things.

Ms. STEFANIK. So are increased public-private partnerships a way we can improve that? How can we better employ public-private partnerships?

Dr. PARKER. Well, I think they are key, because there is no way that government alone can do this, there is no way industry can

do this. This is a space that, just like tropical neglected diseases, biodefense, there is no commercial market, or very little commercial market. So that public-private partnership is going to be key.

Some of the things I would say actually that DOD does pretty well is has a little bit more transparency in what their requirements are and what the 5-year planning budget cycle looks like. So a little bit more transparency in what the needs are, what the requirements is kind of critical. Reducing some of the bureaucratic decisionmaking delays is very critical, particularly for industry. The panel heard that a lot from industry during our look at this.

Even in DOD, the Federal acquisition contracting, is not best business practices for the small companies. We are not talking about large pharmaceutical companies that are part of the biodefense space. It is primarily small biotechnology companies that are having a difficult time surviving. And many of the Federal acquisition contracting is not conducive to that industry best practices.

I would applaud DOD. Recently, particularly the Joint Program Executive Office, has announced an intention to use more use of other transactional authorities. That is a move in the right direction.

Ms. STEFANIK. Mr. Wainstein, do you have anything to add?

Mr. WAINSTEIN. No, thanks. He covered it.

Ms. STEFANIK. Great.

Well, I have 1 minute left. Can you elaborate on possible incentives that could be used to improve public-private partnerships? So we understand this is a way to bring innovation to the table, but what specific incentives should we put into place?

Dr. PARKER. Well, there are a number of, I think, incentives that the panel heard during our study. And since I am not from industry, I am academia now, I may not be the best to actually get down in the details of specific incentives that would be good for industry.

But I think the point is, what we recommend in this, is that we really need to have industry and government come together and really talk about what works. And industry will no doubt come up with a pretty good list. And there is no doubt that some of those may not work for government. But on the other hand, government is going to have to be a little bit more open than they have in the past and actually not just listen, but do something about it.

So I think the real key thing I think that we captured pretty well in this report is the need to really identify those with the public and private partners, talk about what is practical and can be done, and begin to implement. And there has been discussion about it before, but nothing has been implemented, or very little.

Ms. STEFANIK. Thank you. My time has expired.

Mr. WILSON. Thank you, Congresswoman.

We now proceed to Congressman Brad Ashford of Nebraska.

Mr. ASHFORD. Thank you.

Doctor, thank you, and thanks for the report.

We at the University of Nebraska have engaged in—and I know you are aware of this—a number of initiatives, starting with Dr. Phil Smith a few years—well, 10 or 12 years ago—in some of his initiatives that have evolved into the Ebola facility at UNMC [University of Nebraska Medical Center]. And there is great hope that

they can expand that facility further to provide training and other, obviously not only for Ebola, but for the whole grouping of threats here.

And again, I thought Congresswoman Stefanik's point is well taken, is that facility and that initiative at UNMC is a public-private partnership as well. And so the kind of training that would go on there, and I know your report reflects this, is not only would be training healthcare professionals, training others that are going to be engaging in these threats.

How would you see that training regimen working? And I know you have mentioned it in the report, but if you could just elaborate on it.

Dr. PARKER. Well, first, thank you for the contribution by the University of Nebraska, outstanding professionals that really stood up to the task when the Nation needed them very badly. So thank you for that.

And it really is that training education. We really need to go back to the basics. And I think back, actually, after the anthrax letter attacks that we have already talked about here early on, a lot of the programs, particularly, say, the hospital preparedness, the CDC [Centers for Disease Control and Prevention] public health preparedness grant programs that really expanded after 9/11 really focused a whole lot of effort on infection control, the medical management of biological casualties, some of the basics that were really needed across this country so that we could do that.

I think somewhere in that intervening time, 2005, 2006, we began to lose that edge, and I think that is apparent in the Ebola outbreak.

Mr. ASHFORD. There seems to be such a—your report reflects this—but such a revival in this comprehensive approach now. It is not just about reacting, obviously, but it is being very proactive, and it is a very welcome report.

I hesitate to mention to the chairman that in Nebraska—not everything happens in South Carolina, I don't want to make light of that—but, I mean, we have certain—we love South Carolina, but—thank you, Mr. Chairman.

Dr. PARKER. But I would say, just to follow on, we have only made recommendations.

Mr. ASHFORD. Right. No, I understand. But had that roadmap——

Dr. PARKER. These recommendations need to be implemented and acted upon so that we can correct some of the deficiencies that I think are apparent in the system now.

Mr. ASHFORD. And what is interesting about the effort, I think, not only at UNMC, but certainly Emory and other institutions around the country, is these institutions do stand ready to make the investment in plant and equipment to move forward.

So thank you very much. It is a great report.

Dr. PARKER. Thank you.

Mr. WILSON. Thank you very much, Congressman. And, hey, from a South Carolina perspective, we really appreciate Nebraska. You are a hearty people to live where you live.

And, hey, talk about hearty people, it is really tough, San Diego. Congressman Duncan Hunter from California.

Mr. DUNCAN. Also in the South.

Mr. WILSON. Yes, yes.

Mr. DUNCAN. Southern California.

I just want to piggyback on Ms. Stefanik's question. You didn't really answer. What are the actual incentives? Besides saying transparency and let's get together and sing Kumbaya, what are the actual incentives to keep private companies with stockpiles or to keep them ahead of the whole curve in the first place? What is DOD doing, with the FDA, for instance, to say, hey, we are going to add you to the, what is it, the priority voucher program, like we added Ebola to last year, what are we going to do to add anything else that our service members face overseas with the FDA and DOD so that industry is ahead of it and not playing catch-up when bad things happen?

Dr. PARKER. Well, I think actually I go back to perhaps what the panel actually concluded, that maybe the most important incentive goes back to the original Project BioShield in 2004, that having that appropriation up front so that industry knew that there was going to be a market for the countermeasures that were going to be developed, that is probably the single most valuable incentive.

Mr. HUNTER. And then DOD says, hey, we are going to focus in these three areas, for instance, and that is where the appropriation is going to go towards, we are going to go towards that?

Dr. PARKER. Well, I guess, Project BioShield, that is focused on HHS and DHS and the relationship of who does the threat determinations, who works on the countermeasure development against those threats.

DOD doesn't have a similar appropriation like that, but at least DOD has 5-year budgeting plans, that short of an appropriation up front, that 5-year budgeting plan for DOD is pretty solid and does give industry an idea of what is going to come. Of course, those budgets can change every year, again——

Mr. DUNCAN. How do you know what to stockpile or what you need private industry to do when you don't know what the bad guys may have or what they may use?

Dr. PARKER. In the old days, I would say the Cold War, post-Cold War era, it was much easier. There was a list of and the intelligence had a list of potential pathogens, and they have been codified in the CDC list. And so that could be anthrax, smallpox, plague, the hemorrhagic fever viruses, botulinum neurotoxins.

Those are traditional BW threats. We still need to be worried about those. There is a reason why we need to have a huge stockpile of antibiotics against anthrax. Anthrax is special.

But actually you asked a very good question, because the problem is getting harder. In fact, lists are really no more applicable today, although we still need to pay attention to those six I mentioned, but it is getting harder today in the era of biotechnology, synthetic biology. It could be anything. And so it is a challenge.

Again, go back to BW intelligence. We need to put more emphasis on that. And in defense of the intelligence community, it is a hard, hard problem. Bio in the WMD [weapons of mass destruction] space is the hardest of the hard.

Mr. DUNCAN. I want to ask you this. So you know where we have people at throughout the world. So I would just ask, is there one,

is there anything just screaming at you in the face where you are like, we have people here and we are not prepared for this?

Dr. PARKER. Yes, there are certain areas. I would say on the Korean Peninsula, I will give you an example, that we have been—the DOD, in fact, has been working very hard with counterparts in the Korean military and the CDC against some pretty known thought to be high priority threats. And the doctrine is evolving and should be different, because we need to be worried about not only force-on-force military deployment of biological weapons in a scenario like that, we need to be concerned about covert use against not only the military, but the civilian population.

So these are areas where we have not only a large number of military forces, we also have strategic partnerships with our allies that happen to be in very large population centers that are living very close to a determined enemy.

Mr. DUNCAN. Let me ask this, you made me think of another question, then. You talk about Korea, so I am guessing China and Russia have the technological capability to be able to develop different bad things to affect people. Do you have to worry about that in places like Syria, where the lab might be in someone's kitchen? I mean, it is not like they are high tech compared to the North Koreans or the Russians or Chinese or even the Pakistanis.

Dr. PARKER. Well, I think, yes, the first question really kind of got into that. These areas, the problem is very hard. And these small clandestine labs, it would be very difficult for our intelligence community to ever discover these.

Mr. DUNCAN. But they don't have the technology to be able to make more sophisticated bad things either, do they? You can't make that in a kitchen in Syria. It takes a lab.

Dr. PARKER. You can make some BW pathogens that can cause significant number of casualties in a relatively small clandestine laboratory, and also get it in a condition that would be relatively easy to disseminate. It is a serious threat.

Mr. DUNCAN. Thank you. Thanks, Mr. Chairman.

Mr. WILSON. Thank you, Congressman. And thank you for citing the threat to the concentrated population of Korea, because actually what you are saying is the capital Seoul has a population of nearly 20 million people, very compact, very much at risk.

Congressman Pete Aguilar.

Mr. AGUILAR. Just one more question, gentlemen, since we have you and I get one more bite at the apple. And, Dr. Parker, you talked about leadership. And could you just describe to me the discussion and the decision by the panel to institutionalize and empower the Vice President as the kind of point of contact and the focal point within the report?

Dr. PARKER. Yes. I will start. Ken probably has some observations as well due to his White House experience.

It became pretty clear early on that leadership was an issue, it was a factor, and the need to somehow instill, inculcate stronger leadership. So the panel actually looked at various options, to include reinstituting the special advisor for health security and biodefense, even actually had the three previous special advisors testify before the committee. Looked at that model. Looked at the so-called czar model. And several other things were considered.

But it kept coming back to who has got really the ear of the President, that also has the ability to make some hard decisions, that can affect the budget, and who can really also represent those outside of government the best, speak on their behalf, and also encourage those outside government, particularly State governments, local governments, and lead efforts needed there as well. And it really kind of backed into the decision that the position who is best suited to do that is the Vice President.

Ken, do you want to——

Mr. WAINSTEIN. Good question. And I concur with everything Jerry just said. I mean, at first blush when you hear a panel recommending that the Vice President should take on this one sort of discrete area, you think, gosh, that is a little bit of a bold proposal. But for all the reasons Jerry mentioned, I thought it made sense. And I was the Homeland Security Advisor the last year of President Bush's administration and obviously my job was to ensure that there is coordination on major issues and that we get progress and we get consensus and the like, and that is tough to do with small issues, day-to-day issues; incredibly difficult to do when you are trying to take the bureaucracy and build something new, something much stronger than what we have now.

And so my favorite reference is what the government did after 9/11, and I think it is pretty much a success story. Not absolute success, but the government really went through an overhaul after 9/11 to meet the traditional terrorist threat that we saw on 9/11, and it had been pretty successful with it. But that took an enormous effort driven directly by the President and obviously with Congress in lockstep.

This is a very serious threat. It is more discrete, it is more focused, but it requires almost as many different actors within the executive branch to work in concert. And our thought was, gosh, we could have one department head sort of anointed as the coordinator, but then you would have the same bureaucratic tensions that you would always have when equals are having to listen to—you know, there is one person designated as higher than the others.

You could just have somebody in the National Security Council, like we have had in the past. Bob Kadlec was the person in the Homeland Security Council when I was there, very effective, but probably not enough to really get across the goal line.

So we thought, look, the Vice President has taken these kind of tasks on before, this Vice President has taken on these kind of tasks, and this is one that really warrants it, given the threat. So we thought, look, we will put that out there. And I know the chairs have had meetings with the White House about this. And I think people are intrigued.

Mr. AGUILAR. Thank you.

Mr. WILSON. And thank you very much, Congressman.

And I would like to thank both of you for being here this afternoon. And Congressman Langevin, the ranking member, sends his regrets. We are imminent to voting and he is close to the floor. But I am very grateful for the work of Ms. Sutton, Ms. Kavanaugh. And we are adjourned.

[Whereupon, at 4:12 p.m., the subcommittee was adjourned.]

A P P E N D I X

February 3, 2016

PREPARED STATEMENTS SUBMITTED FOR THE RECORD

FEBRUARY 3, 2016

Chairman Wilson Opening Statement

Outside Views on Biodefense for the Department of Defense

3 February 2016

Ladies and gentlemen, I call this hearing of the Emerging Threats and Capabilities subcommittee of the House Armed Services Committee to order.

I am pleased to welcome everyone here for today's hearing on outside view on biodefense for the Department of Defense. This hearing will provide an overview of the findings and recommendations from the recent bipartisan report of the blue ribbon study panel on biodefense.

It is critical that the United States maintain a dynamic national defense against the growing threat posed by biological weapons and naturally occurring diseases. The Department of Defense plays a large role in the U.S. biodefense enterprise, contributing bio-detection tools, medical countermeasures, and protection and decontamination technologies. The recent response to the Ebola outbreak illustrates the importance of the Department of Defense's biodefense contributions to broader government and global efforts.

This hearing is especially timely in preparing for our subcommittee hearing next week with the Department of Defense on countering weapons of mass destruction policy and programs for Fiscal Year 2017. The findings and recommendations discussed today will be important aspects of our review of the Fiscal Year 2017 Department of Defense biodefense enterprise.

Our witnesses before us today are:

The Honorable Ken Wainstein
Blue Ribbon Study Panel on Biodefense Panel Member

Dr. Gerald W. Parker, D.V.M., PhD
Blue Ribbon Study Panel on Biodefense Panel Ex Officio Member

I'd like to turn now to my friend Mr. Jim Langevin from Rhode Island for any comments he'd like to make.

Hearing of the House Committee on Armed Services
Subcommittee on Emerging Threats and Capabilities

February 3, 2016

Statement for the Record
The Honorable Kenneth L. Wainstein
Gerald W. Parker, Jr., DVM, PhD

Chairman Wilson, Ranking Member Langevin, and Members of the Subcommittee: thank you for inviting us here to present the perspectives and recommendations of the Blue Ribbon Study Panel on Biodefense and their implications for our national defense. On behalf of our colleagues on the Panel – Former Senator Joe Lieberman and Governor Tom Ridge, who serve as the Panel's co-chairs; former Secretary Donna Shalala, former Senate Majority Leader Tom Daschle, and former Representative Jim Greenwood; and our esteemed ex officios – we come before you with our findings, concerns, and determined belief that the biological threat can be addressed successfully.

We are very concerned about this threat. While many hazards plague the modern world, those rooted in microbiology are among the most dangerous. Through its work on force protection, intelligence activities, and humanitarian response, this committee is well aware of the devastation that highly pathogenic diseases can cause. The impacts of infectious diseases on humanity stretch back across the millennia, from early human encounters with animals and with each other. In recorded history, communicable diseases decimated populations on many occasions, and nations have harnessed their power to create biological weapons. The threat is not new, but we seem to notice and ignore it cyclically.

Take, for example, our reactions to the anthrax events of 2001. Those letters shut down the Hart Senate Office Building for three months, wreaked havoc with the U.S. Postal Service, reduced business productivity, cost the nation more than one billion dollars, and most importantly, took five lives and sickened seventeen more. The Executive and Legislative Branches scrambled to respond and improve the nation's biodefense posture. We created new programs, increased laboratory and other needed capacities, developed and stockpiled medical countermeasures (MCM), increased budgets, hired experts, improved protective over-garments and equipment, re-oriented parts of our intelligence and law enforcement enterprises, and in general, took the threat seriously for a few years. The focus then waned as years went by without another such attack. Unfortunately, criminals continue to use ricin to commit targeted biocrimes, terrorists groups continue to espouse their intent to acquire and use biological weapons, and emerging infectious diseases continue along their damaging trajectory. The threat is real and present.

Many have come before Congress to tell you that the United States is not taking the biological threat seriously enough and is unprepared to deal with a catastrophic biological event. The U.S. Commission on National Security/21st Century raised the issue fifteen

years ago, the National Commission on Terrorist Attacks upon the United States raised it twelve years ago, the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction raised it eleven years ago, and the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Commission) raised it eight years ago. Further, while the Intelligence Community admits to weaknesses in their biological collection and analysis activities, it does not dispute the fact that the biological threat exists and is serious. If you have not yet received a classified briefing on the subject, we highly recommend that you do so.

We began our work with the Panel with two questions in mind: (1) is the United States still vulnerable to the same weaknesses in biodefense that the WMD Commission found in 2008; and (2) what are we doing to heed their advice – and that of the esteemed panels before them – to take decisive action to strengthen our national biodefense?

After a year's work to investigate and answer these questions, we released our findings in our bipartisan report, "A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts," in October 2015. This report was the culmination of our efforts to examine the national state of defense against intentionally introduced, accidentally released, and naturally occurring biological threats. Our primary concerns were those events that could cause catastrophic loss of life, societal disruption, and loss of confidence in our government. We invited more than sixty experts to speak with us in public meetings. These included current and former lawmakers and federal officials, local health department representatives, emergency service providers, academicians, business leaders, and other thought leaders. With their input and significant additional research as outlined in the report's Methodology section, we scrutinized the status of prevention, deterrence, preparedness, detection, response, attribution, recovery, and mitigation – the spectrum of activities that both Republican and Democratic administrations, and many policy experts, deem necessary for biodefense.

Our findings were clear. We identified substantial achievements in our capacity to defend against major biological events, but also found serious gaps that continue to leave the nation vulnerable. Our preparedness is inversely proportional to the severity of the threat – the more catastrophic the potential consequences, the less prepared we are.

We believe this vulnerability is rooted in the lack of strong centralized leadership at the highest level of government – as did the WMD Commission before us. As a component of national defense, the responsibility for biodefense falls squarely within the national security purview of the federal government. Biodefense also touches many aspects of society, from national security, to homeland security, to public health security, to economic security. It requires a highly complex and sophisticated enterprise approach, but what we have is more akin to a loose conglomeration of activities that suffer from insufficient coordination, collaboration, and innovation.

No single individual is imbued with the charge and authority to create a cohesive, effective, and efficient whole of the dozen departments and agencies responsible for some aspect of biodefense. While the last three White Houses have variably appointed

special assistants, czars, and others to be the focal point, jurisdictional and budgetary authorities proved elusive and implementation lacked guidance and accountability. Recent events revealed preventable failings ranging from the Select Agent Program, to global disease surveillance, to rapid response capabilities, which we believe could have been mitigated.

Our premise is that centralized leadership will allow all responsible departments and agencies, as well as non-federal government and the private sector, to coordinate and collaborate in providing for the common defense. The Department of Defense (DOD) has unique capabilities that contribute to the common defense, but also unique requirements that cannot be met by other department and agencies. We dedicate a section of the report, our 26th recommendation, and four action items to building upon defense support to civil authorities – which depends on effective coordination and collaboration. We urge Congress and DOD to formalize collaborative biodefense efforts, clarify support to and coordination with civil authorities in response to domestic biological incidents, exchange knowledge with civilian counterparts, and work with DOD's non-military partners to better protect emergency service providers and warfighters alike.

All responsible federal departments and agencies must also increase their focus on innovation – because biological threats are imminent and the complexity of the threat requires novel solutions. We need to foster entrepreneurial thinking and technological expertise in order to develop radical, effective solutions.

These failings are not abstract: they have real-world implications for the warfighter and for the American people. If rectified, for example, both military and civilian organizations would have the guidance they need to handle diseases like Ebola, wherever they may occur, dispense medical countermeasures to the masses, and solve our greatest challenges in biodetection and biosurveillance. We note especially the risk to our warfighters, who deploy wearing over-garments that may not fully protect against biological agents and use detectors that do not function well on the battlefield (and are not part of an integrated biosurveillance and public health laboratory network). If we are sending our soldiers, sailors, airmen, and marines out to fight – and our emergency service providers out to respond to biological incidents – then we need to make sure we invest in the protection, detection, and surveillance they need to execute their missions in biologically contaminated environments.

We provide 33 recommendations in our report, each of which we believe can individually improve our nation's ability to prevent, deter, prepare for, detect, respond to, attribute, recover from, or mitigate biological events. We also propose specific short-, medium-, and long-term programmatic, legislative, and policy actions for each of these recommendations. Collectively, these serve as a blueprint for biodefense. We highlight the most important here:

1. **Leadership**: First, we must designate a leader at the highest level of government who recognizes the severity of the biological threat and possesses the authority and political will to defend against it. We recommend that this top-level leader be

the Vice President of the United States. The Vice President has a direct line to the President and, when imbued with authority as the President's proxy, can act on his or her behalf. The primary goal of centralizing leadership is to place coordination and oversight responsibility in a location that will have sufficient jurisdictional and budgetary authority regardless of personalities or party in power, and will have the ability to make executive decisions. The Vice President possesses these attributes. The Vice President should also establish and lead a Biodefense Coordination Council to drive a coalition of government and non-government partners toward solutions.

2. **Strategy**: These solutions will depend on a well-considered and comprehensive biodefense strategy, which the nation currently lacks. Our top priority must be development of the National Biodefense Strategy of the United States of America. This strategy should be in keeping with the National Defense Strategy, it should be all-inclusive and harmonized, and it should define all Executive Branch organizational structures and requirements, lead and supporting roles, modernization and realignment plans, and resources necessary for implementation. This strategy should also contain the action plan for holding department and agencies accountable for their leading and supporting responsibilities. We recommended that White House staff collate existing strategies and plans, identify requirements within extant policies, and assess spending history and value (although others in the Executive Branch could do so as well, with White House direction). They can then draft a comprehensive strategy that policymakers can use to assess where we are falling short of meeting the strategic approach outlined therein. We also strongly recommend that the President implement a unified biodefense budget. This suite of tools will allow the President and the Congress to determine appropriate resource allocation and oversight in a systematic way.

3. **Biosurveillance**: One of the most important actions we can take to protect ourselves is to improve our capacity for rapid detection of dispersed or circulating biological agents. We recognize that DOD and the Department of Homeland Security (DHS), as well as a few other departments and agencies, are working toward this goal. From the fielding of biodetectors, to the collection and integration of biosurveillance data, DHS has made some progress. In our view, DOD fares better, but even its technology and activities in this regard fall short of what the warfighter and nation need. We have two choices: either we make existing biodetection and biosurveillance programs work, or we replace them with solutions that do. Many departments and agencies are supposed to coordinate with DHS on detection and the integrated, common operating picture for biosurveillance. We believe that this will only happen if someone at the White House is forcing coordination and holding members of the Executive Branch accountable for participating in these activities.

4. **Medical Countermeasures (MCM)**: Former Senator Jim Talent told us that in order to achieve near-term progress in biodefense, policymakers should prioritize

the development of MCM because we know that success is achievable in this specific area. The technological and resource challenges to eliminate threats with MCM are tough, but surmountable. Industry and academia are replete with innovative ideas. We must reduce bureaucratic hurdles and increase efforts to incentivize and fund what is still a rather nascent MCM industry for biodefense and emerging infectious diseases. This includes simple steps like returning contracting authority to the Director of the Biomedical Advanced Research and Development Authority and convening industry partners to help determine which incentives will work for them and how. But there is also a need to include specific acquisition reform in DOD policies that are tailored to medical countermeasures development. We must also work to more quickly and efficiently share innovations developed by governmental agencies [such as the Defense Advanced Research Projects Agency (DARPA) and the National Aeronautics and Space Administration (NASA)] with industry and more seamlessly identify transition partners in both government and industry.

5. **One Health**: None of the efforts we described will have comprehensive impact without considering animal health and environmental health as equal to human health. The vast majority of emerging infectious disease threats faced by humans, and the pathogens the Intelligence Community is most concerned about terrorists acquiring, are zoonotic. They interact with their environments and move between animals and people. Ebola came to humans through animals and spread in part because of worsening environmental conditions that brought humans in closer contact with infected animals. We must take a One Health approach and fund programs that address all three elements together, not individually and not in ignorance of one another. We must prioritize, properly guide and fund, and fully integrate Department of Agriculture and Department of the Interior animal infectious disease surveillance, as well as state, local, territorial, and tribal planning and surveillance for zoonoses, into all biodefense efforts. We must also ensure that DOD infectious disease and global health programs – including overseas medical research laboratory activities, the Global Emerging Infectious Disease Surveillance system, and the Cooperative Biological Engagement Program – address animals and the environment, as well as human beings.

This representative list does not diminish the importance of the other recommendations in our report. We submit that all 33 recommendations are necessary. Enhanced intelligence collection, protection of pathogen data and cybersecurity, overhaul of the Select Agent Program, support of hospital preparedness and public health preparedness grants, U.S.-led international efforts in global health security, and biological weapons prohibition diplomacy will lead us to a position of much greater strength – if executed efficiently, effectively, and in an integrated fashion.

Congress will play a critical role in conducting oversight and providing authorities and funding. Our report provides a number of recommendations to amend legislation and coordinate congressional oversight. Appendix A provides an extensive list of suggested topics in need of oversight – we call out six for the attention of the Armed Services

committees – that we hope you and your colleagues on other committees and in the Senate will consider.

As we close, we ask you to keep in mind the concerns of our citizenry. They watched with concern as we deployed military personnel to Africa to help contain Ebola there, and as the disease spread to the United States. Today, they read newspaper reports of devastating illnesses caused by Chikungunya and now Zika viruses, for which (like Ebola) we lack vaccines and treatments and to which our citizens and warfighters alike may be exposed. They learn that Al Qaeda and the Islamic State of Iraq and the Levant (ISIL) are actively pursuing the development and use of biological weapons on the United States and its interests abroad. While they understand that some outbreaks and attacks are unpredictable, they expect their lawmakers to plan for their occurrence.

It is too late to get ahead of this threat – it is already out there – but we can get ahead of its impact. Effective national defense against infectious disease threats requires the systematic and strategic use of intelligence, science and technology, and government policy. We believe that we can leverage and improve all of these right now to address threats, strengthen vulnerabilities, and reduce consequences. Our citizens and warfighters deserve no less.

Thank you again for this opportunity to appear before you. We would also like to thank Hudson Institute and the Inter-University Center for Terrorism Studies at Potomac Institute for Policy Studies (our institutional sponsors) and all of the organizations that supported our efforts. We look forward to working with you to strengthen national biodefense.

Please see our bipartisan report, "A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts" for our 33 recommendations and associated action items. Those of our recommendations that address DOD directly are Recommendations 3, 7, 9, 10, 26, 27, and 28. We also describe DOD as a participant in or affected by a number of the other recommendations.

Recommendations of the Blue Ribbon Study Panel for Biodefense:

1. Institutionalize biodefense in the Office of the Vice President of the United States.
2. Establish a Biodefense Coordination Council at the White House, led by the Vice President.
3. Develop, implement, and update a comprehensive national biodefense strategy.
4. Unify biodefense budgeting.
5. Determine and establish a clear congressional agenda to ensure national biodefense.
6. Improve management of the biological intelligence enterprise.
7. Integrate animal health and One Health approaches into biodefense strategies.
8. Prioritize and align investments in medical countermeasures among all federal stakeholders.
9. Better support and inform decisions based on biological attribution.

10. Establish a national environmental decontamination and remediation capacity.
11. Implement an integrated national biosurveillance capability.
12. Empower non-federal entities to be equal biosurveillance partners.
13. Optimize the National Biosurveillance Integration System.
14. Improve surveillance of and planning for animal and zoonotic outbreaks.
15. Provide emergency service providers with the resources they need to keep themselves and their families safe.
16. Redouble efforts to share information with state, local, territorial, and tribal partners.
17. Fund the Public Health Emergency Preparedness cooperative agreement at no less than authorized levels.
18. Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.
19. Minimize redirection of Hospital Preparedness Program funds.
20. Provide the financial incentives hospitals need to prepare for biological events.
21. Establish a biodefense hospital system.
22. Develop and implement a Medical Countermeasure Response Framework.
23. Allow for forward deployment of Strategic National Stockpile assets.
24. Harden pathogen and advanced biotechnology information from cyber attacks.
25. Renew U.S. leadership of the Biological and Toxin Weapons Convention.
26. Implement military-civilian collaboration for biodefense.
27. Prioritize innovation over incrementalism in medical countermeasure development.
28. Fully prioritize, fund, and incentivize the medical countermeasure enterprise.
29. Reform Biomedical Advanced Research and Development Authority contracting.
30. Incentivize development of rapid point-of-care diagnostics.
31. Develop a 21st Century-worthy environmental detection system.
32. Review and overhaul the Select Agent Program.
33. Lead the way toward establishing a functional and agile global public health response apparatus.

Kenneth L. Wainstein
Partner – Washington
Cadwalader, Wickersham & Taft LLP

Kenneth Wainstein is Chair of the firm's White Collar Defense and Investigations Group. He focuses his practice on corporate internal investigations and civil and criminal enforcement proceedings. With experience in significant positions in the U.S. government in the areas of criminal enforcement and national security, he brings clients a deep understanding of the substantive and procedural issues involved in white collar defense. His 20 years of public service have garnered him an intimate knowledge of Justice Department policy, extensive crisis management skills, credibility among prosecutors and regulators, and strong relationships with Congress, the District of Columbia bench and bar and U.S. Attorneys around the country.

In 2008, after 19 years at the Justice Department, Ken was named Homeland Security Advisor by President George W. Bush. In this capacity, he coordinated the nation's counterterrorism, homeland security, infrastructure protection, and disaster response and recovery efforts. He advised the President, convened and chaired meetings of the Cabinet Officers on the Homeland Security Council, and oversaw the inter-agency coordination process for homeland security and counterterrorism programs.

Prior to his White House service, Ken was twice nominated and confirmed for leadership positions in the Justice Department. In 2006, the U.S. Senate confirmed Ken as the first Assistant Attorney General for National Security. In that position, Ken established and led the new National Security Division, which consolidated DOJ's law enforcement and intelligence activities on counterterrorism and counterintelligence matters, and also oversaw the Department's role in regulatory mechanisms such as the Committee on Foreign Investment in the U.S. (CFIUS). Ken led several national security initiatives, including the launch of the national, inter-agency Export Control Enforcement Initiative targeting illegal exports of sensitive technology and weapons components.

In 2004, he was appointed, and later confirmed as, the United States Attorney in Washington, DC, where he managed the largest U.S. Attorney's Office in the country and oversaw a number of high-profile white-collar and public corruption cases. Prior to that, Ken served as General Counsel of the Federal Bureau of Investigation and then as Chief of Staff to Director Robert Mueller. At the FBI, Ken was involved in myriad sensitive national security and criminal enforcement matters, as well as a variety of civil litigation, managerial, and Congressional oversight issues. In 2001, Ken was appointed Director of the Executive Office for U.S. Attorneys, where he provided oversight and support to the 94 U.S. Attorneys' Offices.

From 1989 to 2001, Ken served as an Assistant U.S. Attorney in both the Southern District of New York and the District of Columbia, where he handled numerous criminal trials and appellate arguments.

Ken's work has been recognized with the Edmund J. Randolph Award for Outstanding Service to the Department of Justice, the Department of Justice Director's Award for Superior Performance, and the Lawyer of the Year Award from the Bar Association of the District of Columbia, and he was recently named as a top national security lawyer by Washingtonian magazine. Ken has served as an adjunct professor at Georgetown University Law Center since 2009, teaching National Security Investigations and Litigation. He is a Panel Member of the Blue Ribbon Study Panel on Biodefense; a member of the Director's Advisory Board of the National Counterterrorism Center; a member of the Director's Advisory Board of the National Counterterrorism Center; a member of the Public Interest

Declassification Board; a member of the CIA General Counsel's External Advisory Board; chairman of the Legal Panel of the National Security Agency Advisory Board; a member of the Webster Commission on the FBI, Counterterrorism Intelligence, and the Fort Hood Shootings; co-chair of the Committee on National Security Law, Policy & Practice of the District of Columbia Bar Association; a member of the Council on Foreign Relations; serves on the Board of Directors for the Center for Cyber and Homeland Security at the George Washington University; and a member of the Board of Directors of the National Association of Former United States Attorneys. Ken is ranked as a Washington, D.C., Litigation Star by Benchmark Litigation.

Ken earned his B.A. from the University of Virginia, with high distinction and Phi Beta Kappa. He earned his J.D. from the University of California at Berkeley, where he was a moot court board member and the Note and Comment Editor of the California Law Review. Following law school, Ken served as law clerk to the Honorable Thomas Penfield Jackson of the U.S. District Court in the District of Columbia.

Gerald W. Parker, Jr., DVM, PhD
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Dr. Gerald W. Parker joined the Texas A&M University in November 2013 as associate vice president for Public Health Preparedness and Response, and principal investigator for the Texas A&M Center for Innovation in Advanced Development and Manufacturing. Dr. Parker was recently appointed. Interim Director, Institute for Infectious Animal Diseases in AgriLife Research and Adjunct Professor in the Department of Pathobiology, College of Veterinary Medicine; and he is a guest lecturer in the School of Public Health. Prior to his appointment to Texas A&M University, Dr. Parker served 36 years as a scientist, leader, career officer and senior executive at the federal level in public service for global health and national security.

As a senior executive, Dr. Parker was the deputy assistant secretary of defense for Chemical and Biological Defense at the Department of Defense from 2010 to 2013, and the principal deputy assistant secretary for Preparedness and Response at the Department of Health and Human Services from 2005 to 2010. He also served at the Department of Homeland Security from 2004 to 2005. He was a 2009 recipient of the Distinguished Executive Presidential Rank Award, and awarded the Secretary of Defense Medal for Meritorious Civilian Service in 2013.

Before his selection into the Senior Executive Service, Dr. Parker held a variety of assignments during his 26-year military career in the U.S. Army (1977-2004), including: assistant deputy for medical research and development; director for the Medical Chemical and Biological Defense Research Program; deputy director for the Combat Casualty Research Program at the U.S. Army Medical Research and Materiel Command; and commander and deputy commander of the U.S. Army Medical Research Institute of Infectious Diseases.

Dr. Parker graduated from Texas A&M University with a Bachelor of Science in Veterinary Medicine in 1976 and a Doctor of Veterinary Medicine the following year. He holds a Doctorate in Physiology from Baylor College of Medicine in Houston and a Master of Science in Resourcing the National Strategy from the Industrial College of the Armed Forces.

Dr. Parker is married to the former Denise Joy Sonnen and the have three sons: Jamison (26), Jeramie (24), and Jonathan, (21).

DISCLOSURE FORM FOR WITNESSES
COMMITTEE ON ARMED SERVICES
U.S. HOUSE OF REPRESENTATIVES

INSTRUCTION TO WITNESSES: Rule 11, clause 2(g)(5), of the Rules of the U.S. House of Representatives for the 114th Congress requires nongovernmental witnesses appearing before House committees to include in their written statements a curriculum vitae and a disclosure of the amount and source of any federal contracts or grants (including subcontracts and subgrants), or contracts or payments originating with a foreign government, received during the current and two previous calendar years either by the witness or by an entity represented by the witness and related to the subject matter of the hearing. This form is intended to assist witnesses appearing before the House Committee on Armed Services in complying with the House rule. Please note that a copy of these statements, with appropriate redactions to protect the witness's personal privacy (including home address and phone number) will be made publicly available in electronic form not later than one day after the witness's appearance before the committee. Witnesses may list additional grants, contracts, or payments on additional sheets, if necessary.

Witness name: Kenneth L. Wainstein

Capacity in which appearing: (check one)

○ Individual

◉ Representative

If appearing in a representative capacity, name of the company, association or other entity being represented: Blue Ribbon Study Panel on Biodefense

Federal Contract or Grant Information: If you or the entity you represent before the Committee on Armed Services has contracts (including subcontracts) or grants (including subgrants) with the federal government, please provide the following information:

2015

Federal grant/ contract	Federal agency	Dollar value	Subject of contract or grant

2014

Federal grant/ contract	Federal agency	Dollar value	Subject of contract or grant

2013

Federal grant/ contract	Federal agency	Dollar value	Subject of contract or grant

Foreign Government Contract or Payment Information: If you or the entity you represent before the Committee on Armed Services has contracts or payments originating from a foreign government, please provide the following information:

2015

Foreign contract/ payment	Foreign government	Dollar value	Subject of contract or payment

2014

Foreign contract/ payment	Foreign government	Dollar value	Subject of contract or payment

2013

Foreign contract/ payment	Foreign government	Dollar value	Subject of contract or payment

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COMMITTEE ON ARMED SERVICES
U.S. HOUSE OF REPRESENTATIVES

INSTRUCTION TO WITNESSES: Rule 11, clause 2(g)(5), of the Rules of the U.S. House of Representatives for the 114th Congress requires nongovernmental witnesses appearing before House committees to include in their written statements a curriculum vitae and a disclosure of the amount and source of any federal contracts or grants (including subcontracts and subgrants), or contracts or payments originating with a foreign government, received during the current and two previous calendar years either by the witness or by an entity represented by the witness and related to the subject matter of the hearing. This form is intended to assist witnesses appearing before the House Committee on Armed Services in complying with the House rule. Please note that a copy of these statements, with appropriate redactions to protect the witness's personal privacy (including home address and phone number) will be made publicly available in electronic form not later than one day after the witness's appearance before the committee. Witnesses may list additional grants, contracts, or payments on additional sheets, if necessary.

Witness name: Gerald W Parker, Jr., DVM, PhD

Capacity in which appearing: (check one)

(•) Individual

( ) Representative

If appearing in a representative capacity, name of the company, association or other entity being represented: _____

Federal Contract or Grant Information: If you or the entity you represent before the Committee on Armed Services has contracts (including subcontracts) or grants (including subgrants) with the federal government, please provide the following information in the tables below.

I am testifying on behalf of the Biodefense Blue Ribbon Panel, and the panel does not have contracts or grants with the federal government or foreign entities. I am also an employee of Texas A&M University. Although I am not representing Texas A&M at this hearing, I have included the grants, cooperative agreements, contracts and subcontracts in the following tables wherein I serve as the principal investigator at Texas A&M, and in the appropriate year that I have served in a principal investigator capacity.

2015

Federal grant/ contract	Federal agency	Dollar value	Subject of contract or grant
Contract	DHHS	$176M	MCM Advanced Development & Manufacture (CIADM)
Cooperative agreement	DHS	$10.6M	University Center of Excellence for Infectious Animal Diseases
Research task order	DHS	$260K	Laboratory virus repository support
Research task order	DHS	$998K	Laboratory information technology support
Research task order	DHS	$800K	Animal Vaccine International trial support
Research task order	DHS	$8.6M	Infectious animal disease surveillance
Research task order	DHS	$186K	Support to joint task force exercise development
Research contract	DHS	$69K	Support to livestock emergency plan evaluation
Research grant	DOS	$330K	Laboratory diagnostics training
Research task order	DHS	$140K	Vehicle and premise decontamination
Research contract	DHS	$147K	Diagnostic assay development
Research contract	DHS	$497K	Diagnostic assay development
Research contract	DHS	$266K	Diagnostic assay development
Research contract	DHS	$192K	Diagnostic assay development

2014

Federal grant/ contract	Federal agency	Dollar value	Subject of contract or grant
Contract	DHHS	$176M	MCM advanced development and Manufature

2013

Federal grant/ contract	Federal agency	Dollar value	Subject of contract or grant
Contract	DHHS	$176M	MCM advanced development and manufacture

Foreign Government Contract or Payment Information: If you or the entity you represent before the Committee on Armed Services has contracts or payments originating from a foreign government, please provide the following information:

2015

Foreign contract/ payment	Foreign government	Dollar value	Subject of contract or payment
None			

2014

Foreign contract/ payment	Foreign government	Dollar value	Subject of contract or payment
None			

2013

Foreign contract/ payment	Foreign government	Dollar value	Subject of contract or payment
None			

QUESTIONS SUBMITTED BY MEMBERS POST HEARING

FEBRUARY 3, 2016

QUESTIONS SUBMITTED BY MR. WILSON

Mr. WILSON. The report discusses the importance of "building upon defense support to civil authorities." The panel found that "U.S. warfighter preparedness for and protection against biological attacks is inadequate" and that the "current military biodefense doctrine and policy falls short of adequately protecting the warfighter and ensuring that military operations continue unimpeded." Can you describe the information that the panel gathered to reach this conclusion? What specific shortcomings need to be addressed to improve warfighter preparedness and protection against biological attacks?

Mr. WAINSTEIN and Dr. PARKER. The Panel gathered information to support these conclusions from subject matter experts, including Dr. George Poste (one of our ex officios) and others who spoke at our major meetings held on December 4, 2014; January 14, 2015; March 12, 2015; and April 2, 2015. Please see Appendix C of our bipartisan report, A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts for meeting agendas and speaker names. A number of open source documents also support our conclusions regarding the characteristics of personal protective equipment (also referred to as protective overgarments), medical countermeasures, detectors, and surveillance systems, as well as doctrine and policy that would lead to the likely exposure of military personnel to biological weapons before they were able to don protective equipment/garments and take other protective actions during attacks. The Department of Defense also freely describes and admits to difficulties in preparing warfighters to execute combat operations in biologically contaminated environments. The Department clearly communicates its concerns regarding biological (and other) weapons of mass destruction threats and uses those concerns to justify funding for its research and development programs (e.g., those that produce and improve upon medical countermeasures, protective overgarments and equipment, detectors, surveillance systems). Specifically, although their biodefense laboratories appear to be doing exemplary work in the science and technology discovery phase, the lack of progress on biodefense vaccine development (where some vaccine candidates have languished in advanced development for close to 15 years) is not encouraging and serves as an example of the inability to improve readiness through the use of preventive vaccines. To improve warfighter operational preparedness, the Panel recommends that the military go beyond using smoke and other non-biological visually obvious 2 substitutes and find ways to realistically simulate the use of biological agents in training environments. Additionally, the Panel recommends that the military require its personnel to do more than wear protective overgarments and work in areas thought to have sufficient protections against these agents for hours on end, as this sort of training only tests warfighter ability to withstand such conditions and not the ability to prevent infection. To improve protection against biological attacks, the Panel supports ongoing military research efforts (particularly those conducted by the Defense Advanced Research Projects Agency and the National Laboratories on behalf of the Department of Defense) to improve materials used in overgarments and equipment, all military biodefense efforts, and the military-civilian exchange of relevant information. The Panel also supports similar efforts made by civilian public and private sector agencies, but notes that needed exchange of information does not occur automatically. While both military and civilian sectors would benefit from information exchange, the Department of Defense must necessarily take the lead and initiate such exchanges for the benefit of its warfighters.

Mr. WILSON. The Department of Defense played a large role in the U.S. Government response to the Ebola crisis. What do you think is an appropriate role for the Department of Defense to play in responding to global epidemics, such as Ebola? Are there aspects of the response that would be more appropriate for other parts of government? What role would you recommend the Department of Defense play in response to the recent Zika virus outbreak?

Mr. WAINSTEIN and Dr. PARKER. The Department of Defense often provides humanitarian aid during domestic and international crises that exceed the ability of the civilian sector to respond effectively. For example, during the recent Ebola crisis, the Department of Defense provided the United States Agency for International De-

velopment efforts with logistics, engineering, and training support. The Department of Defense also undertakes a number of other activities that not only support the warfighter but also support broader U.S. governmental responses. For example, the National Center for Medical Intelligence gathers epidemiological, biostatistical, health care, and public health infrastructure data and information to characterize environments to which warfighters deploy, and shares this information. The Department of Defense also sometimes shares with civilian agencies information produced by its laboratories, surveillance systems, and intelligence activities throughout the world. In addition, the Department of Defense supports the Global Health Security Agenda through the Global Emerging Infectious Disease Surveillance and Response System and the Department of Defense Overseas Research Laboratories. These unique laboratories directly and indirectly support deployed forces and contribute to medical and public health diplomacy in support of U.S. foreign policy and national security objectives. These are all appropriate activities. The Department of Defense Chemical and Biological Defense Program develops medical countermeasures to protect military forces facing biological threats. While the Panel believes it is within Department of Defense purview to develop medical countermeasures for its own personnel, we note that its civilian counterpart (i.e., the Department of Health and Human Services Biomedical Advanced Research and Development Authority, BARDA) often works on similar medical countermeasures for non-military purposes. While the Public Health Emergency Medical Countermeasures Enterprise (an interagency coordinating body) exists and the Department of Defense is a member, the Panel does not believe that these two agencies coordinate optimally to cover gaps, avoid redundant efforts, and aggressively accelerate development efforts between outbreaks. This became clear in 2014 when in response to the global crisis, BARDA announced it would fund the development of Ebola vaccines. This surprised the Department of Defense, which had been working on vaccines for some time without knowing that BARDA was interested in producing Ebola vaccine for civilian purposes. This situation occurred because there is no leader who stands above the departments and agencies, maintains awareness of their activities, ensures the appropriate prioritization and execution of a medical countermeasure strategy, and prevents redundant efforts. 4 In 2014, military personnel deployed to West Africa without the benefit of Ebola vaccine or therapeutics. The lack of vaccine limited both civilian and military responses and readiness. These biodefense vulnerabilities place Department of Defense missions at risk. The threats of biological weapons, as well as emerging and reemerging infectious diseases, imperil force protection and force projection at home and abroad. While the Department of Defense trains and equips its forces to operate in radiologically contaminated environments, this is far from the case for biologically contaminated environments, where related training is inadequate and equipment is far less advanced. Diseases that spread across the world quickly affect the United States. It is, therefore, entirely appropriate to question the role of the Department of Defense in both international and domestic response. The Department's role in civil support lacks clarity and dedicated resources. There is a mutual lack of understanding between the military and civilian sectors and considerable suspicion regarding operational capabilities. The Department of Defense must enunciate a technically feasible and politically acceptable doctrine for biodefense activities if it is to fulfill its primary responsibilities for force protection and projection while planning for an inevitably expanded role in domestic/homeland defense and global response during major biological events. If the Department of Defense proactively takes needed steps to develop a robust biodefense capability to protect its own assets, it will be better able to meet broader civil support requirements. The U.S. Government cannot deploy Department of Defense personnel and assets each time a new disease emerges. Military involvement must be limited to assisting with those diseases that impact national security and take into consideration the current spread of military resources, as well as the possibility that the military may need to move to defend against enemy activity that poses a greater threat to the nation. In the case of Zika response, the Panel believes that the role of the Department of Defense should include many of the same activities it executed during Ebola, with the exception of targeted deployments of military personnel (due to the current spread and nature of the virus and disease). As stated in Recommendation 33 of the Panel's report, the nation and the world need a new global response apparatus based on public-private partnerships, not solely on U.S. military resources and capabilities.

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