

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. **Strategy:** These solutions will depend on a well-considered and comprehensive biodefense strategy, which the nation currently lacks. Our top priority must be development of the National Biodefense Strategy of the United States of America. This strategy should be in keeping with the National Defense Strategy, it should be all-inclusive and harmonized, and it should define all Executive Branch organizational structures and requirements, lead and supporting roles, modernization and realignment plans, and resources necessary for implementation. This strategy should also contain the action plan for holding department and agencies accountable for their leading and supporting responsibilities. We recommended that White House staff collate existing strategies and plans, identify requirements within extant policies, and assess spending history and value (although others in the Executive Branch could do so as well, with White House direction). They can then draft a comprehensive strategy that policymakers can use to assess where we are falling short of meeting the strategic approach outlined therein. We also strongly recommend that the President implement a unified biodefense budget. This suite of tools will allow the President and the Congress to determine appropriate resource allocation and oversight in a systematic way.
3. **Biosurveillance:** One of the most important actions we can take to protect ourselves is to improve our capacity for rapid detection of dispersed or circulating biological agents. We recognize that DOD and the Department of Homeland Security (DHS), as well as a few other departments and agencies, are working toward this goal. From the fielding of biodetectors, to the collection and integration of biosurveillance data, DHS has made some progress. In our view, DOD fares better, but even its technology and activities in this regard fall short of what the warfighter and nation need. We have two choices: either we make existing biodetection and biosurveillance programs work, or we replace them with solutions that do. Many departments and agencies are supposed to coordinate with DHS on detection and the integrated, common operating picture for biosurveillance. We believe that this will only happen if someone at the White House is forcing coordination and holding members of the Executive Branch accountable for participating in these activities.
4. **Medical Countermeasures (MCM):** Former Senator Jim Talent told us that in order to achieve near-term progress in biodefense, policymakers should prioritize

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

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

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

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

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

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

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

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

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

Recommendations of the Blue Ribbon Study Panel for Biodefense:

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

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