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BIODEFENSE: WORLDWIDE THREATS AND COUNTERMEASURE EFFORTS FOR THE DEPARTMENT OF DEFENSE

HEARING

BEFORE THE

SUBCOMMITTEE ON INTELLIGENCE, EMERGING THREATS AND CAPABILITIES

OF THE

COMMITTEE ON ARMED SERVICES
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

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BIODEFENSE: WORLDWIDE THREATS AND COUNTERMEASURE EFFORTS FOR THE DEPARTMENT OF DEFENSE

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ARMED SERVICES,
SUBCOMMITTEE ON INTELLIGENCE, EMERGING THREATS AND CAPABILITIES,
Washington, DC, Friday, October 11, 2013.

The subcommittee met, pursuant to call, at 11:11 a.m., in room 2118, Rayburn House Office Building, Hon. Mac Thornberry (chairman of the subcommittee) presiding.

OPENING STATEMENT OF HON. MAC THORNBERRY, A REPRESENTATIVE FROM TEXAS, CHAIRMAN, SUBCOMMITTEE ON INTELLIGENCE, EMERGING THREATS AND CAPABILITIES

Mr. THORNBERRY. The subcommittee will come to order.

Mr. Langevin, I am sure, is on the way, and he will be here in just a moment, but we will go ahead and get started.

Today's hearing is a reminder that the national security threats to our Nation do not go away or wait patiently while we try to straighten out our budget woes. There are very real and very significant dangers in the world, and the foremost target is America and Americans.

Part of our job on this subcommittee is to look ahead for the threats coming down the road and for those that may loom larger in the future. Biological threats must be at or near the top of that list.

For example, while the world's attention has been focused on Syria's chemical weapons, DNI [Director of National Intelligence] Clapper testified earlier this year that Syria's biological program may be more advanced than we previously thought. We believe that other nations, such as North Korea, have such capability, as well.

David Hoffman's book, *The Dead Hand [The Dead Hand: The Untold Story of the Cold War Arms Race and Its Dangerous Legacy],* discusses the Soviet program, which engineered a pathogen within a pathogen so that victims got sick, seemed to get better, and then got hit with a second pathogen and quickly died. In other words, there seems to be an endless number of biological threats, from the crude to the sophisticated.

And then, of course, there are terrorists. The former chief technology officer for Microsoft, Nathan Myhrvold, recently published a paper on the Lawfare Web site, entitled "Strategic Terrorism," that has been generating a fair amount of discussion in national security circles. He argues, convincingly I think, that technology gives

small groups more lethality than ever, that the incentive for more spectacular attacks will grow, that biological weapons may be the most dangerous form of attack, that terrorists using such weapons cannot be deterred, and that we are not adequately prepared.

We are anxious to get our witnesses' perspectives on these issues, and they are well qualified to provide that. We want to examine the threat, the Department of Defense's (DOD) role in meeting the threat, and other Government and national resources that should also play a part.

I would yield to Mrs. Davis for any opening comment she would like to make at this moment on behalf of Mr. Langevin.

Mrs. DAVIS. Mr. Chairman, thank you very much.

This is important. And part of it is under what circumstances we believe our most pressing threat in this area might be. So I look forward to the discussion, and thank you very much.

And I believe Mr. Langevin is here, and we will give him an opportunity when he comes in. Thank you.

Mr. THORNBERRY. Excellent timing for an entry. And I yield to the distinguished ranking member for any opening comments he would like to make.

STATEMENT OF HON. JAMES R. LANGEVIN, A REPRESENTATIVE FROM RHODE ISLAND, RANKING MEMBER, SUBCOMMITTEE ON INTELLIGENCE, EMERGING THREATS AND CAPABILITIES

Mr. LANGEVIN. Thank you, Mr. Chairman.

And to our witnesses, I appreciate you being here today on this very important topic. It is obviously very timely and a timely hearing.

And I want to thank the chairman for focusing the Nation's and the subcommittee's attention on this issue of biowarfare.

Biowarfare is obviously a very troubling prospect, something that weighs heavily on all of us. And while less prevalent in the news than nuclear or chemical warfare, it is an extraordinarily lethal capability that poses a significant threat to the United States, including from terrorism.

Now, there are also many unknowns and problems unique to biowarfare, including, most obviously, the unlikelihood of an attack warning and the difficulty in crafting effective countermeasures, if they can be created at all.

And these organisms can be incredibly lethal, as Major General Russell highlighted in his written testimony. Tularemia is one of the most infectious agents know, with an infectious dose containing less than 10 bacteria, an infinitesimal amount when one considers that a simple powder aerosol can deliver hundreds of thousands of those organisms.

Further, other agents such as botulinum toxin, plague, and many viral hemorrhagic fevers lack approved vaccines at the present time.

These difficulties are put into stark relief when we look at the use of weapons of mass destruction in Syria. Although the nerve agent sarin was used as opposed to a biological agent, the attacks in Syria nonetheless demonstrated the reality of the WMD [Weapons of Mass Destruction] threat to U.S. and allied forces. Even

more troubling, given Syria's past biological warfare capability and the instability, to put it mildly, in the country, the threat of proliferation is real and serious.

Now, that is the background for today's hearing, and it should add some urgency to the issue. This is not an academic discussion. And I certainly look forward to what our panel has to say about proliferation risks from Syria and elsewhere.

Now, within the United States Government, the problem is obviously compounded by the wide spectrum of agencies with a piece of the biodefense puzzle. Outside of DOD's [Department of Defense] Chemical and Biological Defense Program, the Department of Health and Human Services, Agriculture, Homeland Security, and the Food and Drug Administration each have a role, and each has their own specialties, capabilities, and responsibilities in addressing biothreat preparedness and response. I remember well the complications of this interdependency from my time chairing the Homeland Security subcommittee with oversight of biodefense.

Since my departure from that subcommittee, we have seen the GAO [Government Accountability Office] report that showed the Governmentwide biodefense enterprise as being fragmented and sometimes duplicative as well as lacking strategic oversight mechanisms. Now, this committee and the Congress have acted to ameliorate those concerns and enhance the interagency process. And I certainly look forward to hearing from our witnesses on what progress has been made and how far we still have to go.

So, with that, Mr. Chairman, in the interest of time, I want to leave it there. I want to thank you again for convening the hearing. And I want to thank, obviously, our witnesses for appearing this morning. And I look forward to a very informative and interesting discussion.

With that, I yield back.

Mr. THORNBERRY. I thank the gentleman.

And before going to our panel, I ask unanimous consent that other committee and non-committee members be allowed to participate in today's hearing after all subcommittee members have had a chance—have had the opportunity to ask questions. Is there objection?

Without objection, it is so ordered.

Let me now turn to our witnesses.

Thank you all for being here.

We have—everybody is a doctor—Dr. Amy Smithson, Senior Fellow at the Monterey Institute of International Studies; Dr. Bruce Bennett, Senior Defense Analyst for RAND; retired Major General Dr. Philip Russell, who is a retired Army medical officer and professor emeritus at Johns Hopkins School of Public Health; and Dr. Brett Giroir, Interim Executive Vice President, Health Science Center, Texas A&M University.

Again, thank you all for being here.

Dr. Smithson, please proceed.

STATEMENT OF DR. AMY E. SMITHSON, SENIOR FELLOW, MONTEREY INSTITUTE OF INTERNATIONAL STUDIES

Dr. SMITHSON. Good morning. And thank you for the opportunity to testify before the committee on matters of vital importance to the defense of this Nation.

Mr. THORNBERRY. Dr. Smithson, if you would hit the microphone. And try to get it up kind of close to you. Some——

Dr. SMITHSON. All right.

Mr. THORNBERRY. They work better that way.

Dr. SMITHSON. Sorry about that faulty start.

Mr. THORNBERRY. Thank you.

Dr. SMITHSON. I thank you for the opportunity to testify before the committee on matters of vital importance to the defense of this Nation.

As you have already noted, the number of known biological weapons proliferators is relatively small today. I would add to that list North Korea, which I am sure Dr. Bennett will address. And over the past two decades, terrorists have wreaked havoc with bombs and bullets far more frequently than with disease. But no one should be complacent about the biological weapons threat.

Regrettably, states and subnational actors alike can co-opt the fruits of the life sciences revolution for germs weapons programs, which are always shrouded in the utmost secrecy. Proliferators can use synthetic biology to create from scratch notorious killers like the 1918 influenza virus and even smallpox virus. And they can highjack other new life sciences technologies to manipulate and control human behavior.

One of our other problems is that we don't know what we don't know. The intelligence community's performance assessing the biological weapons threat leaves a great deal to be desired. I will give you an idea why.

Prior to the 1991 gulf war, U.S. intelligence did not identify Iraq's principal biological weapons production facility at Al Hakum, nor did they pick up on Iraq's purchase of an astounding 30 metric tons of growth media, which is used to grow biowarfare agents.

Moreover, public health authorities, not law enforcement or intelligence officials, connected the dots in a 1984 surge in gastrointestinal illness in Oregon to the Rajneesh cult, which sickened 751 people when it decided to test its plot to foil an election by sprinkling salmonella on restaurant salad bars.

U.S. intelligence agencies admitted in 1996 testimony that they were oblivious to Aum Shinrikyo's unconventional weapons programs until after the cult's infamous attack in the Tokyo subway on March 20th, 1995. Fortunately, Aum failed when it tried to acquire and disperse on several occasions biowarfare agents.

And last but not least, the FBI [Federal Bureau of Investigation] turned to Dr. Bruce Ivins, a 26-year veteran of the U.S. Army Military Research Institute for Infectious Diseases, USAMRIID, to help them investigate the 2001 anthrax attacks, only fingering him as the culprit in 2008.

Now, the Select Agent Rules, the centerpiece of the U.S. biosecurity approach, would not have stopped Bruce Ivins, who was mentally unstable and abusing drugs and alcohol. These rules do not require substance abuse screening, and they address mental health

issues tangentially. Moreover, a 2001 inventory of USAMRIID's culture collection turned up an amazing 9,220 vials not listed in the facility's computerized inventory, including vials of botulinum neurotoxins and the Ebola virus. USAMRIID's inventory saga illustrates just how misapplied the paradigm of nuclear controls is in a life sciences world.

With all of this in mind, I offer the committee three recommendations to consider.

The concept and practice of biosecurity is in serious need of an overhaul, in part because evidence indicates that the Select Agent Rules have important opportunity costs for biodefense. Top scientists in laboratories have apparently opted out of work with high-risk pathogens already. Therefore, Congress should require the executive branch to prepare a cost-benefit study of the Select Agent Rules and alternative approaches to biosecurity.

Second, far, far too often, scientists' knowledge of important biosafety, biosecurity, and research oversight procedures falls to the inclinations and sometimes shoddy practices of their laboratory supervisor. No time should be wasted in correcting this ad hoc situation. Congress should consider how mandatory education and competency demonstration requirements could be instituted in all colleges and universities granting life sciences degrees in all institutions working with high-risk pathogens

Third, the United States needs to go back to the drawing board on data-collection strategies, tactics, and tools that can be used to assess the biological weapons threat. Among other things, a congressionally mandated study would evaluate the limitations and prospective contributions of intelligence and inspections to the detection and deterrence of bioweapons proliferation.

The United States Government appears to have done little to learn from the incredible experience of the United Nations Special Commission. With ordinary inspection tools and old-fashioned, gumshoe detection work, UNSCOM [United Nations Special Commission] inspectors collected considerable evidence that Iraq was hiding a bioweapons program behind the facade of civilian activities. UNSCOM compelled Iraq to admit this.

Inspections can work. And this experience stands as a direct challenge to the conventional wisdom that the Biological and Toxin Weapons Convention is inherently unverifiable. This study would be a springboard to identify alternatives to give U.S. policymakers more data of a more reliable quality about suspected biological weapons activities, which would, in turn, inform U.S. biodefense programs.

With that, I would be pleased to answer any questions about my testimony.

And I would also add a note of today's news that the OPCW, the Organization for the Prohibition of Chemical Weapons, has been awarded the Nobel Peace Prize. These inspectors are undertaking an unprecedented task, but for 17 years they have been going around the world monitoring the destruction of chemical weapons. And it is something that, perhaps, if you would also like to ask questions about the situation in Syria, I would be delighted to entertain them.

Thank you for your time and attention.

[The prepared statement of Dr. Smithson can be found in the Appendix on page 33.]

Mr. THORNBERRY. Great. Thank you.

Dr. Bennett.

STATEMENT OF DR. BRUCE W. BENNETT, SENIOR DEFENSE ANALYST, RAND CORPORATION

Dr. BENNETT. Thank you very much, Chairman Thornberry, Ranking Member Langevin, and members of the subcommittee. Thank you for inviting me to testify at this hearing.

While there are many evidences of the North Korean biological weapons, North Korea has been very effective at hiding that information, denying us information in the world about its biological weapons programs and making the threat very uncertain. Still, because biological weapons pose a fearsome threat, South Korea and the United States need to be prepared, hedging against the uncertainties.

I will discuss that threat and then turn to means for countering that threat, though I will focus on the nonmedical counters, given the expertise of my colleagues.

In my written testimony, I have provided several open descriptions of the North Korean biological weapons program. To summarize, most observers believe that North Korea has pursued a serious biological weapons development program focused on a dozen diseases, to include anthrax, cholera, smallpox, and plague, the latter two being contagious diseases.

It is not known whether these agents are currently weaponized, though there are a number of testimonies of North Korea testing these agents against people in its prison camps. Thus, even if these agents are not currently weaponized, the north should be able to weaponize them once it decides to prepare for war.

North Korean special forces are a likely means of delivering biological weapons. The North has some 200,000 special forces, some of whom could deliver devastating biological attacks against South Korea, Japan, and even the United States. Depending upon wind, atmospheric conditions, and population density, these forces could infect perhaps 500—or 50,000 people per kilogram of anthrax used. Alternatively, with contagious diseases like smallpox, even if only 1,000 people were initially exposed, thousands more could be infected as the disease spreads.

Biological effects are not limited to casualties and fatalities. As in the case of the anthrax letters, biological agents can deny the use of facilities, potentially for years. They can put overwhelming demands on the medical system. They can force people to use protective measures, measures that would particularly degrade military operations. They can cause psychological reactions like the 600,000 people who fled a city in India one night in 1994 after what turned out to be 167 cases of plague.

And how many cases of smallpox would have to be brought back into the United States, for example, among evacuated noncombatants, combat casualties, or aircrews, before the United States would face substantial economic and psychological impacts?

So how can we prepare for and respond to these potential attacks? We must prepare to counter the effects of biological attacks.

Such capabilities would also help deter the attacks in the first place, and deterrence is clearly the preferred option. As noted above, I will focus here on the useful nonmedical counters.

In peacetime, North Korean special forces seeking to covertly introduce biological weapons for future attacks could be stopped at South Korean or U.S. borders if immigration was connected to the passport databases of Asian countries and able to detect falsified passports. In crisis and conflict, the U.S. and South Korea could use robust air and missile defenses if they are deployed in Korea against North Korean military aircraft or missiles that might carry biological weapons.

With contagious diseases, exposure can be prevented in various nonmedical ways. Schools can be closed, public activities suspended, those sick can be physically isolated, and those exposed could be subjected to quarantine if the laws exist to facilitate these arrangements.

People arriving at international air and sea ports should be scanned for a fever. Those with fever should be isolated until their fever subsides or testing determines they are not contagious. This procedure continues in South Korea, for example.

The United States and South Korea should buy respirators now that they would use to block disease should there be an outbreak of biological agents. And collective protection should be provided with us building military facilities in Korea now at Camp Humphreys, as they were provided when we built those facilities—similar facilities at Osan Air Base.

In conclusion, the North Korean biological weapons pose potentially serious though uncertain threats to South Korea and to the United States. This threat should press the United States and South Korea to pursue more complete protections.

Thank you.

[The prepared statement of Dr. Bennett can be found in the Appendix on page 42.]

Mr. THORNBERRY. Thank you.

General Russell.

STATEMENT OF MG PHILIP K. RUSSELL, USA (RET.), SABIN VACCINE INSTITUTE

General RUSSELL. Thank you, Mr. Chairman, members of the committee. I appreciate the opportunity to discuss an issue that has been—I have been concerned about for about 35 years or more. And I would like to present my views on what I believe is a significant unaddressed threat to our Armed Forces and to our national security.

Over the past two years, my colleagues Mr. Joel McCleary and Dr. Keith Wells and I have conducted a study of the impressive achievements of the U.S. offensive biowarfare program to learn what that means in terms of modern threat assessment. We conducted a parallel study of how advancement in pharmaceutical manufacturing can benefit and enable our adversaries. Our study of the offensive program was based on existing unclassified documents and on the oral history of one of the scientific leaders of the program, Mr. Bill Patrick. A parallel study of classified materials by Dr. Robert Kadlec supported our findings.

The U.S. offensive biowarfare program was very large, very well-funded, and very successful. By 1969, when the program was terminated, it had achieved the ability to deliver lethal and incapacitating agents in a dry powder aerosol over very large areas, up to hundreds of square miles. The effectiveness of the program was conclusively demonstrated in large-scale field tests such as Red Cloud, Watch Dog, and Speckled Start. These were enormous trials, many of them conducted over the Pacific.

The two agents chosen by the program after years of research to be the most effective were tularemia and staphylococcal enterotoxin B, or SEB. Tularemia is one of the most infectious agents known and, when delivered by aerosol in high doses, causes a severe respiratory disease that can be fatal. Tularemia is widely disseminated in nature and easily obtained. SEB causes rapid incapacitation and is also lethal in high concentrations.

These agents, along with delivery systems, were manufactured and stockpiled. There were plans to use them in combination, one for rapid effect and one for lethality. Both of these agents are readily available to anybody who can isolate a bacterium.

Very few of our present Government officials understand the achievements of that program and what it means to our current security. Our analysis of the advances in biologic manufacturing technology and bioprocessing leads to the conclusion that it is now possible for a small group of adversaries to produce these same weapons in quantities large enough for a strategic attack. Advances in aerosol delivery of therapeutics have provided our adversaries with greatly enhanced capability.

We now have no specific licensed preventive medical countermeasures for these two agents. We rely on antibiotic therapy for tularemia and supportive care for SEB. The deficiencies in our national medical countermeasures development programs have been very well documented. The Department of Defense created a joint program for advanced development of medical countermeasures for biodefense in 1996. The joint vaccine acquisition programs, I think started in 1997, was a major component of this.

A tularemia vaccine was at the top of the requirements list, which included several other biodefense vaccines against—most of them up against viruses. It is now 17 years later and no new licensed products have been developed.

Several independent reviews of the DOD programs, including one directed by Congress and two by the Institute of Medicine, were highly critical of the management of the program. To my knowledge, the recommendations of outside panels have been largely ignored.

In summary, I believe that a significant national vulnerability exists that will persist unless action is taken to improve our countermeasures development efforts.

I thank you for your attention to this issue. I will be happy to answer questions.

[The prepared statement of General Russell can be found in the Appendix on page 61.]

Mr. THORNBERRY. Thank you.

Dr. Giroir.

STATEMENT OF DR. BRETT P. GIROIR, M.D., INTERIM EXECUTIVE VICE PRESIDENT, TEXAS A&M HEALTH SCIENCE CENTER, TEXAS A&M UNIVERSITY

Dr. GIROIR. Chairman Thornberry, Ranking Member Langevin, members of the committee, Congressman Flores, thank you for the opportunity to be here today.

I am here as the principal investigator for the Texas A&M Center for Innovation in Advanced Development and Manufacturing, a public-private partnership with the Biomedical Advanced Research and Development Authority, also known as BARDA, of the U.S. Department of Health and Human Services. This partnership is designed to enhance the Nation's preparedness against pandemic influenza as well as chemical, biological, radiological, and nuclear threats.

My previous experience includes Government service as the director of DARPA's [Defense Advanced Research Projects Agency] science office and also as chair of the Chemical and Biological Defense Panel of the Threat Reduction Advisory Committee at Defense Threat Reduction Agency (DTRA).

At DARPA, we identified a critical national need for core biomanufacturing facilities that would be low-cost, flexible, adaptable, capable of simultaneously producing multiple products to support biodefense, while maintaining the ability to surge to a single product during a national emergency. In 2008, when my assignment at DARPA was completed, I joined the Texas A&M system, secured a $50 million investment from the State of Texas to demonstrate those flexible manufacturing capabilities originally envisioned at DARPA.

Beginning in 2009, Texas A&M designed, developed, constructed, and is now operating a revolutionary first-in-class, 150,000-square-foot facility that has pioneered highly flexible, adaptable, and even mobile manufacturing platforms at a capital cost of about 80 percent less than the current state of the art. This project, called the National Center for Therapeutics Manufacturing, is a primary infrastructure asset for the HHS [U.S. Department of Health and Human Services] center, which I will now describe.

The Texas A&M Center for Innovation is one of three national centers competitively awarded by HHS in June of 2012 and is the only one led by an academic institution. It is found on an initial 5½-year base period contract consisting of $176 million in funding from HHS and a $109 million cost-share by our center's academic, commercial, and State of Texas partners. The total potential duration of the contract is 25 years, with options for an additional $2.4 billion in readiness stipends and task orders.

The high-level objectives of our center are: first, to provide a national vaccine response against pandemic influenza, defined as 50 million doses delivered in 4 months, with initial doses available to the U.S. Government in 12 weeks; second, to perform what is called the advanced development and manufacturing of vaccines and medical countermeasures against chemical, biological, radiological, and nuclear threats as tasked by HHS; and, third, and very importantly, to train the future domestic U.S. workforce.

To achieve these objectives, Texas A&M is leading a multidisciplinary team with expertise spanning from research through clin-

ical trials, including GlaxoSmithKline, or GSK, Vaccines, the world's largest vaccine developer, with over 1.4 billion vaccine doses distributed worldwide annually and 11 vaccines in the United States.

The center is also actively expanding domestic U.S. infrastructure. First, our preexisting facility is undergoing a capabilities upgrade that will be completed in March of 2014. Second, we are building a new, dedicated pandemic influenza vaccine facility to meet our 50-million-dose requirements. Construction and facility commissioning will be completed in the third quarter of 2015. Third, we are building a new live-virus vaccine facility to produce vaccines up to the BSL–3 biosafety level. Construction and facility commissioning will also be completed in the third quarter of 2015.

I would like to finish my remarks highlighting opportunities for collaboration with the Department of Defense.

First, Texas A&M is highly motivated to continue our distinguished history of service to the Nation by supporting the DOD and supplying improved vaccines and countermeasures to the warfighter. Of particular interest would be DOD partnerships to develop and manufacture products for their stockpile and special immunizations programs and, perhaps more importantly, to be the cornerstone for an emergency response to genetically modified, or chimeric organisms as well as other unexpected agents that we believe are a growing real threat to our national security and public health.

According to our contract with HHS, at least 50 percent of our center's capabilities are available for non-HHS projects. Therefore, there is an immediate opportunity for the DOD to utilize our center's capacity and expertise, which has already been funded by HHS. We believe such collaborations would not only reduce DOD operational risks but would also reduce DOD expenditures, potentially by hundreds of millions of dollars that could then be reallocated to provide additional vaccines, countermeasures, and capabilities to our warfighters.

Thank you very much for this opportunity, and I am pleased to answer any questions.

[The prepared statement of Dr. Giroir can be found in the Appendix on page 65.]

Mr. THORNBERRY. Thank you.

And, without objection, you all's full written statement will be made part of the record as well, but I appreciate the oral comments from each of you.

Let me just begin with one question that I would invite each of you to address, and that is referencing back to the paper I mentioned on terrorists' use of biological weapons.

And I would just—you all were not asked to testify as experts on terrorism, but I would be interested in whatever thoughts you may have about the likelihood of such a thing, what some of the challenges would be, you know, whatever you feel comfortable in commenting on a terrorist attack using these sorts of weapons.

Dr. Smithson.

Dr. SMITHSON. I have looked at the statistics of terrorist activity, and it is clear that, for the time being at least, they are far more interested in bombs and bullets over the past couple of decades.

But it is also equally clear, by the attempts to acquire substances and the uncovering of plots, that there is increasing interest among terrorists.

The other thing that I think brings this within the reach of not just terrorist groups but individuals is the de-skilling of equipment. In other words, things that used to take Soviet bioweaponeers thousands and thousands of man-hours can now be accomplished by a piece of equipment in a fairly short time. They are currently working on desktop printers for DNA [Deoxyribonucleic Acid].

So it is a very fast-moving technical situation that will allow terrorist groups to acquire this capability. And we know that there are terrorist groups out there, like al Qaeda, that have the intent to kill indiscriminately.

So I am very concerned about the prospects for the future. I don't know exactly when, but I do believe we will see bioterrorism again.

And in my prepared remarks, I quote another individual who agrees with this study cited, and it is Martin Shubik, who views this situation in an equally grave manner.

Dr. BENNETT. I think we have to face the fact that some of the state actors we look at look a lot like terrorists when they actually go out. Some of my colleagues in the South Korean military believe that they have been subjected to testing by the North Korean special forces in recent years. Anthrax, probably several other diseases, they believe, have been tested in their territory to see what kind of reaction there would be and the ability to cope. That is clearly a terrorist kind of action.

I think we also have to recognize that some of these state actors are very closely tied to Iran, to Syria, where you have the potential for state-sponsored terrorists and would be quite pleased to see terrorists also using these capabilities and have done a fair amount of transferring of technology and capability to other states. We don't know about to specific terrorist groups, but you have to wonder if that isn't coming, if it hasn't already occurred.

General RUSSELL. Unfortunately, some of the best potential bioweapons exist in nature and are readily available, so locking up bacteria and viruses is not going to solve the problem.

The advances in biologic manufacturing that I mentioned include the drying methodologies and production of aerosol powders. This information is widely available on the Internet. The equipment is for sale on the Internet. I think we have seen a tremendous shift of advantage to the adversaries in this regard because of the ability of a very small group of people with the expertise to manufacture these weapons. And the weapons are very, very dangerous.

Dr. GIROIR. I certainly share the other witnesses' concerns.

And I will reemphasize what Dr. Smithson said, is I believe the barrier to entry into this has dramatically decreased, both because of the biomanufacturing advances that General Russell has said but also the ubiquitous nature of DNA technology, recombinant DNA technology, synthetic DNA technology. Literally, what took me weeks during medical school to produce in a multimillion-dollar laboratory can be done in an afternoon on a benchtop by someone with a relatively less degree of scientific training. So the barriers to entry have decreased.

I share General Russell's concern about the known threats. As a critical care physician, I have treated both SEB and tularemia, and the thought of having hundreds or thousands of such patients cannot even be comprehended by the medical community, much less addressed.

And, third, I share the concern about some of your remarks, sir, about masked or chimeric organisms that I think leverage current vaccine technologies that are developed for the betterment of mankind. These are very, very concerned to mask very dangerous organisms within infectious aerosol organisms.

So, again, I share the threat and wanted to re-echo some of their themes.

Mr. THORNBERRY. Mr. Langevin.

Mr. LANGEVIN. Thank you, Mr. Chairman.

Again, thanks to our panel. This is obviously a very sobering discussion. And I am reminded that there are obviously many threats that we face, particularly from terrorism, and as horrific as a nuclear attack on the country would be, thankfully Mother Nature didn't make it easy to make weapons-grade plutonium or highly enriched uranium. However, developing bioweapons and using them against our population is something that terrorists could do not just once but again and again and again, and it poses great risk.

This is something, as I mentioned in my opening statement, I spent quite a bit of time on when I chaired the Subcommittee on Emerging Threats, a subcommittee on Homeland Security.

And I would like to just start by asking your concerns about what are the more likely pathogens that we have to worry about. I know we talked about tularemia. Would you put that as number one on the list? Or is it weaponized aerosolized anthrax? Where should we be targeting our resources to develop countermeasures?

These are obviously important discussions for us to contemplate. And it is also important to remember that people would be kidding themselves or grossly misinformed if they thought that terrorists and the various groups and forms that they take are uneducated. These are actually highly educated people, in many ways, in the STEM [Science, Technology, Engineering, and Mathematics] fields, in the biosciences. And this issue of threat of bioweapons attack on the country is something that, it is one of those things that does keep me up late at night.

But I would like to talk about, in terms of prioritization, what do you think are highest on the list? We can go right down the line.

Dr. SMITHSON. Thank you, Congressman. And I am afraid my answer may disappoint you somewhat.

Yes, everything on the list is a problem, but so are things that aren't on the list. And this is one of the things that I learned from the inspectors of the United Nations Special Commission. We tend to look at these problems through the lens of our past program and of what we know about other past state-level programs. And then along comes a country like Iraq, and they choose to weaponize an agent that causes liver cancer and something that causes gas gangrene.

So when you go in looking for something that you expect—and I guess my message in this case is that things that are not on the list could be very problematic. They can be genetically engineered

to increase their lethality and contagiousness. We know that the Russians did a lot of this work. I have been in over 20 of the facilities that were part of the former Soviet program.

So, in considering what is a problem, I know we have to prioritize, but I would encourage everyone to keep in mind that it is not just about a list. It is about a world of potential problems.

Thank you.

Dr. BENNETT. I think we have to recognize the fact that it depends upon what the target is. If someone is trying to attack the civil population, which could happen in this country, they can use almost any of the agents. Whatever is easiest to produce could cause the effects.

If they are trying to go after our military, and we are properly vaccinated in certain areas, they are going to go after things that are different. And their knowledge, which is pretty well-established on what kind of protections we have fielded, will lead them to some differences. But those differences, as Amy has just said, are pretty easy to come by. There are lots of alternatives out there.

General RUSSELL. I have a slightly different view of that because if you look at the characteristics of biologic agents, microbial agents, and their suitability for use of weapons, there is a hierarchy. Some are easily manufactured. The bacteria are much more easily manufactured than viruses, for example. It takes a lot of expertise to grow viruses in cell culture. Bacteria are easy. The stability of the organism, both in growth and in aerosol, is a huge issue and one that was solved by the two programs. And the availability, I do not have a high level of concern about chimeric agents, about engineered agents, simply because Mother Nature is a much better bioengineer than anybody has published so far. But there is a hierarchy.

Tularemia came to the top of the list from the two offensive programs. Anthrax is ten-thousand-fold less infectious, but it is a persistent agent and it is very, very dangerous. But there is a hierarchy. I think we have a pretty good posture in terms of smallpox, a pretty good posture in terms of anthrax, but I think we have a couple more on the list that we need to take off as major concerns. And then we can worry about downstream engineered organisms.

Dr. GIROIR. I certainly agree that the likely existential threats, such as smallpox, likelihood of anthrax, et cetera, need to be taken off the table very early.

I don't share the opinion that the genetically modified or chimeric organisms are lower down the list. And I think that is based on good information about what is capable and what was thought of. That is not to say that nature doesn't always throw something at you naturally; I completely agree with you. But I do believe that the genetic modifications and chimeric organisms are an important threat.

The last thing I would say is a prioritization on the list needs to be the unknown unknown, what were not expected for. And we, at least I believe, nationally need to take a lot of lessons from the DOD in exercising the capability and doing tests and exercises that, if we see something we don't know of, how does this actually happen? How does my center interact with other centers? How does the DOD interact with HHS? How do we do it and distribute it in

a very short timeframe? Which is a very different problem than taking 10 years to make your next anthrax product and stockpiling it.

Mr. LANGEVIN. Thank you, Mr. Chairman.

Mr. THORNBERRY. Mr. Nugent.

Mr. NUGENT. Thank you, Mr. Chairman.

And I want to thank this panel. I don't feel very comfortable. Thank you so very much in doing that.

And, particularly, you know, there was a GAO report out in regards to biodefense efforts being somewhat fragmented. And, obviously, there are a lot of different takes on what we should address and what we should look at, so that makes it even more difficult, I am sure.

I would love to hear your input in regards to what you think—I mean, there has been some legislative, I guess, tries to fix, but what do you think we need to do to try to coordinate and use best practices or—you know, when we are spending money, let's get the best bang for our buck.

Dr.—right? Doctor, doctor, doctor, but Dr. Smithson.

Dr. SMITHSON. Apologies. A group like us does tend to be, shall we say, the skunk at the cocktail party. But we are all here in the service of defense and peace.

I think the coordination of a government as large and unwieldy as ours is a never-ending challenge. And the only surefire way to ensure that more, as opposed to less, of that happens is to have White House attention and dedicated responsibility on issues just like this and to have, quite frankly, the whip cracked from that location frequently in terms of oversight and coordination.

Otherwise, I think there are organizations and even scientists that have their own preferred solutions, and you don't get too much of an agreed agenda. And so, yeah, I would put a strong vote for more attention from the White House.

Mr. NUGENT. Dr. Bennett.

Dr. BENNETT. I think what we have to recognize—I think the medical responses are extraordinarily important, but there are a lot of nonmedical responses that also have to be coordinated in here. Our legal framework for doing things like quarantine and isolation is not really there.

In the 1970s, when you had the outbreak of smallpox in Yugoslavia, they forcefully vaccinated almost 90 percent of the population, even though it was already vaccinated, to try and get it under control. They threw over 10,000 people into quarantine for several weeks. They took very extreme measures.

Now, they got it under control relatively quickly as a result, but it was a combination of the medical and the nonmedical actions. And, as Amy has suggested, somebody needs to be looking at that combination and making sure we have the full package of tools so that we can proceed.

Mr. NUGENT. General.

General RUSSELL. In our Government, everybody is in favor of coordination, but nobody wants to be coordinated. It is a very, very difficult issue, one I struggled with when I was in the Army, when I was at HHS.

And the fundamental answer is senior leadership and direction. If there is strong central senior leadership, the agencies will respond and work together. If there is not, they will not; they will go their own way. And there is a lot of history to support that view.

And Dr. Bennett has it absolutely correct, medical countermeasures are only a piece of the issue. We need a focus on biologic terrorism and the threat, and we need a coordinated across-the-Government effort to do it, but that takes centralized leadership to do it.

Mr. NUGENT. Doctor.

Dr. GIROIR. I am going to echo, centralized leadership is key. I think some structures have been made in the last few years that are very positive. The so-called PHEMCE, the Public Health Emergency Medical Countermeasures Enterprise, where everyone is at the table—DOD, DHHS, FDA [Food and Drug Administration], NIH [National Institutes of Health], et cetera—I think that is very, very positive. It is done at a high level, Assistant Secretary, then at a level below that where the work gets done.

But, again, everyone around the table. There is no substitute by having someone calling the leadership of that group and helping people who may not want to be coordinated to be coordinated.

I only give you my experience when I was at DARPA. The day that Dr. Kadlec took a special assistant to the president position, in terms of biosecurity, the world changed instantaneously, because everyone was around the table and someone told us all what was expected of us and held us accountable to that. And I thought that was a very important lesson that I learned.

Mr. NUGENT. Seems like a key theme across the board, though, is about leadership from the top.

Thank you so very much.

I yield back.

Mr. THORNBERRY. Mrs. Davis.

Mrs. DAVIS. Thank you, Mr. Chairman.

And I am glad we are having the interagency discussion. And as I know the chairman knows, it has been an issue, of course, on the Armed Services Committee.

I actually recall that when I first came to Congress, NDU, National Defense University, did a lot of those simulations. And, you know, we had one biological attack and, you know, another week came over, and you see the map and the changes. And it is actually something that is not being done anymore, I don't believe. And I thought it was educational. It was scary, but it did give us a sense.

And having everybody around the table, the difficulty, as you say, is, where does the leadership come from, and how do we actually move forward with that? You have all basically talked a little bit about that. You see that in the executive branch. Could you help us understand? I mean, how often do you think these issues come up? How prevalent is—you know, how much a part of the discussions do we have biowarfare?

And, also, in terms of public-private partnerships, Dr. Giroir, you were talking about Texas A&M and the fact that, in terms of research and development, you are kind of asking the question, is there something more that could be done? DARPA led some of

those efforts, but then it moves over to the private sector or at least the academic sector.

How do you see that working better together? Are there authorities that are needed? Is there something else that perhaps Congress should be doing to facilitate that? How good an idea is that? And are we putting our efforts into R&D [Research and Development], and whether it is DARPA or ARPA, whatever, that should be more focused in this regard, preventative as well as the others?

Dr. SMITHSON. Thank you for your question.

As somebody who has specialized in chemical and biological weapons nonproliferation for over two decades, I can tell you that it can be a lonely place in a very nuclear, nuclear-centric world.

Look, it is understandable that decisionmakers and think tanks and everybody else worries perhaps first and foremost about these things. And I think if there is something positive to be taken out of the anthrax letter attacks in 2001, it is that biological is now part of that conversation more frequently. It is on people's minds.

But it is an incredibly complicated thing to parse. Sometimes what you do that has a benefit in one instance—for example, increasing the disease surveillance capacities of overseas laboratories so that they can detect an outbreak before it reaches U.S. shores—might also have a downside if you don't properly train those laboratory technicians in the biosafety precautions they need and must have. And if they don't have a concept of security and responsibility for the work that they do—they are not even aware, often, that agents have been weaponized and even used in war in this field.

So it is a very complicated situation to get decisionmakers to focus on. And sometimes, quite frankly, they just throw up their hands, "What are we to do," in these circumstances.

Get more people like us in the room with you more frequently. And if you would like another thrilling scenario exercise, I can provide one of those, in terms of even the challenges of attributing a biological weapons attack, which is the first part of a response.

Dr. BENNETT. Let me give you an example along the lines you are talking about. Let's say that there is a collapse of the North Korean Government, that some of the factions decide that they are going to use some of the smallpox, which they may well have, and they simply sprinkle it among the American communities in Seoul.

But, of course, in that kind of situation, we would want to evacuate the noncombatants, because a civil war might break out in the North and difficult situation develop, and we evacuate them back to the United States. And, of course, smallpox takes 12, 15, 20 days to develop. Those people come back to the United States and you get the disease once they are back here, and it is already spreading. So where is our concept for quarantine of those people we would be evacuating out if there really is a risk?

Part of the problem is we need to be discussing these things more to recognize where those vulnerabilities are. Those discussions, I don't see them going on. And I think that is the kind of thing, exactly as you suggest, where we need to raise the consciousness in order to address it.

General RUSSELL. The biologists are a minority in the—in this discussion. Most of the discussion is so dominated by the nuclear and the chemical communities, that the—and the leadership thinks

along the lines that they are used to dealing with those threats, and they are so very, very different from the biologic threat, that the medical countermeasure development has always struggled because to a large extent, the leadership in the Department of Defense doesn't understand the vaccine industry, doesn't understand the biology, and it doesn't understand the science.

That expertise has been largely developed and stayed within the medical departments of the armed services, but the Defense Department is quite separate from that and has not benefited from the transfer of that information. I hope that things will change in the future, because we do have a really major problem.

Dr. GIROIR. Just want to make a comment or two about the coordination, and there is an analogous side on the DOD, but I will stick to DHHS since I am now one of the centers. I think it is important to understand how things link. The National Institutes of Health, particularly NIAID [National Institute of Allergy and Infectious Diseases], is responsible for doing the basic work that sets the groundwork for all the countermeasures in vaccines that are actually done. They bring it to a certain level, either late preclinical, or what is called phase one, and then it is transitioned to BARDA, the Biomedical Advanced Research and Development Authority, to do what is called advanced development in manufacturing, the scale-up, the readiness. This is very, very expensive; the later stage clinical trials to bring them.

So the first set of coordination is within the agencies themselves. And personally I am seeing that being very positive, that the NIH and BARDA are working very closely together. People like me from the academic community on the advanced development side are being invited to all the critical meetings on the NIH side, so we know what is coming down the pike back and forth. So I just wanted to make that kind of clear about how this works. And there is an analogous situation on the DOD side between basic research and acquisition.

Two things you asked for specific suggestions, so I will give them to you. At least on the advanced development side, it is critical to have commercial partnerships in this venture, because the expertise, the critical mass, the knowledge primarily resides in large or even medium companies who do this for a living every day, and in order to be cost-effective but also reduce the risk, we have got to bring commercial partners. Again, this was a major effort of BARDA, and we brought in GSK, who is working with us primarily on pandemic influenza.

I think anything that could be done to incentivize commercial pharma to get in this area, which is not profitable and is of high risk, would benefit us very much. And I think one thing that can be done is ease of Government contracting and lack of administrative burden imposed on companies who, quite frankly, don't have the time, willingness or ability to take that risk that Government contracts put on them.

The third thing I would say is I would have Congress encourage agencies like BARDA on the contracting side to use the flexible authorities that they were given to expedite contracts and make them more goal-oriented except—instead of cost-based contracts where basically every nut or bolt has to be justified and there is a margin

put on that. I think the contracting authority that was given is plenty sufficient, but it needs to be exercised in a more rigorous way. If you ask me what I think you could do, I would have Congress encourage them to use the authorities that were already given. And maybe General Russell disagrees with that, but——

General RUSSELL. I do not.

Dr. GIROIR. Okay.

General RUSSELL. I heartily agree with that.

Mr. THORNBERRY. Well, that is a story we have heard in other places, as you can imagine. Federal contracting is one of our biggest problems. And I remember some of those exercises you were talking about dealing with anthrax, for example, which got to be in my part of Texas, and it just shut down the country once you start quarantining places off. It really does open your eye. We have got our own doctor, Dr. Heck.

Dr. HECK. Thank you, Mr. Chairman. Thank you all for that excellent review of where we are at and the discussions of the needs for physical and medical countermeasures and the importance of addressing the genetic and chimeric organisms, but I think, in my mind, Dr. Bennett hit it on the head, which our underlying issue is the lack of discussions and how are we going to address the issues that we face? I remember in 1997 when then-Secretary of Defense Bill Cohen was on ABC's "This Week" and held up the 5-pound bag of sugar and said, if this was anthrax and spread over D.C., it would take out half the population.

So we are about 16 years later and still waiting for meaningful discussions to take place. And while the things that you talked about are important, critically important, I think there are a lot of other simpler things that we have yet to talk about, like the identification of dual-use technology and how we are going to figure out if what they are doing is for licit purposes or illicit purposes.

The chronic underfunding of public health infrastructure in this Nation, who actually will be the first responders, as Dr. Smithson pointed out, was the group that figured out what was going on in The Dalles, Oregon, salmonella outbreak.

And, of course, Dr. Giroir, you mentioned the overwhelming of our healthcare system by mass casualties. And you look at the statistics that in most mass incidents, it is about a seven-to-one ratio of those who are actually affected versus those who are unaffected but show up just because—I am an emergency medicine doc—just because they want to get checked, and they are concerned, the psychological fears.

So how would you address those things? Dual use; figuring out who is good, who is bad; the chronic underfunding of public health, or how do we enforce public health infrastructure; and how are we going to prepare our healthcare system to deal with the casualties?

Dr. SMITHSON. I always love a simple question. Thanks for that. I could not agree with you more that investment in public health is always a sound idea. And in this case, it doesn't necessarily matter, in terms of casualty care, whether it is Mother Nature or a deliberate attack, so that is always a good idea.

In terms of identifying dual-use technology, this is something that concerns me greatly, because of how quickly this—the equipment and knowledge is—is advancing at this very time. And there

are tools like the Australia Group, which was formed in the mid 1980s in response to the attempts of Iran and Iraq to acquire chemical weapons precursors from a variety of supplier nations, and so we began to harmonize our export controls. And that group now also addresses biological materials and dual-use biological equipment, but it is tough for the Government to agree how to address some of these issues, in part, because there are so many things happening, and there are so many different opinions about what is most important.

So here is what I would encourage us to do, and that is actually to get industry into that equation as well, because there are some very constructive things that can be done in terms of public-private partnerships with regard to control of dual-use equipment. Name me a company that wants to have its piece of equipment end up on the front page of *The New York Times* or some other media outlet as being part of a terrorist attack or a state-level biological weapons program. So we need to work with industry to provide them with some access to the information that we collect and get their cooperation in terms of screening customers more effectively than perhaps even the Government can accomplish.

Dr. BENNETT. Let me turn to the military in particular and some things we could be asking the military to do. I think we need to recognize the fact that this kind of threat could overplay any kind of future contingency, whether it is a challenge like a provocation in North Korea or some major conflict. So do we ask all of our soldiers that are deployed in the field to report in as soon as they are sick with any kind of virus or whatever? Most of them are typical military personnel. They are a little reluctant to do that until they are sure they are really sick, just like many of us are. Rules on that kind of thing could be very important.

Similarly, let's think about the military. If we can't evacuate casualties from the theater, our current concepts for military medical care are very much challenged. We may have to plan to do much more medical care in a theater in order to take care of our personnel who have become casualties, conventional casualties, if there is the threat of contagious disease coming back with them. So this is all a matter of starting to think in this context of if this really is a threat, let's take it seriously.

General RUSSELL. Shortly after 9/11 and the anthrax attacks, there was a huge investment in the public health infrastructure of this country. A lot of manpower was added and a lot of capability, both for surveillance and for first response. I believe that that has seriously deteriorated over the succeeding years, and our public health infrastructure, I think, needs a lot of attention.

One of the operational aspects of military medicine has been the overseas laboratories of the armed services, and they have provided both an enormously effective base for research in the epidemiology of infectious diseases in various parts of the world, and they are also good listening posts. They interact with the medical and public health communities of their countries. And I think that one thing we could do to improve our ability to understand what is going on in the rest of the world in terms of infectious diseases is to increase our investment in the overseas laboratories.

Both the Army and the Navy have very good labs that have in recent years not been very well supported.

Dr. GIROIR. I am in the enviable position to be last, so I can agree a lot, but the public health system will likely be tasked to handle such an outbreak. I think it is also very likely that it will be the first detectors of an outbreak, the first responders, the emergency room physicians, the infectious disease physicians, so any investment into public health is an investment in national security in this regard, and I feel that very, very strongly.

I also agree that industry involvement is very important in this, both from the dual-use technologies, to bring them onboard and help solve the problem, and as the dual-use technologies do proliferate, I think it is important to understand that they are all computer-based technologies, digital-based technologies, so quite aside from what we are talking about, I would hope that the intelligence communities have avenues into collaboration with biologists to understand what those signals can be, which may be very, very rich.

I do want to say that as hard as all this is, and as much as we are sort of laying crate today, I think these are all tractable problems. These are all solvable problems if there is coordination and leadership. There is not—as a critical care and ER [Emergency Room] doctor, there is not a day in the winter that you don't have 100 patients more than you deal with—that you can deal with comfortably. So people on the front lines, whether it be military or health responders, know how to handle this problem, but they need some help, they need some coordination, they need to be involved and educated to help solve this problem. And it is solvable. These are solvable problems. They may not be 100-percent solvable, but 80- or 90-percent solvable is a whole lot better than where we are right now.

Dr. HECK. Thank you. Thank you, Mr. Chairman.

Mr. THORNBERRY. Mrs. Hartzler.

Mrs. HARTZLER. Thank you, Mr. Chair. This has been very enlightening and disturbing all at the same time, but it is good that we are starting—not starting the discussion, but bringing it up today. But I wanted to go back to part of your testimony, Dr. Smithson, about Syria, and we haven't really touched on that. Could you give us an update on what is really taking place there and how likely you believe will be the ultimate success, will we be able to identify and access all of the different chemical sites, will we be able to do away with these weapons? Can you give us an update?

Dr. SMITHSON. Thank you. And I think we have got a tremendous challenge on our hands with Syria, in part because of Bashar al Assad's track record with regard to cooperation with nuclear inspectors. If you will recall, in 2007—or 2006, Israel bombed a nuclear reactor there, which the Syrian government built in secret, but they were a member of the Nuclear Non-Proliferation Treaty since 1968. And after they built this place, they tried to disguise it with an outer building that didn't make it look like a nuclear reactor. And after it was bombed, they immediately cleaned up the site and then delayed the inspectors from getting in there. And even when they found evidence of manmade uranium, they simply

pointed to that as the fault of the Israelis who bombed the site and said it was part of the bomb particles.

The track record in collaborating with the chemical inspectors, yes, we have all seen the footage of the chemical inspectors inside a facility, and methinks perhaps he is really, really trying to persuade us that he is going to cooperate, but keep in mind that already he has shot at the chemical investigators that Secretary General Ban Ki-moon sent in there, he tried to bomb away the evidence of the attacks of August 21st. It is a very mixed track record.

And it is an incredibly difficult thing that they are going to attempt to do. I am not confident that U.S. intelligence or any other intelligence has identified all of the sites involved in this program. And I am very appreciative that the Defense Department has assets, as do the Russians, which can be brought into this equation to hydrolyze and degrade the agent if it is stored in bulk quantities, as well as to literally blow up in boom boxes in a contained situation munitions.

Getting there is going to be tough, because if you have got to try to move these things, oh, my gosh. Think about the security environment: Hezbollah, Hamas, Al Qaeda are in the neighborhood. So these are very, very early days, and I think it would be a tremendous thing if indeed the Assad government does want to really forfeit its weapons. I am just not convinced that that is the case yet.

And I think that the Nobel Prize money that will now come to the OPCW is sadly needed. We need to provide resources to this organization so that they can attempt to do this job. So stay tuned. There could be some bumps in the road ahead, and it could be also an incredible victory for international peace and chemical disarmament.

Mrs. HARTZLER. I haven't read extensively at all about this, but isn't like the sarin gas in different components and then they have to mix it? And so if the theory is they are going to take it out, they could take it out in separate stages and so they are—all the components wouldn't be together, or can you kind of explain, and then how do they actually give—I remember you said something about hydrolyze.

Dr. SMITHSON. Yes. Certainly. There are two different types of chemical weapons basically when it comes to the form that they are in. One is a unitary agent, and they are mustard gas, which is a World War I agent that was first used in World War I is thought to be already mixed.

Mrs. HARTZLER. Okay.

Dr. SMITHSON. And whether it is stored in bulk containers or in a munition that is already mixed. But you have probably heard the term binary chemical weapon.

Mrs. HARTZLER. Uh-huh.

Dr. SMITHSON. In this case, the last two chemicals that would be used to make the warfare agent is sarin or VX [nerve agent] are going to be combined, either right before they are filled into the munition or, in the case of the U.S. program, which was rather advanced and the Soviet program, they would literally be mixed inside the munition on the way to the target. So at this point, we are not exactly sure, although a lot has appeared in the media, about the character of what the stockpile is.

It is reasonable to expect that some of this will be in bulk quantity, others will be in munitions. And when it is munitions, keep in mind that the U.S. chemical weapons program, the destruction program, as well as the one in Russia, put their destruction facilities right beside the storage sites, because it is considered a safety hazard just to transport these things a short distance even to destroy them.

And so transporting them through a civil war is—really, again, it boggles the mind to think about the courage that these inspectors are going to have to exercise in order to get this job done.

And, so the destruction process, there is a capability called the U.S. field hydrolysis system, which literally is transportable, there are two units that I believe are probably headed to Syria, or off the coast as we speak. And this system, you would use hot water or other chemical reagents, depending upon what you put in there, to degrade the bulk agent down to 99 percent or even better. So that is definitely a step in the right direction.

And the boom boxes, we have a couple of different systems that have also been used in the United States where you can put a munition of a certain size inside the boom box and it will literally heat up over the course of 2 days, destroy the agent and decontaminate the remaining parts of the weapons system.

So these are some of the options, but right now, we really don't have a concrete idea of the condition of this stockpile or exactly what the game plan is to getting this very difficult job accomplished.

Mrs. HARTZLER. Thank you very much. Thank you, Mr. Chairman.

Mr. THORNBERRY. Thank you. Let me ask General Russell and Dr. Giroir about the relationship between DOD and HHS, because some folks believe that DOD has got to focus on protecting soldiers, HHS focus on protecting the civilian population, and so we have basically two different missions that need to be conducted separately. Other folks think that there could be much more interaction and collaboration. You heard Mr. Nugent ask about fragmentation of effort. So I would just be interested in y'all's view about how the two perspectives work together and could and should there be more, or is it just two different missions and it is not going to work to do more?

General RUSSELL. The medical countermeasures requirements for DOD are quite different from HHS. They do overlap in some areas, and—but the basic research and the underlying biologic research that is needed to develop the countermeasures is fundamentally universal. And so I think the DOD historically has drawn on research done at NIH and in the civilian community, as well as in its own labs.

I think the coordination historically has been fairly good. There are interagency committees that meet regularly and exchange information and discuss how they can work together. I know the DOD is using the HHS stockpile for rolling over the anthrax vaccine, and if necessary, smallpox vaccine. There are interagency agreements that are working.

On the other hand, there are requirements that the DOD has for immunizations, because protecting the warfighter with immuniza-

tion is an important issue, and these are requirements that HHS does not have. So there has to be some separate activities at the advanced development and purchasing level, but the—on the other hand, the military laboratories have focused on the problems of the military and have provided the important basis for moving ahead. All of the advances in tularemia vaccine that have been made came out of military efforts. The rPA [Recombinant Protective Antigen] Anthrax vaccine came out of USAMRIID, and the military laboratories, especially USAMRIID, are still doing very, very good basic research that are underpinning the development efforts that are needed.

Dr. GIROIR. I will just add to that by saying, although there are different mission requirements and clearly more of an emphasis on vaccines and certain types of vaccines, programs such as our HHS center is fully capable of performing the advanced development and manufacturing on both military or civilian measures. The technologies are all the same, the platforms are all very similar. So there is a great ability at that level specifically, once they are out of the basic laboratory or out of USAMRIID, this very expensive infrastructure critical manufacturing piece can certainly be shared to a really great degree, because the technologies for making military or civilian are all about the same. There is nothing that the DOD needs to produce that can't be done with the technology that we are developing or have developed with HHS at that manufacturing stage.

Mr. THORNBERRY. And that infrastructure you talked about has been paid for largely by HHS, right?

Dr. GIROIR. Yes, sir. There are three centers, and they all have different developments. Our center will be fully developed in 5½ years, but we are ready to take on task orders now. Novartis, which is the second center, will be fully developed in 4 years, and Emergent Biosolutions, I believe they are in a 7- or 8-year contract, but there will be a rolling set of improving, increasing capabilities.

And, again, our contract is cost shared. We have a lot of skin in the game, $176 million from the Government and $109 million from our partners, but all of our centers are ready to start working today. We will be fully ready within a few years to meet all of the requirements that were brought to us by HHS.

Mr. THORNBERRY. Okay. Thank you.

Dr. Smithson, I am not sure if I got this exactly right, but I think part of your testimony talked about who had access to certain agents and the screening for individuals who worked in certain situations. Obviously, security clearance reform is a very significant issue these days, as it should be. Can you elaborate just briefly on—you talked about a cost benefit study for select agent rules or something like that. Can you just elaborate for a second what you are talking about? Are we talking about basically a security clearance for people who have access to these pathogens or am I misinterpreting?

Dr. SMITHSON. It is not sometimes just about the security clearance. In the case of Bruce Ivins, who brought the notion of an insider threat to everyone's attention, it is about whether or not the people who were working in these very high-pressure environ-

ments, and quite frankly, I have never worked with an agent where if I pricked my finger, there is no medical treatment or vaccine, and basically I am a dead woman walking, so I think this is a very high-stress environment. And in the case of Bruce Ivins, yes, he did incredible work on the anthrax vaccine, but he was also apparently, according to the FBI, mentally unstable, he had made death threats and he was abusing substances. And this is what is not addressed in the select agent rules in a comprehensive manner. For example, the screening that the FBI does, according to the select agent rules, asks if you have ever been adjudicated mentally deficient. It doesn't say, "are you off your rocker now?"

And we need to make sure, quite frankly, that the people, first and foremost, who are handling these substances and doing the work that we all very much want and need them to do have—have sound judgment exercised. And so that is what I am asking for, is to kind of shift the emphasis away from trying to count things that are found in nature and that can be replicated, you know, on an incredible scale in fermenters toward a system of mutual accountability in the laboratory and sound judgment in the laboratory. I think these are going to be better defenses than trying to lock up pathogens that you can find in Mother Nature.

Mr. THORNBERRY. Thank you. Mr. Langevin.

Mr. LANGEVIN. Thank you, Mr. Chairman. And, again thanks, to our panel. As often happens, the chairman and I often are on the same wavelength on a lot of these issues, and I would like to go back to the question that he asked on DOD and HHS resources. And I want to ask, I think, a slightly different way, just a different spin on it, but obviously, DOD and HHS, in particular, have unique capabilities when it comes to biowarfare. To what extent does DOD leverage HHS resources? And is it reasonable to expect greater efforts here? And how do DOD priorities affect HHS's work? Are we properly leveraging the resources of the other, going both ways?

Dr. GIROIR. I am just going to say from our standpoint in the HHS center, I can't comment on Novartis or Emergent, but we have had a visit from the joint program executive officer with all of his staff to look at our facility probably about 7 months ago. We have had no direct interaction funding task orders requests from DOD specifically. We are obviously highly motivated to support, because we have tremendous infrastructure now and being built. I think HHS is certainly willing to do that. Even in our facility, we could dedicate capacity to DOD should that be wanted.

So I would say the conversation, at least in terms of our facility, which I could speak definitively about, has started to—has begun with high level visits. Where that leads, we really don't know.

Mr. LANGEVIN. Is there anything that you can recommend that we do to encourage that?

Dr. GIROIR. I think there should be expectations that where resources can be shared, they need to be shared, because I believe, as—I would much rather several hundred million dollars be put into a tularemia vaccine that achieves the capability than duplicating what HHS and the taxpayer has already funded.

Mr. LANGEVIN. I agree. Anybody else want to add anything, or I will go to another question?

General RUSSELL. I have worked on both sides of the fence, and the requirements of Department of Defense, although somewhat different, are—do overlap tremendously, and as Dr. Giroir said, the manufacturing base is fundamentally the same.

I think we can expect in the future to—DOD requirements may benefit by the HHS investments. Whether that is effectively coordinated and maximized is, I think, going to be up to the senior leadership of the Government.

Mr. LANGEVIN. I think that is something we have got to spend more time focusing on, because we will definitely be able to yield better outcomes if we are properly resourced.

Let me turn to another area. Given the difficulty and the time requirements of developing effective countermeasures for biological weapons, obviously intelligence plays a critical role in identifying potential threats.

So can you explain the interplay of the intelligence community with the biodefense enterprise? And what can be done to better identify biological weapon threats that adversaries might be developing? And do you see DOD's ability to mitigate threats hindered by intelligence capabilities, particularly HUMINT [Human Intelligence]?

General RUSSELL. I think the difficulties that the intelligence community has had in dealing with the biologic threat is a matter of history. They have not distinguished themselves greatly, partly because of a very, very difficult intelligence target, probably the single most difficult target there is. And in the past, the attention of the intelligence community has been on other threats, and the internal capability and knowledge about biology has just not been there. I think it is improving to some extent.

Your question about HUMINT, I think, is right on, because I think the only way we are going to get decent intelligence regarding the biologics threat is by accentuating the human side. The other intelligence-gathering methods don't seem to work very well against a biothreat.

Dr. SMITHSON. The Biological and Toxin Weapons Convention, which is the treaty that bans biological weapons doesn't have any verification provisions, and that is largely, I think, at this point because people refuse to consider the experience of the United Nations Special Commission, which I referred to in my testimony. What is quite astonishing there is that a very small group of inspectors, working off of scant, incomplete, and sometimes inaccurate intelligence about Saddam Hussein's biological weapons program and working against a government that had a game plan to hide that biological weapons program at all costs were able to go in and uncover it.

So the conventional wisdom, again, needs to be rethought. And it is far better to have eyes inside a facility, to have inspectors engaging with the scientists there, literally looking at what they are doing. And, yes, they may not always be able to catch everything that is going on, but you are far better informed from inside a facility than you are from 3 miles above the ground with satellite images.

And having asked any number of former biological weapons scientists what they would do if they were to get back into the game,

they would aim for the incapacitating agents that I referred to earlier, the things that control human behavior, because this is considered amongst the weapons scientists to be the brave new frontier.

And last but not least, on the wisdom of relying on human intelligence, let's keep in mind the case of "Curveball," and this is the Iraqi defector that simply made it up. And he made up the whole shebang about Iraq having mobile biological weapons production capabilities. If anyone had bothered to ask the UNSCOM inspectors at that time whether or not that was a realistic scenario, they would have explained that when Iraq talked about mobile, they meant moving one part of the program, doing one part of the program in one location and another part of the program here, and not putting things like that on wheels.

So conceptually to them, both in terms of the way that the Iraqis did both chemical and biological weapons programs and also from a scientific standpoint and a safety standpoint, the idea of putting mobile biological weapons production out there, even if you are a desperate proliferator, just didn't make sense. Just a few thoughts for consideration.

Mr. LANGEVIN. Very good. Thank you. Thank you, Mr. Chairman.

Mr. THORNBERRY. Mrs. Davis.

Mrs. DAVIS. Thank you, Mr. Chairman. This has been very interesting. It is always a difficult question. We all could like to see more resources, but if I guess the first question is, do you think that the resources match the need as we know it today and as we are planning in terms of if—perhaps if we were better coordinated, but if not, is there any consensus among the four of you that there is a place particularly that those resources should be going to that would make it—that would make a difference overall in terms of the ability to leverage those resources for a better outcome? Any consensus?

Dr. SMITHSON. The increase in U.S. biodefense programming after 2001, some would say, and I would agree, was long, long overdue. There are a lot of resources being put into this arena.

At this point, I would rather have us do it smarter, as a taxpayer, than simply plus up budgets without having the types of discussions and decisions that this panel is talking about. Let's do it smarter first.

Mrs. DAVIS. I think I did hear that. Okay.

Dr. BENNETT. I would suggest, though, much as you were suggesting earlier, the military has to pay attention, and they are not paying a whole lot of attention to this threat at this stage. They are not trained in it, they don't understand in many cases at the senior level of the theater commanders, for example, the implications it would have for them, that sort of thing. So a small investment in the education, I think, and focus in requiring it in planning and so forth would make a huge impact, at least as far as the military is concerned.

Mrs. DAVIS. Thank you.

General RUSSELL. Yeah. I don't think it is the total amount of resources that is as important as the way it is being managed and distributed. I think there has been an enormous amount of wasted effort in some of these programs, and I think better management would accomplish more than just plussing up the budget. I think

attention to the problem at the highest levels is probably more important right now than other aspects of it.

Dr. GIROIR. I agree that resources need to be spent smarter; the first of that is eliminate all duplication of resources across the agency, and I think there is very significant ability to do that with sort of upper-level management and leadership.

Secondly, I will say it again, I think efficiency in the contracting process and being more outcomes-oriented and less micromanagement would certainly improve our efficiency probably 20 or 30 percent within our center.

Third, I think the Government should explore more public-private partnerships where there is cost-sharing. I think there can be tremendous alignment with the pharmaceutical industry for which their research and development budgets are dwindling, to align priorities so there is a little skin on both sides so you get more out of the Government dollar than you would otherwise, and enable industry to do that.

And the fourth point I would make is the only area that I really think needs more quantitative instead of just smart investment is to prepare for the unknowns, and you heard me say that before, to try to get a system to understand if something we don't expect that we haven't stockpiled for 15 years come down the pipeline, what is our capabilities? How do the DOD and DHHS work together? How do we attack it, maybe not 100 percent, but 80 percent, 90 percent enough to stop the major outbreak? I think more resources need to go to that type of threat. The others, I think you'd be smarter and you would go a long way.

Mrs. DAVIS. Thank you.

Mr. THORNBERRY. Well, thank you all. Needless to say, we on this committee have limited jurisdiction dealing with DOD, and this is not a problem that will be solved within DOD, but on the other hand, it seems to me your central point is we need to pay more attention to this stuff and DOD can help us do that as a Government. And that and a number of other suggestions, I think, are helpful to us.

Again, thank you all for being here. I thought it would be good to have a distraction from a budget discussion, but you all may drive me back to it, so—but I really do appreciate your time and expertise. Thank you again.

With that, the hearing is adjourned.

[Whereupon, at 12:48 p.m., the subcommittee was adjourned.]

A P P E N D I X

OCTOBER 11, 2013

PREPARED STATEMENTS SUBMITTED FOR THE RECORD

OCTOBER 11, 2013

House Armed Services Committee
Subcommittee on Intelligence, Emerging Threats, and Capabilities

Hearing on Biodefense:
Worldwide Threats and Countermeasure Efforts for the Department of Defense

Prepared Statement of Amy E. Smithson, PhD
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October 11, 2013

Since the beginning of time man has co-opted nature's sources of poison and disease for weaponry. Ancient warriors dipped their arrows in poison; fouled water supplies with feces and dead animals; bombarded enemies with containers filled with snakes, disease-bearing rodents, and scorpions; and hurled human plague cadavers over the walls of besieged cities. These rudimentary forms of biowarfare gave way to more advanced weapons in the World War I era, when governments put scientists into the equation, asking them to figure out how to wage germ warfare more effectively. At that time, advocates of biological weapons lauded their cheapness in comparison to other weapons, their ability to offset an opponent's conventional military advantage, their deep psychological impact on an opponent if used, the difficulty of pinpointing a biological attacker, and the self-perpetuating nature of a strike involving contagious diseases. Finally, proponents noted that, biological weapons leave infrastructure standing, allowing the victor to take over the defeated nation's intact industrial and other capacities.

Not so long ago, a group of countries known as the "dirty dozen" were thought to be harboring offensive biological weapons programs. Today, the number of suspected proliferators is down to a handful as concerns have faded about possible programs in Cuba, Libya, Iraq, and Egypt. A great many nations, including China, India, Pakistan, and Taiwan, have pharmaceutical and biotechnology industries and the scientific know-how to pursue biological weapons, but little public evidence exists to sustain suspicions of anything other than that they may be "leaning" offensively behind the guise of their biodefense programs.

The "usual suspects," however, have apparently not forsaken germ warfare. According to U.S., South Korean, and Russian intelligence estimates, North Korea is strongly suspected of having an offensive bioweapons program that dates to the 1960s. At universities, medical, and specialized institutes North Korea reportedly continues military-applied research on anthrax, botulinum toxin, cholera, plague, and perhaps smallpox. Some assessments state that North Korea is engaged in research but is poised to weaponize a range of pathogens, while others assert that Pyongyang has stockpiled biowarfare agents. When considering this spectrum of possibilities, it is useful to keep in mind that scientists in this isolated dictatorship may lack the state-of-the-art skills and equipment necessary for advanced biological weaponry. North Korea belongs to the treaty that prohibits the development, production, and stockpiling of biological weapons, the Biological and Toxin Weapons Convention (BWC).

* Affiliation provided for identification purposes, only. The James Martin Center for Nonproliferation Studies does not take institutional positions on public policy issues.

Syria, which has been embroiled for more than two years in an ongoing civil war that has taken over 100,000 lives, is also strongly suspected of having a germ weapons program. In July 2012, Syrian Foreign Minister Jihad Makdissi stated that Syria would never use chemical or biological weapons and that the Syrian military controls all such stockpiles and sites, though he later attempted to walk back his perhaps unintentional confirmation of Syria's unconventional weapons capabilities. A United Nations investigative report released on September 16th contained overwhelming evidence that the regime of Bashir al Assad committed the August 21st poison gas attacks on the suburbs of Damascus. Assad has since joined the Chemical Weapons Convention, and inspectors have taken modest initial steps to begin overseeing the dismantlement of Syria's chemical weapons capability. Syria has signed, but not ratified, the BWC. In March 2013 testimony before the Senate Select Committee on Intelligence, Director of National Intelligence James Clapper gave the U.S. government's assessment: Syria has stockpiles of biological warfare agents.

Three other states are suspected of bioweapons activity. Over the past two decades, intelligence agencies have voiced concerns about an offensive Iranian biological weapons program, but publicly available information is largely inconclusive on the matter. Iran has a well-developed biotechnology and pharmaceutical industry that could mask and support a significant program, and Tehran's attempts to acquire dual-use equipment and materials are documented. Israel also has a robust biotechnology sector and is believed to have conducted extensive biodefense research. The work done in this program is of course relevant offensive research, but few experts appear to believe that Israel has stockpiled biowarfare agents. Israel has neither signed nor ratified the BWC, but Iran is a BWC member state.

Russia, which inherited a Soviet germ weapons program of unparalleled scale and sophistication, also remains on the list of suspects. Insider accounts of former Soviet bioweaponeers and the distinctive features of many weapons institutes that outsiders have observed demonstrate that the USSR's investment in bioweapons rivaled its nuclear weapons program. After inaugurating the BWC in 1975 as a depository nation, Moscow accelerated its bioweapons program with a work force of over sixty thousand scientists and technicians, including ten thousand who developed and tested anti-crop and anti-livestock agents. The Soviets went far past the classic agents like anthrax, pioneering the militarization of hemorrhagic fever viruses by successfully weaponizing Marburg, developing two different strains of plague to resist five known antibiotics apiece, and also making strains of anthrax, tularemia, and glanders resistant to known antibiotics and vaccines. With genetic engineering, the Soviets attempted to create entirely novel virulent strains, including ones that produced toxins. Other Soviet bioweaponeers conducted research with bioregulators and neuro-modulating peptides, which are incapacitating agents that can affect individual behavior, for instance by stimulating insomnia and increasing aggressiveness. The capstone of this massive covert weapons program was stockpiles of hundreds of tons of anthrax and dozens of tons of plague and smallpox, mainly for use against U.S. and other Western non-battlefield targets.

In the spring of 1992, Russian President Boris Yeltsin stated the bioweapons program would be closed, but thereafter Moscow quickly began denying that the program ever amounted to anything and to this day maintains a stony silence about the Soviet bioweapons program. In

its 1992 voluntary declaration under the auspices of the BWC, Russia stated that the USSR did not amass biological weapons and claimed that inadequate methodology, equipment, and materials meant that Soviet bioweaponeers failed to achieve anything militarily significant. Governments and former top Soviet bioweapons scientists have publicly voiced suspicions that Russia continues to conduct offensive research and development. Russia still denies outsiders any access to key military biological facilities that were critical components of the Soviet germ weapons program, including the Center for Military-Technical Problems of Anti-Bacteriological Defense at Ekaterinburg, formerly Sverdlovsk; the Scientific Research Institute of Military Medicine in St. Petersburg; the Scientific Research Institute of Microbiology at Vyatka; and the Virology Center of the Scientific Research Institute of Microbiology at Sergeev-Posad. For these and other reasons, the 2013 U.S. arms control compliance report states that it remains "unclear if Russia has fulfilled its obligations under . . . . the BWC."

The BWC contains no on-site verification measures to ascertain treaty compliance, so the onus for estimating the number, scale, and sophistication of state-level bioweapons programs falls to the intelligence community. This situation is problematic because from the outside looking in, the intelligence "signatures" of biological weapons programs are far less discernible than nuclear or chemical weapons programs. Even the telltale signs, such as the presence of high-level biosafety containment, that do exist are not always reliable. Prior to the 1991 Gulf War, U.S intelligence did not identify Iraq's principal bioweapons production facility, Al Hakem, even though this site had a layout very similar to Iraq's main chemical weapons production site, Al Muthanna. Without biosafety containment equipment, Iraq produced anthrax and botulinum toxin at Al Hakem. In the late 1980s, Iraq powered up its germ weapons program with huge purchases of the nutrients needed to grow biowarfare agents. Before that, under the guise of legitimate research Iraqi scientists ordered the seed cultures for anthrax, botulinum toxin, and other agents from culture collections in the United States and France. U.S. intelligence apparently did not detect these activities, although in the mid-1990s Israeli intelligence did pick up indications of Iraq's growth media purchases. In 2005, the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction stated that the U.S. intelligence community "substantially underestimated the scale and maturity of Iraq's" bioweapons program prior to the 1991 Gulf War and that the US intelligence assessment about the threat of Iraq's rejuvenated biological and chemical weapons programs, notably its alleged mobile bioweapons production trailers, prior to the 2003 Gulf War was "simply wrong."

Finding signs of terrorist interest and activity in biological weapons arena is even more difficult. In the past couple of decades, sub-national actors also have occasionally turned to germ warfare. Aum Shinrikyo, the Japanese cult best known for its mid-March 1995 attack with the nerve agent sarin in Tokyo subway system, also tried to master biological weaponry. However, the cult's scientists failed utterly at two essential steps. First, they did not acquire virulent strains of the disease-causing agents they tried several times to disseminate from 1990 to 1995. Second, Aum was unable to develop and test effective dispersal systems for biowarfare agents. U.S. intelligence agencies admitted in 1996 testimony before the Senate Committee on Government Affairs that they were not aware of the cult's unconventional weapons programs until after the subway attack.

In America, another cult, the Rajneesh, tested a plot in 1984 to keep voters away from the polls in a Wasco County, Oregon, election by sprinkling *Salmonella typhimurium* on salad bars and elsewhere, sickening 751. Public health authorities, not law enforcement and intelligence officials, connected this surge in gastrointestinal illness to deliberate acts. According to the Federal Bureau of Investigation, Dr. Bruce Ivins, a 26-year veteran of the U.S. Army Military Research Institute for Infectious Diseases (USAMRIID) sent five letters with freeze-dried anthrax to U.S. senators and media outlets in the fall of 2001. The FBI originally turned to Ivins to help them investigate the attacks, only fingering him as the culprit in 2008. Evidence indicates that Ivins may have prepared the anthrax used in the 2001 attacks inside his Ft. Detrick laboratory. The 2001 anthrax attacks inspired a wave of bioterrorism hoaxes and plots and a handful of genuine events. For example, in 2003 an unknown person or group tried to blackmail the U.S. government not to implement new trucking regulations by sending a chain of letters with containers of powdered ricin and threats to make Washington, DC, "a ghost town." Ricin-laced letters reappeared in 2013; two U.S. citizens have been charged with mailing ricin to prominent politicians, a judge, and a gun control advocacy group.

Despite increase indications of terrorist interest in and intent to commit acts of bioterrorism, sub-national actors are still much more likely to attack with traditional tools (e.g., bombs, guns) rather than disease. Nonetheless, experts and policy makers alike consider a major bioterrorist attack to be a when-not-if matter, predicting such an attack in the near- to mid-term future. Economist Martin Shubik argues not just the inevitability, but the "high probability" of mass casualty biological attacks because "[b]iological weapons, with their easy accessibility, lack of effective international controls, and disproportionately large effectiveness, offer a singularly attractive mix to radical groups."

The history of biological weapons activities to date has few concrete patterns save one: bioweapons proliferators shroud their activities in utmost secrecy. Beyond that, biowarfare programs come in all sizes and types, from grandiose, resource rich, high-tech ones to small, almost primitive, efforts funded on a shoestring. Some state-level proliferators aimed for incapacitating diseases, others only weaponized the anti-personnel diseases for which vaccinations and medical treatments were available, and yet others turned untreatable and even entirely novel diseases into weapons. Some bioweapons possessors used their arms against humans and animals, others amassed but did not use their germ arsenals. Terrorists have shown little, if any interest in anti-agricultural agents, but some nations devoted considerable resources to anti-agricultural agents. These variances complicate the efforts of security and intelligence analysts to identify or anticipate the nature of current and future offensive bioweapons programs, of U.S. scientists to improve defenses against biological weapons, and of policy makers to formulate steps to prevent and punish proliferation.

Research with pathogens is essential to decode the inner workings of diseases and to develop diagnostics, therapeutics, and vaccines to combat infectious disease. This research forms the core of U.S. biodefense and is also necessary to safeguard the public from natural eruptions of disease. In the wake of the 2001 anthrax attacks, the U.S. budget for biodefense has increased manifold, from $414 million in FY 2001 to $5.54 billion in FY2013. Likewise, the number of U.S. high containment, biosafety-level 4 laboratories, which increase the safety of research with highly lethal and contagious diseases, jumped from five to fifteen.

The U.S. boom in biodefense has caused some at home and abroad to question whether the United States may have resumed the offensive bioweapons activity that U.S. President Richard M. Nixon shut down on November 25, 1969, with the observation that "mankind already carries in its own hands too many of the seeds of its own destruction." U.S. scientists have spoken of their apprehensions about the type of research performed at the some of the new BL-4 facilities and lack of access to those sites, and representatives of other countries have expressed concerns about possible U.S. noncompliance with the BWC. Therefore, it is worth keeping in mind that the more transparency the Defense and Homeland Security Departments provide into this programming, the more likely such worries will be allayed and the less likely it will be that U.S. biodefense programming will unintentionally launch an arms race in germ weapons by other countries that miscalculate U.S. intentions and activities.

U.S. biodefense programs already have and will continue to benefit from the new techniques, equipment, and knowledge that are propelling life sciences developments at a breakneck pace. The life sciences revolution will also boost environmental remediation, energy generation, agricultural productivity, and other discoveries in medicine. Cutting-edge life sciences techniques, knowledge, materials, and equipment may, however, be deliberately or inadvertently misapplied. The field of life sciences is so dynamic that do-it-yourselfers, known as biohackers, are being drawn to it. Along with countless others, those in DIY bio are availing themselves of the advantages of advanced automated equipment that "de-skills" complex life sciences techniques and processes.

One of the new life sciences disciplines that has raised security concerns is synthetic biology, the ability to generate microorganisms *de novo* from base pairs of nucleic acids. Already, among other pathogens, scientists have artificially created the polio and 1918 influenza viruses that killed and crippled tens of millions worldwide in the twentieth century. With each passing year, scientists can assemble more complex microorganisms from scratch in shorter amounts of time. Base pairs for synthetic assembly can be purchased for just a few dollars, so synthetic biology opens the way for governments and sub-national actors alike to put together rare and tightly controlled pathogens as well as eradicated diseases. Moreover, before long proliferators will be able to print whatever DNA sequences they wish. Several companies are developing desktop DNA printers.

Other important new technologies at the forefront of the life sciences revolution, like RNA interference and nanobiotechnology, are also vulnerable to abuse. Malicious actors could combine sophisticated targeted-delivery technologies with bioregulators, which can be directed to manipulate the human immune, nervous, and endocrine systems. In June 2000, geneticist and molecular biologist Matthew Meselson observed: "A world in which these capabilities are widely employed for hostile purposes would be a world in which the very nature of conflict has radically changed. Therein could lie unprecedented opportunities for violence, coercion, repression, or subjugation." These worrisome possibilities simultaneously underscore the need for biodefense programs and the need to consider how the architecture that governs life sciences research can be strengthened to reduce the chances that the governments and sub-national actors will exploit the dark side of the life sciences.

Conceptually, institutional peer review boards are the watchdogs that help ensure that life sciences research is performed responsibly and safely. In the United States and many other countries, peer governance of scientific research is not exercised comprehensively or evenly. Evidence also indicates that where such committees exist they do not always function effectively. Not only are these committees an unfunded mandate, the self-regulatory approach is innately handicapped because scientists are sometimes reluctant to restrict the work of other scientists. As the debate about various governance approaches for the life scientists has unfolded, plenty of its practitioners have grumbled about oversight of their work, resisting constraints that might serve the interests of security. The flood of advances in the life sciences has underscored the need to update oversight mechanisms, and esteemed scientific advisory panels proposed upgrades to existing oversight procedures.

Much of the debate has revolved around biosecurity, which consists of measures that are intended to foil the theft or diversion of high-risk pathogens. U.S. biosecurity procedures, known as the Select Agent Rules, took shape after a 1995 incident when a lieutenant in the Aryan Nations, Larry Wayne Harris, used false pretenses to buy three vials of bubonic plague from a U.S. pathogen repository. Though the ruse was spotted before Harris could attempt foul play, the incident sparked the maiden U.S. biosecurity regulations to control the transfer of and access to select pathogens. Known euphemistically as the "guns, guards, and gates" approach because physical security is one of its core components, biosecurity can also encompass licensing of facilities to work with pathogens; procedures to ensure the accountability of pathogens and to ascertain personnel reliability; pre-transport approval of transfers of pathogens and appropriate security during transport; oversight of scientific, commercial, and defense work with pathogens; and appropriate security for information related to processes and techniques useful in weaponizing an agent.

Poorly designed regulations do not ameliorate a problem, they exacerbate it. Current select agent regulations, it is important to recognize, would not have stopped anthrax letter attacker Ivins. In its indictment of Ivins, the FBI released information that shows that Ivins was mentally unstable and that he was abusing alcohol and drugs. Employees hired through a personnel screening process that concentrates on criminal, financial, and professional background checks but superficially addresses mental health, substance abuse, and lifestyle issues means that laboratory workers could be high or inebriated on the job, emotionally disturbed, or extorted to reveal private matters (e.g., nudist club membership). U.S. biosecurity procedures do not require substance abuse screening and address mental health matters tangentially. In 2009, the U.S. National Advisory Board on Biosecurity declined to recommend full-scope screening for researchers working with high-risk pathogens, citing worries that more intrusive initial and ongoing personnel screening could cause scientists to abandon this specialized area of research.

A 2009 inventory of USAMRIID's culture collection revealed yet another shortcoming of the Select Agent Rules approach. This inventory turned up 9,220 vials not listed in the facility's computerized inventory, including vials of botulinum neurotoxins and the Ebola, Junin, Rift valley fever, and Venezuelan and Western equine encephalitis viruses. USAMRIID officials chalked this jumble up to errors made when the facility computerized its pathogen inventory in 2005 and samples that departing workers left behind in the facility's 335 freezers and

refrigerators. Unable to rule out foul play, including the possibility that someone smuggled out vials, USAMRIID officials pointed to deterrent measures that they have since added, such as video cameras in the laboratories, exit checks of personnel, stepped up personnel screening and pathogen cataloging and auditing procedures, and random internal inspections. If USAMRIID's 2009 inventory saga illustrates anything, it is just how misapplied the paradigm of nuclear controls is in the life sciences world.

The protection, control, and accountability of nuclear materials can be exercised because of the ability to detect, weigh, and confirm quantities of nuclear materials. In contrast, scientists consider a precise inventory of culture collections to be somewhat futile first because microorganisms can be isolated from nature. Laboratory pathogens can also be replicated and stored in deliberately mislabeled containers without drawing undue attention. Moreover, as synthetic biologists worldwide sharpen the techniques to create pathogens artificially, the concepts of restricting access to pathogens and taking precise inventories will become less relevant to preventing villainy. For these reasons, life scientists regard "locking up" pathogens as a costly hindrance with dubious security gains.

The concept and practice of biosecurity is in serious need of an overhaul, but the Executive Branch seems inclined to live with the devil it knows, the Select Agent Rules, despite evidence that those regulations may have important opportunity costs for U.S. biodefense. Some top scientists and laboratories have apparently opted out of work with high-risk pathogens. Therefore, Congress should require the Executive Branch to prepare a cost-benefit study on the Select Agent Rules and alternative approaches to biosecurity.

Common sense indicates that the emphasis in biosecurity should be placed on personnel reliability rather than guns, guards, and gates. The time has come for life scientists to accept that working with certain materials, equipment, and technology is a responsibility, not a right because their mistakes could have severe consequences for the public at large. Several professions with a significant bearing on public safety−law enforcement officers, airline pilots, those working in the U.S. nuclear weapons program−have mandatory full-scope personnel screening to help short-circuit accidents and other employee misdeeds. Similarly, scientists in high-biosafety containment laboratories should be screened initially and periodically after hiring for problems (e.g., depression, substance abuse, susceptibility to coercion) that could negatively influence their reliability, trustworthiness, and reasoning. Accordingly, reconfigured regulations for high-biosafety level laboratory work should step up personnel screening requirements, streamline and reduce inventory control requirements, and establish procedures to create a "culture of responsibility" in life sciences laboratories.

Far, far too often, a scientist's knowledge of important biosafety, biosecurity, and research oversight procedures depends on the inclinations and practices of their laboratory supervisor. No time should be wasted in correcting this ad hoc situation; Congress should consider how mandatory education and competency demonstration requirements could be instituted. All colleges and universities granting undergraduate and graduate life sciences degrees should be required to include instruction on the ethical aspects of life sciences research, the BWC's prohibitions, and the fundamentals of biosafety, biosecurity, and research oversight in their curricula. All institutions working with high-risk pathogens should be obligated to

provide regular refresher training on these matters. All scientists handling high-risk pathogens should have to demonstrate competency in biosafety, biosecurity, and research oversight procedures that is commensurate with their job responsibilities.

For the time being, the most severe biological threats that America faces will be from natural disease outbreaks and state-level bioweapons programs. As noted, the ability of intelligence to find and characterize covert bioweapons programs is lacking, so the United States needs to go back to the drawing board on data collection strategies, tactics, and tools that can be used to monitor biological facilities. The U.S. government appears to have done little to learn from the invaluable experience of the United Nations Special Commission's biological inspections, and this oversight merits correction. With ordinary inspection tools−observation, document tracking, interviews−and old-fashioned gum-shoe detective work, the inspectors collected considerable evidence that Iraq was hiding a bioweapons program behind a façade of civilian activity. The United Nations Special Commission reported Iraq's development, production, and weaponization of biowarfare agents to the Security Council, compelling Iraq to admit culpability. Thus, the experience of the United Nations Special Commission stands as a direct challenge to the conventional wisdom that the BWC is "inherently unverifiable."

Since the effectiveness of U.S. biodefense depends in no small part on the quality of U.S. biological threat assessments, Congress should require a study evaluating the limitations and prospective contributions of intelligence and inspections to the standing need to detect and deter bioweapons proliferation. The study should address the utility of these tools in isolation of each other as well as the potential synergy between intelligence, increasingly powerful sampling and analysis capabilities, analysis of import/export data, and other on-site inspection tools. This study should include an assessment of how the global institutionalization of cross-cutting biosafety, biosecurity, and research oversight standards might benefit detection of covert bioweapons activity. Such standards would generate a voluminous data that can be perused to aid efforts to separate legitimate peaceful biological work from illicit biowarfare activities. This appraisal could find that inspections can be expected to detect certain biowarfare activities reliably, such as the stockpiling of biological weapons and bulk agent production, but not necessarily to catch offensive research and development of biological weapons. Whatever the study's conclusions, the analytical process entailed would be a springboard to identify alternatives to give U.S. policy makers more data of a more reliable quality about suspected bioweapons activities, which would in turn inform U.S. biodefense programs.

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Amy E. Smithson specializes in in-depth field research on issues related to dual-use chemical and biological technologies, weapons proliferation, threat reduction mechanisms, defense, and homeland security. She has addressed such topics as the reduction of US and Russian weapons capabilities, the overhaul of China's regulations related to the conduct of life sciences research, the status of international treaties outlawing these weapons, export controls, unconventional terrorism, and preparedness for biological and chemical disasters. Often fashioning untraditional issue alliances that cross the private and public sectors and international borders, Smithson's work recommends practical steps that blend technical and policy instruments to reduce threats and to enhance civilian and military defense, preparedness, and response capabilities. Before joining the Center for Nonproliferation Studies, she worked at the Center for Strategic and International Studies and the Henry L. Stimson Center, where in January 1993 she founded the Chemical and Biological Weapons Nonproliferation Project. Previously, she worked for Pacific-Sierra Research Corporation and the Center for Naval Analyses.

Smithson's work has prompted numerous invitations to testify before Congress, and she has frequently assisted the electronic and print media. Her latest work, *Germ Gambits: The Bioweapons Dilemma, Iraq and Beyond*, debunks myths about how United Nations Special Commission inspectors uncovered Iraq's covert bioweapons program after the 1991 Gulf War. The vice chair of the World Economic Forum's Global Agenda Council on Nuclear, Biological, and Chemical Weapons, Smithson earned a PhD in political science at George Washington University, an MA in international relations at Georgetown University, and BA's in political science and Russian at the University of North Carolina, Chapel Hill.

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Testimony

The Challenge of North Korean Biological Weapons

Bruce W. Bennett

RAND Office of External Affairs

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Testimony presented before the House Armed Services Subcommittee on Intelligence, Emerging Threats and Capabilities on October 11, 2013

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The RAND Corporation

The Challenge of North Korean Biological Weapons[2]

Before the Committee on Armed Services
Subcommittee on Intelligence, Emerging Threats and Capabilities
United States House of Representatives

October 11, 2013

Chairman Thornberry, Ranking Member Langevin, and members of the Subcommittee, thank you for inviting me to testify at this hearing, "Biodefense: Worldwide Threats and Countermeasure Efforts for the Department of Defense." While there is evidence of North Korean biological weapons, little is known with certainty about the biological weapon agents the North has developed, which of these agents it has weaponized, and how it would use them. Still, North Korean biological weapons could pose a fearsome threat to the Republic of Korea (ROK) and even the United States, and the ROK and the United States need to be prepared for that threat to be carried out.

This testimony addresses the nature of the potential North Korean biological weapon threat and how the ROK and United States should prepare to counter potential biological weapon attacks. It discusses the biological agents that North Korea may have pursued, how those agents could be spread, and the potential damage that biological weapon attacks could cause. It then describes options for countering biological weapon attacks, from interdicting such attacks to detecting them and treating the affected people. Some of these counters have been fielded, supporting deterrence of a North Korean biological weapon attack. But more effort is warranted in these areas in order to avert the effects North Korea could cause and thereby strengthen deterrence of a North Korean biological weapon attack.

North Korean Biological Weapons

North Korea has been very effective in denying the world information about its biological weapon programs. North Korea practices such information denial across almost all of its military

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[2] This testimony is available for free download at http://www.rand.org/pubs/testimonies/CT401.html.

activities.[3] Biological weapon programs are easier to hide than most military programs because they can be developed in a university setting or hidden within efforts to develop related vaccines. As a result, the outside world has little direct information on North Korean biological weapons and therefore has mainly indirect inferences, creating substantial uncertainties.

Information Available About North Korean Biological Weapons

Among the evidence available, several observations stand out. The first, from a Republic of Korea Ministry of Defense White paper, traces the initiative for North Korean biological weapons development back to the 1980s.

> "In the 1980s, the military turned to the development of biological weapons according to Kim Il-sung's directive that 'poisonous gas and bacteria can be used effectively in war.' … The North is also suspected of maintaining numerous facilities for cultivating and producing the bacteria of anthrax and other forms of biological weapons."[4]

A second observation comes from a Russian intelligence report from the early 1990's.

> "In 1993, the Russian Foreign Intelligence Service, successor to the Soviet Union's KGB, released a statement that said, in part: 'North Korea is performing applied military-biological research in a whole number of universities, medical institutes and specialized research institutes. Work is being performed in these research centers with inducers of malignant anthrax, cholera, bubonic plague and smallpox. Biological weapons are being tested on the island territories belonging to the DPRK (Democratic Peoples Republic of Korea).' Mr. Gordon Oehler, director of the CIA's [Central Intelligence Agency's] Non-Proliferation Center, confirmed this Russian report."[5]

And a third open-source reference cites reports from North Korean defectors over the past decade.

> "Sporadic reports by defectors during 2003–2004 and 2009 state that the DPRK has conducted testing of biological agents on political prisoners. For example, '...tests are conducted on political prisoners by the College for Army Doctor and Military Officers and Kim Il-sung University Medical College.' While these reports present numerous details, they are extremely difficult to confirm. They do, however, conform to older reports of this nature that have occasionally appeared since the late 1970s. Taken as a whole, and within the context of what is currently known about the treatment of political prisoners within the DPRK, such

[3] "The DPRK [Democratic People's Republic of Korea] is the most closed and security-conscious society in the world. This situation has developed since the earliest days of Kim Il-sung's rule as a means of isolating and eliminating potential internal threats, controlling society and limiting foreign intelligence collection. The KWP [Korean Workers' Party] and National Defence Commission, through a host of overlapping organisations and security agencies, maintain near-absolute control over its citizens and soldiers and the information to which they have access." "North Korea: Strategic Weapons Systems," *Jane's Sentinel Security Assessment* - China and Northeast Asia, July 7, 2011.

[4] The Republic of Korea Ministry of National Defense, *Defense White Paper, 2000*, p. 58.

[5] Frederick R. Sidell, et al., *Medical Aspects of Chemical and Biological Warfare*, 1997, pp. 461–462, available at http://www.bordeninstitute.army.mil/published_volumes/chemBio/ch21.pdf (accessed on Oct. 23, 2009). This document cited the original source as: J. Fialka "CIA says North Korea appears active in biological, nuclear arms," *Wall Street Journal.* Feb 25, 1993, p. A-10.

> reports suggest a long-standing DPRK policy of low-level lethal testing of biological agents on unwilling human subjects."[6]

Other suspicions grow out of the North Korean vaccine programs:

> "During the past ten years DPRK scientists and researchers have engaged in research to produce vaccines and diagnostic test kits for avian flu, Severe Acute Respiratory Syndrome (SARS) and anthrax. In 2004 scientists and researchers from the Central Hygiene Center, Ministry of Health, produced a[n] anthrax rapid diagnostic kit. Such research is not only valuable for defensive biological warfare but could be directly applicable to offensive operations."[7]

Since anthrax is not a major health concern in North Korea, one must wonder, in particular, about the motivation behind the North Korean anthrax defensive programs.

As another example, Korean Hemorrhagic Fever (also called Hemorrhagic Fever with Renal Syndrome, or HFRS) is endemic to North and South Korea. Anxious to reduce the impact of this disease, Dr. H. W. Lee of South Korea developed a "human inactivated" virus vaccine for Korean Hemorrhagic Fever.[8] More than 20 years ago, Dr. Lee reported that the North Koreans developed a similar vaccine, which in 1990 had already been given to 30,000 people.[9] Since North Korea rarely provides antibiotics for most public health challenges, the development of this vaccine suggests a possible military interest in its availability.

Likely North Korean Biological Agents

The many biological agents that North Korea apparently has been or could be developing are listed in Table 1. This table shows the type of each biologic agent, its potential lethality, the number of cases reported in Korea and the United States in recent years, and references (if any) that identify these agents as part of the North Korean biological weapon program.

It is important to note that the initial detectability of an attack varies by biological agent. With diseases like malaria, Korean Hemorrhagic Fever, and especially tuberculosis, the initial number of cases resulting from a biological weapon attack might not differ from the number of naturally occurring cases enough to cause doctors or other health care professionals to recognize that an attack has occurred. It may take many hours or longer before it is clear that a disease outbreak is not a natural occurrence.

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[6] "North Korea: Strategic Weapons Systems," *Jane's Sentinel Security Assessment* - China and Northeast Asia, July 7, 2011.

[7] *Ibid.*

[8] H. W. Lee, *et al.*, "Field trial of an inactivated vaccine against hemorrhagic fever with renal syndrome in humans," *Archives of Virology*, Supplement 1, 1990, pp. 35–47.

[9] *Ibid.*, p. 46.

There has been widespread discussion of North Korea developing anthrax as a biological agent, as well as many references to it developing cholera, plague, and smallpox. For example, speaking of the smallpox virus, Dr. Ken Alibek, a former senior scientist in the Soviet biological weapon program, has said:

> "I'm 100% sure North Korea still has this virus. Even in the late 80s, we had some information obtained from Soviet intelligence service that North Korea was developing biological weapons, involving anthrax, plague, smallpox and several others."[13]

Potential North Korean Uses of Biological Weapons

The Republic of Korea Ministry of Defense asserts that "[t]he North may also dare to launch a secret attack in the rear through its SOF [special operations forces] troops armed with biological weapons."[14] Even a kilogram of many types of biological weapons could disrupt most military targets if delivered properly,[15] and this quantity could easily be delivered by special operations forces. Missiles and aircraft could also deliver this quantity of biological weapons.[16]

Indeed, North Korea special forces are a likely means for delivering North Korean biological weapons. North Korea has some 200,000 special forces,[17] a small fraction of which could deliver devastating biological attacks against South Korea, Japan, and even the United States.[18] North Korea could use biological agents in isolation, perhaps as an escalated provocation in which it seeks to infect a limited number of people, or it could use biological agents as the leading edge of an invasion of the ROK, hoping for thousands or even more infections to weaken the ROK's defenses and will to fight. Biological weapon use in the latter context is particularly worrisome.

[13] "Interview —Dr. Ken Alibek," Homeland Defense, September 28, 2000.

[14] The Republic of Korea Ministry of National Defense, *op. cit.*

[15] As will be discussed below, 1 kilogram of anthrax would potentially infect people in a 2.6 square kilometer area.

[16] For example, the AN-2 aircraft North Korea would use for delivering special forces into the ROK are difficult to intercept, and could carry biological weapon sprayers in addition to special forces.

[17] The Republic of Korea Ministry of National Defense, *2012 Defense White Paper,* p. 31.

[18] North Korean special forces could bring biological agents into the United States covertly, long before an attack. They could also infect the noncombatants leaving Korea with contagious biological agents, causing disease to emerge, after incubation, in the United States.

Table 1
Potential North Korean Biological Agents

BW Agent	Type of Agent	Untreated Lethality	Korean Cases		U.S. Cases	NK BW Source[19]
			2010*	2011*	2011**	
Anthrax	Bacteria	High	0	0	1	KRIS, USFK, Alibek, WP
Botulinum	Toxin	High	0	1	153	USFK
Brucellosis	Bacteria	<5%	31	19	79	KRIS
Cholera	Bacteria	50+%	8	3	40	KRIS, USFK
Dengue fever	Virus	1%[a]	125	72	3	—
Diphtheria	Bacteria	5–10%	0	0	?	KRIS
Dysentery	Bacteria	Low	?	?	?	KRIS
E. coli	Bacteria	3-5%[a]	56	71	2,575	—
Hemorrhagic fever (HFRS)	Virus	5–15%	473	370	23	KRIS, USFK, Alibek, WP
Hepatitis	Virus	Low	?	7,247[c]	4,301[c]	KRIS
Japan. Encep.	Virus	≤60%	26	3	?	—
Malaria	Parasite	Low	1,772	838	1,724	—
Pertussis	Bacteria[b]	Low[a]	27	97	18,719	—
Pnm. plague	Bacteria[b]	High	0	0	3	KRIS, USFK, Alibek, WP
Q Fever	Bacteria	Low	13	8	134	—
Smallpox	Virus[b]	20–40%	0	0	0	USFK, Alibek, WP
Tuberculosis	Bacteria[b]	High	36,305	39,557	10,528	KRIS
Tularemia	Bacteria	Moderate	0	0	166	KRIS, WP
Typhoid fever	Bacteria	Moderate	133	148	390	KRIS, USFK
Typhus	Rickettsia	Moderate	54	23	?	KRIS
Yellow fever	Virus	Moderate	0	0	0	Alibek, USFK

[a] With treatment
[b] Contagious
[c] Hepatitis A and B
* Data from the Korea Centers for Disease Control and Prevention (KCDC): http://www.ksid.or.kr/admin/mail/download.php?num=69
** Data from the U.S. Centers for Disease Control and Prevention (CDC): http://www.cdc.gov/mmwr/PDF/wk/mm6053.pdf; typhus is not reported.

[19] Sources: USFK = General Leon J. LaPorte, "Statement before the Senate Armed Services Committee," April 1, 2004; KRIS = *The Strategic Balance in Northeast Asia, 2003*, Korea Research Institute for Strategy (KRIS), December 2003, p. 363; Alibek = "Interview—Dr. Ken Alibek," Homeland Defense, September 28, 2000 and "Biological War: Are We Prepared? Dr.'s Q&A," Ivanhoe Broadcast News, October 2001 (http://search.ivanhoe.com/archives/ p_archive.cfm?storyid=1437& channelid=CHAN-100021); WP = The Republic of Korea Ministry of National Defense, *2012 Defense White Paper,* p. 36.

The Potential Effects of North Korean Biological Weapons

The People Infected. North Korea could use biological weapons against a variety of military and civilian targets in South Korea. Biological weapons would likely be delivered as an aerosol of some kind that would be dispersed and then carried by the wind. Many people downwind of the release location would be exposed unless they wore some form of protection or were physically located in a place that protected them from exposure. This is particularly true if the attacker creates a line source by spraying, for example, the BW agent while driving along a road perpendicular to the wind. According to one source, 1 kilogram of anthrax could spread lethal effects over 0.2 to 2.6 square kilometers, depending on wind and weather conditions.[20] The nighttime population density of Seoul averages about 20,000 people per square kilometer, meaning that upward of about 50,000 people could be effectively exposed by 1 kilogram of anthrax. But in conditions less favorable to the attacker, including poor atmospheric conditions and many people living in high-rise buildings that lack central heating and ventilation, as few as 2,000 people might be effectively exposed by 1 kilogram of anthrax. Multiple attacks could increase these results.

Contagious Agent Infections. A key agent characteristic is whether the agent is contagious, as in the cases of plague and smallpox. These diseases may affect not only those exposed by an initial North Korean attack, but those who become sick by being infected by others. The ability to spread a contagious disease is reflected in the term R_o, which represents the average number of people who are infected by each person having the disease. The R_o for smallpox is estimated as 5 to 7.[21] For example, with an R_o of 6, if 1,000 people initially became sick from a smallpox attack, they could infect 6,000 others, and those 6,000 could infect 36,000, and so forth—the secondary and tertiary infections would, of course, occur over time. But if the R_o were 15 (true for diseases like Pertussis and measles), a first generation of 1,000 cases could swell to 15,000 cases in the second generation and to 225,000 cases in the third generation in a heavily populated area unless there was an intervention in the form of treatment, vaccination, isolation of the infected, or quarantine.

Physical Effects After Infection. As the result of an anthrax attack, some of those exposed would develop inhalation anthrax (quite deadly), and some would develop cutaneous (through the skin) anthrax (less deadly). By three or four days after the attack, many people would be sick, and

[20] Steve Fetter, "Ballistic Missiles and Weapons of Mass Destruction," *International Security*, Summer 1991, pp. 25–26.

[21] See W. Orenstein, Director of the National Immunization Program, "Introduction to Smallpox," briefing for the Centers for Disease Control. Available at http://www.bt.cdc.gov/agent/smallpox/overview/intro-to-smallpox.pdf.

some of those sick would be dying. By day 10, roughly 60 percent of those exposed would be dead unless effectively treated with antibiotics. Even if treated with antibiotics, many of the survivors of an anthrax attack could suffer debilitating chronic illness. A study done at the end of 2002 examined 15 of the 16 victims of the anthrax letters mailed in 2001. The study found:

> "…that the infected adults experienced physical ills, psychological distress and a reduced quality of life. They had chronic coughs, fatigue, joint swelling and pain and memory loss, and suffered from depression, anxiety, obsessive-compulsive disorders and displays of hostility, researchers found. Survivors who had inhaled anthrax suffered worse health problems than those who became ill through skin contact with the biological agent. Eight of the study participants had not returned to work by December 2002, more than a year after anthrax was delivered by mail to Washington, New York and other areas…."[22]

Protracted Incapacitation. In the 1960s, the U.S. offensive biological weapons program pursued nonlethal, incapacitating agents. The U.S. program reportedly focused on a cocktail of SEB, VEE, and Q-Fever,[23] each having different incubation and effects periods. This cocktail would have led to the SEB toxin affecting people in roughly 3 to 12 hours and incapacitating them for a week or so.[24] Before the SEB effects would fully wear off, VEE would make people sick, and as the VEE effects wore off, Q-Fever would make people sick. The illness from each of these diseases can be incapacitating, keeping many people from performing their missions for a month or more, though relatively few people would die.

Other Effects. While the casualties caused by biological weapons are a concern, biological weapons would have many other effects. These include:

- **Loss of facilities.** In the aftermath of the 2001 anthrax letters, it took months to several years to fully decontaminate the facilities where anthrax had been spread, and those facilities were not used until decontamination was completed. Most biological weapons decay within hours to days of their release, but some, like anthrax, can persist indefinitely.

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[22] Only five of the 16 survivors had inhalation anthrax. Chris Schneidmiller, "Anthrax Survivors Suffered Long-Term Effects, Study Finds," Global Security Newswire, April 28, 2004.

[23] Judith Miller, Stephen Engelberg, and William Broad, *Germs: Biological Weapons and Americas Secret War*, (New York: Simon and Schuster), 2001, pp. 56–57.

[24] Some in the infectious disease community debate the ability of SEB to incapacitate for very long. The US military's official reference book says: "Although an aerosolized SEB toxin weapon would not likely produce significant mortality, it could render 80 percent or more of exposed personnel clinically ill and unable to perform their mission for 1-2 weeks." *USAMRIID's Medical Management of Biological Casualties Handbook*, USAMRIID, 5th Edition, August 2004, p. 93.

- **Medical care.** A large number of persons sick from biological weapons could overwhelm the medical care system. In addition, many people who were not sick would be diverted from their normal activities to help sick family members or friends obtain medical care. And there is a tendency of uninfected persons to perceive that they have been infected, constituting a so-called "worried well" population. In the aftermath of the terrorist use of the chemical weapon Sarin in Tokyo in 1995, the number of "worried well" people who sought hospital care (many because of acute anxiety that caused physical symptoms) was three times the number of people who actually had physical symptoms of chemical exposure.[25]

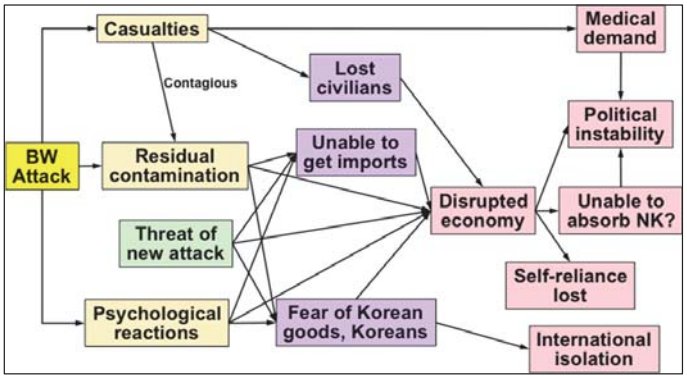
- **Biological weapon protection.** Once the symptoms of biological weapons began to develop somewhere, people throughout the area would seek protective measures. With biological weapons, that would imply the use of at least a surgical mask, though P-95 respirators would provide better protection against biological weapons. These protective measures would impose some degree of degradation in people's actions, especially as they avoid physical activities that could break the seal on their masks.
- **Psychological reactions.** Biological weapon use would cause severe psychological reactions in some percentage of the population in addition to the "worried well" problem. For example, during the 1994 natural plague outbreak in Surat, India, some 600,000 people fled the city in one night, responding to 5,000 reported plague cases, of which only 167 cases were confirmed.[26]

Societal Effects in the ROK. Biological weapons can cause these and other strategic impacts, as illustrated in Figure 1. Thus the civilian casualties and loss of infrastructure from biological contamination could significantly impact a nation's economy. Especially if contagious biological weapons were used, many trading partners would refuse to send their goods to the affected country and more likely would not accept goods from the affected country, fearing that the goods could be contaminated. There would also be the fear of new biological weapon attacks, particularly against those countries "helping" the country that was initially attacked. The country affected by biological weapons could also suffer international isolation. For example, during the 1972 outbreak of smallpox in Kosovo, neighboring nations closed their borders with Yugoslavia.[27] There could also be second- and third-order effects if health care and other resources were

[25] Rosalee Meyer, *The Psychological Effects of a Chemical Attack on Military and Civilian Personnel*, Battelle Memorial Institute, January 2003, section 3.2.3.
[26] V. Ramalingaswami, "Psychosocial Effects of the 1994 Plague Outbreak in Surat, India," *Military Medicine*, Vol. 166, Supplement 2, December 2001, pp. 29–30.
[27] D.A. Henderson, "Bioterrorism as a Public Health Threat," *Emerging Infectious Diseases*, Vol. 4, No. 3, July–September 1998, p. 490, at http://wwwnc.cdc.gov/eid/article/4/3/pdfs/98-0340.pdf.

insufficient to meet demands. Much of the military could be diverted to sustaining internal order and/or imposing quarantine and vaccination requirements.[28] In Korea's case, the ROK could even find itself unable to carry out a counteroffensive into North Korea or to deal with a failed government in North Korea, being fully absorbed with internal problems and losing the economic resources to cover the costs of unification.

Figure 1
Potential Strategic Impacts of Biological Weapon Use



To illustrate the potential challenges, consider the terrorist attacks on the United States that occurred on September 11, 2001. In those attacks, the United States lost less than 0.002 percent of its population, but various estimates put the loss of gross domestic product that year due to the attack in the 1 to 5 percent range. If the economic impact of such events can be hundreds of times the casualty percentage impact, consider the implications of biological attacks that would affect, say, 100,000 people in the ROK, or about 0.2% of the population.

[28] After an outbreak of smallpox in Kosovo in 1972, "Health authorities launched a nationwide vaccination campaign. Mass vaccination clinics were held, and checkpoints along roads were established to examine vaccination certificates. Twenty million persons were vaccinated. Hotels and residential apartments were taken over, cordoned off by the military, and all known contacts of cases were forced into these centers under military guard. Some 10,000 persons spent 2 weeks or more in isolation." In that outbreak, there were a total of 175 cases of smallpox. *Ibid*.

Preparing for and Responding to Biological Weapon Attacks

North Korea's apparent development and testing of biological weapons on certain members of its own population suggests that the ROK needs to be prepared for North Korean biological weapon use against the ROK. Indeed, while there have been no proven North Korean uses of BW against the ROK, North Korea may have experimented with small amounts of endemic biological agents, like dysentery, to assess the ROK's ability to detect biological agents use and manage the consequences of that use.[29] It is clearly important to identify the means for countering North Korean biological weapon use.

There are many ways to respond to the North Korean biological weapon threat. At the strategic level, it is best to deter North Korean biological weapon use. But deterrence rests squarely on being able to deny North Korea the effective use of biological weapons. Denial capabilities also provide the means to defeat biological weapon use. The plan for defeating North Korean biological weapons must focus on preventing the delivery of biological weapons against the ROK, detecting the presence of biological weapon agents or disease, preventing exposure to biological weapons, preparing people physiologically to prevent biological weapon infection, and handling the consequences of biological weapon use.[30]

Preventing the Delivery of Biological Weapons. North Korea may attempt to deliver biological weapons in a number of ways. The ROK must be prepared to intercept each of these delivery methods. A failure to protect against any option makes North Korean use of that option more likely. The first step in interception is to detect any delivery systems carrying biological weapons, followed by efforts to intercept those delivery means.

North Korean use of special forces to deliver biological weapons seems most likely.[31] The technology involved is fairly simple, and North Korea has a large number of special forces who would want such empowerment. The special forces would seek to covertly deliver biological weapons against the ROK before the start of a conflict, making their actions difficult to detect. One intercept opportunity is at the ROK border, where ROK immigration should be connected to

[29] This point was suggested by a senior ROK military officer several years ago.

[30] In theory, the ROK could also destroy the North Korean biological weapons in their storage sites or other areas in North Korea before the weapons are used. But such efforts are beyond the scope of my testimony today.

[31] The North Korean military culture is important to understand. The founder of North Korea, Kim Il-Song, felt he had served as a special forces operator against the Japanese. He thus gave priority to special forces capabilities, as did his son, Kim Jong-Il. Biological weapons would significantly empower special forces, consistent with this culture.

the passport databases of its Asian neighbors and able to identify a falsified passport (since North Korean special forces are unlikely to enter the ROK on North Korean passports).

Inside the ROK, organizations that have the ability to spray in broad areas (such as crop dusters or commercial pest control organizations) should be periodically examined to discern any connections to North Korean culture or groups. Suspicious behavior such as spraying outside of normal seasons or in unexpected areas should be investigated.

It would be relatively easy to detect North Korean military aircraft or missiles that might be carrying biological weapons. The interception of aircraft would be easier than the interception of missiles. When possible, the ROK and/or the United States should destroy the North Korean delivery means over North Korean territory, as some of the biological weapons would likely survive interception and reach the earth's surface.

Detecting the Presence of Biological Weapon Agents or Disease. Protections against biological weapon agents are difficult and expensive to sustain; they are usually relaxed when an immediate threat is not perceived. Detecting the presence of a biological weapon agent is therefore critical to significantly enhancing the level of protection in a timely manner. Identification of the agent's use is also critical to appropriately treating those infected.

Detection can be done in several ways. First, a biological weapon agent can be detected by sampling the environment, including air, water, and food. Because U.S. military facilities, including those in Korea, would be likely targets of biological weapon attacks[32] if North Korea was preparing for a major war, air sampling is done continuously around some bases with a system called portal shield, which can provide warning of a biological weapon attack. The ROK also has means for detecting biological weapon attacks.

An alternative detection approach is disease surveillance. Typically performed in a hospital setting, this procedure is applied to people with flu-like symptoms to determine what disease they have contracted. If the disease is determined to be a potential biological weapon agent, detection provides warning unless the disease is endemic to that area, in which case local health authorities must look for other cases to determine whether the disease development is normal or reflects an unusual pattern that could have resulted from a biological attack. The ROK and U.S. authorities in Korea have developed good, well-coordinated disease surveillance.

[32] For example, North Korea cannot defeat US/ROK combat aircraft in the air. The North must instead attack them on the ground, and biological weapons would give them an option for doing so.

Preventing Exposure to Biological Weapons. There are various ways to prevent exposure to biological weapons once they have been used. One primary approach is to stop the movement into or out of areas where BW contamination is known to exist. Another approach used after the 2001 anthrax letter attacks involved closing the buildings where exposure occurred until they could be decontaminated.

Because many biological agents decay rapidly, decontamination will not be required after all biological weapon attacks. But with diseases like anthrax, decontamination is required due to the length of time that the agent can survive and remain a threat. Decontamination of most biological agents can be done with anything that kills biological agents, though with spores like anthrax, a more complex decontamination protocol is required. The ROK and the United States can likely handle selective decontamination in the ROK but would have problems handling many buildings or large areas.

With contagious diseases, exposure can be prevented in various ways, as illustrated by the 1972 smallpox outbreak in Yugoslavia. Neighboring countries closed their borders with Yugoslavia until the spread of the disease was under control. Also, schools can be closed and public activities suspended.[33] Those infected with a contagious disease should be physically isolated from healthy people as long as they are contagious. And those who may have had contact with the infected can be put into quarantine for the incubation period of the disease to make sure they do not develop the disease.[34] The ROK and the United States are not well prepared to implement isolation and quarantine in Korea or in the United States, generally lacking the laws and plans for such efforts.

Another approach was applied during the SARS outbreak in 2002–2003 (and subsequently), in which people arriving by aircraft in some countries (including the ROK) were (and are) scanned for a fever to determine if they had been infected with some disease,[35] and if so, they were isolated until their fever subsided or further testing determined that the cause of their illness was not threatening.

Preventing Biological Weapon Infection. There are also several ways to prevent infection. Vaccines improve the individual immunity to a disease and are usually sufficient to prevent disease development during their effective period. Unfortunately, despite the long list of potential

[33] F. Fenner, D. A. Henderson, I. Arita, Z. Jezek, I. D. Ladnyi, *Smallpox and its Eradication*, (Geneva: World Health Organization, 1988), p. 1093.
[34] As noted in an earlier footnote, during the 1972 Yugoslavian smallpox outbreak, “Some 10,000 persons spent 2 weeks or more in isolation [quarantine].” D. A. Henderson, *op. cit.*
[35] Some countries still scan all arriving visitors to determine if they have a temperature.

biological agents in Table 1, current vaccines are disease-specific. Of these agents, the U.S. military focuses its preventative measures on anthrax and smallpox because of the severity of the threat they pose.

Vaccines can also be effective in preventing the spread of contagious disease. For example, the use of smallpox vaccine eventually led to the eradication of natural smallpox. The spread of contagious disease can be controlled through vaccination by reducing the rate of disease transmission to less than one person per previously infected individual. The level of vaccination required to stop disease spread is referred to as "herd immunity," and equals: $(R_o - 1)/R_o$. Thus, if the smallpox R_o value is 6, herd immunity would require vaccinating about 83 percent of the population,[36] especially in the geographic area around the infection. In the years during the eradication of smallpox, most countries achieved herd immunity levels of vaccination or more. However, since the late-1970s, almost none of the world population has been vaccinated, making it vulnerable to smallpox. To be prepared against North Korea's use of smallpox, the Korea Centers for Disease Control (KCDC) acquired 7 million doses of smallpox vaccine, not enough to cover the entire country (just 15 percent of the population), but hopefully enough to cover the area where the disease breaks out if disease spread is contained. But the media has reported that the smallpox vaccines acquired by the ROK "…have either expired or failed to pass toxicity tests."[37]

It is worth noting that vaccines are not always assured protection. For example, the individual who was the source of the 1972 smallpox outbreak in Yugoslavia had been vaccinated for smallpox two months before he went to Iraq, where he was apparently exposed to smallpox. But the vaccine only suppressed his symptoms, preventing him from developing the kind of rash that usually leads to a prompt clinical diagnosis of smallpox. As a result, 11 people who had contact with him after he returned to Yugoslavia developed the disease, while medical officials were unaware that he was suffering from smallpox.[38]

Another way to prevent infection is through the use of face masks to block inhalation of a biological weapon agent. Surgical masks are typically used for this purpose, but they provide inadequate protection because some air can move around the mask. Respirators provide better protection, as they create a degree of seal with the face. The ROK should have in supply tens of

[36] In practice, the required level of smallpox vaccination appears to be less than this herd immunity value. See W. Orenstein, *op. cit.*

[37] Robert Lee, "Smallpox vaccines against N.K. attack unusable," *The Korea Herald*, September 7, 2011, at http://www.koreaherald.com/national/Detail.jsp?newsMLId=20110907000602.

[38] F. Fenner, *op. cit.*, p. 1092.

millions of P-95 respirators, and the U.S. military in Korea should have tens of thousands of such respirators to be used in areas where full chemical masks are not required.

Some diseases can also affect people through the eyes or through cuts in the skin,[39] and thus precaution must be taken for broader protection against those diseases. This can be done with a typical chemical agent face mask, but the use of such a mask significantly impacts the performance of individuals, and few people other than the military have such masks in the ROK. Also, some diseases are carried by mosquitos, fleas, or other insects. With such diseases, action needs to be taken to protect people from those vectors and reduce the vector population.

Another way to prevent infection is through collective protection that can be added to a facility. Such a collective protection system filters all incoming air, preventing most or all biological weapon agents from entering the facility. The facility needs to maintain a degree of overpressure that keeps air from coming in when people enter. Facilities also need a means for decontaminating people as they enter to prevent them from bringing in the biological weapon agent on their clothes or bodies. It does not appear that there are many such protected facilities in the ROK—more efforts in this area are required and hopefully will be taken as U.S. facilities are built at Camp Humphreys.[40]

Treating the Consequences of Biological Weapon Use. Once it is known that a biological agent has been used, and the agent has been identified, medical treatment can focus on countering that agent. As noted above, with bacterial agents, some form of antibiotic can be used to treat the victims. In practice, treatment of the inhalation anthrax victims in 2001 employed a mixture of antibiotics to increase the chances of success.[41] While the ROK likely has a good supply of antibiotics for everyday use, it likely has far less than would be demanded by those who are sick and the "worried well" in the aftermath of a major biological weapon attack.

Against viruses, antivirals offer the possibility of countering the diseases (antivirals do not always work against all viruses). Where vaccines are available, they may also be useful in treatment, especially in that of people who have been exposed but are not yet symptomatic.[42] The ROK

[39] For example, percutaneous anthrax infections can become serious at cuts in the skin.

[40] Buildings with collective protection potential were built at the U.S. Osan Air Force Base in Korea.

[41] John A. Jernigan, et. al., "Bioterrorism-Related Inhalational Anthrax: The First 10 Cases Reported in the United States," *Emerging Infectious Diseases*, Vol. 7, No. 6, November-December 2001.

[42] For example, the smallpox vaccine is considered very useful especially during the first five days after exposure. Even if it does not prevent the disease from developing, it tends to produce a more mild case of the disease. D.A. Henderson, "Smallpox as a Biological Weapon: Medical and Public Health Management," *Journal of the American Medical Association*, Vol. 281, No. 22, June 9, 1999, p. 2132.

does not appear to have large stockpiles of antivirals; both the United States and the ROK should assure the ability to treat large parts of their populations in Korea for many days.

Finally, with regard to toxins, an agent-specific antitoxin is required. There are relatively few kinds of antitoxins that have been developed, and they are available only in small quantities in most countries, in part because of their cost.

As suggested in the discussion of the effects of biological weapon attacks, the inability to treat people exposed to biological weapons could lead to very high numbers of casualties and many deaths. The ROK should thus seek to participate in the development of new vaccines and treatments, an area in which the United States appears to be making some progress.[43]

Managing Human Remains. Many biological weapon attacks will lead to fatalities. Because some diseases (especially ones that are contagious) will remain a threat inside infected cadavers for a period of time, cremation of the dead is often recommended to prevent further spread of the disease. If cremation is not practiced, the body should be contained in some way (e.g., the use of a body bag and a sealed coffin) to prevent disease spread. It is unlikely that sufficient supplies of containment items exist in the ROK.

Conclusions

North Korean biological weapons could pose serious threats to the ROK, other countries in Northeast Asia, and the United States. The exact nature of the North Korean biological weapon threat is not known, but a variety of serious biological weapons agents may have been developed by North Korea, and North Korea is also reported to have experimented on political prisoners with some of these agents. While it is therefore difficult to determine when or how North Korea would use biological weapons, any such use could cause many casualties and be highly disruptive to ROK and even U.S. society.

The ROK and the United States have made efforts to prepare for biological weapon attacks and be ready to respond to them. Given adequate ROK/U.S. preparations, North Korean biological weapon attacks will hopefully remain deterred. But such preparations are technologically challenging and costly, and much more can be done. If assessments of North Korean capability

[43] "A significant number of experimental vaccines and other drugs for treating people exposed to biological weapons agents are due within a half-decade to undergo federal assessment, a U.S. Health and Human Services Department office said in a five-year plan issued on Tuesday." "Bioweapon Countermeasure Progress Seen Within Half-Decade," Nuclear Threat Initiative, October 7, 2011, at http://gsn.nti.org/gsn/nw_20111006_4385.php.

are correct (or if North Korean capability is even at the mid-point of these estimates), then the following recommendations should be pursued:

- The ROK and U.S. governments should protect themselves against the delivery of biological weapons. In peacetime, their immigration authorities should link to the passport databases of Northeast Asian countries in order to aid in the identification of forged passports that North Korean agents would be using to carry BW into the ROK or the United States. In crisis and war, the ROK and U.S. militaries should be better prepared to detect and intercept North Korean aircraft and missiles.
- The ROK and U.S. governments should detect and attribute biological weapon attacks and identify the biological weapon agents used. They should pursue research to better perform these tasks.
- The ROK and U.S. governments should prevent exposure to and infection with biological weapons and be ready to deal with the consequences of biological weapon infection. They should prepare to close or closely regulate borders, close schools and other venues where disease spread is expected, impose isolation on those with contagious disease and the quarantine of those potentially exposed, and decontaminate infected areas when necessary. They should make sure the legal basis for these actions is in place and provide for the personnel needed to perform these functions. And they should pursue cooperative research on potentially needed vaccines and treatments and acquire appropriate amounts of such vaccines and treatments.

Chairman Thornberry, Ranking Member Langevin, and members of the Subcommittee, thank you again for inviting me to testify before you today. I look forward to taking your questions.

Bruce W. Bennett is a senior defense analyst at The RAND Corporation. He specializes in strategy formulation, force requirements, and responding to "asymmetric threats" such as weapons of mass destruction (WMD). His work applies deterrence-based strategy, competitive strategies, risk management, military simulation and analysis, and war gaming. He has examined the operational/strategic implications of possible chemical, biological, and nuclear threats, including nontraditional agents, posed in the United States, Northeast Asia, and the Persian Gulf. His most recent project is working with the operational commanders in Korea to examine force requirements for WMD elimination. He previously supported the US Pacific Command and the US Forces Korea in designing and moderating the Coral Breeze exercises (on chemical and biological agent threats) and the biological weapons countermeasures initiative.

He is an expert in Northeast Asian military issues, having visited the region some 90 times and written much about Korean security issues. His regional research has addressed issues such as deterrence of North Korean threats, the North Korean weapons of mass destruction threats and how to counter them, future Korean military force requirements, the Korean military balance, and dealing with a North Korean government collapse. He recently completed a book on "Preparing for the Possibility of North Korean Collapse."

At RAND, Dr. Bennett has worked with the Office of the Secretary of Defense, the Defense Threat Reduction Agency, the U.S. Army, the U.S. Air Force, the U.S. Pacific Command and Central Command, U.S. Forces Korea and Japan, the South Korean and Japanese militaries, and the South Korean National Assembly.

Dr. Bennett received a Ph.D. in policy analysis from the Pardee RAND Graduate School and a B.S. in economics from the California Institute of Technology.

Statement of Major General (ret.) Philip K. Russell, MD

Before

The House Armed services Committee

Subcommittee on Intelligence, Emerging Threats, and Capabilities

October 11, 2013

Mr. Chairman, members of the committee, thank you for inviting me to discuss problems with the preparedness of our armed forces to deal with the threats posed by biological weapons. It is a problem that I have been deeply concerned about for over thirty years, first as an Army Medical Corps officer and later at Department of Health and Human Services. During my government career, I have had the privilege of managing the development of several vaccines, antitoxins and other medical countermeasures for both biodefense and public health purposes.

In this testimony I would like to make two points. First, the threat that a biologic attack by terrorists or other adversaries poses to our armed forces or our nation is not fully understood or recognized by the leadership of our defensive programs. Second, the medical countermeasure development programs of the Department of Defense essential to protecting our armed forces and our nation have a long, very well documented, record of failure and will continue to fail if no corrective actions are taken.

The first point is based on three in depth studies of the achievements of U.S. offensive biowarfare program which was terminated in 1969 and on analysis of the impact of the technical progress made in recent years by the pharmaceutical industry in terms of the potential capability it provides to our adversaries. These studies, which were conducted by Mr. Joel McCleary, Dr. Keith Wells and myself over the past two years, are based on the existing unclassified documents concerning the former US program and on the oral history of one of its last surviving senior scientific leaders. We also looked at how the advances in biologic manufacturing, bioprocessing, stabilization methods, spray drying and lyophization can be utilized by bioterrorists to produce weapons as effective as those produced by offensive programs of the US and the Soviet Union. Results of these studies have been provided in briefings to members of the intelligence community and to key personnel in the Departments of Homeland Security, Defense, and Human and Health Services.

The most significant finding of these studies was that, after years of research and testing the most effective agents chosen for use as strategic offensive weapons, were tularemia and staphylococcal enterotoxin B (SEB). Plans and equipment were made to use these agents in combination. The bacteria was chosen for its lethality and the toxin for its rapid incapacitation. Extensive field tests including “Red

Cloud," "Watch Dog," and "Speckled Start" proved that these agents used as dry powder aerosols could deliver very high doses over large areas.. Tularemia is one of the most infectious agents known; the human infectious dose determined by studies in volunteers is less that 10 bacteria. It can be grown in culture in a fermenter to concentration of 10^{11} bacteria per ml. A dry powder aerosol can deliver hundreds of thousands of organisms to exposed personnel. Recent studies in monkeys conducted by the Lovelace Institute have proven that very high doses delivered by aerosol cause a devastating pneumonia with a very short incubation period making post-attack therapeutic treatments with antibiotics problematic. Virulent strains of tularemia are readily found in nature. SEB was chosen because is a fast acting incapacitating agent when delivered by aerosol. It causes a pneumonitis and is lethal at high doses. It is stable and relatively easy to produce in culture. High producing strains are widespread and easily found.

The offensive program created very effective strategic weapons but needed industrial level capability to manufacture the weapons they tested and stockpiled. However advances since 1969 in technology now put this capability within reach of any nation state or small number of dedicated terrorists. The pharmaceutical industry in the course of developing delivery of multiple drugs by aerosol and refining biologics manufacturing processes has created the technology and equipment to make bioweapons much more readily available. The information on the new processes is widely published in the public domain and the equipment is available for sale and resale on the internet. The obstacles that the former U.S. offensive program had to overcome such as stability and uniform particle size have been mitigated by modern technology. Our conclusions in regard to the ability of motivated terrorist group to exploit modern technology to achieve what was once only a state weapon's monopoly is accepted without reservation by the leading technical experts in our intelligence community.

The accomplishments of the offensive programs of the U.S. and the Soviet Union have largely been forgotten or ignored by policy makers and product developers. Consequently, there is no specific licensed preventive medical countermeasure available for either of the leading lethal agents of the US offensive program, tularemia or SEB. We rely on antibiotics to deal with tularemia post-exposure and on supportive medical care for SEB. This is an unaddressed national vulnerability.

The Department of Defense created a joint program for advanced development medical countermeasures in 1996. The Join Vaccine Acquisition Program (JVAP) was a major component. A tularemia vaccine was at the top of the requirements list which included several other biodefense vaccines. It is now seventeen years later and no new licensed products have been developed. The deficiencies in our national level of preparedness have been described in detail by the Commission on the Prevention off Weapons of Mass Destruction, Proliferation and Terrorism chaired by Senators Graham and Talent and by the "Bioresponse Report Card" issued by the Bipartisan WMD Terrorism Research Center.

The Department of Defense efforts to develop vaccines have been reviewed and criticized by several independent groups. The "Top Report", a Report to the Deputy Secretary of Defense by an Independent Panel of Experts concluded in 2000 that the program is "insufficient and will fail". Reports by committees of the Institute of Medicine in 2002 and 2004 documented the program failures, criticized

the management of the program, and made recommendations for change. The National Biodefense Science Board addressed the issue of lack of countermeasures in 2010. These external independent advisory groups have had no impact on the program.

Since the origin of the DoD program billions of dollars have been spent. Yet only two vaccines, a plague vaccine and a botulism vaccine, are in advanced stages of development. The attempts to develop an early live attenuated tularemia vaccine to licensure have failed and no significant progress on a second generation product is evident. The problems with the program are detailed in multiple reports. Problems include the DoD contracting mechanisms, which are largely unsuited to working with the vaccine industry, lack of knowledge of the vaccine industry by program managers, and reliance on prime contractors with limited capability. Uncertain funding disrupts programs and, most importantly, lack of accountability by the leadership allows failure to continue.

There is some good news. The basic research programs at USAMRIID continue to be very productive and are creating the scientific basis and early prototypes for several vaccines including the hemorrhagic fever and encephalitis viruses.

In summary, lack of understanding of the threat that the strategic bioweapons produced by the U.S. program continue to pose a major threat coupled with an ineffective countermeasure development program has created a significant vulnerability for our Armed Services and our nation .

Philip K. Russell, M.D.

Retired Major General Philip K. Russell, M.D. served in the U.S. Army Medical Corps from 1959 to 1990, pursuing a career in infectious disease and tropical medicine research.

Following his training in internal medicine, he assumed a succession of research assignments at the Walter Reed Army Institute of Research and overseas laboratories in Pakistan, Thailand, and Vietnam. He conducted laboratory and clinical research on a variety of viral and parasitic infectious diseases, including dengue, malaria, hepatitis, and respiratory viruses.

Russell authored or co-authored more than 100 research publications and contributed to the successful development of several vaccines important to the military and public health, including those of adenovirus, meningitis, and hepatitis A and B. Later, as director of the Walter Reed Army Institute of Research, he led research on vaccines against dengue and malaria. As commander of the U.S. Army Medical Research and Development Command, he spearheaded a major effort to increase the capability of the armed forces to defend against biological agents. His military awards include the legion of Merit and the Distinguished Service Medal.

Following his military service, Russell joined Johns Hopkins University's School of Hygiene and Public Health as professor of international health and worked closely with the World Health Organization as special advisor to the Children's Vaccine Initiative. He was founding board member of the International AIDS Vaccine Initiative. After becoming professor emeritus in 1997, he served as an advisor to the Bill and Melinda Gates Foundation as well as several vaccine programs and was instrumental in creating the Malaria Vaccine Initiative.

Russell has served on numerous advisory boards of national and international agencies, including the Centers for Disease Control, Nation Institutes of Health and the Institute of Medicine, He served on the Boards of Directors of the International Vaccine Institute, the Aeras Foundation, and the Albert B. Sabin Vaccine Institute. Following the anthrax attacks in 2001, Russell led a Department of Health and Human Services effort to develop and stockpile vaccines and other medical countermeasures against bioterrorism agents. He continues to work on the development of vaccines for the developing world.

HEARING BEFORE THE ARMED SERVICES COMMITTEE
SUBCOMMITTEE ON INTELLIGENCE,
EMERGING THREATS AND CAPABILITIES
U.S. HOUSE OF REPRESENTATIVES

"Biodefense: Worldwide Threats and Countermeasure Efforts for the Department of Defense"

October 11, 2013

Brett P. Giroir, M.D.
Interim Executive Vice President and CEO
Texas A&M Health Science Center

Chairman Thornberry, Ranking Member Langevin, and members of the committee, thank you for the opportunity to be here today. I appreciate the opportunity to discuss government efforts and opportunities for collaboration to address our nation's biodefense priorities.

I am currently the Interim Executive Vice President and CEO of the Texas A&M Health Science Center and Principal Investigator for the Texas A&M Center for Innovation in Advanced Development and Manufacturing, a public-private partnership with the U.S. Department of Health and Human Services designed to enhance the nation's emergency preparedness against emerging infectious diseases.

My pathway to this position includes a career as an academic physician scientist, focusing on life threatening infectious diseases, particularly those diseases affecting adolescents and young adults. As a result of work in this field, I was invited to serve on one of DARPA's non-governmental science and technology assessment panels, the Defense Sciences Research Council (DSRC), which was responsible for developing concepts that could potentially lead to DARPA initiatives and "game-changing" capabilities benefitting national security. In this role, I chaired or co-chaired numerous intensive studies on chemical, biological, radiological, and nuclear (CBRN) security and countermeasures, decontamination, and warfighter performance under extreme conditions.

After five years on the DSRC, I was privileged to serve as Deputy Director, and then Director, of the Defense Sciences Office at DARPA, and honored to be the first medical doctor to become an office

director in the 50 year history of that agency. In my role as Director, working with a multidisciplinary team of the nation's finest scientists, physicians, and engineers, and with the budgetary opportunities provided to us by Congress, we developed and implemented an integrated platform of research initiatives, named Accelerating Critical Therapeutics (ACT), designed not only to provide new, highly effective medical countermeasure capabilities, but also to provide an unprecedented, flexible, adaptable, and rapid response to address and defeat the pervasive and growing threat of highly genetically modified or chimeric organisms for which the nation had no pre-existing vaccines, countermeasures, or technical approaches. Many DARPA programs begun at that time are now operational and have made an enormous impact on our public health preparedness and response.

One aspect of the portfolio that was extraordinarily challenging, even by DARPA standards, was the ability to develop low cost, highly flexible and adaptable manufacturing technologies capable of providing tens of millions of doses of vaccines or medical countermeasures (such as monoclonal antibodies or antidotes to chemical weapons) within weeks of notification. Such a capability did not exist in the civilian or military experience, and there were profound technical barriers to overcome. Among these barriers were traditional manufacturing facility architectures that were generally single use, and cost $1 billion or more. In addition, production platforms such as fertilized chicken eggs necessitated an enormous logistics tail, and therefore had very limited rapid response capabilities, even when heroic efforts were made by the U.S. Government and industry, as demonstrated in the 2009 H1N1 pandemic.

The concept of developing 21st century manufacturing capabilities had many champions, including DARPA and its technical assessment panels, leading academic groups such as the National Academy of Engineering and the University of Pittsburgh Medical Center, as well as many senior government officials including the President's Special Assistant for Biosecurity. Nonetheless, there was no obvious mechanism to test and implement these concepts, because there were no U.S. Government programs in place, and the concepts were far too innovative and high risk to be adopted by the commercial biopharmaceutical industry.

Implementation of 21st Century Manufacturing and Response at Texas A&M

The Texas A&M University System (TAMUS) is one of the largest systems of higher education in the nation, with a statewide network of 11 universities, seven state agencies, two service units and a comprehensive health science center. Led by Chancellor John Sharp, A&M System members educate more than 125,000 students and reach another 22 million people through service each year. With more than 28,000 faculty and staff, and a budget of approximately $3.8 billion annually, the A&M System has a physical presence in 250 of the state's 254 counties and a programmatic presence in every one. In 2011, externally funded research expenditures exceeded $780 million making it one of the premier research and development institutions globally.

In 2008, my assignment to DARPA was completed and I joined the Texas A&M System. Because the nation's security against CBRN threats was dependent on the development of highly flexible and adaptive manufacturing technologies, and to protect the U.S. commercial industry and tens of thousands of domestic jobs, we assembled a core team of scientists and engineers to fully leverage Texas A&M's robust resources and historical commitment to national service. Our mission was to perform the "proof of concept" breakthrough implementation of a flexible manufacturing facility that eventually could be the technological model for a national program.

With the enthusiastic support of Texas Governor Rick Perry, the Texas A&M Regents, and Chancellors McKinney and Sharp, and with a $50 million investment from Texas Emerging Technology Fund, our team aimed to design, develop, build, and operate a facility and associated program that would demonstrate: 1) highly flexible, adaptable, mobile manufacturing architectures and platforms, 2) an unprecedented response capability against emerging and intentional threats, and 3) a capital cost at least 80% less than the current state of the art. We named the project the National Center for Therapeutics Manufacturing (NCTM). The NCTM is now the core facility and primary site for developing and manufacturing Medical Countermeasures and Vaccines against CBRN threats for the Texas A&M Center for Innovation. A full description of the NCTM is provided below.

Overview of the Department of Health and Human Services Texas A&M Center For Innovation in Advanced Development and Manufacturing (CIADM)

The Texas A&M CIADM is the most highly funded of three national centers competitively awarded by the Department of Health and Human Services in June 2012, and is the only Center led by an academic institution. It is founded on an initial $285.6 million public-private partnership, consisting of approximately $176 million committed investment by the HHS, and $109 million supplied as cost share by academic, commercial, and State of Texas stakeholders and collaborators. The Center is designed to enhance the nation's preparedness and response against emerging infectious diseases, including pandemic influenza, and chemical, biological, radiological and nuclear threats. The Center will perform advanced research, facilitate development, ensure domestic manufacturing capacity, enable product FDA approval and mentor the next generation of public health professionals through education, training and outreach. The initial $285.6 million contract, over a five-and-one-half year base period, will result in the establishment of ***all capabilities*** required by the U.S. Government. In addition, there is a total potential contract duration of 25 years, including an additional >$2.4 billion in readiness and task order options that can be exercised at the discretion of the U.S. Government.

The Center leverages over $200 million in prior investments by the Texas A&M University System and the State of Texas in facilities and programs dedicated to advanced development and manufacturing of biopharmaceuticals. The specific high level objectives of the Center are the following:

- Provide the strategic national vaccine response to pandemic influenza, defined as 50 million vaccine doses delivered to the U.S. Government within four months, with initial doses available in 12 weeks;
- Research, develop, and manufacture vaccines and medical countermeasures to chemical, biological, radiological, and nuclear (CBRN) threats as requested by HHS; and
- Train the U.S. national workforce in biopharmaceutical manufacturing, animal model development, biosecurity-related clinical trials, and regulatory approval processes.

Subcontractors and Collaborators

Texas A&M has assembled a multidisciplinary team of subcontractors with expertise that spans the spectrum of disciplines needed to achieve the objectives, including process development, flexible manufacturing, preclinical testing (including BSL3 and BSL4 capacity), clinical trials, quality assurance/control, and regulatory affairs. Key subcontractors include:

- GlaxoSmithKline Vaccines (GSK): The world's largest vaccine developer with 30+ vaccines marketed worldwide, 11 licensed by the FDA, and 1.4 billion doses distributed annually. GSK is providing the cell based pandemic influenza vaccine candidate, as well as their proprietary adjuvant technology, to TAMUS in order to meet the nation's pandemic influenza vaccine surge requirements.

- Kalon Biotherapeutics (Kalon): The commercial development and manufacturing organization (CDMO) founded and owned by Texas A&M and the State of Texas, which provides core process development and manufacturing services for CBRN vaccines and medical countermeasures. Kalon is also GSK's development partner for its cell-based pandemic and seasonal influenza vaccines. Kalon staff includes former leaders from the global biopharmaceutical industry including Sanofi-Pasteur, Novartis, and Medimmune. These experienced professionals are already being supplemented by recent graduates from the Center's workforce development program.

- Other CIADM Partners include Lovelace Biomedical and Environmental Research Institute (non-profit research organization that conducts pre-clinical CBRN studies including nerve agents), UTMB-Galveston National Laboratory, Lonza (global pharmaceutical services company), Caliber Biotherapeutics (plant made vaccines and biopharmaceuticals), the Sabin Vaccine Institute at the Baylor College of Medicine (non-profit vaccine development institute), Sartorius (leading global bioprocess technology provider), and multiple Texas A&M System Components including the Texas A&M Institute for Preclinical Studies, the Texas A&M Engineering Experiment Station, Texas A&M University, and the Texas A&M Veterinary Diagnostic Laboratory.

- Collaborations: In addition to the above established partnerships, TAMUS has new collaborations with multiple entities focused on specific aspects of the CIADM, or related product development. Among these collaborations are confidential global pharmaceutical corporations, biotechnology companies, adult stem cell and cell therapeutics companies, the MD Anderson Cancer Center, and the University of Texas in Austin.

Biomanufacturing Infrastructure

The CIADM is leveraging pre-existing process development and manufacturing infrastructure at Texas A&M, but will also design, construct, and validate additional core facilities to supplement existing infrastructure. Among the key Center facilities now in design and/or construction are the following:

- National Center for Therapeutics Manufacturing (NCTM)
  Status: Operational and undergoing expansion and enhancement. All retrofit and upgrade activities are scheduled for completion by March 2014.

  The NCTM is a revolutionary, first-in-class, multi-product, multi-technology, 150,000 sq. ft. biopharmaceutical development and manufacturing facility. A key feature of the NCTM is the use of Modular Clear Rooms (MCRs), which are newly-developed, standalone, modular, **mobile**, self-contained and fault-tolerant biopharmaceutical clean rooms. The initial MCR concept was funded by the Department of Defense through DARPA and ARO. Through the NCTM project, TAMUS has developed, implemented, and validated novel bioprocess architectures that provide solutions for the commercial industry and the U.S. Government.

  These solutions include: the ability to accommodate multiple (up to six) simultaneous products up to the 1000 liter (L) scale in support of Phase I through Phase III clinical trials, as well as commercial manufacturing; flexibility to fundamentally rearrange, in near real-time, entire unit processes and clean room suites without disruption of simultaneous ongoing operations; the ability to surge multi-fold on a single product, within 24 hours, as needed to support biosecurity or commercial clinical needs. The NCTM also maintains limited fill and

finish capabilities primarily in support of clinical trials.

The NCTM is being expanded, enhanced, and outfitted for large scale operations via the CIADM contract, including the provision of an additional eight MCRs.

- Pandemic Influenza Vaccine Facility (PIF)
  Status: Design development completed; construction and initial facility commissioning are scheduled for completion by the 3rd quarter of 2015.

  The PIF will be a new, stand-alone, 100,000 sq. ft. facility designed to supply bulk antigen to meet the U.S. Government requirements for 50 million doses of pandemic influenza vaccine within four months, with the first doses supplied in twelve weeks. The PIF emphasizes the use of flexible, single use technologies, made possible by the highly advanced cell based production system from GSK. Within seven years, it is expected that the PIF will have no ongoing readiness costs charged to the U.S. Government, because it will also function as the licensed manufacturing facility for GSK's cell based seasonal influenza vaccine for North America. When not supplying commercial or pandemic influenza vaccines, the PIF is available for production of other CBRN countermeasures, particularly monoclonal antibodies and therapeutic proteins. The PIF will be operated by Kalon in partnership with GSK.

- Live Virus Vaccine Facility (LVVF)
  Status: Completed advanced schematic design, scheduled for completion of construction and commissioning by the 3rd quarter of 2015.

  The LVVF will be a new, stand-alone facility, adjacent to and synergistic with the PIF, dedicated to the process development and manufacture of live virus vaccines including products that require BSL-3 level biosafety. The LVVF will primarily focus on vaccines and countermeasures for biothreat agents, but also on commercial vaccines that utilize similar technologies. Live virus vaccines are emerging as a major platform technology for a variety of civilian diseases, including cancer. The current concept calls for an approximately 70,000 sq. ft. facility utilizing a combination of fixed modular, and mobile modular (MCRs), and the ability to more than triple its initial capacity as demand for live virus vaccines increases in

the next decade. To reduce capital and operational costs, the LVVF will leverage core infrastructure, such as power and utilities, from the adjacent PIF.

- Fill and Finish Facility
  Status: In phase of defining a program of requirements.

  This facility, to be located within the United States, will provide comprehensive large scale fill and finish capabilities for the CIADM as well as other government and commercial customers. The primary objective is to supply the CIADM with capability for fill and finish of live virus vaccines, to the level of two million vials per year. We also expect the facility to maintain additional capabilities including lyophilization for both viral and non-viral based vaccines. The operational partner for this program is currently under evaluation and selection by Texas A&M leadership team in collaboration with HHS.

- Process Development Facility (PD Facility)
  Status: In concept design, scheduled for completion in early 2015.

  To expand on current PD capabilities, the CIADM will build a flexible PD capability designed to support a full range of manufacturing platforms and products, from microbial to insect cell and mammalian systems, and products ranging from personalized protein and DNA vaccines, to monoclonal antibodies and therapeutic proteins.

- Caliber Biotherapeutics Facility
  Status: Completed and operational.

  Developed and built through a consortium comprised of Texas A&M and G-CON, LLC, and funded by the DARPA Blue Angel Program, the CIADM has partnered with Caliber Biotherapeutics to make available Caliber's plant-made pharmaceutical facility for HHS task orders, including vaccines and monoclonal antibodies. The facility has the capability to produce up to 20 kg of purified protein per month through its highly automated, *Nicotiana benthamiana*, plant-based production system; we consider this program to be the most responsive, secure, and capable plant-made vaccine program currently available worldwide.

Workforce Training

The Texas A&M Engineering Experiment Station (TEES) and TEES subcontractors {(Baylor College of Medicine, Blinn College, and Texas A&M Engineering Extension Service (TEEX)}, are already providing comprehensive workforce training in all aspects of process development and biopharmaceutical manufacturing at the technical certificate level through post-graduate, professional training.

TEES has already performed a workforce needs assessment, established an advisory committee that includes multiple industry partners, developed preliminary curricula, begun training courses, and implemented an internship program with CIADM pharmaceutical partners. As an option to the US Government which may be exercised in the future, TEES and subcontractors will also provide training in preclinical models, including BSL-3 and BSL-4 procedures, as well as diagnostics and regulatory science.

The workforce training program builds on a pre-existing program initiated by TEES under the sponsorship of the Texas Workforce Commission. TEES has also begun an innovative STEM summer initiative for high school students, primarily from historically underserved groups, aimed at developing a diverse, highly qualified work force. TEES completed is second summer program in 2013, all self-funded by TEES, with remarkable successes in generating both strong interests as well as life-changing experiences for underserved students. It is hoped that the federal government will support such efforts aimed at underserved STEM education, and expand these programs nationally, to assure a future workforce that is both diverse and capable.

Department of Defense Opportunities

As a leading academic institution with a history of dedicated national service, TAMUS is highly motivated to leverage its capabilities to support the Department of Defense (DoD) requirements for CBRN vaccine and medical countermeasure development, manufacturing, licensure, and delivery to warfighters. In addition to pre-existing capabilities at TAMUS and its subcontractors, at least 50% of CIADM capabilities will also be available for non-HHS projects. As such, TAMUS has been independently monitoring and submitting proposals to DoD through open solicitations, including two

recent Requests for Information (RFI) seeking capabilities for the development and manufacturing of vaccines and therapeutics of interest to the DoD.

Of particular interest to TAMUS is the exploration of partnerships within the LVVF and NCTM, as well as the Process Development facility, all of which could develop and manufacture DoD products for the stockpile, special immunization programs, as well as provide the basis for emergency response to "unknown unknowns" including genetically modified or chimeric organisms. The available Texas A&M capacity, which is already funded by HHS, would not only dramatically reduce operational risks, but would also substantially reduce DoD capital expenditures and operational costs. It is important to note that the HHS capacity is meant to serve 300 million civilians, so the addition of capacity for DoD personnel, staff and families could be easily accommodated. Moreover, the great majority of vaccines and countermeasures will be identical to those developed for civilians.

There are several models for partnership that would provide priority for DoD needs over commercial or academic projects. Among these of high interest to TAMUS is a "civil reserve air fleet, or CRAF, model" in which the DoD reserves space with priority for an annual fee which can be applied to DoD task orders.

By leveraging nearly $500 million in Texas, Texas A&M, and DHHS investments, we believe that the DoD could achieve its mission at low risk, minimal initial capital outlay, and easily sustained operational costs. Our preliminary estimates suggest that by utilizing the pre-existing and already funded capacity provided by HHS, the DoD can guarantee all the availability required, with substantially less risk, for *ten years*, at approximately half of the initial facility costs budgeted for a dedicated DoD facility. This would free up substantial resources that could be reallocated to provide additional vaccines, countermeasures, and capabilities to our warfighters. Furthermore, the co-location of HHS and DoD programs would enhance cooperation, reduce duplication, and increase the likelihood for enhanced quality and responsiveness.

In conclusion, I believe the federal government's current investment in biodefense and CBRN countermeasures, primarily through HHS, should be a focus for collaboration, risk reduction, and cost effectiveness for the DoD. Through the three recently awarded Centers for Innovation in Advanced Development and Manufacturing (ADM) , the nation now has the capacity to develop,

manufacture, and stockpile a wide array of medical countermeasures arising from diverse platforms. Better coordination and collaboration among the DoD, HHS, and these public-private partnerships would maximize the use of limited resources and provide a more efficient and productive return on the government's overall investment in this critical area of national security.

HEALTH SCIENCE CENTER
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Dr. Brett Giroir assumed interim leadership of Texas A&M Health Science Center in October 2013. The Texas A&M Health Science Center is a premier assembly of colleges devoted to educating health professionals and researchers that seeks to transform health through innovative teaching and research in dentistry, medicine, nursing, biomedical sciences, pharmacy and public health.

Prior to joining the Health Science Center, Dr. Giroir served as Vice Chancellor for Strategic Initiatives for the Texas A&M University System and Principal Investigator for the Texas A&M Center for Innovation in Advanced Development and Manufacturing, a public-private partnership with the U.S. Department of Health and Human Services designed to enhance the nation's emergency preparedness against emerging infectious diseases, including pandemic influenza, and chemical, biological, radiological and nuclear threats.

Dr. Giroir received his undergraduate degree in Biology, *magna cum laude*, from Harvard University and his medical degree from the University of Texas Southwestern Medical Center, *Alpha Omega Alpha*. His post-doctoral training was conducted at the Howard Hughes Medical Institute in Dallas under the mentorship of Dr. Bruce Beutler. Dr. Giroir remained on the faculty at UT Southwestern from 1993-2004, achieving a rank of tenured Professor. He held two endowed chairs, and served as the Associate Dean for Clinical Affairs at UT Southwestern Medical Center, as well as the first Chief Medical Officer at Children's Medical Center of

Dallas. He has published extensively in both the basic and clinical literature, with special emphasis on host-pathogen interactions and novel therapies for life-threatening infectious diseases.

As a member of the Defense Research Council from 1999-2004, he served as Co-Chair for several studies including Advanced Biological Weapons Decontamination, Joint Studies on Biological and Chemical Weapons Proliferation, Universal Medical Countermeasures to Biological Threat Agents, and Agricultural Biotechnology and Bioterrorism. From 2004 until 2008, Dr. Giroir accepted the opportunity to serve in the Federal Government as Deputy Director, then Director, of the Defense Sciences Office of the Defense Advanced Research Projects Agency (DARPA) in Arlington, Virginia. Dr. Giroir directed a research portfolio of approximately $450 million annually that spanned from fundamental physics to biodefense. Dr. Giroir was appointed by USD-ATL to serve on the Threat Reduction Advisory Committee (TRAC) from 2008 – 2010, during which time he chaired the Chemical and Biological Defense Panel.

Dr. Giroir is currently a member of the Scientific and Prevention Advisory Council of the Cancer Prevention and Research Institute of Texas (CPRIT), the Scientific Advisory Boards of the Biodesign Institute at Arizona State University and the A. Alfred Taubman Medical Research Institute at the University of Michigan, and on the Board of Directors for BioHouston and NASA's National Space Biomedical Research Institute. Dr. Giroir is a former member of the American Board of Pediatrics, the Defense Sciences Research Council, The NASA Planetary Protection Panel, and an alumnus of the Defense Sciences Study Group.

Dr. Giroir is the recipient of the Secretary of Defense Medal for Outstanding Public Service, the Texas A&M University System Excellence in Innovation Award in 2010, and was a finalist for the 2012 Dallas Morning News Texan of the Year Award. He is a native of Marrero, Louisiana, is married to Jill S. Giroir, J.D., and has two daughters, Jacqueline (Texas A&M '11) and Madeline (Texas A&M '15).

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