NATIONAL STRATEGY FOR COUNTERING BIOLOGICAL THREATS: DIPLOMACY AND INTERNATIONAL PROGRAMS

HEARING

BEFORE THE

SUBCOMMITTEE ON TERRORISM, NONPROLIFERATION AND TRADE

OF THE

COMMITTEE ON FOREIGN AFFAIRS
HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

MARCH 18, 2010

Serial No. 111–91

Printed for the use of the Committee on Foreign Affairs

Available via the World Wide Web: http://www.foreignaffairs.house.gov/

U.S. GOVERNMENT PRINTING OFFICE

55–516PDF WASHINGTON : 2010

For sale by the Superintendent of Documents, U.S. Government Printing Office
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CONTENTS

NATIONAL STRATEGY FOR COUNTERING BIOLOGICAL THREATS: DIPLOMACY AND INTERNATIONAL PROGRAMS

THURSDAY, MARCH 18, 2010

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON TERRORISM,
NONPROLIFERATION AND TRADE,
COMMITTEE ON FOREIGN AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:07 a.m. in room 2172, Rayburn House Office Building, Hon. Brad J. Sherman (chairman of the subcommittee) presiding.

Mr. SHERMAN. We are going to have a special treat at today's hearings. In the past, witnesses have been confined to only 5 minutes. Today's witnesses will be speaking for 7 minutes or less. That will bring a special entertainment value. We are in tough competition on C-SPAN for higher ratings. The questioning period will be 5 minutes and opening statements will be five or seven or however long we take.

There has been much recent attention to the threat that bioterrorism poses to our national security. Today's hearing provides a broad overview of our diplomatic and international effort to counter that threat. Earlier this year, the Weapons of Mass Destruction Commission, chaired by Senators Graham and Talent, issued a report card that included an assessment of our progress in biodefense.

Their initial report found biological weapons are more likely to be acquired and used by terrorist groups than nuclear weapons. Although I might add that it is my belief that bioweapons would cause a lesser number of casualties; a smaller though more likely disaster.

Indeed, the commission found that unless the world community acts decisively and with great urgency, it is more likely than not that a weapon of mass destruction would be used in a terrorist attack somewhere in the world by the end of 2013. Since we have already seen the use of anthrax and the use of chemical and biological weapons in Japan over recent decades, this seems to be relatively safe prediction.

The report further identified several weaknesses in our national biodefense, including the need for stronger Congressional oversight. This hearing is part of that oversight, and follows my request that the International Security and Biopolicy Institute prepare a report on our international efforts to counter biological threats.

Without objection, I would like to put that study into the record of this hearing. Hearing no objection, so ordered.

The hearing also provides us an opportunity to examine the Obama administration's national strategy to address biological threats.

When the Graham/Talent Commission issued its assessment and report card on national progress in the WMD area, it contained sharp criticism of our national efforts to improve biodefense.

The commission issued a failing grade, a grade of F, for U.S. efforts to mitigate the effects of biological attack. I do not fully agree with this grade. And it found that our international efforts, personified by our first witness here deserved a grade of between A and B; considerably better than most other aspects addressed in the report.

It is important to note that others have countered that the commission has over-estimated the threat of biological attack. Some critics contend that we have spent too much on domestic preparedness, some $64 billion since 9/11 and the anthrax attacks.

I have often said that the use of the term WMD is misleading, because it lumps into one category mustard gas and hydrogen bombs, along with all chemical, radiological and biological and nuclear threats.

Even a crude nuclear explosive with a small yield could kill tens of thousands of people. Those uses of biological and chemical weapons against first world countries—here in the United States, Japan, and elsewhere, have involved dozens of casualties, rather than tens of thousands.

I would hope our witnesses would be able to describe how they believe biological threats could lead perhaps to a mass casualty event; and it is important that we understand the nature and the possible casualties of different types of biological attacks.

When it comes to biological threats confronting us today, we must consider the parallel threats from state-sponsored use of biological weapons, and from biological attacks perpetrated by terrorist groups. One of the longest-standing efforts to counter state-sponsored biological weapons programs is the Biological Weapons Convention, the BWC, which went into effect in 1975. Since that time, the BWC has not had a verification regime anywhere similar to the verification regimes we have for nuclear and chemical weapons.

Some, including past administrations, have argued that traditional verification protocol could not keep pace with rapid developments in biological research; that basically biological weapons can be created in so many different facilities, legitimate facilities like the vaccine plant, "too hard to detect," say some.

Most recently in December, our good friend, Under Secretary for Arms Control Ellen Tauscher, reaffirmed the U.S. position on BWC compliance without seeking a verification protocol. The administration instead—and I think this is somewhat controversial—is trying to control biological weapons by disclosing the bioresearch that we are doing in Maryland and elsewhere.

Some were saying this is telling the terrorists what defenses we have. Others would say that this is reassuring other countries in

the world that our bioresearch is only for defense and constitutes a confidence-building measure (CBM).

I look forward to learning more about how the United States can promote greater BWC compliance and verification without letting the bad guys know what our defenses are.

The threat of a biological attack from a terrorist group presents a more amorphous problem, and they have argued that recent progress in biological research has greatly reduced the barriers to the development of bioweapons by relatively small groups and even individuals; provided they have the necessary technical competence.

United States Government programs seek to engage foreign scientists and give them something to focus on, and not be up for hire by those seeking to create proliferation, now focus on the biological sciences as well as the nuclear sciences.

I am eager to hear about the State Department's efforts in this regard through the Biosecurity Engagement Program and other diplomatic efforts.

Finally, the ability to detect and assess infectious disease outbreaks, whether naturally occurring or intentionally instigated, is both important from a global public health standpoint, and from the standpoint of mitigating the impact of a biological attack.

The internal health risk posed by H1N1 and SARS indicate that pathogens show little regard for national borders, and modern jet travel can transport these infectious agents from anywhere in the world to the United States.

The Obama administration's national security strategy to counter biological attacks emphasizes the need for global disease surveillance as part of our national defense. Similarly, instruments like the International Health Regulations provide a framework for improving disease surveillance and reporting worldwide.

In this regard, I continue to be concerned that Indonesia is not cooperating with the United States, particularly by not providing samples of avian flu found in that country; and I will address that in the questioning of the witnesses.

Such efforts can simultaneously improve health, even in the most impoverished parts of the world; while at the same time fostering international biosecurity. I think I will conclude now, since my time has expired, and hear the words of our ranking member, Mr. Royce, from the great State of California.

Mr. ROYCE. Thank you very much, Mr. Chairman, for calling this hearing. I think that bioterrorism really demands a lot greater attention by the administration, by the Congress, frankly, by everyone.

This biological warfare really dates back to the beginning of recorded history. The world's first true historian, Thucydides, almost lost his life as a result of a technique that Persians and Greeks and Romans used of throwing carcasses down a well to poison it.

And I think Athens lost a greater percentage of its population in the war with Sparta to this biological effect, than they did to the Spartan war machine. So it has a long history of being used in warfare.

And today, germs present really a mass destruction threat, if we think about it. Scientists have been able to assemble infectious vi-

ruses, including the formerly extinct 1918 influenza strain. That strain killed 30 million people.

So every advancing technology and biotechnology just continues to proliferate. Several years ago, just outside of Moscow, I met with the so-called Father of the Plague; and I think his moniker might have been a bit overstated. But that is how the Russians referred to him. He was the top Russian scientist, and he had allegedly developed a genetically altered pathogen that had no antidote.

He wanted us to meet with him, because he had been able to at least put an alarm system into the Moscow subways. He had never been outside of the country. But presuming we used subways, he wanted us to have this technology.

You know, he really was sort of an insight. He wanted Jim Saxton and I to know the extent of what they had done. They had 50,000 people in the Soviet biological weapons program at one point; a massive USSR violation of its BWC Treaty commitment, by the way. And he shared with me his concern that some of this legion had sold their expertise to Middle East countries.

It is regrettable that the Russians have lessened their cooperation with our joint efforts to contain this proliferation. Over 10 countries today may have bioweapons programs.

Al-Qaeda has sought biological weapons. Evidence seized in the 2003 arrest of Operations Chief Khalid Sheikh Mohammed revealed impressive technical sophistication, including information on weaponizing anthrax. Now that is one of those subjects that I discussed with the Russian scientist.

That was 7 years ago. By the way, one of his students subsequently defected, and we had a chance to talk with him here in the United States. He confirmed what his professor had taught him; or what his mentor had taught him in this technology, and he was now trying to help us better understand what had been developed.

Unfortunately, I am afraid that there is a great deal of complacency; and maybe complacency is normal. But the 2001 anthrax attack—that little fiasco—cost us $6 billion and some American lives. Local officials speak of having to fight citizens' indifference to bolster our resilience to attack; that is just a realty.

Ringing an alarm is the Bi-Partisan Commission on the Prevention of Weapons of Mass Destruction, Proliferation, and Terrorism. It concluded that "our margin of safety is shrinking; not growing." The commission believes that unless decisive and urgent action is taken, then a WMD terrorist attack is likely to occur somewhere within 4 years. "This attack" the commission speculates, "is more likely to be biological than it would be nuclear."

The commission reports that each of the last three administrations have been slow to recognize and respond to bioterrorism. The Obama administration, it found, lacks a sense of urgency. The commission gave the administration an "F" for not improving our biological attack response capabilities.

I am looking forward to hearing from the administration today about why it thinks the commission gave it too tough a grade. Thank you, and I yield back, Mr. Chairman.

Mr. SHERMAN. We will now hear an opening statement, if he chooses to give one, from our vice chair, Mr. Scott.

Mr. SCOTT. Thank you, Mr. Chairman. This is a very timely hearing; very important hearing. I think we do face a serious probability and possibility of a bioterrorist attack.

In my capacity as chairman of our Agriculture subcommittee on food safety, it is an issue of soaring magnitude. Largely because of our food supply, the nature of it, the free movement of it, the international aspects of it, the fact that we are, in fact, the bread basket of the world certainly looms very large in terms of the attractiveness as a target by terrorist groups.

So as scientific progress marches on, we certainly have the potential and increasingly the capabilities to address many of the threats that we are facing. From developing new strains of rice to address world hunger; for vaccines that prevent the spread of disease like H1N1, scientific knowledge can and largely has led to the betterment of mankind, and continues to raise our living standards for all.

But, however, like any knowledge, there is the potential for those who would wish us harm to unleash devastating attacks. We must not only prepare for that chance; but do our very best to prevent.

Our most recent attack from a chemical biological weapon shows the sophistication and the change of tactics of terrorists, from our Christmas Day underwear bomber over a plane in New York. Who would have thought that a mere mixing of a chemical in one's under garments could blow a plane out of the sky?

But this very serious scientific technological knowledge that we have to unleash great goodness across the world is the same technology that can be used in a warped backward evil sense, to cause us great harm. And we have got to be prepared to do everything we can to prevent this.

In my travels to Russia and to Africa, every part of the nation we have been in, in the part of the world that we have been in, it just alarms me as to the laxness of our international approach; and trying to get an international cooperation, to understand the urgency of it; and our food supplies are so interchanged nationally.

Just to take one example, 90 percent of all of the tomatoes that we use in this country come from outside this country. We are so inter-dependent internationally that we must move very rapidly to understand.

As I said, biological science has led to great advances in addressing our food shortages and develop famine resistant crops. However, the agriculture sector in our nation's food supply overall can be very enticing targets for acts of bioterrorism.

As our agriculture sector, as I mentioned, is known as the bread basket of the world, it is important to note that any attack on our food supply could have the devastating effects for the rest of the world.

And then I mentioned, we are moving very rapidly in our own home state of Georgia, where the University of Georgia's very prestigious agriculture department is putting first a world class food supply, food security process that we are all going to be taking a closer look.

And while, of course, we must make sure to address preventing the spread of disease outbreaks and protecting our water supply, or counter or avert direct attacks like the 2001 anthrax attack,

which we thought was a systematic, well orchestrated attack from multi-faceted approaches. But we come to find out, it was by one man; one man responsible for that devastating anthrax attack.

So this looms big, Mr. Chairman; and I am very delighted that you put this together. I think we can get some answers to some questions. We need to have uniform definitions. What constitutes a biological weapon; and is that constitution accurate for every country? How can we tighten our international cooperation? Because that is the key.

They are very, very serious questions. I look forward to the witnesses; and thank you, Mr. Chairman for putting this together.

Mr. SHERMAN. Thank you. At this point, we will hear from our first witness. Oh, excuse me, Ambassador Watson has come, and we wish to hear her opening statement.

Ms. WATSON. I would say good morning to the chairperson; and thank you for convening today's hearing to review our national and international response to countering biological threats.

It is never too early to discuss and review the effectiveness of current policies and practices, so that we might learn what works; evaluate what does not; and revise or strengthen national and international efforts to prepare for and hopefully prevent the next biological attack.

In recent history, when we think of a biological terrorist attack, it is not hard to forget the aforementioned anthrax attacks here in Washington, after the tragedy of September 11, 2001; where five people were killed and 17 others infected.

Since then, agencies across Federal, state, and local governments have taken steps to address issues of prevention, training, evaluating resources, and coordinating efforts; as well as increasing public education, participation and awareness.

Some have noticed that while there are many agencies in departments that have resources dedicated to prevention and mitigating damage and harm to the public, there is still a large gap in interagency and inter-governmental communications and coordinations.

Others have also noted that while it is important to have regulation and oversight of bi-containment technologies and control of high containment laboratories, the Federal Government must not stifle or inhibit international academic collaboration in order for the scientific community to continue its study on biological chemicals.

In this committee, we have addressed export controls and review of the Arms Export Control Act, and the Export Administration Act, which operates on the principal that the export of certain goods requires licensure specifically denying such licenses if the items will contribute to biological weapons proliferation.

Mr. Chairman, as lawmakers, we have a responsibility to evaluate policy and close gaps in order to strengthen and protect our citizens. We also have an obligation to work toward international transparency and diplomatic efforts.

I appreciate the panel for taking time to appear before this committee. I look forward to hearing and listening to the witnesses testimony. And I do indeed want to thank you, and I yield back the balance of my time.

Mr. SHERMAN. I thank the Ambassador for joining us here and for that opening statement. We now turn to our first witness. I want to introduce Vann Van Diepen. Mr. Van Diepen has been the Principal Deputy Assistant Secretary of State, PDAS, for International Security and Nonproliferation since June 2009.

The International Security and Nonproliferation Bureau spearheads U.S. efforts to promote consensus on WMP proliferation through bilateral and multi-lateral diplomacy; Mr. Van Diepen?

STATEMENT OF MR. VANN H. VAN DIEPEN, ACTING ASSISTANT SECRETARY, BUREAU OF INTERNATIONAL SECURITY AND NONPROLIFERATION, U.S. DEPARTMENT OF STATE

Mr. VAN DIEPEN. Thank you, Mr. Chairman and members of the subcommittee. I want to thank you for the opportunity to appear today. The President's new National Strategy for Countering Biological Threats signals a major development in our international efforts to combat those threats. And today, I would like to share more information on the activities that we conduct at the State Department to implement that strategy.

I would like to request that my prepared testimony be included in the record of today's hearing; and I will present a shorter version here in my oral statement.

What I intend to do is to take a moment to outline the threat, and then describe some key activities that the State Department is undertaking internationally to implement the strategy.

As already indicated in many of the opening statements, Congress is keenly aware that there is a real and present danger of biological attack, given the 2001 anthrax attacks. The most obvious and recent danger comes from terrorist groups that have expressed an intent to obtain biological weapons, especially al-Qaeda. And we are also concerned about the ambitions of some nation states to develop biological weapons.

A successful attack using a pathogenic agent could not only result in sickness and death; but could cause panic, loss of public trust, and enormous economic damage.

The President's strategy complements our preparations to respond to biological events, by placing more emphasis on efforts to prevent such events; or at least to reduce the likelihood that they will take place.

State's efforts to implement the strategy internally are focused on reducing the likelihood that terrorists or states interested in biological weapons could obtain the experience or materials to develop and use them. Working with the international community to transform the dialogue on biological threats is a key objective in the strategy; and State plays a critical role in achieving this objective by working through existing multi-lateral mechanisms.

Today, I am going to highlight our work in the Biological Weapons Convention, the State Department's Biosecurity Engagement Program, and in the G–8 Global Partnership against the spread of WMD.

In each of these areas, there is a new-found urgency related to the need to work together to strengthen our collective security against biological threats.

A key element of the strategy is revitalizing the Biologic Weapons Convention, which we intend to use to promote and globally advance our biosecurity objectives, through using the BWC as our premier forum for global outreach and coordination.

In particular, we will tighten the linkage between global security against infectious disease; through strengthening basic health capacities on the one hand, and on the other hand, the security community's need to counter man-made disease threats.

Last year, the Biological Weapons Convention States, Parties and experts from a wide range of health, science, and security organizations focused on disease surveillance and related capacity building, with a particular emphasis on implementation of the World Health Organization's International Health Regulations.

The focus of BWC meetings in 2010 is on providing assistance in the event of an unusual disease outbreak or an alleged use of biological weapons. On our part, we are going to have the FBI and the Centers for Disease Control brief on their efforts on training for joint criminal epidemiological investigations.

And there will be several U.S. sponsored conferences on bio-risk management and on scientific and technical breakthroughs that can be applied to disease surveillance. And we are looking forward to the seventh 5-year BWC Review Conference in 2011 as an opportunity to further the objectives of the strategy.

In addition to BWC, State's Biosecurity Engagement Program (BEP) is working to reduce the threat of bioterrorism through cooperative activities to prevent terrorist access to potentially dangerous biological materials and expertise, while supporting legitimate efforts to combat infectious disease and enhance public and animal health worldwide.

Since 2006, the BEP program has matured into a $37-million-a-year effort, focused on regions and countries where there is a nexus of terrorism, emerging infectious disease, and rapid growth in biotechnology in high containment laboratories.

BEP provides support for and closely coordinates activities abroad with other U.S. departments and agencies, particularly Defense, Health and Human Services, and Agriculture, to directly address several key objectives of the strategy.

BEP provides assistance to improve laboratory biosecurity and biosafety best practices, improves capacity for infectious disease detection, surveillance and control, and engages biological scientists and public and animal health experts to reduce the potential for exploitation of biological expertise, information, and material. And BEP not only improves international security; but provides a dual-benefit of improving global health.

We are also addressing another key challenge identified in this strategy; that of reinforcing norms for safe and responsible conduct of biological activities.

For example, we are sponsoring biological safety associations across Southeast Asia and in the Middle East that can provide a sustained mechanism for countries to provide training to life scientists and public and animal health professionals on bio-risk management and responsible scientist conduct.

State also coordinates and promotes additional cooperative international efforts to counter the biological threat via the G–8 Global

Partnership; a 10-year, $20-billion nonproliferation effort that was launched in 2002, and has thus far focused on programs in the former Soviet Union.

This year, we are working closely with the Canadian G–8 Presidency and with the other G–8 partners, to extend the partnership beyond 2010. This expanded program will bring additional resources from partner countries to bear on addressing global biological threats and also threats beyond those in the former Soviet Union.

We are also working to help U.N. member states manage biological security threats by helping them implement U.N. Security Council Resolution 1540, which requires all U.N. members to have proliferation export controls and to secure dangerous materials.

Mr. Chairman, I hope that I have been able to provide you with a better understanding of the serious efforts by the Department of State against the biological threat. I have appreciated the opportunity to outline for the subcommittee what we are doing in concrete terms to implement the international aspects of the national strategy.

State, of course, does not work alone, and relies on its close working relationship with other U.S. Government agencies, the Congress, and the international community to expand these efforts and make them more successful; thank you.

[The prepared statement of Mr. Van Diepen follows:]

Testimony of Acting Assistant Secretary Vann H. Van Diepen

The National Strategy for Countering Biological Threats: Diplomacy and International Programs

House Foreign Affairs Committee

Subcommittee on Terrorism, Nonproliferation, and Trade

18 March 2010

Thank you, Mr. Chairman, for the opportunity to speak on behalf of the Department of State about important efforts we have undertaken to address the President's priorities for countering global biological threats. As you are aware, the President issued the *National Strategy for Countering Biological Threats (Strategy)* in December of last year. Emblematic of the critical role that State plays in implementing the *Strategy*, it was first publicly announced by Under Secretary Ellen Tauscher in Geneva during the Annual Meeting of States' Parties to the Biological Weapons Convention (BWC).

I want to emphasize that this *Strategy* provides the first U.S. Government-wide effort focused on preventing the spread of disease outbreaks, whether deliberate or naturally-occurring, and in the context of a wider public health preparedness, control and response approach. This is based on the widespread recognition that global public health is deeply interconnected and that outbreaks of

disease, whatever their origin, will affect many nations in time and in some manner.

The Department of State leads the U.S. Government effort on the pillar of the *Strategy* that emphasizes the need to "Transform the International Dialogue on Biological Threats." In particular, State coordinates with and provides assistance to international partners to address biological risks, particularly in countries and regions facing a high risk of terrorism or that serve as potential terrorist safe havens. I want to begin by first briefly outlining the threat and then I will emphasize some key activities that State is undertaking with the global community pursuant to the *Strategy* that are principally encompassed by our efforts under the Biological Weapons Convention (BWC) and our Biosecurity Engagement Program (BEP).

The Threat

Congress is keenly aware that a biological weapons attack is a real and present danger, particularly in light of the 2001 anthrax attacks.

The biological threat has several important components, including intent from groups that have expressed interest in obtaining biological weapons and expertise, emerging infectious diseases that create new opportunities for havoc, and growing biotechnology capacity in areas of the world with a terrorist presence.

The most obvious and worrisome threat comes from terrorist groups that have expressed intent to obtain biological weapons – for example, Al Qa'ida has shown strong interest in biological weapons for over a decade. We have tangible evidence that Al Qa'ida leadership directed a focused effort to develop the capability to conduct a biological attack with anthrax. Al Qa'ida ran an anthrax project in parallel with its nuclear efforts, and in 2001 U.S. forces discovered a lab in Kandahar, Afghanistan that was built for this purpose. In 2006, Al Qa'ida in Iraq issued a decree, specifically recruiting experts to help them in this effort, saying that "the field of jihad can satisfy your scientific ambitions… and the large American bases [in Iraq] are good places to test your unconventional weapons, whether biological or dirty…."

Other organizations that have masterminded WMD plots, such as Aum Shinrikyo, have also pursued and tried to use biological weapons. Fortunately, to date, these attempts have largely been unsuccessful – as in the 1993 case of Aum Shinrikyo - due to the use of a non-pathogenic strain and ineffective dispersal of the anthrax agent the group produced.

The bacterium causing anthrax has been a sought-after agent in the context of state bioweapons programs, and of terrorist plots informed by widespread public information on bioweapons. The bacteria that causes anthrax, *Bacillus anthracis*, can be isolated from natural sources without sophisticated technical skills, has a

very high lethality rate in its pulmonary form and not treated quickly, and - when in its spore form - is extremely hardy and can survive the rigors of aerosol dissemination with high efficiency. UN inspectors in Iraq found 18 50-liter fermentors that have been used to produce anthrax at Al-Hakim in the early 1990's; in addition, the Soviet's probably produced multi-ton quantities of anthrax. Importantly, while anthrax may be the agent most frequently associated with biological weapons, at least a dozen other organisms hold potential for deliberate misuse to catastrophic effect. Other agents of concern include those on the U.S. Select Agent program list, such as *Brucellosis* and *Tularemia species*, which the Soviets also grew in large quantities. Wheat Rust and Foot and Mouth Disease (FMD) virus are also of concern for the possible disruption their deliberate introduction could cause to our food supply. A successful attack using anthrax, FMD, or another infectious agent could not only cause disease and even deaths, it could cause panic, loss of public trust, and enormous economic damage. For example, the U.S. anthrax attacks in 2001 caused 22 illnesses, 5 deaths, and had substantial direct economic and cleanup costs; the UK conducted mass livestock cullings in response to the FMD outbreaks.

And while we are focusing many resources on preventing terrorists from acquiring and using biological weapons, we also have concerns that as many as half a dozen state actors may harbor ambitions – and may even be advancing their

capability - to develop or otherwise acquire dangerous pathogens for use as biological weapons.

State plays a major role in working with the international community to counter BW through a number of bilateral and multilateral mechanisms, and I am going to focus my testimony on four activities that form a major part of our toolbox: the BWC, our Biosecurity Engagement Program, the G8 Global Partnership Against the Spread of WMD (G8 Global Partnership), and UN Security Council Resolution 1540. I will not be discussing State's Foreign Consequence Management Program, which assists partner nations in building capacity for response and recovery following a CBRN incident and coordinates the U.S. response to a request for assistance from a stricken nation.

The Obama Administration's *Strategy* for countering biological threats – both natural and man-made – rests upon the main principle of the BWC, that the use of such weapons is "repugnant to the conscience of mankind." That is why we are promulgating an approach that strikes a balance between supporting scientific progress -- for example, working hand-in-glove with industry and academia on screening measures for synthetic DNA sequences -- and curbing the potential for abuse of biology through export controls and other national and international measures, to include promoting joint bioterrorism response protocols between law enforcement and public health agencies. There has been no comprehensive

strategy before this time that addresses gaps in our efforts to prevent the proliferation of biological weapons and scientific abuse. The *Strategy* promotes global health security by increasing availability and access to knowledge and products of the life sciences that help reduce the impact from outbreaks of infectious disease whether natural, accidental, or of deliberate origin. We intend to establish and reinforce norms against the misuse of the life sciences through a culture of responsibility, awareness and vigilance. We also seek to implement a coordinated approach to influence, identify, inhibit, and interdict those who seek to misuse scientific progress to harm plant, animal and human life. By obtaining timely and accurate information on the full spectrum of risks, we hope to be able to take appropriate actions to manage the evolving risk.

The BWC Reinvigorated

As Under Secretary Ellen Tauscher stated during her address rolling out the *Strategy* at the BWC Annual Meeting last December, "we want to make the BWC the premier forum for discussion for the full range of biological threats." As a result of the successful BWC Work Programs of annual expert and political meetings, we now enjoy a remarkable and productive intermingling of biological communities focusing on practical and real-world activities that have a direct and immediate impact. For example, 500 people attended the 2009 BWC Experts Meeting and are actively engaged in the BWC annual Work Program. Participants

come from Foreign Affairs, Defense, Health, Justice, and Agriculture Ministries, are members of national scientific academies and university representatives, industry representatives, non-governmental think tanks, and from intergovernmental agencies such as the World Health Organization (WHO), Food and Agriculture Organization (FAO), the World Organization for Animal Health (OIE), and Interpol. The BWC is a significant place to introduce national priorities, promote scientific exchange, and to ensure that cooperation and assistance reaches those that make a conscious request for it.

The BWC already provides an international forum for advancing the dialogue on pathogen security and laboratory safety practices, and for promoting legislation, guidelines and standards through cooperation and partnership. We also want the BWC to help improve countries' abilities to respond to natural outbreaks, and thus to mitigate the consequences of disease outbreaks regardless of origin, to fully and effectively implement the BWC, and to better deal with bioterrorism.

We intend to promote confidence in BWC compliance by encouraging increased participation in its voluntary confidence-building measures (CBMs), assessing the forms for effectiveness and identifying areas for improvement. CBMs already are an important tool for promoting transparency and clarifying the intent of national biodefense activities, including activities that countries may undertake through private, public (academic), and governmental entities . And in

the same light, in an effort to provide transparency into our own ongoing biodefense efforts, the United States has invited the 2010 Chairman of the BWC to tour our biodefense campus in Frederick, MD. We are also considering the risks and benefits of putting our future CBMs on the public access part of the website belonging to the BWC's Implementation Support Unit (ISU).

BWC Priorities in 2009-2010

To give you insight as to how this plays out in practical terms, let me highlight the efforts going on in Geneva under the BWC Work Program last year and this year. State coordinates these efforts.

The focus of the BWC States Parties during 2009 was on the importance of disease surveillance, as well as related capacity building in detecting and containing dangerous outbreaks of disease, whether natural or deliberate in origin. As emphasized in the *Strategy*, there is broad recognition in the security community that developing overseas health capacity strengthens our national security. If international labs are secure and scientists are engaged in responsible behavior and thus able to detect, report, and respond to public health emergencies, our collective security is enhanced. Because the BWC Experts Meeting brings together such a confluence of participants, it is the ideal setting to reinforce this point. The Director of the Global Disease Detection program of HHS's Centers

for Disease Control and Prevention (CDC), which is building capacity around the world to detect and respond to emerging public health threats, briefed the meeting on extensive efforts by the U.S., in fifty countries, to provide assistance in the implementation of the WHO's International Health Regulations (IHRs). Many of the 194 States Parties to the IHRs will not have the required basic core competencies in place within their national health systems by the 2012 deadline. Without the measures in place under the IHRs, detection of the initial outbreak of H1N1 would have been delayed and the necessary coordination between States and with the WHO would not have been as efficient. Since that time, the role of IHR measures and related assets in detecting, diagnosing and containing other infectious diseases have only reinforced these important cooperative relationships.

Another area where we highlighted U.S. assistance during the BWC Experts meetings was through NASA's ability, based on 30 years of data, from using satellite imagery to predict disease outbreaks, through examination of weather, air and sea temperatures and other factors that can influence environmental conditions that support transmission of particular diseases. This information is easily accessible on the internet. To emphasize the importance we place on surveillance of animal and plant diseases, the Department of Agriculture shared its extensive international collaborative efforts. The U.S. and Georgia made a joint presentation on cooperative disease surveillance capacity building.

To follow-through on our 2009 initiatives, and encourage a sustainable IHR implementation process, we will be hosting a workshop in Washington in June, promoting best practices in implementation of the IHR's. This was one of the activities highlighted in Under Secretary Tauscher's address. Another meeting will be held on the margins of the August BWC session to review the bidding on IHR implementation, sharing lessons learned from the many stakeholders.

The focus of BWC work this year encompasses efforts to assist States Parties in the event of a suspicious outbreak of disease or where there is a case of alleged use of a biological weapon. Issues for discussion include response, mitigation, and identification/attribution of such outbreaks/use. We will bring our FBI and CDC experts to Geneva to highlight their ongoing training efforts in promoting joint public health and law enforcement responses to intentional biological threats. In particular, FBI and CDC have developed best practices and guidelines on the conduct of joint criminal and epidemiological investigations of suspected BW terrorism. This model has gained world-wide acceptance through successful coordination of bilateral and multilateral trainings. We also intend to host a meeting shortly after the August Expert's Meeting to share information on bio-risk management training, standards and needs. We will likely also promote new scientific advances in genomics and developments in detection capabilities, as showcased by our national labs and the CDC.

As we begin to prepare for the Seventh 5-year BWC Review Conference in 2011, we will be accentuating the concepts put forth in the *Strategy* and working with partners to identify ways and means to continue the successful and productive approach that has characterized the work of the past eight years. The concepts of pathogen security, biosafety, codes of conduct for responsible behavior of life scientists, disease surveillance, and assistance in case of attack or suspected attack have weathered the test of time since they were put forth in 2001 as real-world, practical steps that States could take immediately. We will be looking for similar foci that will also enable us to better implement the *Strategy*.

State's Primary Foreign Assistance Mechanism to Implement the *Strategy*: Global Biological Engagement in Practice

State is also on the front lines of providing tangible assistance to states to address the challenges outlined in the *Strategy*. State's Biosecurity Engagement Program (BEP) was created in 2006 to reduce the bio-threat by preventing unauthorized access to potentially dangerous biological materials and dual-use infrastructure and expertise, while supporting legitimate efforts to combat infectious disease and enhance public and animal health worldwide. BEP has now matured into a $37 million a year effort, which is active throughout the world to address biological threats. BEP is a threat-driven program designed to prevent, detect, and respond to existing and emerging global biological threats, focusing on

regions and countries where there is a nexus of terrorism, emerging infectious disease, and proliferation of biotechnology and high-containment laboratories. BEP provides support for and closely coordinates activities abroad to directly address several key objectives of the President's *Strategy*.

Promoting Global Health Security

Promoting Global Health Security is a key objective of the *Strategy* that BEP promotes primarily through collaboration with such organizations as the Department of Health and Human Services and its components such as the CDC, the Food and Drug Administration and the National Institute for Allergy and Infectious Diseases (NIAID) within NIH; Department of Agriculture; the World Health Organization (WHO); and the World Organization for Animal Health (OIE). As an example, BEP is working with the CDC to develop a training program in Morocco to improve training among public health professionals to rapidly detect and properly diagnose disease outbreaks within the country. State is not only helping to support this effort to build this much-needed capacity within Morocco, but we are also providing additional funding to ensure that the laboratory component of this program is carried out in a safe and secure manner.

Reinforcing Norms of Safe and Responsible Conduct

One of the difficult challenges addressed by the *Strategy* is establishing and reinforcing norms across the global life sciences community. BEP is working with the U.S. National Academies of Science (NAS) to identify gaps in the education system for life scientists on responsible conduct of research and to develop materials and methods that can inform scientists with a wide variety of scientific backgrounds and from a number of different cultures worldwide. We also are working to improve international best practices in laboratory biosafety and biosecurity, which helps to promote global health security, reinforces norms of safe and responsible conduct, and reduces the potential for exploitation of biological expertise, facilities, information, and material.

We help gain buy-in for this by sponsoring targeted efforts by biological safety associations across South and Southeast Asia and the Middle East that provide sustained training to life scientists and public and animal health professionals on biorisk management and responsible scientific conduct. For example, we have helped establish the Philippines Biosafety & Biosecurity Association (PhBBA) to promote best practices in laboratory biosecurity and biosafety. This year, through this partnership, BEP organized the first biorisk awareness workshop in Mindanao, which brought together more than 200 biological scientists from public, private, and academic institutions in Western Mindanau, with robust participation from the

Government of the Philippines. This model is now being replicated and tailored for application across the globe, and we are supporting additional efforts like this in Afghanistan, Egypt, Morocco, and across Africa.

Critical to our success has been our activities to reach across the governmental, academic and public health sectors to raise awareness to improve laboratory biosafety and biosecurity. For example, last year we sponsored a seminar in Baghdad, which was attended by representatives from several Baghdad-area academic and governmental organizations. We are now expanding efforts to promote biosafety and biosecurity in Iraq this year.

Reducing the Potential for Exploitation

Another key component of the *Strategy* is reducing the potential for terrorists to exploit knowledge and capabilities within the life sciences. BEP works with Sandia National Laboratories and the U.S. Naval Medical Research Unit No. 3 (NAMRU-3) to perform laboratory risk assessments in laboratories housing dangerous pathogens across South and Southeast Asia, the Middle East, and Africa. Once these assessments are complete, we will work with governments and laboratories to minimize the risk of potential accidents or misuse of infectious biological agents.

Expanding Our Capability to Prevent, Attribute, and Apprehend

Our major focus has been on developing the capability to prevent and reduce the likelihood of a deliberate or accidental release of a biological agent. We have provided funding and expertise for security upgrades to labs in high-risk areas to safeguard against theft and diversion, and to implement risk assessments that reduce the probability of an accidental release. We also coordinate our work with local law enforcement entities and INTERPOL to promote collaboration and information sharing with public health agencies and scientific communities so that these communities can provide early warning and detection if a suspicious incident or threat arises.

Communicating Effectively with Stakeholders

Effective communication with our international stakeholders across ministries, institutes, scientists and public and animal health organizations is critical to our success in reducing the biological threat abroad.

The U.S. Can't Do it Alone: Role of the G-8 Global Partnership and UNSCR 1540

In addition to our work through the BWC and BEP, we are also working with the international community through other critical multilateral mechanisms. The biological threat is global, and we cannot combat it alone. Chief among our activities to coordinate and promote additional assistance to counter the biological threat are the G8 Global Partnership and United Nations Security Council

Resolution (UNSCR) 1540. State has the lead for the USG for the G-8 Global Partnership, a 10-year (2002-2012), $20 billion effort to prevent the spread of WMD worldwide that has traditionally focused on activities in the former Soviet Union to destroy chemical weapons, dismantle nuclear submarines, improve fissile material security, and employ former weapons scientists. This year, we are working closely with the Canadian G8 Presidency and with other G8 Partners to extend the Partnership beyond 2012 and to develop a broader effort to include addressing global biological risks, bringing to bear additional resources from Partner nations. The G8's *Global Initiative* provides a coordination mechanism to ensure that efforts are not duplicated and sustainable capacity is created in countries where multiple Partners are working. We hope that other Partners will be able to contribute funding to this effort, either through existing mechanisms like the World Health Organization or through direct collaboration with the U.S. or other nations. As an example, South Korea funded enhanced biosecurity programs in Afghanistan through the State Biosecurity Engagement Program and under the auspices of the G8 Global Partnership.

We are also working through the UNSCR 1540 mechanism. In February 2010, in coordination with DoD, the UN 1540 Committee, and the United Nations Office of Disarmament Affairs, State's BEP program co-organized an African Regional Workshop on Biosafety and Biosecurity that brought together

representatives from 19 African nations to discuss how the international community could help them successfully implement UNSCR 1540 to effectively manage biorisks within their countries. This effort builds upon the work to promote global health security, while reinforcing norms of safe and responsible conduct and taking responsible steps to reduce the potential for exploitation of materials and knowledge in several of these countries. As an example of these efforts, BEP is working with the U.S. CDC's Global Disease Detection Regional Center in Kenya to develop laboratory diagnostic and biosafety capacity. The Uganda National Academy of Sciences will host a regional conference on establishing and promoting good laboratory practices for funding safe, secure, and sustainable labs.

Concluding Thoughts

The Department of State's serious efforts to address the biological threat have improved biological security and safety and are making an impact on global infectious disease detection. We are transforming the international dialogue between the many sectors within and outside the United States that affect our global health and security. Combating the biological threat provides us with a very real opportunity to improve international security, while providing a dual benefit of improving global health. This "Dual Benefit" makes it even more important that

we work within the U.S. and with our international partners to ensure that all of our efforts are coordinated and linked together to create global systems for detecting outbreaks of infectious disease, regardless of the cause. It is only through the process of cooperation within and between governments, academia and industry, and other non- and inter-governmental entities will we be able to truly make an impact on preventing bioterrorism and addressing global infectious disease outbreaks, whether naturally occurring or man-made.

Thank you.

Mr. SHERMAN. Thank you; I am going to recognize the other members of the subcommittee for questions first, and do my questioning last. So I first recognize Mr. Scott.

Mr. SCOTT. Thank you very much; welcome Mr. Van Diepen. Let me ask you this question if I may. In one respect, we have been very fortunate that we have not had a biological terrorist attack since 2001 and with the anthrax scare. How do you account for that? Why do you say that has happened?

Mr. VAN DIEPEN. Well, I think there is probably a complex of answers to that question, Congressman. First of all there, of course, has been a very intensive U.S. counter terrorism effort, assisted by international partners, and various biological related activities have been disrupted, such as the anthrax activities in Afghanistan that are noted in my written testimony.

Likewise, I think biological attack is more difficult for a terrorist to perpetrate, especially significant ones, than the kinds of conventional attacks that they are used to perpetrating.

And of course, there has been a lot of effort to try and improve our export controls, border surveillance, other kinds of activities to try and inhibit and deter such activities. So I think it is probably a complex of a variety of different things that have been happening since 2001.

Mr. SCOTT. How would you describe for us, and as a matter of fact, I would like for you to describe for us how the Federal Government works, from a standpoint of inter-agency cooperation? How do you coordinate what you do with other agencies, and what are the other agencies who work together with you to form this very strong front line defense of our country from a biological attack?

Mr. VAN DIEPEN. Well, that, of course, is something that is a center piece of the President's new strategy to improve that inter-agency coordination.

But in terms of the international activities that we engage in, everything that we do is very thoroughly inter-agency coordinated. In fact, many of the implementers of the State Department programs in this area are, in fact, other agencies such as HHS and Agriculture.

There are various standing working groups where we try and coordinate and de-conflict our various programs. To help implement the strategy, the National Security Counsel staff has put together an ongoing effort to come up with detailed inter-agency implementation plans for each aspect of the strategy and those are in development right now.

Also, we have in place a new special coordinator for cooperative threat reduction in the Department, Ambassador Bonnie Jenkins. And part of her job is to make sure that State Department programs are well coordinated with those of other agencies, as well as with similar activities that other countries conduct.

Mr. SCOTT. Now let me ask you about the funding level. Do you believe that we, in Congress, are giving you the necessary amounts of resources to get the job done; or are there areas or is there more funding that you feel we need to provide for you?

Mr. VAN DIEPEN. Well, Congressman, I suppose every bureaucrat would be remiss if he did not say that he could use more money.

But I think realistically, in terms of the absorptive capacities of a lot of the countries that we are dealing with, in terms of trying to make sure that we apply our resources in places where there are clearly identified threats, and recognizing that there are all sorts of other tradeoffs and opportunity costs involved in these decisions, I think that we have got, you know, sort of a fair and reasonable amount of money allocated to these activities.

And I would say that Congress has been very supportive of the BEP and, in fact, has had certain earmarks to make sure that certain amounts of money are spent on BEP.

Mr. SCOTT. Let me ask you about our level of international cooperation. If you could describe for us what that is, how would you rate it, and where are the weak links around the globe that we have to be concerned about—what countries, what areas are our most significant worries?

Mr. VAN DIEPEN. Well, I think probably the areas of the highest direct threat potential are the areas that we in fact are working in in the BEP, because it is a threat directed program.

Places where you have got a nexus of terrorist activity and substantial biotechnology—places in the Middle East, South Asia—sort of fall into that category. But bioterrorism is something that, for better or for worse, can happen almost anywhere, almost any country has within its borders a hospital or a scientific facility that has pathogens.

And so where we can, we are reaching out to try and improve things in those areas, as well. So we have a new focus, for example, in trying to do some operations in Africa and Latin America, to help deal with that aspect of the problem, as well.

Mr. SCOTT. And one of the areas that, as I mentioned, I am very much concerned about, of course, as the subcommittee chairman for Food Safety in Agriculture, is to keep our food supply safe.

Does your agency work in collaboration with our Agriculture Department, especially in very critical areas where we are moving forward to help with this in the area, for example, animal ID, which we feel is very important? And how do you feel about that? Do you believe that we should have mandatory animal ID; or should we continue to leave that on a voluntary basis?

Mr. VAN DIEPEN. Well, Congressman, I would have to say on that specific issue, that that really, you know, has not fallen into my area of responsibility. So I am not sure I am in a position to give you a meaningful response.

But on the larger question, I am very glad that you identified the potential threat of biotechnology against the food supply; because oftentimes, the discourse on this issue only focuses on the human aspect of it. And because of the indirect human aspect and the very significant economic impact of the agricultural part, I am very glad that you raised that.

Because of that, that has always been a focus of our activities. Whether it is securing dangerous pathogens, those have always included pathogens against food crops and livestock. Whether it is building a culture of safety and security, we include the animal agriculture health communities in those activities.

Mr. SHERMAN. The time of the gentleman has expired. Let me now recognize Mr. Royce from California, our ranking member.

Mr. ROYCE. Thank you, Chairman Sherman. At least one of our witnesses today is going to speak of the importance of intelligence and the inadequacy of our intelligence in bioterrorism. And this is an issue that the chairman and I were very involved in at the time. But in 2007, the intelligence community produced a National Intelligence Estimate, which you were certainly involved with. You were the National Intelligence Officer for Nonproliferation.

That NIE concluded with high confidence that Iran had halted its efforts to develop nuclear weapons in 2003; and it assessed with moderate confidence that Iran had not re-started this program.

In a report last month, the IAEA recited a number of concerns about military related nuclear activity in Iran; and asserted that these activities seem to have continued beyond 2004.

Now at the time the NIE was released, the chairman and I denounced it as naive and harmful; and you were centrally involved in that. I remember at the press hearing with Chairman Brad Sherman, holding up the Time magazine cover that exonerated the Iranians; exonerated them on the basis of your assessment, which turned out to be wrong.

My question is, what went wrong? Is now the time maybe to revisit the issues addressed in the NIE? I do not think the stakes could be any higher. Let me ask you that question.

Mr. VAN DIEPEN. Well, thank you, Congressman. I guess the starting point on that is, of course, that is not the business I am in any more. But I think the fair way to answer that question is, the intelligence community right now is preparing a follow-on National Intelligence Estimate on that subject.

And I think the thing to do is to wait for that to come out and see the extent to which that assessment differs from the one in the 2007 NIE. I would suggest that that should probably be the basis of deciding what was right and what was wrong.

Mr. ROYCE. I think the covert illegal enrichment facility at a military base outside Qom, that was disclosed last fall to all the world. So I think the case is pretty clear. Surely you agree that something went wrong, in your assessment.

Mr. VAN DIEPEN. Well, and one thing that is inherent is by definition. Information comes in after you publish. The intelligence business is one of working with the information you happen to have at hand at any particular time; comparing it to the old information, and trying to then project both what is actually going on, since objective reality is difficult to determine, and what you think is likely to happen in the future. And by definition, new information keeps coming in. It does not respect publication dates of NIEs.

Basically, in the intelligence community, you are in the business of trying to predict the outcome of a movie that you only get to see glimpses of. You do not know how long the movie was going on before you started glimpsing. You do not know how long the movie is going to be going on; and half of your glimpses actually come from other people's glimpses of the movie. So you have to sort of put all that together and put together a picture.

I think that NIE was very clear and very responsible in its use of so-called intelligence trade craft—confidence levels; descriptions of alternative scenarios. In fact, I think there were eight alternative scenarios beyond the main line estimate that were included

in that assessment. There was a very extensive discussion of, what if we are wrong; how could we be wrong?

Mr. ROYCE. I think part of your argument basically was, the burden of proof to determine proliferation activity should be as high as in the average U.S. court room; at least that is the way I recall your assessment of the situation.

As one press report said afterwards, there was never a sanction that Van Diepen liked, never, said one official. It was a point of religion for him. He thought anything we did outside of teacup diplomacy was counterproductive and wrong.

There are decisions we are going to make, in terms of sanctions, on the basis of assessments which you helped make, that frankly turned out to be wrong. I would like to just add a couple of other concerns I have.

I brought up Russia. The WMD Commission noted that over the last several years, Russia has been less and less interested in cooperating with U.S. Biological Threat Reduction Programs that had some success in re-directing former Soviet bioweapons scientists to peaceful activities.

The commission expressed concern that "the large cadre of former bioweapons scientists remains a global proliferation concern."

You barely mentioned Russia in your testimony. And I was going to ask you, can you explain the Russian position and the United States response; and is there still a role for these programs?

Mr. VAN DIEPEN. Thank you, Congressman; first of all, I do not think I can let go the first part of what you had to say; and frankly those quotes against me are utter nonsense.

I, in fact, have been involved in sanctioning more entities and more countries for more acts of proliferation than any human being on the planet. So I am quite comfortable with——

Mr. ROYCE. But the bottom line, for the chairman and me, who were involved on the other side of the table from you in your last position, was a very, very different conclusion about what was going on in Iran and what we should do about it. So we just disagreed at the time.

I think that all that is in the papers subsequently bear out the chairman's and my observations on this. But you have got your opinion and I have got mine. But let us go to the question on Russia and the role of these programs.

Mr. VAN DIEPEN. I am very happy to do that. Anyway, yes, clearly, there is still an issue. You know, there is a fair amount or a substantial amount of biological weapons applicable material, equipment, and expertise in Russia. And you, in your opening statement, mentioned some examples of that being the case.

And one of the long-standing objectives of our various engagement programs, including the Science Centers Program, the BEP and others, has been to work with the Russians to try and put in place better barriers to make sure that that expertise does not go to BW programs in other countries or to BW terrorism.

You know, Russia now, however, is different than the Russia we dealt with in the early 1990s, in the sense that it is much more economically viable than was the case before. It is much more nationalist and resurgent than it was before.

You know, frankly, the Russians are less interested in looking like they are supplicants and recipients of aid, than looking like they are partners. And they are less interested in looking like they are a potential source of proliferation; than they are looking like they are partners.

And so the challenge that we face in continuing to pursue these programs in Russia, which we are doing and which we think we still need to do—because again, that repository of expertise is, you know, unquestionably there—is to try and work within the parameters set by the current Russian Government and the current situation within Russia, to continue to try to make progress.

Mr. ROYCE. Let me ask you one last question. Why is it that a bi-partisan panel gave an "F" grade—there was a bi-partisan panel of nine experts. Why were they wrong; the WMD Commission in January, that gave you that grade? What grade would you give yourself, I would ask?

Mr. VAN DIEPEN. Well, as I recall, the "F" grade mostly focused on the domestic side of things which, of course, the State Department does not have responsibility for. As the chairman noted in his opening statement, the State Department's end of this actually got relatively high grades.

I guess what I would say is that it should be less of an issue of grades than to realize that this is an extremely daunting and challenging problem. The fact is that since bioterrorism ranges from everything from a disgruntled individual putting salmonella in a salad bar; all the way up to an all-out, strategic level attack by another country using ICBMs filled with genetically engineering pathogens.

There are a lot of potential opportunities for a biological attack against the United States. And because we are sophisticated and inter-dependent with other countries, there are a lot of vulnerabilities that we have.

And so, given all those opportunities for potential threat, given all the vulnerabilities that we have, it is a very daunting task to try and totally protect ourselves against every aspect of such a threat.

Mr. ROYCE. Thank you very much; thank you, Mr. Chairman.

Mr. SHERMAN. Thank you; before I recognize Ambassador Watson, just a minute of personal privilege, since my name was so mentioned.

I agree with the ranking member. I may even overstate his position by saying that the NIE was perhaps the worst example of a political document masquerading as an intelligence document.

I do not know the degree to which our witness was involved in it. But we, in the Legislative Branch, are utterly helpless when it comes to missing the facts or mischaracterizing the degree of confidence. But it has the facts, and so we have to accept what the Executive Branch does in those two areas; and I cannot quibble with the NIE on that.

But what makes a document political is where certain facts that are important are brushed off to the side, and facts that are not important are emblazoned as major reasons to affect U.S. policy. In that NIE, the most important fact was pushed to the side and mentioned in the first footnote, and most of the document, including

the first three paragraphs, were all focused on facts that not only turned out to be irrelevant but were obviously irrelevant at the time.

The key to developing a nuclear weapon is getting the fissile material; and only a political document would focus on other, far less important aspects of a nuclear program.

With that, I yield to the gentlelady from not only Hollywood but so many other outstanding neighborhoods in the Los Angeles area.

Ms. WATSON. Which will soon be addressed by—thank you so much, Mr. Chairman. Speaking of other nations and continents, I would like to go to Africa and talk about the October 2005 Kampala Compact, resulting from an African meeting.

It states that it is illegitimate to address biological weapon threats without simultaneously addressing the enormous health crisis in Africa, such as HIV AIDS, TB, Malaria, and other infectious diseases.

So what can the United States do to help African nations achieve the duo goals of improved global health and biosecurity? Can you just bring us up on that?

Mr. VAN DIEPEN. Well, to start off with, I guess I would not use the descriptor illegitimate. But certainly, we have always tried to take advantage——

Ms. WATSON. Oh, that was the State in quoting from the compact. But clearly we understand that we can get nonproliferation value out of help in global health; just as there can be global health value gotten out of doing BW nonproliferation.

And so as I indicated in my testimony, you know, we are looking for opportunities to do both; and particularly where we are trying to promote improved disease surveillance, improve public health—you know, we are doing that specifically because it also provides an important collateral benefit to protect us against potentially manmade biological threats.

One example of an activity that we have conducted—in cooperation with DoD's cooperative threat reduction program and with the United Nations, we organized an African Regional Workshop on biosafety and biosecurity. Experts from 20 African nations discussed the kinds of assistance they need in implementing better biological controls, pursuant to U.N Security Council Resolution 1540.

And we work not only with other agencies; but also the World Health Organization and the Food and Agriculture Organization. So I think that is a good example of how we are trying to do exactly that.

Ms. WATSON. Well, thank you; because the need is so great, as you know, on the continent. In addition to an overarching Federal strategy, many agencies have developed their own strategic documents to address their responsibilities with respect to bioterrorism threats.

Coordinating these strategies across multiple agencies is a challenge. So how is State working to harmonize its strategies with other agencies, so as to reduce unnecessary duplication and close security gaps; and let me just go on to my next. You can answer them all together.

How did State determine the optimal level of funding against bioterrorism threats; and are there any areas that you feel are currently under-resourced or should otherwise be emphasized?

Mr. VAN DIEPEN. Thank you, Congresswoman; in terms of coordination, I think the two main things we are doing is participating in the National Security Council-led process to come up with specific implementation plans for the President's new bio-strategy.

And then we participate and run a number of standing interagency working groups that deal specifically with the kinds of international assistance programs like our Biosecurity Engagement Program.

In addition, under this administration, a new coordinator for cooperative threat reduction has been appointed, Ambassador Bonnie Jenkins. She works to make sure that our programs are well coordinated with those of other agencies and with other countries.

In terms of determining the levels of funding, you know, that is a very complex issue. But I think the critical thing is what we try to do; to determine where we put that funding, based on a very clear assessment of the risk, informed by the U.S. Government scientific experts and by the intelligence community. So we are trying to identify and address the highest risks as a priority in our funding. Then, I am sorry, the last question?

Ms. WATSON. The last question, are there any other areas that you feel are currently under-resourced or should otherwise be emphasized? And I want to just ask, do you work with NGOs or do you work with their State Departments in these various countries?

Mr. VAN DIEPEN. A mix—we work with not just State Departments; but Ministries of Health, Ministries of Agriculture, as well as NGOs and international organizations like the World Health Organization.

Ms. WATSON. Well, as we look at AIDS and look at the funding we have given, we are finding that a small amount of money in a village can go a long way when you use the NGOs.

They know the customs, traditions. They know the people and how they respond. And I am finding that it looks like when we work through the actual inhabitants of a particular area, $1 goes a long way. So if you can respond to how the State Department looks at that, and will we do more business with the NGOs?

Mr. VAN DIEPEN. Again, a critical part of this new strategy is the idea of international partnership, and that is international partnership not just with countries; but with relevant organizations within countries.

Ms. WATSON. I thank you, and I yield back.

Mr. SHERMAN. Thank you; I will take a minute to address the witness's statement that he has done more sanctions than anyone else. That may, in fact, be true; but it is pitiful. You are comparing yourself, for example, to the German Foreign Ministry. Their idea of sanctions is, let German businesses do everything they want.

You are comparing yourself to the rest of the State Department. You are basically bragging about being the tallest jockey at the race.

We are now being told by the State Department that they favor smart sanctions, by which they mean dumb sanctions, which is to

say they are in favor of sanctions so long as it does not actually hurt the economy of Iran.

And in fact, no one at the State Department has been able to point to a single publicly traded corporation anywhere in the world that is selling for one cent per share less as a result of American sanctions. So our idea is we are for sanctions as long as they do not inconvenience anyone or at least they do not inconvenience anyone that has the slightest amount of political clout.

My best example is that we continue to import caviar from Iran because why should American Epicureans have to make due with Northern Caspian caviar? So you may be the tallest jockey. But that is hardly a reason for personal celebration.

With regard to these hearings, putting aside the state sponsors of terrorism countries and looking at the countries that we would hope would be cooperative, which country is least cooperative, in terms of controlling biological proliferation; and is the most troublesome, as far as complying with U.S. Security Council Resolution 1540?

Mr. VAN DIEPEN. I am not sure that——

Mr. SHERMAN. Aside from the state sponsors of terrorism, they are all doing a great job?

Mr. VAN DIEPEN. Well, I think it is less an issue of being troublesome, than the fact that for a lot of countries, the 1540 mandates are a much lower priority than things like, you know, keeping the population fed, you know——

Mr. SHERMAN. Okay, which country is giving the lowest priority to meeting its obligations under Resolution 1540?

Mr. VAN DIEPEN. Again, I would not single out a particular country. But clearly, in places like sub-Saharan Africa, you know, you have got countries that, again, just are not in a position to put that kind of priority on that.

Mr. SHERMAN. Of those countries that are at least in the middle tier of wealth of countries, which ones are giving the least cooperation or priority to Council Resolution 1540?

Mr. VAN DIEPEN. I think probably the thing to do is to try and get back to you with a considered answer to that, Mr. Chairman. Off the top of my head, I am not sure I am able to.

Mr. SHERMAN. Okay, now of those countries, how long will it take for you to get back to us with an answer on that?

Mr. VAN DIEPEN. A week?

Mr. SHERMAN. A week is fine. Of the countries that are state sponsors of terrorism, which is the greatest biological terrorism concern, or biological weapons concern?

Mr. VAN DIEPEN. Well, I think because of the nexus with terrorism, I think Iran would probably be near the top of my list of concerns. Because you have got the issues not only of the potential nation-state angle of that; but because they are a state sponsor of terrorism, and have provided other kinds of weapons to terrorists groups, you know, they would certainly be, for me, a concern.

Mr. SHERMAN. I mean, there are two areas in the State Department. One is trying to coordinate our response to the spread of disease, such as avian flu. The other is your efforts. The pathogens do not even know whether they were deliberately created or not.

How closely do you work in a coordinated way, so that we can respond internationally to the outbreak of a pathogen, whether it is intentional or unintentional?

Mr. VAN DIEPEN. That is exactly a key part of the philosophy behind much of our Biosecurity Engagement Program activity; the idea that if we can assist in the detecting, surveillance, and fighting of disease regardless of its origin by definition, we are helping ourselves out in the biological weapons area.

Mr. SHERMAN. Now Indonesia has refused to let any of the developed countries in the world get adequate samples of avian flu. They have taken the peculiar position that this is a property right of theirs; which means they claim it as property on the theory that they can get money for it.

But all legal systems provide that if an animal is your property and it causes damage, you are responsible for the damage; and a pathogen is an animal.

So from that standpoint, is Indonesia willing to claim not only the rights of ownership of these strains of avian flue; but also to claim responsibility for the harm done by the avian flu; and have they adequately set up reserves to reimburse the world for the harm that may be done by the avian flu and their failure to provide developed nations with the samples necessary to develop a vaccine?

Mr. VAN DIEPEN. I am really not in a position to answer that question, Mr. Chairman. I just am not aware of what the answers to those questions might be.

Mr. SHERMAN. Well, it is pretty apparent that we could see hundreds of thousands of innocent deaths because of the position of the Indonesian Government; a government where tens or hundreds of thousands of people were saved by the world aiding Indonesia after the tsunami. And the fact that the State Department is not making a bigger deal of this non-deliberate possible Indonesia-caused holocaust is surprising to me; and I will look forward to seeing the State Department making a bigger deal of this issue.

With that, I do not think there is interest in a second round with our first panel. After all, America does not torture; and accordingly, we will allow you to leave.

[Laughter.]

Mr. SHERMAN. Let us bring up the second panel; and thank you for your testimony.

First, I would like to introduce Barry Kellman, president of the International Security and Biopolicy Institute. Mr. Kellman is a professor of international law and director of the International Weapons Control Center at DePaul University College of Law.

He has prepared for the subcommittee a report on United States foreign policies and programs to reduce bio-dangers. I want to thank you for that work.

Our next witness is Jonathan Tucker, who is a senior fellow at the James Martin Center for Nonproliferation Studies, the CNS, of the Monterey Institute of International Studies, where he specializes in the control of biological and chemical weapons. He joined CNS's main office in March 1996 as founding director of the Chemical and Biological Weapons Nonproliferation Program.

And finally, we will hear from Stephen Rademaker. I will try to pronounce your name correctly. It is not that tough. In 2008, he

was appointed by the congressional leadership to the U.S. Commission on the Prevention of Proliferations of Weapons of Mass Destruction and Terrorism. He currently serves as senior counsel for BGR Group Government Affairs; Mr. Kellman?

STATEMENT OF BARRY KELLMAN, J.D., PRESIDENT, INTERNATIONAL SECURITY AND BIOPOLICY INSTITUTE

Mr. KELLMAN. Chairman Sherman, Congressman Scott, thank you for the opportunity to discuss policies for preventing for the violent infliction of disease.

Envision 10 terrorists spreading highly weaponized anthrax in 10 cities around the world: Nairobi, Warsaw, Tokyo, Mexico City, et cetera. Assume not a single American is touched by any of these attack, none of which happen on American soil. Would anyone suggest that we are unharmed?

If instead, a smallpox pandemic is ignited, killing perhaps millions worldwide, if Americans are effectively immunized, does that mean that we are okay?

If I might, Mr. Chairman, I have to take issue with your opening statement that biological weapons will not kill more people than any nuclear weapon. I simply disagree, and we can come back to that, if you like.

Bioattacks that devastate allies, transform developing societies into chaos, stop transport and trade cause trillions of dollars of losses; and so worldwide panic would catastrophically wound the United States.

As to biothreats, Homeland Security is international security and vice versa. We cannot wall ourselves off from worldwide bioattacks.

Mr. Chairman, Congressmen, global preparedness must be a high foreign policy of the United States, working with our allies and the international system. By global bio-preparedness, I mean having a global network of stockpiled medicines, linked to delivery systems, to get them where they are needed quickly, with effective plans to ensure their distribution.

A principal value of global bio-preparedness is deterrents. Why weaponize pathogens to populations can be effectively immunized or treated. The best outcome of global bio-preparedness is having medicines and delivery capabilities that are ready but never used; precisely because our enemies cannot advance their horrific goals by committing bioattacks.

Moreover, allow me to say as the lead author of the Kampala Compact, global bio-preparedness can and must be a boon to public health. Global bio-preparedness is, in effect, a highway system. Once built, it can carry any medicines for any diseases rapidly and effectively.

Consider the diplomatic implications of the United States making global bio-preparedness a top policy priority, as the United States approaches the seventh review conference of the Biological Weapons Convention next year. Strengthen security from biothreats; strengthen the convention; strengthen global public health—altogether, exercise U.S. leadership for multiple benefits.

But there are challenges. In small part, there is a supply challenge; having sufficient drugs for the spectrum of potential agents.

But at least with regard to anthrax antibiotics and vaccines, there is vast, untapped capacity.

The greater challenger is delivery. If we turn to the hypothetical anthrax in tent cities around the world. The white powder must be collected and sent to diagnostic facilities for analysis. Once confirmed as anthrax, vaccines and antibiotics must be transported perhaps thousands of miles to the target site, where they must be dispensed to victims. All this must happen in less than 72 hours; outside perhaps two dozen countries in the world, mere fantasy.

Of greater significance, I posit, is that the are legal potholes scattered all over this topic. Allow me to highlight a mere handful.

There are legal challenges that disincentivize the bio defense sector from participating. Licensing requirements vary radically from country to country. How should medicines for weaponized pathogens be tested? What standards are there for emergency use authorization?

Also, there is the prospect of ruinous liability for the manufacturers of such medicines, if they have adverse consequences. These issues must be resolved now, if we want the private sector to supply a bio-preparedness network.

Two, there are legal challenges associated with stockpiling medicines. Regional stockpiling requires binding agreements, so that victimized nations can get what they need, when they need it. Also, stockpile managers must have proper authority for maintaining the surety of their contents.

Three, there are legal challenges associated with delivery. What carriers will be involved? What are their rights and responsibilities? Who is authorized to decide how to allocate scarce supplies?

A clear command and control architecture is imperative. Without elaborate planning, what will be the authority of public health officials to commandeer resources and triage patients? How will medical records be accessible? How will quarantines be enforced?

Mr. Chairman, in the wake of bio attacks, we cannot tolerate delay, as officials question their legal authority to act. We would not tolerate such delays, challenges to domestic preparedness; and our Government deserves commendation for addressing many of these challenges inside the United States since 9/11.

To call domestic preparedness a failure unjustifiably derogates the enormous effort of dedicated public servants, and suggests to our allies that they should not emulate our example when precisely the opposite message is required and appropriate.

Mr. Chairman, global bio-preparedness is not about generosity. It is about protecting the American people from international threats in an inter-connected world. Taking the benefits of our experience and capacity to the international community epitomizes what America does best; promoting the rule of law.

By building global bio-preparedness, we would engage all nations that share concern about biothreats. We would advance public health readiness, and we would establish a security framework upon which additional positive initiatives can be built for meeting evolving threats.

Moreover, we would accelerate the development of biotechnology with positive implications for our economic recovery.

I ask this subcommittee to consider three questions. One, does the State Department have all the authority it needs to plan, negotiate and implement global bio-preparedness?

Two, does the State Department have the authority, resources, and capacity to develop optimal answers to the many legal challenges confronting global bio-preparedness? If not, how can these issues be addressed?

Three, I have already mentioned the importance of taking global bio-preparedness to the BWC. But there are many opportunistic venues for advancing this objective, including the U.N. Security Council, NATO, the World Economic Forum and the G8. How precisely to do this is a matter for the subcommittee to consider.

Finally, allow me to ask you all, what would Congress do, in the wake of biocatastrophies that relegate every other policy priority to insignificance? What would Congress do to prevent a second series of attacks? Amid mass deaths and huge economic losses that demonstrate the horrific implications of procrastination, what will you do?

I respectfully ask you not to wait for the first attacks to prepare for the second attacks. Thank you very much for your attention.

[The prepared statement of Mr. Kellman follows:]

TESTIMONY BY

PROFESSOR BARRY KELLMAN

PRESIDENT, INTERNATIONAL SECURITY & BIOPOLICY INSTITUTE

TO THE HOUSE OF REPRESENTATIVES

FOREIGN AFFAIRS SUBCOMMITTEE ON TERRORISM, NONPROLIFERATION AND TRADE

MARCH 18, 2010

Chairman Sherman and distinguished members of the subcommittee, thank you for the opportunity to discuss the international security dimensions of preventing and preparing for violent infliction of disease.

Mr. Chairman, with your permission, I would like to formally submit for the record a report prepared by the International Security & Biopolicy Institute at the request of you and this subcommittee's staff: *United States Foreign Policies and Programs To Reduce Bio-Dangers*. This report provides an overview of relevant policies and describes the various USG agencies and offices that manage programs to counter biothreats internationally. I would like to thank the many Executive branch officials who assisted us in this study as well as my principal co-authors, Michael Kraft, Zachary Clopton and Orley Lindgren. The report's full text can be found at http://www.biopolicy.org/sites/default/files/documents/ISBI%20Congressional%20Report%20Final.pdf. We hope this report will be useful as you consider possible legislation for strengthening the United States' capacity for countering biothreats.

Today, I would like to focus on five major points:

1. The United States is not secure from catastrophic bioterrorism if our foreign allies and partners are unprepared for bio-attacks. Unfortunately, most nations are unprepared.
2. The highest policy priority is to prevent biothreats through global biopreparedness – building capacity to treat bio-attack victims and contain the spread of disease.
3. Engaging the international community in biopreparedness could have significant benefits, advancing public health and promoting a mutual and integrated global security system.
4. Global biopreparedness is impeded by legal problems that: disincentivize private sector engagement; obstruct implementation of an efficient regional stockpiling system for medical countermeasures (MCMs); undermine MCM delivery planning; and hinder dispensation of MCMs to victims.
5. These legal challenges should be addressed now, before a bio-attack. Congress should authorize a study of these legal challenges and their solutions in order to enable the State Department to identify optimal international biopreparedness policies.

OVERVIEW OF THE THREAT

A strategically executed series of anthrax attacks in major cities could kill tens of thousands, perhaps far more, and sow panic of unprecedented proportions. No one in Congress need be reminded that, following 9/11, a relatively small release of anthrax caused widespread disruption. Use of a contagious virus for which none of us carry immunity would have vastly worst consequences.

The emergence of synthetic genomics opens new opportunities to modify existing diseases, re-create maladies from our past, or create altogether novel ailments. How many might succumb to a release of synthesized smallpox or other genetically modified disease? What if other orthopox viruses—monkeypox or camelpox—can be manipulated to be resistant to the vaccines and therapeutics that are stockpiled against smallpox?

According to the National Academies of Science, "The threat spectrum is broad and evolving—in some ways predictably, in other ways unexpectedly. . . . In the future, genetic engineering and other technologies may lead to the development of pathogenic organisms with unique, unpredictable characteristics."[1] Every passing day it will be slightly easier to commit a violent catastrophe than it was yesterday. As far as can be seen is the prospect of bioscience for life inseparably intertwined with bioscience for violence.

Nor, amid such a catastrophe, could any one know where the next attack might happen. Multiple unseen disease attacks with ceaseless nightmares about where and when the next attack might occur could well serve terrorists' interests. Disease agents are available, cheap, easy to move and to release, undetectable, and could have widespread, long-lasting, and devastating effects. If a terrorist's ambition is to rattle the pillars of modern civilization and perhaps cause it to collapse, violent infliction of disease is the way to go.

NEED FOR AN INTERNATIONAL PERSPECTIVE

All this leads to the question that is raised by this hearing: are we secure even if U.S. domestic resilience capacities are optimal? The answer is No.

America is not secure if our allies and trading partners are vulnerable. As President Obama recently asserted, "a biological incident that results in mass casualties anywhere in the world increases the risk to all nations from biological threats."[2] More than any other threat of violence, the inherent nature of intentionally inflicted disease is international.

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[1] NATIONAL RESEARCH COUNCIL, GLOBALIZATION, BIOSECURITY, AND THE FUTURE OF THE LIFE SCIENCES 49 (2006).

[2] NATIONAL SECURITY COUNCIL, NATIONAL STRATEGY FOR COUNTERING BIOLOGICAL THREATS, p. 3, Nov. 2009.

Even if our labs and culture collections are secure, a terrorist can likely get lethal agents overseas. Even if our law enforcement communities are trained and equipped to interrupt bioterror plots, law enforcers in most foreign nations lack comparable capacities. Even if the best bio-sensors can detect a release in major hubs and venues, a contagious disease could be spread in an overseas airport and build into a firestorm before anyone knows of the attack.

Most important, even if Americans could be immunized against every bioviolence agent, no one should think that America will be just fine. A series of bio-attacks against our allies and partners could readily cripple the international economy. Important to remember in this context is the unique capacity for repeated attacks that biological agents afford to a potential attacker. Bio-attacks that devastate allies, transform developing societies into chaos, cancel transport and trade, and sow worldwide panic would beget a profoundly catastrophic environment. If only for the potential magnitude of loss, perhaps counted in millions of lives and trillions of dollars, Americans would be gravely wounded by a foreign bioviolence attack.

THE PRIORITY OF GLOBAL BIOPREPAREDNESS

Threats of violently inflicted disease call for an array of international policies, many that the United States is currently promoting, a few of which should be substantially accelerated. Among the high priorities are: strengthening law enforcement globally, promoting secure bioscience, and enhancing situational awareness and diagnosis of disease. There is no single cure-all in this context, nor do palliatives about enhancing international conventions (as important as these conventions are) offer a potent recipe for security.

Mr. Chairman, I want to emphasize the single highest priority: *global biopreparedness* by building capacity worldwide to treat victims and contain the spread of disease and clarifying legal rules that apply to that endeavor. In the past eight years, the United States has made considerable progress toward domestic preparedness. However, vast shortfalls among our allies and partners expose substantial vulnerabilities. Put simply, the Achilles Heel of U.S. policies for confronting biothreats is the rest of the world.

Today, there is an appalling inadequacy of medical countermeasures (MCMs) to meet bio-attacks. Consider smallpox, arguably among the gravest of potential bioviolence agents. Global stockpiles of smallpox vaccine are less than 800 million doses – enough, at best, for 12% of the world's population if ideally distributed. Over 80% of these doses are stockpiled in six countries. Ten countries have appreciable stockpiles of vaccine (relative to their population size). Nearly all other countries have little or no vaccine.

Responsibility for saving lives following bio-attacks will fall on the United States and a few allies. Time is critical. Envision, for example, release of weaponized anthrax in a foreign sports arena, infecting thousands of victims. The white powder must be collected and sent to a

diagnostic facility for analysis. Once confirmed as anthrax, stockpiled vaccines and antibiotics must be allotted; those MCMs must then be transported to a cargo plane that will take them perhaps thousands of miles to the target site where they must be dispensed to victims. All this must happen within less than 72 hours (likely less). Outside perhaps two dozen countries in the world, meeting this medical deadline is little more than a fantasy. This situation must be improved now, before a crisis demonstrates the consequences of being unprepared.

Biopreparedness policies have obvious benefits, including deterrence. If medical countermeasures (MCMs) are available, the victims can be treated and the consequences of an attack can be contained. By reducing damage and containing losses, we can deter attacks. A culprit who seeks to inflict mass violence and panic will be less inclined to use disease in the face of organized and efficient measures to limit the consequences.

Importantly, engaging the international community on biopreparedness could have powerfully beneficial effects. It is in everyone's interest to ensure MCM availability because an effective plan for MCM stockpiling and distribution could be dual-use – it could be a major tool of public health for addressing natural pandemics as well as bioviolence. Engagement of international organizations, the private sector, along with many States could thus be transformative of this entire policy arena, designing an integrated global system where benefits are shared, responsibilities are common, and security is mutual.

The good news here is that the challenge of global preparedness is not centrally about devoting enormous resources to new medicines, although better medicines to treat emerging diseases will be useful long-term. For now, we should increase stockpiles of available medicines and link those stockpiles to logistical capacities for rapid deployment.

Policies to advance multilateral coordination with key allies should focus on three key dimensions.

1. Facilitate use of MCMs by: exchanging information about threats and relevant vaccines/treatments; promoting harmonized licensing standards for mutual approval of useful MCMs; and ensuring that intellectual property protections for developers of new MCMs are effective.
2. Implement a stockpiling strategy that: provides guidance for MCM stockpile location and contents; assesses MCM procurement and surge capacities; sustains MCM stockpile surety and security; and ensures rapid deployment of MCMs as necessary in response to outbreaks.
3. Encourage MCM delivery planning that focuses on: command and control responsibilities for triggering and supervising MCM delivery, logistics for fast and efficient distribution, and public health readiness and training to receive and dispense MCMs.

In this year's State of the Union, the President announced a new and very significant initiative for responding faster and more effectively to bioterrorism at home and abroad. This initiative will expand on the Administration's newly announced *Strategy for Countering Biothreats*. This is an auspicious initiative for enhancing preparedness against global biothreats by enhancing capacities for rapid delivery of MCMs.

Yet, there are reasons to be less than optimistic about prospects for progress. *Global biopreparedness* requires a vital commitment, not only by Executive Branch officials but by Congress as well.

LEGAL CHALLENGES CONFRONTING GLOBAL BIOPREPAREDNESS

Among the challenges that Congress should confront, perhaps the most significant with the most long-lasting implications, are those associated with gaps and inconsistencies of law. The United States can propel progress in this domain. By exercising leadership in addressing these legal challenges, we would reinforce our stature as the global flag-bearer of the rule of law.

Very briefly, there are legal problems that:

- Disincentive the private sector from developing medical countermeasures

It is widely appreciated that private sector entities are important for developing and producing relevant medical countermeasures. There are substantial obstacles, however, that discourage their engagement. Because nations have inconsistent licensing standards, a producer of medicines must run a gauntlet of testing procedures for a drug that might never be used. If an emergency evokes a sudden need for their products, they could lose protection of their intellectual property rights; their return on investment might evaporate. Moreover, if their product causes any injury, even if it saves many more lives, could give rise to ruinous liability.

- Impede implementation of regional stockpiling of medical countermeasures (MCMs)

It is imperative that MCMs be forward deployed to ensure that they can get to an attacked target rapidly when necessary. It is prohibitively expensive for each nation to have its own stockpile, but a more efficient regional stockpiling system will require extensive legal arrangements to ensure that victimized nations will have access to such stockpiles as necessary. For this system to work, legal arrangements must stipulate command and control authority that keeps those stockpiles secure. Moreover, harmonized standards for emergency use of MCMs must ensure that, when needed, they can actually be put to use.

- Undermine planning for the efficient delivery of stockpiled MCMs

To distribute stockpiled MCMs efficiently to perhaps many thousands of victims requires advance planning. Packaging standards and delivery logistics must be harmonized among nations. All delivery components, including air and ground transport systems, must be networked. Again, command and control authorities must be clear and must have appropriate

capacity to coordinate with their counterparts in neighboring nations. Critical decisions must be made in advance to rationalize domestic authorities for ensuring distribution to victims. Planners must also develop contingent plans for estimating which public and private assets and personnel will participate.

- Will likely obstruct dispensation of MCMs to victims of a bio-attack during conditions of extraordinary panic when the last thing that should be done is consulting with lawyers to determine what is legal and what is not.

On the ground, law enforcers will struggle to maintain order while thousands of people, facing quarantines or other restrictions, try to get life-saving treatment. Plans should also provide guidance on preparation of medical personnel for mass countermeasure administration, specifying the appropriate number of staff at each dispensation site. It will be necessary to track adverse consequences, implicating victims' privacy rights. During an outbreak, authorities will have little time to discuss the issue, much less engage in a protracted legal process to authorize mandatory administration of MCMs. The fact that various nations resolve these questions differently can impede a multinational response.

ADDRESS PREPAREDNESS CHALLENGES

The time to address these legal challenges is now. In the United States, most of these issues have received attention, albeit unevenly. It is important to acknowledge the enormous strides that have been and continue to be made by dedicated people throughout our government. It is simply wrong – to say nothing of insulting to the many hard-working government officials dedicated to keeping us safe – to suggest that these policies are a failure. But it would be equally wrong to not identify remaining gaps, to deny that we can and should be doing more.

Mr. Chairman, as I earlier indicated, global biopreparedness is not about generosity, it is about the national security of the United States. With regard to biothreats, there is no security in isolation. Taking an international perspective means exercising leadership in the way that America does best and has earned us global respect, by promoting the rule of law. By advancing global biopreparedness, we would significantly assist all nations that share concerns about bio-threats; we would advance public health readiness; and we would accelerate the development of bioscience and technology with positive implications for our economic recovery. And, we would establish a security framework upon which additional positive initiatives can be built – a framework that can build capacity for meeting constantly evolving threats.

Mr. Chairman, Congress can take two important steps to advance global biopreparedness, two steps that carry negligible cost. First, authorized officials would be hard pressed to find serious analyses of the legal and other issues that must be the prerequisite of effective discussions about global biopreparedness with our allies and in global institutions. Congress can

usefully instruct the State Department to identify effective legal modalities to resolve preparedness challenges. Second, Congress should consider calling on the President to convene a *Global Biological Terrorism Summit*, modeled on the upcoming *Global Nuclear Terrorism Summit*. The reality here is that while the United States can and should exercise leadership in this domain, biothreats compel engagement of foreign nations at the highest level. Solutions will be more successful if our allies comparably appreciate why biopreparedness should be a high priority and how collectively we can reduce risks. A Global Summit would be a valuable step in the right direction.

Allow me to conclude on a sour note. From President Obama to this subcommittee to everyone in this government, there can be no serious question that catastrophic bio-attacks will relegate every other policy priority to insignificance. Amid a disease cataclysm that demonstrates the horrific implications of procrastination, mustering the commitment and energy to build a preparedness infrastructure for security against a second such cataclysm will be easy. In view of the potential magnitude of harm that the first attack of bioviolence could cause, we should not wait for it before preparing for the second attack.

Thank you, and I am happy to respond to any questions.

STATEMENT OF JONATHAN B. TUCKER, PH.D., SENIOR FELLOW, JAMES MARTIN CENTER FOR NONPROLIFERATION STUDIES, MONTEREY INSTITUTE OF INTERNATIONAL STUDIES

Mr. TUCKER. Chairman Sherman and distinguished members of the subcommittee, thank you for the invitation to appear before you today.

Last November the Obama administration released a National Strategy for Countering Biological Threats, containing broad guidelines for U.S. policy. The challenge facing the administration and Congress in the months ahead will be to translate these guidelines into a set of concrete policy initiatives and to give them the political and budgetary support they require for effective implementation.

A key strength of the national strategy is that it integrates public health and security concerns into a single paradigm. This approach makes sense from a policy standpoint because it promotes efforts to strengthen global public health infrastructure in a way that bolsters U.S. defenses against both natural epidemics and bioterrorist attacks.

The national strategy also emphasizes the potential risks associated with emerging biotechnologies. Synthetic genomics, for example, provides the capability to synthesize long DNA molecules from scratch and assemble them into the genome of a virus. This ability raises security concerns because it could potentially enable sophisticated terrorist groups to circumvent stringent controls on select agents of bioterrorism concerns, such as Ebola virus. Because the gene synthesis industry is international, the United States will have to work with other countries to harmonize measures to prevent the misuse of this technology.

Other international measures to enhance biosecurity revolve around the Biological Weapons Convention, which remains the cornerstone of efforts to prevent biological weapons proliferation and terrorism.

The Obama administration's assessment that biological verification is not currently feasible is no excuse for inaction or complacency. To move beyond the legacy of the failed BWC Protocol, a package of bold, innovative measures will be needed to build confidence in compliance and to deter violations.

One critical element is to increase the transparency of biodefense research programs, which have expanded dramatically in the United States and other countries since the terrorist attacks of 2001 and could theoretically serve as a cover for offensive bioweapons development.

Enhanced transparency is in the United States' interest for two reasons. First, it offers greater insight into the BWC-related activities of other countries, providing greater confidence that they are complying with their treaty obligations. Second, it mitigates international suspicions about U.S. biodefense programs that might drive other nations to pursue questionable research.

Another useful approach to increasing the transparency of BWC-related activities is to build cooperative relationships between biodefense scientists and institutions in the United States and those in countries of proliferation concern.

In recent years, the Defense Department's Biological Threat Reduction Program and other U.S. biological engagement programs have reduced their activities in Russia because of bureaucratic and political difficulties in dealing with the Russian Government. Nevertheless, these engagement efforts are crucial for transparency and should be reinstated.

Another important biosecurity measure lies with the United Nations. Because of the failure to conclude the BWC Protocol, the only option for investigating an alleged use of biological weapons is a long-standing mechanism under the auspices of the U.N. Secretary-General.

At present, however, the U.N. lacks the resources to rapidly field teams of suitably trained and equipped investigators. To remedy this problem, the United States should lead efforts to update and strengthen the Secretary-General's mechanism. This capability would have an important deterrent effect by making it more likely that a covert biological attack will be attributed to a state or non-state actor.

Yet another way to strengthen global biosecurity is to improve systems for infectious disease surveillance and response. In today's globalized world, an outbreak of serious epidemic disease anywhere in the world poses a potential risk to Americans here at home.

Global networks for infectious disease surveillance and response provide an extended defense perimeter for the United States by making it possible to detect and snuff out epidemics, whether natural or human-caused, before they reach our shores. But existing disease-surveillance networks still contain many gaps in coverage, preventing the timely detection and containment of outbreaks close to the source.

The International Health Regulations, which were revised in 2005, require the member countries of the World Health Organization to report in a timely manner all public health emergencies of international concern that could potentially affect more than one country. Nevertheless, because many developing countries lack the financial and technical resources to establish effective national disease surveillance and response capabilities, the United States and other advanced countries must be prepared to help out.

A critical event for advancing all of these biosecurity objectives will be the Seventh Review Conference of the Biological Weapons Convention, which will convene late next year in Geneva, Switzerland.

This comprehensive review of the treaty's implementation will be a make-or-break political opportunity for the United States. But the U.S. delegation will also have to navigate some treacherous political shoals.

It is likely that several BWC member states, including Iran and Russia, will seek to revive the protocol negotiations as a means to pursue their negative agenda of attempting to weaken the convention itself. To block these efforts, the United States will have to offer an alternative package of bold and compelling measures to strengthen the BWC.

Given the high stakes involved in the review conference, it is imperative that the State Department resolve the current internal

dispute over which Bureau is responsible for the BWC and begin preparing for next year's meeting as soon as possible.

Another important task for the Seventh Review Conference will be to address the institutional deficit of the BWC. The last review conference in 2006 established an Implementation Support Unit consisting of three people at the U.N. Office in Geneva. But this entity has limited authority and a temporary mandate that must be renewed by member states in 2011. The Obama administration should push to make the unit permanent, while expanding its staff and responsibilities.

In conclusion, implementing the National Strategy for Countering Biological Threats will require the White House to give the same level of political attention to biological security that it has devoted to crafting and promoting its nuclear security initiatives. It will then be up to Congress to review the administration's agenda and pass legislation and funding needed to implement it effectively. Thank you.

[The prepared statement of Mr. Tucker follows:]

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Addressing the Spectrum of Biological Risks: A Policy Agenda for the United States

Jonathan B. Tucker, Ph.D.
Senior Fellow
James Martin Center for Nonproliferation Studies

Testimony before the House Committee on Foreign Affairs,
Subcommittee on Terrorism, Nonproliferation, and Trade
National Strategy for Countering Biological Threats: Diplomacy and International Programs
March 18, 2010

Chairman Sherman, Ranking Member Royce, and distinguished members of the Subcommittee, thank you for the invitation to appear before you today to discuss the effectiveness of current and planned U.S. international policies and programs to address biological threats, particularly bioterrorism.

Last November, the Obama Administration released a *National Strategy for Countering Biological Threats*, which provides a comprehensive roadmap for addressing the full range of biosecurity and infectious-disease challenges facing the United States. Although the strategy document sets out policy guidelines, it states that their implementation, including specific actions to be taken by Federal agencies, "will be directed separately." Thus, the challenge facing the Administration and Congress in the months ahead will be to translate the broad guidelines in the National Strategy into a set of concrete policy initiatives, and to give them the political and budgetary support they will require for effective implementation.

In my testimony today, I will discuss ways to build on the strengths of the National Strategy and will make recommendations for translating the guidelines into action and for filling a number of gaps. In particular, I will discuss a number of measures to reinforce the norms embodied in the Biological Weapons Convention, which serves as the cornerstone of international efforts to counter biological weapons proliferation and terrorism.

A Holistic, Preventive Approach to Biological Threats

The National Strategy takes a holistic approach to infectious-disease threats by viewing them as a spectrum that encompasses (1) natural emerging infections such as SARS and avian influenza, (2) the accidental release of pathogens from a research laboratory, and (3) the deliberate use of disease as a weapon by states and non-state actors such as criminals and terrorist organizations. In this way, the strategy document integrates public health and security

concerns into a single paradigm, rather than drawing an artificial distinction between natural epidemics and deliberate biological attacks. While it is true that certain attack scenarios involving exotic or bioengineered pathogens would be recognized almost immediately as bioterrorism, in other cases it might not be clear for days or even weeks whether the cause of an outbreak was natural or deliberate. Fortunately, many of the same detection and response measures, such as disease-surveillance systems and the distribution of antibiotic drugs, are effective regardless of the source of an outbreak. Integrating the public health and security dimensions of the infectious-disease threat into a single paradigm therefore makes sense from a policy standpoint because it promotes efforts to reinforce the global public-health infrastructure in ways that bolster U.S. defenses against both natural epidemics and bioterrorist attacks.

The National Strategy also provides some needed balance to the nation's biosecurity posture by placing a greater emphasis on preventive measures to reduce the risks of biological weapons proliferation and terrorism. The Bush administration focused its biodefense efforts on strengthening domestic preparedness and response capabilities through programs such as BioShield and BioWatch, while tending to write off efforts on the prevention side of the equation as too difficult. The Obama administration, to its credit, has recognized the importance of nipping biological threats in the bud before they can materialize fully.

Although terrorist organizations such as al-Qaeda continue to be interested in using standard biological agents such as the anthrax bacterium, which is relatively easy to obtain and weaponize, the National Strategy document emphasizes the dynamic nature of biological threats, including the potential risks associated with emerging biotechnologies. Synthetic genomics, for example, provides the technical capability to synthesize long DNA molecules from scratch and assemble them into a genome, the genetic blueprint of an organism. This feat has already been accomplished for several viral pathogens, including poliovirus, the 1918 pandemic strain of influenza virus, and the SARS virus, and it is only a matter of time before it becomes feasible for larger, more complex biological agents such as the smallpox virus. The ability to synthesize dangerous viral pathogens from scratch raises security concerns because it could potentially enable sophisticated terrorist groups to circumvent stringent controls on "select agents" of bioterrorism concern, such as hemorrhagic fever viruses. Because commercial gene-synthesis providers now exist in countries around the world, including China and Germany, any effective biosecurity regime for synthetic genomics will have to be harmonized internationally, a task requiring outreach and coordination with foreign governments and companies.

Another worrisome development not mentioned in the National Strategy document is the rise of the "open-source biology" and "do-it-yourself-biology" movements, which seek to make sophisticated biotechnologies such as genetic engineering and synthetic biology readily available to amateurs and hobbyists, including those without formal scientific training. Some of these enthusiasts may have benign intentions but may not be fully aware of the potential hazards and security risks associated with the new genetic technologies, while others may be aspiring "biohackers" who are either reckless or malicious. Because microbes are alive and self-replicating, the inadvertent or deliberate release of an engineered microorganism could have serious consequences for the environment and public health. To manage these risks, the U.S. government should undertake a number of measures. In addition to promoting a "culture of responsibility in the life sciences," it will be necessary to introduce effective oversight measures, biosafety and biosecurity training programs, and voluntary or mandatory guidelines to ensure that powerful biotechnologies such as synthetic biology are employed in a safe and secure

manner. It should be possible to devise prudent measures to prevent misuse without impeding legitimate research or curtailing beneficial applications.

Revitalizing the Biological Weapons Convention

The Biological Weapons Convention bans the development, production, stockpiling, and transfer of biological and toxin warfare agents, as well as delivery systems specifically designed for their dispersal, and thus complements the 1925 Geneva Protocol banning the use of such weapons in war. At present, 163 countries are parties to the BWC, and 13 have signed but not ratified it; an additional 19 states have neither signed nor ratified. Since it entered into force 35 years ago, the BWC has embodied the norm against the use of disease as a weapon. Yet because it was negotiated at the height of the Cold War, when the Soviet Union rejected on-site inspections as tantamount to espionage, the BWC lacks any formal verification measures. As a result, it is widely viewed as a weak instrument whose lack of teeth has enabled countries such as the Soviet Union and Saddam Hussein's Iraq to violate their treaty commitments without being held to account.

Unfortunately, the task of verifying the BWC is exceedingly difficult for a number of reasons. First, the fact that biological pathogens and production equipment are "dual-use," meaning that they can be used for either peaceful or hostile purposes, greatly complicates the task of distinguishing legitimate from prohibited activities. Second, although the BWC allows the development of defensive measures, the line between defensive and offensive work can be hard to define and often depends on an assessment of intent. Third, tens of thousands of civilian vaccine plants, industrial fermentation facilities, and legitimate biodefense centers around the world are potentially capable of producing significant quantities of biowarfare agents, making it extremely challenging to ferret out the small fraction of sites that are actually engaged in illicit activity. Finally, the highly intrusive inspections of commercial biotechnology plants that would be required to detect violations of the BWC could put at risk valuable proprietary information, such as genetically engineered microbes used to produce certain drugs and vaccines.

These considerations helped to persuade the Bush administration in July 2001 to reject a draft protocol to the BWC, negotiated over the previous six and a half years, that was designed to bolster the Convention with a system of mandatory declarations and on-site inspections. Also to blame for the failure of the talks were efforts by some states to exploit the protocol negotiations to weaken the BWC itself. Russia, for example, insisted that key terms in the Convention be defined narrowly in an apparent bid to create "safe harbors" for illicit biological weapons development, while Iran, Pakistan, and a few other developing countries sought to dismantle national export controls (harmonized by the Australia Group) on dual-use materials and equipment relevant to biological weapons, on the grounds that such controls "discriminated" against developing countries. Thus, although the U.S. rejection of the draft BWC protocol precipitated the collapse of the negotiations, several other states shared responsibility for creating the impasse that ultimately doomed the talks.

The Obama administration, after weighing the costs and benefits of reviving the BWC protocol, announced last December that it had decided against doing so. Nevertheless, the administration's current assessment that BWC verification is not feasible in practical terms is no excuse for inaction or complacency. To move beyond the legacy of the failed protocol negotiations, the United States must think seriously about alternative ways of revitalizing the BWC and building confidence in compliance. According to the State Department's most recent

arms control compliance report, published in 2005, the U.S. intelligence community suspects four BWC member states (China, Iran, North Korea, and Russia) of violating their treaty commitments. Yet the sole measure mentioned in the National Strategy for addressing compliance concerns—bilateral consultations through confidential diplomatic channels—appears unlikely to make much of a difference.

Bolder, more innovative measures will be required to build confidence in BWC compliance and deter violations. For example, the United States could propose a mechanism for "consultative visits" under Article V of the Convention to address compliance concerns at specific facilities. Such visits would be initiated at the request of a member state and carried out by national experts on a bilateral or multilateral basis; the visits would not be designed to meet the rigorous standards of verification but would seek instead to increase transparency and build confidence. Because the conduct of a consultative visit would require the voluntary cooperation of the host country, BWC member states wishing to resolve concerns and ambiguities about their compliance would presumably cooperate with a visit request, while those countries with something to hide would probably refuse—although they would suffer negative political consequences from doing so.

I will now discuss a number of other measures that could help to reinforce the norms embodied in the BWC and enhance global biosecurity.

Strengthening Global Disease Surveillance

A perennial source of North-South tensions in BWC-related forums is Article X of the Convention, which requires states parties to cooperate in the peaceful applications of biotechnology and to facilitate trade and technology transfer for this purpose. Several BWC member states, led by Iran, have argued that Article X requires the removal of export controls on dual-use biotechnology equipment, yet the Australia Group countries have rejected this claim on the grounds that the BWC obligates them not to aid or abet biological weapons proliferation. One way for the United States and its allies to respond to demands from developing countries for technical assistance without weakening the dual-use export control regime would be to expand global networks for infectious disease surveillance and response under the auspices of the World Health Organization (WHO). Not only would such measures help to meet U.S. obligations under Article X, but they would also directly enhance U.S. national security.

Congress has long tended to view U.S. assistance to the WHO and individual developing countries in combating infectious diseases as a form of foreign aid, divorced from critical U.S. national security concerns. In today's globalized world, however, that perception is increasingly myopic. National borders and oceans no longer pose a barrier to the spread of epidemics: an individual in Africa or Asia incubating a serious viral disease can travel by air to the United States within 24 hours and start transmitting it to others. Indeed, pandemic infections such as SARS and the H1N1 strain of influenza have circled the globe in a matter of months. Although the current flu pandemic has fortunately proved to be less virulent than was initially feared, we may not be as lucky the next time.

Given these facts, the United States can no longer afford to treat epidemics in developing countries as "out of sight, out of mind." As the globe continues to shrink, an outbreak of serious epidemic disease anywhere in the world poses potential risks to Americans here at home. Accordingly, global networks for infectious disease surveillance and response provide an "extended defense perimeter" for the United States by making it possible to detect and snuff out

epidemics—whether natural or human-caused—before they reach U.S. shores. Existing disease surveillance networks still contain many gaps in coverage, however, preventing the timely detection and containment of outbreaks close to the source.

The new realities of public health in a globalized world are finally beginning to sink in. In May 2005, the 192 member countries of the WHO unanimously approved a major revision of the International Health Regulations (IHR), which provide the international legal framework for prevention and response to the cross-border spread of epidemics and other public health emergencies. The updated regulations set new standards for transparency and cooperation, including the timely reporting to the WHO of all "public health emergencies of international concern" that could potentially affect more than one country. Significantly, such incidents could include deliberate releases of biological, chemical, or radiological materials. The revised IHR also require all WHO member states to establish national surveillance and response capabilities for the prompt detection, reporting, and control of public health emergencies of international concern, and expand the WHO Secretariat's powers to monitor and respond to public health emergencies regardless of origin.

The revised IHR are a major step toward global public health preparedness against the full range of biological threats, from natural emerging infections to bioterrorism. Nevertheless, because many developing countries lack the technical and financial resources to fulfill the IHR mandate that they establish effective national surveillance and response capabilities, the United States and other advanced countries must be prepared to help out. For example, Title III, Subtitle B of the Weapons of Mass Destruction Prevention and Preparedness Act (S. 1649), introduced last year by Senators Joe Lieberman (I-CT) and Susan Collins (R-ME), calls for expanding U.S. assistance for this purpose. Although channeling the bulk of U.S. technical and financial assistance through the WHO rather than bilaterally would entail some loss of control, it would give the effort much greater international credibility.

Another major gap in current global disease surveillance systems arises from the fact that many infectious diseases are "zoonotic," meaning that they infect both animals and people. In the case of natural viral infections, such as West Nile encephalitis and avian influenza, wild birds are "sentinel species" that typically become infected before humans and thus provide early warning of an impending epidemic. Similar sentinel species exist for diseases that pose bioterrorism concerns, such as anthrax, tularemia, and plague, yet disease-surveillance systems for animals are significantly less developed than those for humans. It is therefore vital for international health and security to expand the monitoring of zoonotic infections in animals and to integrate them with human disease surveillance networks.

Increasing the Transparency of Biodefense Research

A critical element of building confidence in BWC compliance is to increase the transparency of biodefense research programs, which have expanded dramatically in the United States and other countries since the terrorist attacks of 2001 and could theoretically serve as a cover for offensive bioweapons development. Enhanced transparency is in the U.S. interest for two reasons: (1) it offers greater insight into the BWC-related activities of other countries, thereby providing greater confidence that they are complying with their treaty obligations, and (2) it mitigates international suspicions about U.S. biodefense programs that might drive other nations to pursue questionable research.

At present, the BWC Confidence-Building Measures (CBM) process is the only formal international mechanism for increasing the transparency of national biodefense activities. Under this process, BWC member states are politically but not legally bound to submit specific data about treaty-relevant facilities and activities on an annual basis, including maximum-containment laboratories and unusual outbreaks of infectious disease. Unfortunately, less than half of BWC states parties participate in the CBM process, and many of the submissions are incomplete or inaccurate. In addition, the CBM declaration forms were last revised in 1991, yet rapid scientific and technological advances have rendered them increasingly obsolete. To address these problems, the United States should work with other nations to conduct a thorough review and updating of the CBM mechanism. Activities that might be covered by the updated declarations include studies involving the aerosolization of pathogens and research that could enhance the military potential of biological agents.

Another urgent requirement is for improved oversight of national biodefense programs. Although the BWC allows states parties to conduct defensive research, a lack of transparency about whether or not certain research activities are treaty-compliant can generate corrosive suspicions on the part of other countries. A particularly controversial area of the U.S. biodefense program, for example, involves classified "science-based threat characterization" research at the Department of Homeland Security's National Biodefense Analysis and Countermeasures Center (NBACC) at Fort Detrick in Maryland. Such research seeks to fill "knowledge gaps" about certain pathogens and toxins of biowarfare or bioterrorism concern, including genetically modified agents, in order to guide the development of medical countermeasures. Some observers contend, however, that these efforts blur the line between permitted and prohibited activities under the BWC.

The Departments of Defense and Homeland Security and the Office of the Director of National Intelligence have all established oversight mechanisms to ensure that the biodefense research projects that they conduct or sponsor comply with the BWC. Nevertheless, guidelines and review procedures vary from agency to agency, and there is no established process for high-level, interagency oversight of activities that raise significant BWC compliance concerns. Despite the shortcomings of the U.S. treaty compliance review mechanism, it is still superior to that of other countries with large biodefense programs, such as Russia and China, whose intentions and activities in this field remain largely opaque. Actions by the United States to increase the oversight and transparency of its own biodefense programs would not only demonstrate international leadership by providing a model for other countries to follow, but would put the U.S. government in a position to demand greater openness from others.

To strengthen confidence in BWC compliance, additional efforts will be required. First, the United States should make sustained efforts to engage the Russian and Chinese governments in discussions of biodefense and the control of dual-use biotechnologies. Another useful approach to increasing the transparency of BWC-related activities is to build cooperative relationships between biodefense scientists and institutions in the United States and those in countries of proliferation concern. Expanding international research partnerships and personnel exchanges can provide valuable insights into foreign biodefense programs and build mutual confidence in BWC compliance. After such scientific exchanges have taken place, it is also important to preserve the resulting collegial networks through dedicated websites and "alumni" events. Yet despite the compelling security rationale for increased scientific exchanges, tightened

U.S. visa policies since 9/11 have made it harder for foreign scientists to work at U.S. research institutions and vice-versa.

Expanding U.S. Biological Engagement Programs

Biological engagement programs can also reinforce the goals of the BWC. The Defense Department's Biological Threat Reduction Program (BTRP) and the State Department's Global Threat Reduction Program (GTRP) have long provided financial and technical assistance to improve biosafety and biosecurity at facilities in the countries of the former Soviet Union. In recent years, however, the BTRP and other threat-reduction programs have largely disengaged from Russia because of bureaucratic and political difficulties in dealing with the Russian government, which has refused requests for greater transparency at former biological weapons facilities, particularly those controlled by the Ministry of Defense. As the U.S. National Research Council has pointed out, however, "There are considerable risks entailed in not participating in research engagement activities but instead simply remaining on the sidelines and speculating as to what may be taking place." Accordingly, the United States should seek to reengage with the Russian biodefense institutes by offering to conduct collaborative research in areas of mutual interest.

Biological threat-reduction programs should also be expanded globally. In recent years, the State Department's Biosecurity Engagement Program has initiated pilot programs outside the former Soviet Union, with an emphasis on countries such as Indonesia, Pakistan, and the Philippines, that harbor collections of dangerous pathogens and have active Islamist insurgencies that could seek biological weapons. Nevertheless, the State Department lacks sufficient resources to assess biological threats in other parts of the world, such as sub-Saharan Africa. The effectiveness and sustainability of U.S. bioengagement programs has also suffered from a gap between U.S. biosecurity goals and the needs and priorities of the recipient states, which are usually more concerned with natural infectious disease threats than with the prevention of bioterrorism. While securing collections of dangerous pathogens to keep them out of the hands of terrorists is an important objective, the United States also needs to develop an appreciation for how combating natural epidemics is relevant to U.S. national security. Accordingly, Congress should increase funding for biological engagement in countries around the world that face biosecurity threats, while transitioning from U.S.-directed assistance programs to true partnerships that focus on areas of interest to both sides.

Strengthening the UN Mechanism to Investigate Alleged Use

The Chemical Weapons Convention, which entered into force in 1997, includes a set of multilateral procedures for investigating allegations of chemical weapons use. In the biological weapons area, however, the failure to conclude the BWC protocol, which would have included field-investigation measures, means that the only option for investigating the alleged use of biological weapons is a long-standing mechanism under the auspices of the United Nations Secretary-General. During the early 1980s, a series of resolutions in the UN General Assembly and the Security Council gave the Secretary-General the authority to launch field investigations of the alleged use of biological or chemical weapons in violation of the 1925 Geneva Protocol. Such an investigation can be launched either on the Secretary-General's own initiative or at the request of a UN member state. About a dozen UN field investigations took place during the

1980s and early 1990s in Southeast Asia, Iran, Iraq, Mozambique, and Azerbaijan, but since then the mechanism has been inactive.

In 2006, the UN General Assembly urged the Secretary-General to update the nearly 20-year-old roster of experts and reference laboratories that can be made available on short notice and to revise the technical guidelines for conducting investigations of alleged use. Although the UN updated the roster of experts in 2008, it made little progress in revising the investigation procedures because of the sovereignty concerns of some countries, notably China. Another problem is that the UN lacks the resources to rapidly field a team of suitably trained and equipped investigators. Instead, the Secretary-General must hastily assemble a team from the experts provided by member states on an *ad hoc* basis. Such individuals have varying degrees of expertise and training and no previous experience of working together, reducing their effectiveness.

In order to remedy these problems, the United States should launch a high-level diplomatic initiative to build an international consensus in favor of updating and strengthening the Secretary-General's field investigation mechanism. To that end, the State Department should work closely with the UN Secretariat, other member states, and the International Criminal Police Organization (Interpol) to train a multinational cadre of experts capable of investigating complaints of biological weapons use, create logistical arrangements for conducting short-notice field investigations anywhere in the world, and adopt validated methods for the collection, chain-of-custody, and analysis of environmental and biomedical samples. The United States should also offer scientific and technical support to UN investigation teams, including expertise in microbial forensics and other advanced investigative techniques. Creating an effective UN mechanism for investigations of alleged use would have an important deterrent effect by making it more likely that a covert biological attack will be attributed to the perpetrator, be it a state or a non-state actor.

One drawback of the Secretary-General's mechanism is that it focuses exclusively on investigations of biological weapons *use* in violation of the Geneva Protocol and does not address the earlier phases of the weapons acquisition process prohibited by the BWC. Accordingly, when political conditions permit, it would be desirable for UN member states to broaden the Secretary-General's mechanism to authorize investigations of alleged breaches of the BWC, including the illicit production of biological warfare agents.

Preparing for the Seventh BWC Review Conference

A critical event for advancing U.S. biosecurity objectives will be the Seventh Review Conference of the BWC, which will convene in late 2011 in Geneva, Switzerland. This comprehensive review of the treaty's implementation will be a "make-or-break" political opportunity for the United States.

Ever since the collapse of the BWC protocol negotiations in 2001, the treaty regime has suffered from a lack of U.S. leadership and a sense of marking time inconclusively even as new threats gather on the horizon. In late 2002, the BWC member states agreed to hold annual meetings devoted to exchanges of information on national measures to enhance biosecurity and prevent bioterrorism. This "intersessional work program," which has now gone on for seven years, has addressed such topics as penal legislation, pathogen security measures, infectious disease surveillance, and scientific codes of conduct, and this year's meetings in August and December will discuss investigations of alleged biological weapons use. The intersessional

process has been modestly useful by keeping BWC member states focused on biosecurity issues, engaging a variety of civil-society organizations, and smoothing the ruffled feathers caused by the undiplomatic way the Bush administration rejected the BWC protocol in 2001. Nevertheless, it is clear that the current work program is approaching the end of its useful life and must be replaced in 2011 with a new and more ambitious process.

At next year's Seventh BWC Review Conference, the United States will have a unique opportunity to give new vitality and direction to the Convention. At the same time, the U.S. delegation will have to navigate some potentially treacherous political shoals. It is likely that several BWC member states, including Iran, Pakistan, India, and Russia, will seek to revive the BWC protocol negotiations as a means to pursue their negative agenda of attempting to weaken the Convention itself. Other states, including some U.S. allies, have far better intentions and are eager to return to the protocol talks as a way of moving the regime forward after a long period of stasis and drift. Accordingly, if the United States wants to make sure that proponents of the protocol do not hijack the review conference, it will have to offer an alternative package of bold and compelling measures to strengthen the BWC. Such a package might include credible measures to increase the transparency of national biodefense programs and to address BWC compliance concerns, along with a set of cooperative, multilateral approaches for combating the full spectrum of biological threats.

Because developing and vetting an ambitious package of policy initiatives within the U.S. government will be a long and arduous process, now is the time for the State Department, the lead agency for the Seventh Review Conference, to get the ball rolling. It will also be necessary to coordinate with close allies to generate international political support for U.S. proposals. At present, however, the State Department is embroiled in an internal reorganization of its arms control and nonproliferation bureaus, creating a temporary leadership vacuum. Given the high stakes involved in the review conference, it is imperative that the department resolve the internal dispute over which bureau is responsible for the BWC and begin preparing for 2011 as soon as possible.

Another important task for the Seventh Review Conference will be to address the "institutional deficit" of the BWC. Whereas the Chemical Weapons Convention has a highly effective implementing body in the Organization for the Prohibition of Chemical Weapons (OPCW) in The Hague, the BWC lacks even a small professional secretariat. The last BWC review conference in 2006 established an Implementation Support Unit (ISU) consisting of three people at the UN Office in Geneva, but this entity has limited authority and a temporary mandate that must be renewed by the member states in 2011. The bipartisan Commission on the Prevention of WMD Proliferation and Terrorism recommended in 2008 that the United States "support an appropriate increase in the size and stature" of the ISU so that it can serve as "as an effective facilitator and coordinator for an expanded set of BWC activities and initiatives." The Obama administration should accept this advice and push to make the ISU permanent, while expanding its staff and responsibilities.

Finally, although BWC verification measures are currently off the table, the United States should be open to exploring how advanced biotechnologies might be applied in the future to address the task of biological verification. To this end, the Seventh Review Conference could mandate the creation of an expert scientific body to examine the strengths and limitations of advanced biotechnologies such as biosensors, microbial forensics, and bioinformatics for verification purposes. A previous effort to evaluate possible biological verification measures

from a scientific and technical standpoint, known as VEREX, took place from 1992 to 1994. Because this effort involved experts provided by BWC member governments, however, it proved to be overly politicized. To avoid this pitfall, any technical assessment of possible biological verification technologies should be conducted by an objective, non-political entity such as a consortium of national academies of science. The evaluation process must include the active participation of representatives from the biotechnology and pharmaceutical industries in order to ensure that commercial proprietary information can be adequately protected.

Conclusions

The Obama administration's *National Strategy to Counter Biological Threats* describes the full spectrum of biological threats facing the nation and suggests a comprehensive approach for combating them. Nevertheless, the real test of the administration's seriousness in addressing these threats will be its ability to convert the broad policy guidelines in the strategy document into a set of concrete initiatives. Much as President Obama's Prague speech of April 5, 2009 provided the overall vision and political impetus for the administration's ambitious nuclear disarmament and nonproliferation agenda, a "Prague II" speech devoted to biosecurity, infectious disease, and public health would demonstrate that the administration is prepared to allocate political energy and budgetary resources to this set of issues. The President might also consider hosting an international Biological Security Summit, modeled after next month's Nuclear Security Summit, to help build a global consensus behind the U.S. proposals.

In any event, implementing the *National Strategy to Counter Biological Threats* will require the White House to give biological security the same level of political attention that it has devoted to crafting and promoting its nuclear weapons agenda over the past year. It will then be up to Congress to review the administration's biosecurity agenda and appropriate sufficient funds to implement it effectively.

Mr. SHERMAN. Mr. Rademaker?

STATEMENT OF THE HONORABLE STEPHEN G. RADEMAKER, MEMBER, COMMISSION ON THE PREVENTION OF WEAPONS OF MASS DESTRUCTION PROLIFERATION AND TERRORISM, SENIOR COUNSEL, BGR GROUP (FORMER ASSISTANT SECRETARY OF STATE FOR INTERNATIONAL SECURITY AND NONPROLIFERATION)

Mr. RADEMAKER. Mr. Chairman, Congressman Royce, and members of the subcommittee, I appreciate the opportunity to again appear before your subcommittee.

I served as one of the House appointees on the Commission on the Prevention of Proliferation of Weapons of Mass Destruction and Terrorism. Therefore, I especially welcome the opportunity to appear here to report to you and the other members of the subcommittee on the findings and recommendations of our commission.

I have a prepared statement, which I have submitted for the record; and mindful of your observation that we do not condone torture in America, I will not sit here and read my prepared statement to you. Rather, I will summarize it. I also have copies of our commission report, which I would be pleased to distribute, if you have a clerk who wants to bring them to you. They are sitting right here.

Mr. SHERMAN. Do you have enough copies for all members of the subcommittee?

Mr. RADEMAKER. I have about a dozen copies, sir.

Mr. SHERMAN. That will cover the whole subcommittee, even those who are not in attendance; thank you.

Mr. RADEMAKER. Yes, I have them.

The mandate of our commission extended to all weapons of mass destruction. But in our work, we focused on biological weapons and nuclear weapons, because it was our conclusion that those were the two classes of weapons of mass destruction that would most likely be used by terrorists if there is a WMD attack by terrorists against the United States.

As I think you observed earlier in your opening remarks, one of our conclusions was that as between biological and nuclear weapons, we thought the greater likelihood was that biological weapons would be used by terrorists in any WMD attack on the United States.

At the outset of my remarks, I want to stress a key point that informs the rest of our commission's analysis. That is that nuclear weapons and biological weapons are very different. As a nation, we spend a lot more time thinking about nuclear weapons and the nuclear weapons threat; and a lot less time thinking about biological weapons.

If we apply some of the lessons that we have drawn from the nuclear area to the biological area, we will make some big mistakes. So it is important to bear in mind the differences between the two.

The most important difference is that nuclear weapons inflict their damage the moment they are used. The destruction is immediate. It is irreversible. Mitigation measures are of extremely limited utility in dealing with the consequences. The damage has been done.

Biological weapons, on the other hand, do not inflict damage immediately. The damage will manifest itself fairly quickly. But there is a window during which mitigation measures can minimize, and if done properly, perhaps even eliminate the physical damage caused by a biological weapons attack.

That window is of critical importance to us, and it affords an opportunity to basically reduce the utility of these weapons to terrorists or others who might consider using them against us. If we can construct a mechanism within our country to promptly detect and promptly take steps to counteract a biological weapons attack against us, the idea of using these weapons against us will be much less appealing to terrorists and to others.

So that was really the principal recommendation of our commission: That the United States needs to take advantage of that window to make sure that we have measures in place that will minimize the consequences of a bio attack.

The "F" grade that our commission gave in its report card in January to the efforts of the United States Government in this area was really focused on the domestic steps that have been taken to build up mitigation measures. Fundamentally, it was our judgment that not enough money was being put into the development of vaccines and other needed measures to permit us to minimize the damage caused by a bio weapons attack.

Our focus today, however, is in the international area; and so I wanted to turn to that issue. As a commission, we looked at the question of the Biological Weapons Convention. We judged that it remains critically important as part of our international strategy for combatting the bioweapons threat.

Our principal recommendation with regard to the Biological Weapons Convention was to re-double efforts to universalize the convention; to persuade other governments to adhere.

The Nuclear Nonproliferation Treaty—today, all but four countries in the world have ratified the Nuclear Nonproliferation Treaty. The picture is substantially less satisfying if we look at the Biological Weapons Convention. There is still about 40 or 50 countries that have yet to ratify.

We also looked at the question of the inspections protocol that was negotiated during the late 1990s; and as Dr. Tucker indicated, something was likely to come back. The Bush administration killed the Biological Weapons Convention protocol that had been negotiated in the 1990s. But certainly efforts will be mounted to revive it.

As a commission, we considered what the proper policy of the United States should be on this question of establishing an international inspections regime for biological weapons.

As you know, this has been a very controversial issue. I headed the U.S. delegation to the continuation of the fifth review conference in 2002, and this was the focus of the entire review conference. Passions ran extremely high on the issue.

Therefore, to me, it was surprising that within our commission, we came to the unanimous conclusion that the Bush administration had acted properly in killing the protocol in 2001, when it announced its policy on the protocol. And we also reached the unanimous conclusion that it would be a mistake for the next U.S. ad-

ministration, meaning the Obama administration, to agree to revive the inspections protocol.

I was very pleased to see that the Obama administration accepted our commission's advice on this issue. In December of last year, Under Secretary Tauscher announced in Geneva that the Obama administration will not support the revival of an inspections protocol for the Biological Weapons Convention.

I think this was a difficult decision for the Obama administration to come to. I think they were under a lot of political pressure to go in a different direction. So I have very high praise for them for taking the courageous and correct step to defy that pressure and to do what is right on policy grounds.

I see that my time is about to expire, and so I think I will stop there and submit myself to your questions.

[The prepared statement of Mr. Rademaker follows:]

STATEMENT OF STEPHEN G. RADEMAKER
Senior Counsel, BGR Group

"National Strategy for Countering Biological Threats: Diplomacy and International Programs"

Subcommittee on Terrorism, Nonproliferation and Trade
Committee on Foreign Affairs
U.S. House of Representatives

March 18, 2010

Mr. Chairman, Congressman Royce, Members of the Subcommittee, I appreciate this opportunity to testify again before your subcommittee. The last time I appeared, it was as an official of the State Department, but in 2007 I left government to rejoin the private sector. In 2008 I was appointed by the House Leadership to the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, and I welcome this opportunity to report to you on some of our Commission's conclusions and recommendations regarding bioterrorism.

The mandate of our Commission extended to all weapons of mass destruction (WMD), but we chose at the outset of our work to concentrate on the two types of WMD with respect to which we judged there was the greatest risk of use by terrorists seeking to inflict mass casualties in the United States. So we focused on nuclear weapons and biological weapons. We further judged that if there is a WMD attack by terrorists, it is more likely to involve biological weapons rather than nuclear weapons.

The basis of this judgment was our belief that the widespread and growing availability of biotechnology, combined with the relative lack of security awareness in the life sciences community as compared to the nuclear industry, makes biological weapons the more attractive and readily available weapon of mass destruction for terrorists. Accordingly, of our 13 recommendations, the first two related to the prevention of bioterrorism.

Our first recommendation related to measures that should be taken domestically to reduce the risk of bioterrorism, the second to measures that should be taken internationally. Because of the topic of today's hearing, I will direct most of my remarks toward our second recommendation. First, however, I wish to make several points about biological weapons generally.

Differences Between Biological and Nuclear Weapons

Biological weapons are very different than nuclear weapons. The destruction inflicted by nuclear weapons manifests itself the moment such weapons are used, and is irreversible. Therefore it is absolutely essential to prevent nuclear weapons from being used. Mitigation of

the damage after a nuclear attack is of very limited utility. Deterrence has long been a key component of our strategy for preventing the use of nuclear weapons—essentially the threat that if someone uses such weapons against us, we will retaliate against them with our nuclear weapons. And because the technology needed to produce the fissile material required for nuclear weapons is still relatively expensive and hard to come by, export controls and international inspections of nuclear facilities continue to provide meaningful—though certainly not complete—protection against nuclear weapons proliferation.

Biological weapons, by contrast, do not kill instantaneously. It is possible, therefore, with proper preparation and with effective detection and monitoring, to mitigate the damage caused by a biological attack. Indeed, highly effective response capabilities are probably our most effective means of preventing a biological weapons attack. If terrorists or other potential attackers are satisfied that any biological attack on us will likely fail, in the sense that it can be expected to cause few or no casualties due to our ability to rapidly detect and mitigate the effects of the attack, they will be much less interested in attacking us with such weapons.

At the same time, the traditional deterrence model is much less effective against biological weapons. We have renounced the right to posses or use biological weapons, so any retaliation against a biological attack would have to be with other types of weapons, most likely nuclear. Even if the Obama Administration does not abandon the option of responding to a biological attack with nuclear weapons, as press reports suggest it is considering as part of the ongoing Nuclear Posture Review, this is a threat of limited utility against terrorists.

It is hard to imagine terrorists obtaining nuclear weapons without the assistance of a state, and therefore there would likely be a state we could hold accountable for a nuclear attack. But if a single scientist acting alone could perpetrate the 2001 anthrax attack in the United States, as the FBI tells us was the case, then it is certainly plausible that a terrorist group could launch a biological attack without the active assistance of a state.

This is largely a function of the wide diffusion of biotechnology and the very small scale of production required to manufacture biological weapons. These facts also explain the relative ineffectiveness of export controls and international inspections in the biological area as compared to the nuclear area.

Domestic Measures to Prevent Biological Weapons Attack

As suggested by the foregoing, our Commission's most important recommendation overall with respect to bioterrorism was to enhance America's capabilities for rapid response to biological attacks in order to be able to prevent such attacks from inflicting mass casualties. In January of this year, the Chairman and Vice Chairman of our Commission, former Senators Bob Graham and Jim Talent, issued a report card that gave the U.S. Government an F for its efforts in this area subsequent to the December 2008 release of our Commission report. I concur in the

criticisms they expressed regarding the deficiencies of U.S. Government planning and preparation in this area.

International Measures to Prevent Biological Weapons Attack

In the international area, one of the most important issues addressed by the Commission was the proper role of the Biological Weapons Convention (BWC). We concluded that the BWC remains a central element of our international strategy for combating biological weapons, and therefore we called for a concerted U.S. effort to achieve both universal adherence to, and effective international implementation of, the Convention. This recommendation is embraced in the Obama Administration's November 2009 National Strategy for Countering Biological Threats. Accordingly, in their January report card, Senators Graham and Talent gave the U.S. Government a B+ for its efforts in this area. They commented that in order to raise this grade to an A, the Department of State would have to develop a full action plan for increasing international adherence to and implementation of the BWC.

The Commission also addressed the highly controversial question whether the BWC should be augmented with a verification protocol, something which the Convention has never had, but which was the subject of intense international negotiations for almost seven years. Those negotiations ended in 2001, when the Bush Administration announced its opposition to the protocol. I became intimately familiar with passions surrounding this issue as head of the U.S. delegation to the continuation of the Fifth Review Conference of the BWC in 2002.

Following our own review of the issue, the Commission unanimously endorsed the decision of the Bush Administration on the protocol as "fundamentally sound." The Commission went on to recommend that the next U.S. Administration reject any effort to restart negotiations on a BWC verification protocol.

I am pleased that this recommendation has been accepted by the Obama Administration. In December 2009, Under Secretary of State Ellen Tauscher announced in Geneva:

> We have carefully reviewed previous efforts to develop a verification protocol and have determined that a legally binding protocol would not achieve meaningful verification or greater security. It is extraordinarily difficult to verify compliance. The ease with which a biological weapons program could be disguised within legitimate activities and the rapid advances in biological research make it very difficult to detect violations. We believe that a protocol would not be able to keep pace with the rapidly changing nature of the biological weapons threat. Instead, we believe that confidence in BWC compliance should be promoted by enhanced transparency about activities and pursuing compliance diplomacy to address concerns.

This decision was no-doubt unpopular in some quarters, and therefore with even greater reason I believe the Obama Administration deserves credit for coming to the right decision on the issue of the protocol.

Also in the international area, the Commission recommended that the U.S. Government take such steps as strengthening global disease surveillance networks, conducting a global assessment of biosecurity risks, and pressing for an international conference of countries with major biotechnology industries to promote biosecurity.

Last year's National Strategy for Countering Biological Threats calls for expanding America's international engagement on the first two of these issues.

At least as measured by funding levels, there has been progress on global disease surveillance. The Center for Disease Control's Global Disease Detection Program received almost a 50% increase in funding last year.

Helping other countries strengthen their capacity to detect and respond to infectious disease outbreaks can blunt the initial affects of a biological attack, and afford a head start on distributing vaccines and medicines before terrorists have a chance to reload. Further, because it will be very difficult, if not impossible, to distinguish for quite some time a natural epidemic from one perpetrated by terrorists, helping countries strengthen public health surveillance offers many public health benefits as well. For instance, if we had detected that the H1N1 virus was circulating in Mexico a just a few months earlier, governments across the world may have been able to adjust their seasonal flu vaccine to include the new virus instead of waiting months for an H1N1 vaccine that showed up after the outbreak was largely over.

In accordance with our call for a global assessment of biosecurity risks, the Office of the Director of National Intelligence is doing a study on such risks. Our Commission received several progress reports on this effort.

Finally, with regard to our call for an international conference to promote biosecurity, I am not aware of any movement in that direction by the Obama Administration.

So overall, while there are some signs of progress in the international area, much more work remains to be done.

I commend this subcommittee for its interest in the international dimensions of the bioterrorism problem, and look forward to responding to your questions.

Thank you, Mr. Chairman.

Mr. SHERMAN. I will recognize Mr. Scott first, if he prefers.

Mr. SCOTT. Let me start where you left off there for a moment, Mr. Rademaker; is that correct? The issue of the protocols, why do you say we are doing the right thing by refusing to engage in the protocols? What are the benefits and what are the downfalls for us doing so?

Mr. RADEMAKER. Perhaps first I should explain what the protocol would be. It would establish an inspections mechanism. There would probably be an international organization created. It would have inspectors working for it.

And it would be their mission to conduct regular inspections of biological facilities; facilities all over the world where biological research is taking place. It would be their objective to seek to detect potential violations of the Biological Weapons Convention.

There might also be a mechanism for challenge inspections. In other words, if there was a suspicion of cheating on the Biological Weapons Convention, there might be a way to dispatch inspectors to look into whether those allegations are well founded or not.

On paper, all of this sounds very good. Our concern with it—both in the Bush administration and now I think I can probably speak for the Obama administration on it because they have embraced the policy of the Bush administration—it was our judgment that this idea simply would not work in the biological area.

So a great deal of money would be spent. A false sense of security would be created. And there were also very considerable risks to the U.S. biotechnology industry.

I do not know if you have ever talked to an executive of a biotech firm. But I have never spoken to one of them who, when he understood what was being proposed here, did not immediately jump to the conclusion that what was being proposed was international industrial espionage; that foreign inspectors were going to come to his firm to try to steal the intellectual property that they were creating.

I have heard this from so many business executives that I am quite confident that we cannot dismiss that concern out of hand.

There was also great concern about false positives; that unlike the nuclear area, unlike the chemical area, the things that biological weapons inspectors would be looking for—you know, an anthrax spore.

Mr. SCOTT. Right.

Mr. RADEMAKER. These things occur in nature. Highly enriched uranium does not occur in nature. If an inspector goes to a lab and finds highly enriched uranium, there is not a legitimate explanation for that. It did not occur naturally. Somebody put it there, and there is a reason why they created it.

In the biological area, when we are dealing with essentially germs of one type or another, they could be man made or they could be naturally occurring. So the fact that inspectors detect something really does not tell you much.

Mr. SCOTT. Right; thank you for that explanation. So then what alternative do we have? What would you recommend we do in place of that, to ensure international compliance with the Biological Weapons Convention, if we do not use the protocols? What do we do?

Mr. RADEMAKER. Our commission's report is full of recommendations about what should be done in this area to increase assurance and to increase the protections against the production of biological weapons.

The range of measures required mostly are in the area of domestic implementation. Other nations need to do the kinds of things that we have started doing, but we have not finished doing, here in the United States.

At labs where research in this area is done, we need increased protections against diversion of biological material. It used to be that you could essentially order this stuff on the Internet.

Mr. SCOTT. Let me just mention, I want to get another point of view. I want to ask Mr. Kellman, because he raised some issues about our lacks in this area, and it was very alarming in his assessment.

Do you agree with Mr. Rademaker? Is this the way to go, or is there an other alternative to kind of get the international compliance?

Mr. KELLMAN. The verification protocol would be an unnecessary and unproductive use of very limited resources. It would help us confirm where biological weapons are not being produced. It would not tell us anything about where they are being produced.

So it would give us some security about information that we are really pretty secure about without the verification protocol. It would not really tell us anything about the threats that we face. If I might, Congressman——

Mr. SCOTT. Yes.

Mr. KELLMAN [continuing]. I gave a presentation at the Biological Weapons Convention expert meeting that summer on the use of other techniques to detect non-compliance—to verify compliance.

But rather, the important thing, I think, is to detect non-compliance. International law affords us a number of tools, and we do not have to go down the same road. And on this, I think all three of us agree. That road is not a productive road. But there are other ways that we can think about detecting non-compliance that could be advanced at the Biological Weapons Convention.

Mr. SCOTT. All right; thank you very much, Mr. Chairman.

Mr. SHERMAN. Thank you; our current nonproliferation policy with regard to nuclear weapons is obviously a manifest failure. If we continue it, or even if we adopt those changes that are currently under discussion in the administration—either of those, I think it assures that Iran will have nuclear weapons this decade, and that will be the death knell of the NTP.

I say that only because when you then come kind of collectively as witnesses and say our efforts to control biological weapons are the under-funded stepchild of our efforts to control nuclear weapons, it is indeed harsh criticism that our efforts in that area are worse than the manifest failure previously mentioned.

Now, Mr. Tucker, we are dealing with this issue of confidence-building measures. The theory is, we provide this information voluntarily, more or less. This inspires certain countries, say Russian or China, to over-brim with confidence and then do less to develop ugly pathogens.

Now Mr. Rademaker pointed out, this is already a problem from an intellectual property perspective. It is also a problem with regard to state sponsors of terrorism and terrorist groups.

To what extent would these confidence-building measures provide information useful to terrorists and terrorists states? Looking at this threat from that angle, the confidence-building measures do not do any good. Ahmadinejad is not sitting there saying, well, gee, if only they had some confidence-building measures, I would not want weapons of mass destruction.

So how do you confidence-build, vis-à-vis Russia and China, while disclosing no information to Iran and North Korea?

Mr. TUCKER. Well, I think you have identified a very difficult problem. But I do think the types of information that are, for example, included in the confidence-building measure data declarations, which are part of the Biological Weapons Convention process, are not particularly sensitive. They are not providing cookbooks on how to produce anthrax. They are simply identifying activities and facilities that are relevant to BWC compliance.

And I think the argument can be made, as I said in my presentation, that if the United States demonstrates leadership with respect to the transparency of our activities, that puts us in a strong position to——

Mr. SHERMAN. A strong position to affect Russia and China—absolutely not a strong position to, in any way, affect the terrorists states.

Mr. TUCKER. Russia and China are very serious——

Mr. SHERMAN. Yes, I mean, that begs the question that we do not have time for; and that is, what is our nightmare scenario—Russia or China or the terrorist states? I would say if Russia and China want to kill 1 million Americans, they already have a guaranteed way to do so without further research. It is called nuclear weapons.

So my concern is these terrorists states confidence-building measures do nothing to diminish the threat from the terrorist states, and do give them a view or at least a road map to our counter efforts.

Mr. Kellman, you say that our domestic preparedness deserves a grade far better than "F," and Mr. Rademaker was part of the commission that gave it an "F." We have spent $68 billion on this, and I think you correctly point out that if we spent $68 billion and get an "F," other countries are hardly going to be inspired. But if it deserves an "F," it deserves an "F." How did they get it wrong? What grade to do you give our domestic prepardness, and why do you reach such a different grade?

Mr. KELLMAN. In an op-ed, I used the term ridiculous with regard to the "F" grade. Let me see if I can justify that.

I think what the commission was trying to get at was that we are extremely vulnerable to bio attacks; that probably each of us at this table—certainly, I can envision attacks against the United States for which our preparedness would be unsuccessful. There is no question about that.

Mr. SHERMAN. If I can interrupt, there are two types of attacks; those that are not deterrable. I mean, we have no counter measures to the Russian nuclear program.

Mr. KELLMAN. Right.

Mr. SHERMAN. So can you embellish a little and say, "Are there attacks for which we have no defense?," and as to which we will not be able to effectively retaliate?

Mr. KELLMAN. Absolutely, yes; so in the ultimate sense, we are not. And unfortunately, Mr. Chairman, I do not think we seriously can be prepared. I think that what we have to think about here is risk management. I think what we have to think about is a combination of prevention measures and preparedness measures.

But it would be folly of me and certainly disingenuous to testify before you today to say that there is a way to make America safe from biological threats. That cannot be done today.

Mr. SHERMAN. If I can interrupt, you seem to be saying we should grade America on a curve; and if a series of counter measures that we have adopted would limit the deaths under a particular scenario to 100,000, rather than 100 million; that you can not give that an F and say, well, that is 100,000 dead. You have to say, well, that is 99.9 million saved.

Are you saying that our counter measures are useful—not in preventing terrible results; but preventing a terrible result from being even more catastrophic?

Mr. KELLMAN. I am saying that government officials must operate in the real world with real conditions. So yes, what the United States Government has done since the anthrax attack of 2011 [sic], it put us in a substantially better capability to save many American lives.

Mr. SHERMAN. Mr. Rademaker, obviously, we are not safe. We spent $68 billion; but we are not safe. But have we done a good job of putting ourselves in a position where the deaths are catastrophic; but dramatically less than they would otherwise?

Mr. RADEMAKER. Mr. Chairman, I think we have made a good start. But there is a enormous amount of work that remains to be done; and that was the basis of the commission's grade.

To be able to mitigate the consequences of a bioattack, we need detection capabilities. We need a way to mobilize state and local authorities to act in response to the attack. We need vaccines, and we need a way of dispensing the vaccines to the effected population. We need a national plan for responding, should something like this happen.

Today, we have no national plan. We have invested a fair amount of money in this. But the commission found that the annual requirement for vaccines in this area, to be fully prepared, would come to over $3 billion a year to prepare the vaccines.

Mr. SHERMAN. That is a year. So you prepare them, and then you have got to prepare them again and again.

Mr. RADEMAKER. Well, we are spending probably 10 percent of that today.

Mr. SHERMAN. Okay, the issue did come up. It is a bit outside the jurisdiction of the subcommittee. But I am going to go further and ask each of you that feel that it is within your competence to submit how we would spend $10 billion or $20 billion a year to prepare. Because it is easy to come in and say, well, $68 billion total expenditures is not enough. You ought to be spending $168 billion a year.

I need a budget responsible approach to bio-preparedness; and hopefully, for the $10 billion to $20 billion a year, we are getting not only a capacity to respond to bio weapons; but also to disease pathogens, as well.

And many of the things that I think we should be doing do not cost us money. We would have to go to the American people and tell them, you honestly face a threat. In an emergency, your government will take the following highly controversial actions. You will not be as free the day after a biological attack as you were the day before. And as long as none of these are said in my district, I am fine.

So we have to not only spend money on this; but we have to spend political capital. We have to overcome in-bred ideological dispositions, and that may be even more difficult. But I hope that the program you lay out is not just a list of things to spend money on; but a list of things to do that do not cost money, or cost only modest amounts, and where the reason we are not doing them is not budgetary, but political and psychological.

With that, we have our ranking member, Mr. Royce, who is now recognized for 5-ish minutes.

Mr. ROYCE. Thank you, Mr. Chairman. Let me ask Mr. Tucker—you argue that actions by the United States to increase the oversight and transparency of its own biodefense program would not only demonstrate international leadership by providing a model for other countries to follow, but would put the United States Government in a position to demand greater openness from others. I am just wondering what evidence you will base that on. Is that a hunch?

Mr. TUCKER. I would say it is a logical supposition that if we demonstrate leadership in this area, that puts us in a stronger position to pressure other countries to follow suit. Now I should clarify that confidence-building alone is not the solution. It is one of a complex of measures that will work together, that are synergistic.

Mr. ROYCE. Apparently not, because, you know, I opened with my comments about the Russian scientist that Congressman Saxton and I met with. And in response to my questions, he said, no, we had been told in 1969 Nixon abandoned the program. The chemical weapons convention, that dates from 1972, right?

So he told me that after 1972, they were pedal to the metal on this. He even told me a funny story, which is not all that funny, but it is definitely unique from the ones I have heard about him taking an elevator up to Andropov's office, because Andropov wanted to make sure that he really had developed something for which there was no antidote.

He said he was carrying the petri dish in there, going up the elevator; and then putting it on the desk and saying, do not open it. I mean, it really gave me an insight into what these 50,000 employees were doing.

But given the fact that you testified that Russia is moving away from transparency in its labs; and given the fact that in the face of the convention, he is telling me that they were doing that, are you suggesting that Russia today is responding to our lab policies?

Is that what has happened? Because that sounds fantastic to me given the dialogue that I had. I just do not sense a connection here

between what you say and what was really going on in Russia then or now.

Mr. TUCKER. Well, I think if you read, for example, Ken Alibek's memoir——

Mr. ROYCE. Yes.

Mr. TUCKER [continuing]. He was the deputy director of a large component of the Soviet biological weapons program.

Mr. ROYCE. I knew Alibek. He was a student of this.

Mr. TUCKER. He claims that Soviet bioweapons scientists were led to believe that the United States was secretly violating——

Mr. ROYCE. That is what the Soviet state told them, right?

Mr. TUCKER. And it was only when he came to the United States under the trilateral process, which was a series of reciprocal visits to suspected biological warfare facilities, that he suddenly realized that he had been misled and that the United States did not have an offensive program.

Mr. ROYCE. But it was the collapse of the Soviet system that gave us the opportunity basically to swing him.

Mr. TUCKER. He came before the collapse of the Soviet system. He came in early December 1991 under the trilateral process.

Mr. ROYCE. Right.

Mr. TUCKER. And then he later defected to the United States. But when he came to the United States for those transparency visits, he was still a Soviet official.

Mr. ROYCE. Right, but here is the point. There was a window, as the Soviet Union was breaking up, when I got access to this scientist. That window is closed. I am just telling you. China is not going to open its labs. The Russians are not going to open their labs.

You testified that expanding international research partnerships and personal exchanges can provide valuable insight into foreign biodefense programs. And I would like to ask if you speak from personal experience? Because cannot such exchanges also result in foreigners acquiring intelligence we would rather not have them acquire?

I am thinking about China right now; and how much down this road we have already gone and what a cul-de-sac it has been for us, in terms of the consequences of it.

Mr. TUCKER. I think obviously these programs involve a weighing of cost and benefits. They have to be very carefully designed so that they provide insights into foreign programs and the extent to which those programs are treaty-compliant, while limiting the risk of technology transfer. But I think they can be structured in that way. I believe it is important to engage with Russia. Because if we disengage——

Mr. ROYCE. Listen, I agree with you about engaging with Russia. But I just wonder about the naïvete with respect to what I have found is going on, in China and Russia.

Mr. TUCKER. I have spoken to many people who say that the best source of intelligence or information about what is going on in foreign laboratories of concern is the scientists themselves. And establishing personal relationships with these scientists makes them much more likely, if they are aware of something untoward, to con-

tact their former colleagues that they met during an exchange program.

Mr. ROYCE. Do you think that might happen in China?

Mr. TUCKER. I think it is very possible that it would happen in China.

Mr. ROYCE. Let us look at A.Q. Khan and what happened with our programs with Pakistan. How is that working out for us? I mean, anyway, let me ask Mr. Rademaker a question here.

You served in the Bush administration, Mr. Rademaker. Dr. Tucker testifies that the Bush administration wrote off bioterrorism prevention efforts as too difficult. Would you care to respond to that?

Mr. RADEMAKER. I guess I do not know where to begin in responding to that. I think it is very rare for anyone to accuse the Bush administration of not doing enough to combat terrorism generally. Specifically, with reference to bioterrorism, that was a very high priority.

Most of what the chairman was talking about—the billions of dollars that have been spent in this area—were spent during the Bush administration. So to say that the Bush administration wrote this off, I think I could bring in a whole raft of officials from the Department of Homeland Security who I think would take great offense at hearing such a comment.

Mr. ROYCE. Let me ask you another question. Last question, the commission discussed the role of the citizen, and called for better engagement of the populace to combat the threat of bioterrorism.

The commission found that the U.S. public has become complacent. What is the commission's message to the average American, going about his daily business? What is the take-away?

Mr. RADEMAKER. I will tell you, that recommendation was something felt very strongly by the chairman of our commission, former Senator Bob Graham of Florida, who had a long career in public service, as you know.

He felt, and persuaded the other members of the commission, that public engagement is critically important for our efforts against terrorism to succeed—civic involvement, neighbors looking after the neighborhood, being aware.

When we start talking about this, the specific measures that would be needed to respond, for example, to a biological attack, an organized community is really the best preparation—a community in which it is possible, where mechanisms are in place to distribute vaccines if that needs to happen; where a public health infrastructure is in place to detect outbreaks when they occur; and citizen awareness of and involvement in all these matters. Senator Graham, I think, would speak very passionately on this subject if he were here today.

Mr. ROYCE. Thank you, Mr. Rademaker. I think I am out of time.

Mr. SHERMAN. Is there anyone still here, listening from the Bureau of International Security and Nonproliferation?

[No response.]

Mr. SHERMAN. The chair sees none. Is there anyone here from the State Department?

[No response.]

Mr. SHERMAN. The chair sees none—one more demonstration of what the Executive Branch thinks of the Legislative Branch. I am going to send a copy of the transcript of these hearings to Mr. Van Diepen; and I am going to be asking him to confirm to me that he has read every word.

The fact that we would put on a seminar directly relevant to his operation—and those of us who have responsibilities that go from A to Z and from Southern California, we are on different committees, I am missing Financial Services right now—that I have got the time to be here when this is a part of my job, and he does not have the time to be here or even have his number two here, that seems to indicate that he does not believe—and I realize that this is typical of the entire State Department—that anything useful happens here in Congress; that the sole purpose of Congress is to give them money after getting false information as to why we should do it.

So in the future, we will comment on whether the State Department at least bothers to humor us by pretending to listen to hearings that we have.

Is somebody indicating that they with the State Department? Oh, because I asked earlier, and I saw no response. Please identify yourself for the record—deputy director for what?

Okay, well, then I hope that you will report to the PDAS and others what happened here. And I hope in the future that you will overcome your shyness when I ask whether there is someone here from the State Department, and perceptively identify yourself; and I do thank you for being here.

I only partially take back my view of what the State Department thinks of what goes on in Congress. But the fact that they at least have you sit here and report back is slightly more positive than the statements I just made. We stand adjourned.

[Whereupon, at 12:07 p.m., the subcommittee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

SUBCOMMITTEE HEARING NOTICE
Committee on Foreign Affairs
Subcommittee on Terrorism, Nonproliferation and Trade
U.S. House of Representatives
Washington, D.C. 20515-0128

Brad J. Sherman (D-CA), Chairman

March 12, 2010

TO: MEMBERS OF THE COMMITTEE ON FOREIGN AFFAIRS

You are respectfully requested to attend an OPEN hearing of the Subcommittee on Terrorism, Nonproliferation and Trade, to be held in **Room 2172 of the Rayburn House Office Building:**

DATE: Thursday, March 18, 2010

TIME: 10:00 a.m.

SUBJECT: National Strategy for Countering Biological Threats: Diplomacy and International Programs

WITNESSES:

Panel I
Mr. Vann H. Van Diepen
Acting Assistant Secretary
Bureau of International Security and Nonproliferation
U.S. Department of State

Panel II
Barry Kellman, J.D.
President
International Security and Biopolicy Institute

Jonathan B. Tucker, Ph.D.
Senior Fellow
James Martin Center for Nonproliferation Studies
Monterey Institute of International Studies

The Honorable Stephen G. Rademaker
Member
Commission on the Prevention of Weapons of Mass Destruction
Proliferation and Terrorism
Senior Counsel, BGR Group
(*Former Assistant Secretary of State for International Security and Nonproliferation*)

By Direction of the Chairman

The Committee on Foreign Affairs seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202/225-5021 at least four business days in advance of the event, whenever practicable. Questions with regard to special accommodations in general (including availability of Committee materials in alternative formats and assistive listening devices) may be directed to the Committee.

COMMITTEE ON FOREIGN AFFAIRS

MINUTES OF SUBCOMMITTEE ON *Terrorism, Nonproliferation and Trade* MEETING

Day *Thursday* Date *03/18/10* Room *2172*

Starting Time *10:08 a.m.* Ending Time *12:05 p.m.*

Recesses [ ] (____ to ____)

Presiding Member(s) *Mr. Sherman*

CHECK ALL OF THE FOLLOWING THAT APPLY.

Open Session [✓]
Executive (closed) Session [ ]
Televised [✓]

Electronically Recorded (taped) [ ]
Stenographic Record [✓]

TITLE OF HEARING or BILLS FOR MARKUP: *(Include bill number(s) and title(s) of legislation.)*
National Strategy for Countering Biological Threats: Diplomacy and International Programs

SUBCOMMITTEE MEMBERS PRESENT:
Mr. Sherman, Mr. Scott, Ms. Watson, Mr. Royce

NON-SUBCOMMITTEE MEMBERS PRESENT: *(Mark with an * if they are not Members of HIRC.)*

HEARING WITNESSES: Same as meeting notice attached? Yes [✓] No [ ]
(If "no", please list below and include title, agency, department, or organization.)

STATEMENTS FOR THE RECORD: *(List any statements submitted for the record.)*
Mr. Van Diepen - Response to question for the record; Mr. Tucker - Statement for the record

ACTIONS TAKEN DURING THE MARKUP: *(Attach copies of legislation and amendments.)*

RECORDED VOTES TAKEN (FOR MARKUP): *(Attach final vote tally sheet listing each member.)*

Subject	Yeas	Nays	Present	Not Voting

TIME SCHEDULED TO RECONVENE _____
or
TIME ADJOURNED *12:05 pm*

Subcommittee Staff Director

PAGES FROM A REPORT BY THE INTERNATIONAL SECURITY & BIOPOLICY INSTITUTE SUBMITTED FOR THE RECORD BY THE HONORABLE BRAD SHERMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND CHAIRMAN, SUBCOMMITTEE ON TERRORISM, NONPROLIFERATION AND TRADE

[NOTE: The full report is available in committee records or on the Internet at: http://biopolicy.org/sites/default/files/documents/ISBI%20Congressional%20Report%20Final.pdf.]

INTERNATIONAL SECURITY & BIOPOLICY INSTITUTE*

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United States Foreign Policies and Programs to Reduce Bio-Dangers

REQUESTED BY THE HOUSE FOREIGN AFFAIRS SUBCOMMITTEE ON TERRORISM, NONPROLIFERATION AND TRADE

Barry Kellman
Michael Kraft
Zachary Clopton
Orley Lindgren

March 2010

Assisted by Brent Davidson, Michael Kennedy and Alyssa Levy

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EXECUTIVE SUMMARY

This Report describes the many United States foreign policies and programs that are designed or directly contribute to reducing bioviolence. Its purpose is to provide the basis of discussions about whether such programs and policies are optimally comprehensive and synergistic; it is not designed to evaluate those policies and programs nor to propose reforms.

The described policies and programs are organized into two *Cords*: Bio-Prevention and Bio-Preparedness; each Cord contains four sections. This organization reflects the United States Government's policy both to reducing the possibility that bioviolence might occur (prevention) and to reducing the consequences should bioviolence occur (preparedness).

Cord I -- BIO-PREVENTION

Prevention refers to measures that complicate a potential bio-offender's attempts to commit bioviolence and that make it more likely that such attempts will be detected and stopped in advance. Prevention measures include (1) prohibitions on bioviolence including biological weapons nonproliferation policies; (2) controls to secure pathogen strains and laboratories, especially the remnants of the former Soviet Union bioweapons program; (3) efforts to strengthen capabilities for interdicting wrongful conduct pre-attack; and (4) oversight of a small fraction of bioresearch that would enable production of exceptionally dangerous bioweapons.

1 **PROHIBITION OF BIOLOGICAL WEAPONS**

It is United States policy that the production, acquisition, or use of biological weapons (BW) is prohibited without exception or qualification. This prohibition, embodied in the Biological Weapons Convention (BWC) and now part of customary international law, applies to all States as well as to non-State actors of whatever nationality. The USG advances this policy through: (1) the Biological Weapons Convention (BWC); (2) United Nations Security Council Resolution (UNSCR) 1540; (3) the United Nations Global Counter-Terrorism Strategy and related initiatives; and (4) law enforcement (and first responder) communities worldwide

The United States supports the BWC *intersessonal workplan* -- a yearly series of discussions on designated topics designed to promote concrete actions by States and many organizations for combating BW threats. The United States does not favor resumption of the BWC Protocol negotiations or reconsideration of how to verify BWC compliance, preferring direct engagement through the BWC Article V consultation process and other multilateral mechanisms that can be used to investigate allegations of BW use. Notably, the United States has long been a proponent of BWC confidence-building measures for voluntarily exchanging information to demonstrate transparency, repeatedly urging States to submit such information, offering to provide technical assistance, and supporting a 2006 decision to improve the process for submitting such information.

The State Department Bureau of Verification, Office of Biological Weapons Affairs (VCI/BW) monitors BWC compliance and implementation. VCI/BW has developed capacities so that, in the event of an alleged use of BW, the USG can conduct assessments to quickly and accurately trace their origin and determine who may have introduced them. In 2006, VCI/BW asserted that three nations – Iran, North Korea, and Syria – deserve particular attention with regard to BWC compliance; Russia, China, and Cuba are also countries of concern. Moreover, non-State actors are actively seeking weapons of mass destruction (WMD), including biological weapons.

The United States strongly supports UNSCR 1540 which requires all States to prohibit non-State actors from acquiring WMD and to establish domestic controls to prevent WMD proliferation. The USG offers assistance to States to meet their legislative and regulatory obligations for the control of biological agents and related technologies and funds assistance for establishing effective accounting and control mechanisms to secure dangerous pathogens.

The United States actively supports the UN Global Counter-Terrorism Strategy. The USG has proposed a template of the Biological Incidents Database (BID) which, by recording information related to biological incidents, will raise awareness and build capacity with respect to preparedness, risk assessment and consequence management. The USG also provides national expertise and laboratory capacity to the UN Secretary General Mechanism to Investigate Alleged Uses of BW as well as related programs of other international organizations.

The United States supports international initiatives to promote criminalization of BW-related activities and law enforcement training. FBI personnel have helped develop and run the Interpol Program on Prevention of Biological Terrorism, and the FBI, State Department and CDC have participated in its courses. The USG also participates in the G-8 Bioterrorism Experts Group Initiative. The Justice Department strengthens efforts to stop the spread of deadly bio-hazardous materials. Moreover, the USG sponsors foreign law enforcement training programs regarding WMD terrorism that, although not bio-specific, teach useful skills for a bioterrorism situation.

2 BIOLOGICAL THREAT REDUCTION AND ENGAGEMENT

Concerns generated by: (1) discovery of the Soviet Union's biological weapons program, (2) the need to integrate former Soviet Union (FSU) scientists into the global economy, (3) recognition of the worldwide gaps in pathogen and laboratory security, and (4) increasing worries about global pandemics – altogether contributed to a set of programs focusing on threat reduction and scientific engagement. Initially focused exclusively in FSU States, these programs have expanded; some observers advocate more integration with other complementary efforts.

The Biological Threat Reduction Program (BTRP), managed by the Defense Threat Reduction Agency (DTRA) in DoD with other agencies such as USDA and HHS, undertakes projects to redirect key weapons scientists who were involved in BW development and to secure weaponized pathogens in six FSU countries: Russia, Kazakhstan, Uzbekistan, Georgia, Azerbaijan, and Ukraine. BTRP and related programs comprise: (1) biological infrastructure elimination, (2) engaging foreign BW scientists; and (3) biosafety/biosecurity and threat agent detection and response; and (4) the Bio-Industry Initiative. In addition to notable successes in introducing transparency and physically securing lethal pathogen strains, the program is credited with promoting American-style approaches to project management, integrating FSU scientists into global science, and enhancing the quality of local research projects.

The Biological Weapons Infrastructure Elimination program dismantled or permanently converted three FSU BW production facilities and many BW research institutes. Since completion of a project in Georgia in 2006, no new infrastructure projects are anticipated.

Three BTRP-related programs focus on engaging former BW scientists: DOD's Cooperative Biological Research (CBR) Program; the State Department's Science Centers Program and Bio-Chem Redirect Program; and HHS's Biotechnology Engagement Program. These programs seek to engage FSU researchers and institutes in transparent peaceful research projects with U.S. collaborators to prevent proliferation of BW expertise and enhance global preparedness against biothreats through drug discovery and development.

The now-combined Biosafety/Biosecurity (BS&S) Program and the Threat Agent Detection and Response Program (TADR) are designed to upgrade security and safety programs at Russian and other FSU institutes. These programs seek to: (1) consolidate pathogens into secure facilities and eliminate them from facilities that do not meet safety and security standards; and (2) develop a detection and response network of laboratories to facilitate rapid reporting of outbreak data to national authorities and USG counterparts.

The Bio-Industry Initiative (BII) is operated by the DoS ISN/CTR in the FSU to reconfigure large-scale BW production plants and to engage former weapons scientists in accelerated drug and vaccine development, particularly for highly infectious diseases. It pairs partner research institutions with industry partners, seeking to engage U.S. biotechnology and pharmaceutical industries as potential employers of FSU bioscience experts. It is also creating an infrastructure of research institutions with appropriate transparency in biological research.

The Biosecurity Engagement Program (BEP), run by the State Department Bureau of International Security and Nonproliferation, Office of Cooperative Threat Reduction (ISN/CTR) and targeting 44 countries mostly in Southeast Asia, provides assistance for: developing sustainable public and agricultural health infrastructure, ensuring secure pathogen collections, and enhancing international infectious disease surveillance, diagnostics, response and control.

The Sandia National Laboratory, through its International Biological Threat Reduction Program (IBTR), promotes biosafety and biosecurity worldwide by enhancing laboratory biocontainment and infectious disease diagnostics and control. Its efforts include: (1) training and workshops; (2) policy, regulatory, and guidelines support, (3) assessment and analysis, and (4) identification of non-military, commercial applications for former Soviet technologies.

3 Controlling Access to and Interception of Critical Pathogens and Bio-Equipment

Policies and programs that try to restrict access to dangerous pathogens or critical weaponization equipment – allowing these items only to scientists having legitimate research needs but denying them to States or groups who seek to make biological weapons and interdicting illicit traffic in such items -- include (1) export controls as well as training and assistance programs to strengthen other nations' export control systems; (2) securing transit and ports; (3) development of mechanisms to track movement of critical items; and (4) interception initiatives to stanch bioweapons proliferation.

The United States is a member of the Australia Group (AG) which seeks to ensure that exports do not contribute to the development of chemical or biological weapons. The AG Guidelines for Transfers of Sensitive Chemical or Biological Items list items for control and set a non-exhaustive list of considerations for evaluating export applications. The U.S. maintains its own controls lists: the Commerce Control List (CCL) and the United States Munitions List (USML) which require an export license for any biological agents and pathogens on the Australia Group Core Lists as well as additional items. Exports of these items are prohibited altogether to certain recipients and for some foreign destinations.

The USG maintains at least two relevant export control assistance programs: the Export Control & Related Border Security Assistance (EXBS) Program, and the Transshipment Country Export Control Initiative (TECI). These programs provide assistance for improving countries' export and border control systems and for adoption of export and transshipment control regimes that engage the private sector in improving transport security and preventing illicit shipments. The U.S. also supports international standards for port and transit hardening.

The U.S. Customs and Border Protection Service (CBP) operates at least three programs that support hardening of ports and transit systems: the Customs-Trade Protection Against Terrorism (C-TPAT) Program; the Container Security Initiative (CSI); and Operation Safe Commerce. These programs promote implementation of best security practices to protect supply chains against terrorist exploitation and encourage importers and foreign States to provide substantial data to enable effective screening of shipments and investigation of terrorist threats to cargo bound for U.S. ports. Furthermore, the CBP and other agencies offer training to other nations to improve port and transit security and to prevent WMD proliferation across borders.

The USG works to track movements of dangerous pathogens in transit. CBP and other agencies have developed information streams regarding goods entering and leaving the U.S, assisted foreign governments in establishing analogous mechanisms, and promoted information sharing. The USG also works with other nations through the Proliferation Security Initiative (PSI) to provide for the legal interdiction of WMD delivery systems and related materials.

4 OVERSIGHT OF DANGEROUS RESEARCH

Synthetic genomics along with other rapidly-evolving life sciences capabilities promise to accelerate scientific discovery, but at the same time, these technologies can be misused to modify pathogens, increasing their lethality, contagiousness, and/or resistance to immunization. To monitor and regulate such research, therefore, the USG supports several initiatives. There is a fundamental fallacy, however, in addressing the bioscience dual use dilemma in only one country. Effective policies must address the internationalization of leading edge bioresearch.

The National Scientific Advisory Board for Biosecurity (NSABB) has recommended guidelines for dual use research including a code of conduct and has reached out to establish international dialogue on the subject. Among its International Working Group's activities have been a series of International Roundtables, jointly sponsored or planned by the USG and WHO. NSABB has also published guidance on the applicability of the National Select Agent Regulations to synthetic genomics.

The USG's efforts to address dual use research internationally have taken advantage of initiatives pursued by UNESCO and the WHO Advisory Committee on Variola Virus Research. The U.S. is a current member of UNESCO's Intergovernmental Bioethics Committee (IGBC) and has been actively involved in UNESCO's promotion of bioethics through the creation in 2005 of the Universal Declaration on Bioethics and Human Rights. The WHO Advisory Committee on Variola Virus Research manages the two remaining repositories of live smallpox cultures and monitors all research conducted using those cultures. The USG's variola virus research plan, implemented at CDC by scientists from both the Department of Defense and CDC, is undertaken with WHO concurrence.

Cord II -- BIO-PREPAREDNESS

Efforts to prevent bioviolence might fail. It is important, therefore, to be prepared to cope with an attack – to minimize its consequences. USG international bio-preparedness programs have four components: (1) biosurveillance, (2) protection of agriculture and food supplies (3) development and stockpiling of medical counter-measures (MCMs), and (4) attack response and consequence mitigation.

5 BIOSURVEILLANCE AND DISEASE REPORTING

Biosurveillance refers to a process for systematically gathering and analyzing biosphere data in order to achieve early detection of health threats and overall situational awareness of disease activity. Strengthening global disease surveillance has long been a policy priority of the United States and many U.S. agencies gather information about emerging disease outbreaks. To improve global biosurveillance, the USG: (1) complies with the International Health Regulations (IHR) requirements; (2) operates disease reporting networks; (3) operates border biosurveillance initiatives with Mexico and Canada; and (4) receives information from international sources that are incorporated into the U.S. Biosurveillance Integration System.

The Global Health Security Action Group (GHSAG) has identified CBRN early warning as a high priority; in 2008, the members committed to assess their early warning capacities and to consider the possibilities for increasing communication. GHSAG has developed a pilot project to integrate disease reporting and biosurveillance information from various sources in order to study the benefits of a virtual network of analysts for early detection.

The IHR require that States notify the WHO of public health events of international concern in order to prevent or contain them before they spread across borders. The HHS Secretary's Operations Center is the central body responsible for reporting events to the WHO Secretariat. The USDA's Centers for Epidemiology and Animal Health (CEAH) National Surveillance Unit (NSU) complies with the Animal Health Organization's (OIE) requirement that States report certain animal health diseases within its territory.

The CDC, the USG's liaison agency with the WHO, supports the Global Outbreak and Alert Reporting Network (GOARN) -- a WHO-coordinated partnership to rapidly identify, confirm, and respond to international disease outbreaks; HHS and USAID support the GOARN financially. To effectuate pathogen testing during a health emergency, the CDC established the Laboratory Response Network (LRN) which coordinates 150 labs in the U.S., Canada, the U.K., and Australia. The CDC also collaborates with professional societies to monitor international disease through the GeoSentinel project and the Emerging Infections Network.

The Global Disease Detection (GDD) program is the CDC's primary effort to build capacity in developing countries to detect emerging infectious diseases by promoting key collaborations with international and regional partners through its 18 GDD Centers worldwide. The CDC's GDD Centers help establish local diagnostic capacity and function as GOARN members during emergencies, working with the CDC's Headquarters Operations Center. The CDC and USAID also provide technical assistance and expertise for the Integrated Disease Surveillance and Response (IDSR) strategy of WHO/AFRO that aims to improve the availability and use of surveillance and laboratory data to control priority infectious diseases.

PulseNet, a CDC-coordinated network of public health and food regulatory agency laboratories, collaborates with similar foreign networks to build capacity for early detection and identification of international outbreaks. The CDC's Division of Global Public Health Capacity Development (DGPHCD) helps foreign nations build laboratory-based surveillance systems to assist in outbreak response for priority diseases through the Field Epidemiology Training Program (FETP) and the Field Epidemiology and Laboratory Training Program (FELTP).

The DoD also operates disease surveillance programs throughout the world. The Global Emerging Infections Surveillance and Response System (GEIS) coordinates global surveillance of infectious diseases to sustain and strengthen detection and diagnostic capacity through its global DoD laboratory and partner network. Also, through the BTRP (*see* Section 2), DoD

operates the Electronic Integrated Disease Surveillance System (EIDSS) for reporting and monitoring of dangerous infections

The United States, Canada, and Mexico have developed two mechanisms to promote disease surveillance. The Early Warning Infectious Disease Program (EWIDS) provides rapid and effective laboratory confirmation of urgent infectious disease case reports in the border regions; the Security and Prosperity Partnership (SPP) promotes collaboration on disease detection and response.

Finally, the U.S. receives international input to its National Biosurveillance Integration System (NBIS), which aims to detect a biological event that presents a risk to the United States and to alert response authorities. International sources of information for NBIS include the WHO, OIE, Global Avian Influenza Network for Surveillance (GAINS) and the International Species Information System/Zoological Information Management System (ISIS/ZIMS).

6 PROTECTION OF AGRICULTURE & FOOD CHAIN SYSTEMS

Agriculture and food supplies are uniquely vulnerable to bioviolence that could trigger widespread disruption and crippling economic effects. The USG protects domestic agro/food systems from disease through strong customs and border efforts to intercept entry of pathogens into the U.S. To protect foreign agro/food chain systems, USG efforts include: (1) building capacity for agro/food protection and assisting foreign nations and regional organizations to meet international agro/food safety standards; (2) detecting extra-territorial outbreaks and exchanging information about such outbreaks; and (3) promoting outbreak response.

The USG engages with international organizations to develop standards for agriculture and food processes that raise awareness of risks and vigilance in protection. For food safety, the USDA Food Safety and Inspection Service (FSIS) works with the *Codex alimentarius* (*Codex*) - an international mechanism for protecting consumers' health. The USG has proposed that the *Codex* adopt guidelines specifically addressing intentional contamination in world food supplies. Various USG offices, including FSIS, are engaged in building foreign nations' capacity to protect agro/food systems, including the APHIS International Technical and Regulatory Capacity Building (ITRCB) Center. The FDA's MOU's with foreign governments to make sure that their products destined for the United States meet U.S. standards. The FBI and USDA hold international symposia on agroterrorism.

An active foreign dimension of USG agro/food protection is detection of outbreaks that might spread to affect U.S. agriculture, consumers, or economic interests. These efforts entail collecting, integrating, and sharing foreign biosurveillance data from international organizations such as OIE and FAO and foreign food regulatory officials. Other sources of this information include: APHIS's Plant Protection and Quarantine (PPQ) program, which collects information reported as required by the International Plant Protection Convention (IPPC); and the Offshore Pest Information System (OPIS), an international web-based secure information system to facilitate the sharing of risk-based information among authorized experts.

The USG has developed specialized response tools for coping with outbreaks in agriculture or food chain systems, including notification of relevant international organizations. APHIS International Services can reach out to foreign governments and co-sponsor quarantine and eradication programs as necessary. For an animal disease, the U.S. and five other countries have established the International Animal Health Emergency Reserve (IAHER). With regard to food outbreaks, the USDA helped create and provides assistance to the FAO Crisis Management Centre (CMC) which brings rapid-response capacity to transboundary animal and plant diseases.

7 **MEDICAL COUNTERMEASURE PREPAREDNESS**

Medical countermeasures (MCMs) are critical to reducing bio-dangers. HSPD-18 directs the US MCM effort to concentrate on countering threats of weapons of mass destruction. Project BioShield, the comprehensive system for MCM preparedness, is organized around: funding and procurement, facilitation of R&D, and facilitation of countermeasure use in an emergency. Global MCM preparedness, by contrast, lags substantially because of expense, logistical challenges, and varying views of the priority of MCM preparedness. The USG pursues foreign policies that: (1) address international MCM development and stockpiling; (2) guide procurement and import of foreign-produced MCMs, including ensuring that imported MCMs meet U.S. standards; and (3) seek to harmonize international standards for MCM licensing.

It is increasingly the policy of the USG to urge allies and international organizations to plan for handling an overseas bioviolence event and to leverage key allies' demand for U.S.-made biodefense products, thereby reducing the unit costs to fulfill U.S. requirements. With regard to access to pharmaceuticals, the USAID Deliver Project maintains a vaccine stockpile for influenza and is ready to distribute standardized support kits, and the USG supports an initiative in conjunction with the WHO Global Pandemic Influenza Action Plan (GAP) to build vaccine manufacturing capacity in the developing world. The USG has raised the priority of MCM policy, development, and regulation within GHSAG and has emphasized the importance of MCMs for bioviolence. Recently, GHSAG members formally recognized that international coordination is necessary for development and delivery of MCMs.

Regarding procurement of MCMs, foreign entities (with notable exceptions) may freely compete for BioShield MCM R&D funding. The FDA Office of International Programs (OIP) has lead responsibility to ensure that any imported medicines meet high U.S. standards before leaving the exporting country. FDA also helps foreign regulators and industries understand U.S. standards and laws and ensure the safety of the products they sell.

The USG is committed to international efforts to harmonize regulatory approval processes, promoting high standards and incentivizing MCM development within a uniform regulatory environment. The FDA Center for Drug Evaluation and Research (CDER) participates in relevant international discussions, provides information about U.S. drug regulatory processes to other nations and third party manufacturers, and continues to support various international initiatives. Notably, GHSAG's recent interest in MCMs includes addressing regulatory issues related to MCM licensing and distribution.

8 -- INTERNATIONAL RESPONSE

Fast and effective response to bioviolence can save lives, limit the spread of disease, and restore social order. *Response* includes diagnostics, delivery and dissemination of MCMs, quarantines and restrictions on movement, and communications and other actions to quell disorder. Effective response is the result of thorough preparation. USG officials have responded admirably to foreign outbreaks, yet the unique complexities of an intentional outbreak demonstrate the need for formally planned international outbreak response. USG preparations for an international outbreak focus on: (1) international bioviolence response activities; (2) enhancing coordination through the Global Health Security Action Group; (3) response capacity building and coordination with foreign States; and (4) international bio-danger response exercises.

The President is authorized to respond to a CBRN release abroad with military, logistical, and medical assistance. If a response effort is approved, the National Security Staff (formerly

the NSC and HSC) will provide guidance to the executive departments and other organizations to initiate the formal USG response. An FCM Task Force would present the response options to the foreign government. The U.S. military can assist the State Department's operations, providing disaster assistance to respond to a CBRNE incident. DoD forces may also respond when necessary to prevent loss of lives or pursuant to the commander's immediate response authority. Assistance in country in the event of a terrorist event also can be provided by a Foreign Emergency Support Team (FEST) and/or a Consequence Management Support Team (CMST), coordinated by the State Department Office of the Coordinator for Counterterrorism. Paralleling the FCM interagency process is an HHS effort, in response to the Pandemic and All-Hazards Preparedness Act of 2006, to develop a HHS-specific *International Emergency Response Framework.*

GHSAG is central to international coordination in this area. GHSAG's Global Health Security Laboratory Network enables bio-safety level 4 laboratories to coordinate, standardize, and validate diagnostic capabilities. GHSAG has established a Field Epidemiology and Outbreak Investigation program to promote international collaboration in outbreak response. GHSAG is also committed to improving transportation of diagnostic specimens and reference materials and to the strengthening the Global Influenza Surveillance Network and the World Health Organization's processes for achieving consensus on sample-sharing.

Regarding coordination of response planning, GHSAG supports ongoing assessments of threats and risks to collective health security. GHSAG members have focused on national response plans and ongoing implementation of the IHR in concert with the WHO to achieve this goal. GHSAG members also share best practices in borders management for the purposes of health security, assessment of the effectiveness of chosen approaches and technologies, as well as appropriately aligning strategies. Finally, GHSAG engages in emergency exercises to ensure that members can responsively and efficiently address emergency health threats.

Regarding coordinating and capacity building for response in foreign states, various USG agencies and departments (including DoS, USAID, HHS, FEMA, FBI and DoD) are engaged in bilateral and multilateral efforts. The USG works through the WHO, PAHO and national focal points to build IHR-related capacity based on the IHR *Core Capacities for Surveillance and Response*. The USG also works with NATO and with Mexico and Canada on disease information sharing and response systems. Finally, because a key challenge for optimal engagement of law enforcement in bioviolence policies is its coordination with public health and bioscience communities, the CDC and DOJ/OPDAT have developed training courses on inter-sectoral cooperation and the FBI has hosted a number of workshops related to criminal and epidemiological investigations. Internationally, GHSAG has promoted collaboration among public health and law enforcement with respect to border management issues.

Finally, to prepare for an international response operation, the USG has hosted and/or participated in response exercises to test existing capacity, identify gaps, and prioritize future investments in domestic and foreign capabilities. The USG has conducted exercises focused on the threat of bioviolence such as Black ICE (Bio Bioterrorism International Coordination Exercise), a US-Swiss bioterrorism tabletop exercise, and TOP-OFF3, a domestic exercise to deal with a bioterrorism event that has included participation by Canada and the U.K.

March 18, 2010
Vann Van Diepen

Mr. Sherman: Which middle-tier income countries are not complying with or putting a low priority on 1540?

Mr. Van Diepen: UNSCR 1540 requires all member states to adopt domestic controls to prevent the proliferation of WMD, to include relevant domestic laws and other measures, including by establishing appropriate controls over related materials. UNSCR 1540 called for all states to provide initial reports to the 1540 Committee on steps they have taken or intend to take to implement the resolution. The Committee in turn reports to the Security Council on implementation of the resolution.

Nearly 160 UN Member States have reported on their capabilities and gaps in stopping WMD proliferation. The Committee's 2006-2008 analysis shows positive trends across nearly all obligations.

At U.S. urging, a Comprehensive Review was held September 30-October 2, 2009 to assess UNSCR 1540 implementation and provide a recognized benchmark to gauge progress. It was clear that participating member states had undertaken noteworthy efforts to implement 1540 over the previous 5 years.

Only 29 states have not submitted this initial report, primarily due to inadequate bureaucratic capacity. Only two middle-tier states have not reported (list attached). However, this does not necessarily indicate that these states are putting a low-priority on 1540. For example, in February, one middle-tier state participated in a U.S.-sponsored 1540 Workshop on biosafety and biosecurity held in Kenya.

Congressman Brad Sherman
Chairman
Subcommittee on Terrorism, Nonproliferation and Trade
House Foreign Affairs Committee

RE: Comments for the Record, Hearing on "National Strategy for Countering Biological Threats: Diplomacy and International Programs"

March 18, 2010

Dear Chairman Sherman:

I would like to clarify one point that Congressman Royce made during the hearing without giving me an opportunity to respond. He claimed that in my written testimony, I argued that the Bush administration wrote off efforts to counter bioterrorism as "too difficult"—on its face an absurd contention given the huge increase in U.S. biodefense spending that followed the anthrax letter attacks of fall 2001. In fact, Mr. Royce took my statement out of context. My actual written testimony reads: "The Bush administration focused its biodefense efforts on strengthening domestic preparedness and response capabilities through programs such as BioShield and BioWatch, while tending to write off efforts on the prevention side as too difficult."

It is clear from the context that my criticism of the Bush administration did not concern its total level of spending on biodefense but rather the lack of balance in its investment strategy, which focused predominantly on domestic preparedness programs while neglecting preventive, multilateral approaches to biosecurity, such as strengthening global systems for infectious disease surveillance and response.

I would also like to answer your hypothetical question about the most effective way the U.S. government could spend an additional $10 billion to $20 billion to achieve greater preparedness against both natural epidemics and bioterrorism. In my view, the best approach would be to strengthen U.S. and global public health infrastructure, with an emphasis on systems for the rapid detection, diagnosis, and containment of outbreaks of infectious disease—ideally before they reach our shores. Many gaps remain in these networks, which are highly cost-effective because they can counter the full range of biological threats to the United States, whether natural or deliberate in origin.

Sincerely,

Jonathan B. Tucker

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