

**Hearing of the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
"Outbreaks, Attacks, and Accidents: Combating Biological Threats"**

February 12, 2016

**Statement for the Record
The Honorable Donna E. Shalala
Panel Member, Blue Ribbon Study Panel on Biodefense**

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee: thank you for inviting us here to present the views and recommendations of the bipartisan Blue Ribbon Study Panel on Biodefense. I am pleased to join my co-panelist, former Representative Jim Greenwood. We are here on behalf of our co-chairs, former Senator Joe Lieberman and Governor Tom Ridge, and the other members of our Panel, former Senate Majority Leader Tom Daschle, and former Homeland Security Advisor Ken Wainstein.

We are here today to discuss the collective findings and concerns of our Study Panel. While we are optimistic that our nation's weaknesses in biodefense can be addressed, we want to convey to you our deep concern about this threat. As you know, naturally occurring and intentionally introduced diseases decimated populations throughout history, and remain among the most dangerous of hazards of the modern world. We are particularly concerned about emerging infectious diseases, and what they mean for the health of Americans and that of the global community. The emergence Chikungunya, an incurable disease that results in paralysis, is striking. Unlike other viruses that have yet to land on our shores, Chikungunya is already here, with thousands of cases in Puerto Rico, Florida, and New York. Zika virus is following a similar progression, beginning in discrete, remote, and tropical locations and then widening its reach. We appreciate the good work this committee has done to assess and mitigate these kinds of

globally emerging infections, with its oversight on disease surveillance, pandemic influenza, and other serious public health issues. We know that you, too, are familiar with the catastrophic potential of highly pathogenic disease and the challenges inherent in managing them.

Infectious diseases impact the security of every American. Yet our Panel found that our attention *to* the threat is not commensurate *with* the threat. We highly recommend that you obtain a classified briefing on the biological threat as soon as possible and get the Intelligence Community's perspective on the potential for biological terrorism and warfare, as well as the national security implications of catastrophic naturally occurring disease events.

While the Clinton Administration paid increased attention to the biological threat, that interest waned prior to the anthrax events of 2001. Letters containing weaponized anthrax closed 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 by some estimates, and most significantly, took five lives and sickened seventeen more. After those events, Congress and the White House renewed their efforts to improve the nation's biodefense posture. They created new programs, increased laboratory and other needed capacities, developed and stockpiled medical countermeasures (MCM), increased budgets, hired experts, improved protective equipment, re-oriented parts of our intelligence and law enforcement enterprises, and in general, took the threat seriously for a few more years. They lost focus again as years went by without another such attack – despite the fact that criminals continue to commit smaller-scale biocrimes, terrorists groups continue to pursue bioweapons, and emerging infectious diseases continue to march forward. The biological threat is real and present, but our attention span is not.

We are not the first to come before Congress to tell you that the United States is not taking the biological threat seriously enough and that the nation is not preparing sufficiently to deal with a major 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, the Intelligence Community states that the biological threat exists and is serious, while simultaneously admitting to weaknesses in its biological collection and analysis activities in this regard.

When we began our work with the Panel in 2014, we wanted to know: (1) if the United States was still vulnerable to the same weaknesses in biodefense that the WMD Commission found in 2008; and (2) what, if anything, we are doing to heed the advice of that Commission and previous panels to take decisive action in defending against biological events of the order that could cause catastrophic loss of life, societal disruption, and loss of confidence in government?

We held public meetings with more than sixty experts (e.g., current and former lawmakers and federal officials, local health department representatives, emergency service providers, academicians, business executives, and other thought leaders). We scrutinized the status of prevention, deterrence, preparedness, detection, response, attribution, recovery, and mitigation. The spectrum of activities that Republican and Democratic Administrations, as well as many policy experts, deem necessary for biodefense. We used this expert input, and conducted

significant additional research, as outlined in the report's Methodology section. We examined the national state of defense against intentionally introduced, accidentally released, and naturally occurring biological threats and released our findings in our bipartisan report, “A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts,” in October 2015.

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

We also discussed a number of ways we can more effectively address the threat, using resources and infrastructure already have in place. For example, while the Strategic National Stockpile has its role, we also found that community pharmacies (ubiquitous throughout the nation) possess the supply chains, experience with pharmaceutical distribution, and access systems with which the public is already familiar. I believe that these could be used to much greater effect during the response to a biological event and that they may play a significant role in solving the Strategic National Stockpile's inventory management problems. The Institute of Medicine, by mandate of appropriations law, is undertaking a detailed examination of this question and related distribution and dispensing challenges this week.

We believe – as did the WMD Commission before us – that U.S. biodefense lacks a point person. Responsibility for biodefense is one of the federal government's most important functions, with pieces falling within national, homeland, public health, and economic security. As such, it

requires a highly complex and sophisticated enterprise. We have not attained the necessary integration of vision and activity. As a result, the activities we undertake are insufficiently coordinated, collaborative, and innovative. Neither the President nor Congress has charged and authorized an individual to create a cohesive, effective, and efficient whole of the fractionated parts of a dozen departments and agencies responsible for some aspect of biodefense. The last three Presidents appointed special assistants, czars, and others, but jurisdictional and budgetary authorities, guidance, and accountability eluded the individuals holding these positions. We believe that a biodefense leader – and the vision, oversight, and accountability that such an individual brings – could have prevented or mitigated weaknesses in a wide range of activities, including management of the Select Agent Program, implementation of global disease surveillance, and rapid response to public health crises.

Our main recommendation is to install a leader at the highest level of government who recognizes the severity of the biological threat and possesses the authority and political will to defend against it. We recommend that this top-level leader be the Vice President of the United States. The Vice President has a direct line to the President and, when imbued with authority, can act as the President's proxy. The primary goal of centralizing leadership is to place coordination and oversight responsibility in a location with: (1) sufficient jurisdictional and budget authority, regardless of personalities or party in power; and (2) executive decision-making ability. The Vice President possesses these attributes. We also recommend that the Vice President establish and lead a Biodefense Coordination Council, which we envision to be a coalition of public and private sector partners who work together to address biodefense requirements.

(Recommendations 1 and 2)

We provide 33 recommendations in our report, as well as specific short-, medium-, and long-term programmatic, legislative, and policy actions for each of these recommendations. Each of these can improve our Nation's ability to prevent, deter, prepare for, detect, respond to, attribute, recovery from, or mitigate biological events. Together, they comprise a blueprint for biodefense.

I would like to highlight three here:

1. **Strategy development:** The nation currently lacks a well-considered and comprehensive biodefense strategy. Our top priority must be to develop the National Biodefense Strategy of the United States of America. This strategy should be all-inclusive and harmonized, identifying all implementation requirements (e.g., Executive Branch organizational structures and requirements, lead and supporting roles, modernization and realignment plans, and dedicated resources). The strategy should also include a mechanism for holding department and agencies accountable for properly executing their responsibilities as leads or participants. We recommend that White House staff collate existing strategies and plans, identify requirements within extant policies, and assess spending history and value. They should then draft a comprehensive strategy that policymakers can use to assess where the nation is falling short of meeting strategic goals and objectives. We also recommend that the President implement a unified biodefense budget. This will allow the President and Congress to determine appropriate resource allocation and conduct oversight systematically. (Recommendation 3)
2. **Hospital preparedness:** Preparedness of our hospitals rises to the fore each time a natural disaster (e.g., Hurricane Katrina) or significant pandemic (e.g., Ebola) occurs. We

want to see more deliberate and systematic planning. We recommend four areas of focus: clinical infection control guidance, tighter management of Hospital Preparedness Program funds, development of incentives for hospitals to prepare by linking incentives to Centers for Medicare and Medicaid Services reimbursement, and establishment of a biodefense hospital system. While these tasks are numerous, a great deal of thinking has been done on how to implement them. It is now time to implement. Some of this will require legislative authority, or at least encouragement, and we ask you to consider moving bills as necessary to achieve these goals. (Recommendations 18-21)

3. **Global health leadership:** While our Panel focuses mostly on domestic policy, we recognize the foreign origins of many emerging diseases, and the impacts that global health has on U.S. health. We further understood that the United States plays an important role in global health security. We, therefore, want to see the United States renew its leadership role in the Biological and Toxin Weapons Convention by strengthening efforts toward implementation, setting goals for the 2016 review conference, and developing actionable recommendations for verification. Secondly, we propose that the United States should lead a new effort to develop a capable global public (and animal) health response apparatus. The World Health Organization is important, but it is equally important to recognize what it does not do. It is not an operational response organization. The United States should convene global health leaders to develop a plan for a new model of response predicated on public-private partnerships. This planning could be achieved through the existing multilateral efforts of the Global Health Security Agenda. (Recommendations 25 and 33).

We believe all of our 33 recommendations are necessary to advance national biodefense and our other recommendations address a variety of additional issues. For example, enhanced intelligence collection, protection of pathogen data and cybersecurity, overhaul of the Select Agent Program, support of hospital preparedness and public health preparedness grants, U.S.-led global health security efforts, and biological weapons prohibition diplomacy will also make us stronger – if executed efficiently, effectively, and in concert.

Congress plays a critical role in conducting necessary oversight and providing needed authorities and funding. Our report provides a number of recommendations to amend legislation and coordinate congressional oversight. In addition, we provide an extensive list of topics that we believe are still in need of oversight, twelve of which we hope you, your colleagues, and the Senate will consider.

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

Please see our bipartisan report, “A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts” for our 33 recommendations and associated action items.

Recommendations of the Blue Ribbon Study Panel for Biodefense:

1. Institutionalize biodefense in the Office of the Vice President of the United States.
2. Establish a Biodefense Coordination Council at the White House, led by the Vice President.
3. Develop, implement, and update a comprehensive national biodefense strategy.
4. Unify biodefense budgeting.
5. Determine and establish a clear congressional agenda to ensure national biodefense.
6. Improve management of the biological intelligence enterprise.
7. Integrate animal health and One Health approaches into biodefense strategies.
8. Prioritize and align investments in medical countermeasures among all federal stakeholders.
9. Better support and inform decisions based on biological attribution.
10. Establish a national environmental decontamination and remediation capacity.
11. Implement an integrated national biosurveillance capability.
12. Empower non-federal entities to be equal biosurveillance partners.
13. Optimize the National Biosurveillance Integration System.
14. Improve surveillance of and planning for animal and zoonotic outbreaks.
15. Provide emergency service providers with the resources they need to keep themselves and their families safe.
16. Redouble efforts to share information with state, local, territorial, and tribal partners.
17. Fund the Public Health Emergency Preparedness cooperative agreement at no less than authorized levels.

18. Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.
19. Minimize redirection of Hospital Preparedness Program funds.
20. Provide the financial incentives hospitals need to prepare for biological events.
21. Establish a biodefense hospital system.
22. Develop and implement a Medical Countermeasure Response Framework.
23. Allow for forward deployment of Strategic National Stockpile assets.
24. Harden pathogen and advanced biotechnology information from cyber attacks.
25. Renew U.S. leadership of the Biological and Toxin Weapons Convention.
26. Implement military-civilian collaboration for biodefense.
27. Prioritize innovation over incrementalism in medical countermeasure development.
28. Fully prioritize, fund, and incentivize the medical countermeasure enterprise.
29. Reform Biomedical Advanced Research and Development Authority contracting.
30. Incentivize development of rapid point-of-care diagnostics.
31. Develop a 21st Century-worthy environmental detection system.
32. Review and overhaul the Select Agent Program.
33. Lead the way toward establishing a functional and agile global public health response apparatus.