Hearing of the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

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Statement for the Record

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Chairman Murphy, Ranking Member DeGette and Members of the Subcommittee: thank you for inviting me to present at this hearing, Outbreaks, Attacks and Accidents: Combating Biological Threats.

I am honored to testify and share my experience on the evolving biological threat before you today, and to be here with Secretary Shalala and Congressman Greenwood who will report on the Biodefense Blue Ribbon Panel study, "A National Blueprint for Biodefense: Leadership and Reform Needed To Optimize Efforts." I am also honored to be here with Under Secretary O'Toole, one of the Nation's highest regarded leaders in biodefense.

For my part, I have been involved in biodefense since 1982 to the present – from the Cold War to the rise of violent extremism; and the rapidly growing risk of naturally occurring, trans-boundary emerging infectious diseases. I have been at the eye of the storm witnessing the evolving biological threat over my career. Today, I am more concerned than ever about the risk of biological threats – including biological warfare, bioterrorism and emerging infectious diseases. Although we are much better prepared today, the recent Ebola response indicates we have a long way to go.

There are three messages that I would like to make to the Committee:

1. Biological Threats are real, and the bioterror threat has the potential to cause mass casualties on a scale similar to a nuclear weapon
2. The inter-epidemic period requires urgent action to optimize available resources and biopreparedness
3. Strong centralized leadership will be necessary to drive urgent action in the inter-epidemic period

In recorded history, communicable diseases decimated populations on many occasions, and nations harnessed their power to create powerful biological weapons in the 20th century. Some in the scientific community once thought that infectious diseases were conquered after the advent of antibiotics and vaccines, such as smallpox and polio vaccines. The global community similarly thought the world would be free of biological weapons after the Biological and Toxins Weapons Convention (BWC) went into force in 1975. Unfortunately, those projections were wrong.

Antimicrobial resistance has emerged rapidly, and newly emerging and reemerging infectious diseases with devastating consequences are the new normal, as we saw last year with Ebola and as we are seeing now with MERS-CoV and, potentially, Zika. Biological weapons development and stockpiling continued even by signatories of the BWC, some on a massive scale such as the former Soviet Union; and biological weapons proliferation continues to be a major concern and threat today. The Department of State assesses that China, Iran, North Korea, Russia and Syria continue to engage in illicit biological weapons activities, and are failing to comply with the BWC.

Biological threats are not new, but we seem to pay attention only when an outbreak or attack occurs, and ignore it between outbreaks. The time between outbreaks - or the inter-epidemic period - is precisely when urgent actions are needed to optimize preparedness and response systems. However, the current strategy appears that we wait for an outbreak to occur before initiating urgent actions, to include providing emergency appropriations instead of taking urgent actions to optimize available resources and improve outcomes during the inter-epidemic period. The current approach is akin to fighting the last outbreak instead of properly preparing for the future one. More importantly, this is the exactly the scenario that the passage of Pandemic and All Hazards Preparedness Act (PAHPA) and the creation of the Biomedical Advanced Research and Development Authority (BARDA) in 2006 was meant to change. Congress did act to create a program to prepare the Nation during this inter-epidemic period, yet we continue to operate in "crisis mode" seemingly every year.

While many hazards plague the modern world, I believe those rooted in modern microbiology are among the most dangerous. I am well aware that your committee must address many issues well beyond this topic, and it can be difficult prioritizing competing demands. But through your work on biodefense and emergency public health preparedness you are well aware of the impact of emerging infectious diseases and bioterror threats. You are also aware that solutions to these threats require a multidisciplinary, integrated team approach through an enterprise that spans national, state, local and tribal governments, as well as industry, academia, other NGOs, families and individuals.

The Evolving Biological Threat: When the BWC went into force in 1975, the capabilities of nation states to develop and stockpile biological weapons were unquestioned. Biological warfare, and now bioterrorism, has the potential to cause mass casualties on the scale of nuclear weapons. Biological weapons, also known as the "poor-man's atom bomb" are far less costly to produce and the weapon payload – microbial pathogens – are readily available from nature, can be developed in clandestine laboratories with far less technical barriers and delivered by relatively simple and available devises.

The United States engaged in a biological warfare program from 1943 to 1969 not only to develop biological weapons for offensive use, but also to develop countermeasures to defend against the use of biological weapons by the former Soviet Union and other

enemies. The United States terminated the offensive biological weapons program in 1969 largely on moral grounds, and because the use of biological weapons was not the best weapon to achieve tactical military objectives – not because they were not effective strategically.

Recent re-analysis and modeling/simulation of data from technical reports of that era provide new insights on the mass casualty potential of pathogens used as weapons on civilian populations. Today, 4 decades after the BWC went into force, modern biotechnology and molecular biology know-how that was once were the domain of only nation states, is now available to non-state actors and disaffected small groups of scientists around the world, even individual scientists.

In 1995, the citizens of Tokyo and the world were awakened to the reality of chemical terrorism. The Aum Shinrikyo extremist cult in Japan unleashed a crude, but effective sarin chemical weapon on the Tokyo subway system, killing 12 and injuring over a thousand people causing wide spread panic. Law enforcement and other investigators learned after the attack that the Aum Shinrikyo also unsuccessfully attempted anthrax bioterror attacks. Fortunately their bioterror attacks failed, but only because the Aum's biologists selected an avirulent anthrax vaccine strain. Otherwise, there could have been an untold number of anthrax casualties.

On the heels of the Aum Shinrikyo attacks declaring the reality of WMD terrorism and reported proliferation of biological warfare scientific expertise and materials, bioterrorism first became a major national security concern.

Public health authorities similarly became alarmed because local public health would be on the frontline of a bioterror attack in the United States. The laboratory response network, the strategic national stockpile and training on the medical management of biological casualties were established in 1998 that began bioterror preparedness for the civilian population. But, interest quickly waned and concerns were voiced that bioterror preparedness was taking away from day-to-day public health. Progress on bioterror preparedness stalled until the anthrax letter attacks in 2001in the wake of the tragic events of September 11th that began the era of catastrophic terrorism on the United States Homeland.

The anthrax letter attacks marked the first significant act of bioterrorism in the United States. That attack was one of the easiest bioterror attacks to confront, yet the impact was far reaching. As bad as it was, it could have been much worse had the pathogen involved been a contagious agent, resistant to antibiotics, an unknown pathogen, or delivered in a covert widespread aerosol attack across multiple jurisdictions. As it was, the anthrax letters shut down the Hart Senate Office Building for three months, wreaked havoc with the U.S. Postal Service, reduced business productivity, cost the nation more than one billion dollars, and most importantly, took five lives and sickened seventeen more. More than 30,000 people required post exposure antibiotics and countless more worried well casualties. The medical, public health, law enforcement, and intelligence responses were massive across public and private sectors. Although the

response enterprise worked very hard and with the best available knowledge at the time, serious weaknesses were revealed in almost ever aspect of the response.

The Executive and Legislative Branches scrambled to respond and improve the nation's biodefense posture. We created new programs, increased laboratory and other needed capacities, developed and stockpiled medical countermeasures, increased budgets, hired experts, established public health and hospital preparedness programs for infectious disease control and training, re-oriented parts of our intelligence and law enforcement enterprises. In general, we took the threat seriously for a few years and made significant biopreparedness progress. The focus then waned as years went by.

Some question the seriousness of the threat today because further bioattacks have not followed. Fortunately, further attacks have not occurred, which I partially attribute to successful counter terrorism strategies.

Why further attacks have not occurred, given the relative ease of mounting such an attack coupled with our vulnerability is up for debate. I do not want to overstate nor underestimate the threat and risk of a bioterror attack. But, we cannot ignore that violent extremists intend to do us harm by any means, and they are not constrained in the methods they select to use. The intent to acquire and use weapons of mass destruction by the likes of Al Qaeda, the Islamic State of Syria and the Levant (ISIL) and others is known. Intelligence gathering is extremely difficult, particularly for the bioterror threat, but we should not take the lack of tactical intelligence as lack of a threat. It may be that violent extremist groups so far have yet to recruit an individual with the necessary skills, or that a biologist has not become a self inspired violent extremist. We ignore this threat at our peril.

As reported by Rolf Mowatt-Larssen in a study from the Harvard Kennedy School's Belford Center for Science and International Affairs, "The Al Qaeda Weapons of Mass Destruction Threat: Hype of Reality", senior Al Qaeda leadership were committed to acquiring nuclear and biological weapons for their strategic mass casualty potential, and they collaborated with the most senior leaders of other extremist groups indicating that this intent is not limited to just Al Qaeda.

The discovery of an ISIL computer containing plans to develop plague as a bio-weapon underscores this concern. Just yesterday the Director of National Intelligence confirmed reports that the Islamic State used a chemical warfare agent in Iraq and Syria, the first confirmation of such use by an extremist group since the Aum Shinrikyo's attack 20 years ago. The Islamic State is growing rapidly, has resources, necessary infrastructure, controls safe havens, and is apparently recruiting scientists that would be capable of developing chemical and biological weapons. We must assume the threat is real and serious.

There are many reports that have already told us that the United States is not taking the biological threat seriously enough and is unprepared to deal with a catastrophic biological event. The U.S. Commission on National Security/21st Century raised the

issue fifteen years ago, the National Commission on Terrorist Attacks upon the United States raised it twelve years ago, the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction raised it eleven years ago, and the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Commission) raised it eight years ago. Further, while the Intelligence Community admits to weaknesses in their biological collection and analysis activities, it does not dispute the fact that the biological threat exists and is serious.

In addition to bioterror attacks, naturally occurring, emerging and reemerging trans-boundary infectious diseases continue along their damaging trajectory. The human immunodeficiency virus, pandemic potential influenza viruses, severe acute respiratory syndrome, middle east respiratory syndrome, west nile virus, chikungunya, dengue, Ebola, and now Zika are real experiences that tell us we may be on the verge of a global pandemic anytime. Our biological threat preparedness enterprise must also be ready anytime.

The need for strong leadership: There is widespread acknowledgement that the global response to Ebola in 2014/2015 was severely deficient. The domestic response to Ebola was unacceptable too, and tells us that despite significant progress – and with the dedicated and untiring work by many in the biopreparedness enterprise – we are still unprepared and have much work to do.

The preparedness and response enterprise goes well beyond public health and includes federal, state, local and tribal governments, as well as industry, academia and other NGOs. It is a vast enterprise that requires complex public-private partnerships to achieve success – and strong leadership.

The Biodefense Blue Ribbon Panel report, "a National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts" provides 33 recommendations that spans the framework from threat awareness, prevention and protection, surveillance and detection, response and recovery. But from my view, the Panel's most important recommendations are the need for strong centralized leadership, coupled to a focused biodefense policy coordinating council and a new biodefense strategy.

This is a much more daunting task than it appears at first glance to establish centralized leadership and a new comprehensive strategy. I have worked in federal interagency coordinating initiatives in the Clinton, Bush and Obama Administrations with many hard working, dedicated colleagues. It is my experience that in the vast interagency process there are many competing demands, and the process itself significantly delays progress. In my opinion, the best model employed to date to harness the vast federal interagency enterprise before an outbreak was the Pandemic Influenza Strategy and Pandemic Implementation Plan that followed the pandemic emergency supplemental appropriation in 2006. Centralized leadership and the implementation plan were the operative components that drove progress with metrics toward positive outcomes. The

implementation plan had over 300 action items and identified lead and supporting department/agencies, as well as called for effective public/private partnerships. Accountability was built into the plan and departments were held accountable for progress. Frankly, some felt this was micromanagement and superseded department/agency authorities, and maybe it did at times. But, the plan enabled the vast enterprise with our private sector and academic partners to make progress that otherwise would not have been possible. This plan also served us very well in the response to the 2009 Influenza Pandemic, where BARDA was able to get every major influenza vaccine maker under contract and producing vaccine in a matter of weeks.

Enhanced intelligence collection, overhaul of the Select Agent Program, hospital preparedness, public health preparedness, laboratory capacities, medical countermeasures development and deployment, and other actions together with U.S.-led international efforts in global health security, and biological weapons prohibition diplomacy will lead us to a position of much greater strength – if executed efficiently, effectively, and in an integrated fashion.

From my experience, I cannot overstate the importance of the Biodefense Blue Ribbon Panel's recommendation on the need for strong centralized leadership, however implemented, and a new biodefense strategy and focused implantation plan. Without this, we will continue to make progress, but incrementally at best and we will not be in a position to drive urgent action during the inter-epidemic period when urgent action is needed the most.

Thank you again for this opportunity to appear before you and share my experiences on this important national security topic.