

**Full Committee Hearing of the
Senate Committee on Homeland Security and Governmental Affairs**

Assessing the State of Our Nation's Biodefense

October 28, 2015

**Statement for the Record
The Honorable Joseph I. Lieberman
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Chairman Johnson, Ranking Member Carper, and Members of the Committee: Thank you for inviting us here to provide the perspective and recommendations of the Blue Ribbon Study Panel on Biodefense. On behalf of our colleagues on the Panel – former Secretary Donna Shalala, former Majority Leader Tom Daschle, former Representative Jim Greenwood, and former Homeland Security Advisor Ken Wainstein – we present the findings, concerns, and determined optimism of our group.

As you know, we both have addressed homeland security in various capacities for many years. Senator Lieberman served 24 years in the United States Senate, where he spent six years as Chairman of the Senate Committee on Homeland Security and Governmental Affairs. Governor Ridge was the nation's first Secretary of Homeland Security and served six terms in the United States House of Representatives. Although we have left government, we remain committed to public service and concerned about challenges to the homeland.

We are particularly concerned about the biological threat. We did not pick up this mantle lightly – we knew the problems were great. We also understood that the federal government and its many partners began laying a foundation for biodefense before and particularly after the anthrax attacks of 2001 (fourteen years ago this month). Many in Congress well remember the events that autumn. Just a few feet away, in the Hart Senate Office Building, events unfolded that would permanently alter the trajectory of U.S. biodefense. Letters laden with anthrax spores caused the shutdown of that building for three months. Additional letters wreaked havoc in other locations up and down the East Coast. This led, of course, to far more than reduced business productivity and extreme financial costs for the nation – five Americans died and 17 more were sickened with anthrax.

We are hardly the first to come to you with concerns that the United States is not taking the biological threat seriously enough and that as a result, it is not ready to deal with a biological event. The U.S. Commission on National Security/21st Century raised the issue fourteen years ago, the National Commission on Terrorist Attacks upon the United States raised it eleven years ago, the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction raised it ten years ago, and the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Commission) raised it seven years ago.

In December 2008, Senators Bob Graham and Jim Talent sat at this very table to present the findings of the WMD Commission. Their assessment was sobering: they believed that more likely than not, terrorists would use a weapon of mass destruction in a terrorist attack by the end of 2013. Sadly, they were correct: Bashar al-Assad deployed chemical weapons on the Syrian people in 2013. We can only assume that their grave concerns regarding the biological threat were well founded and could come to fruition.

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 Senators Graham and Talent 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 these questions, we offer our findings in our bipartisan report, "A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts." This report is the culmination of our efforts to examine the national state of defense against intentionally introduced, accidentally released, and naturally occurring biological threats. 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 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 deemed necessary for biodefense by both Republican and Democratic administrations, and many policy experts.

First, our findings. We identified substantial achievements in our capacity to defend against major biological events, but also found serious gaps that continue to leave the homeland vulnerable. The more catastrophic the potential consequences, the less prepared we are. We believe that this vulnerability is rooted in the lack of strong centralized leadership at the highest level of government. No single individual is imbued with the charge and authority to create a cohesive, effective, and efficient whole of the dozen responsible departments and agencies responsible for some aspect of biodefense. The last three Presidential Administrations have taken a variety of leadership approaches to address the issue, usually involving a Special Assistant or Czar at the White House. The roles were important and the individuals holding them achieved significant accomplishments. Unfortunately, the fundamental jurisdictional and budgetary authorities necessary to drive all elements of public and private sector efforts eluded them all.

The WMD Commission was similarly concerned about the lack of high-level leadership and the governance structure at the White House. Because this not been resolved, any Commission recommendations implemented suffered from the absence of guidance and accountability that centralized leadership provides. This includes a review of the Select Agent Program, strengthening global disease surveillance, and enhancing the nation's capabilities for rapid response – which recent events demonstrate are all still not functioning adequately.

It has been said that many issues are critically important, complicated, and require a centrally led whole-of-nation effort. A suite of issues from cyber attacks to violent extremism threatens our security. We asked ourselves if this meant that biodefense was no more in need of centralized

leadership than other initiatives. What we came to believe was that biodefense is, in fact, unique. As a component of national defense, the responsibility for biodefense falls squarely within the purview of the federal government as one of its most important functions. 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. It requires the clean alignment of more than a dozen departments and agencies working in tandem toward a common endpoint, with no confusion over intermediate or end goals and without duplicative expenditures we cannot afford in this time of fiscal constraint. This harmonization and prioritization can only occur in the presence of a driving force with policy, political, and budget authority sufficient to achieve what has never been achieved before.

We identified three primary symptoms that result from this lack of centralized leadership: insufficient coordination, collaboration, and innovation. Though well-intentioned departments and agencies have tried to coordinate some aspects of biodefense among themselves, the fact is that their efforts fall short. Overarching leadership is necessary to direct and harmonize these efforts. A leader at the White House must set priorities, goals, and objectives for biodefense, and hold members of the Executive Branch accountable for meeting them.

Additionally, because of the substantial participation required by non-federal partners, such a leader must take charge of intergovernmental collaborative efforts. It is state, local, territorial, and tribal governments, and their non-governmental partners, who will feel and respond to the immediate impact of biological events. The federal government must aid in strengthening their capabilities and increasing the support and access provided to them far beyond current levels – and someone needs to make this a priority.

Finally, biodefense efforts urgently call for a much greater focus on innovation – because biological threats are imminent, biological vulnerabilities have existed for too long, and the complexity of the threat requires equally complex solutions. The government tends toward risk aversion, which is reasonable in certain fora – but in biodefense, it will only result in failure to foster the entrepreneurial thinking and technological solutions we need to develop radical, effective solutions.

These symptoms are not abstract: they have very real-world implications for the security of the American people. If rectified, for example, hospitals would have the guidance they need to handle diseases like Ebola, city governments would have the support they need to dispense medical countermeasures to the masses, and industry would have the incentives and direction it needs to solve our greatest challenges in biodetection.

Next, our recommendations. Our report contains 33 recommendations, each of which we believe can individually improve our Nation's ability to prevent, deter, prepare for, detect, respond to, attribute, recovery from, or mitigate biological events. We also provide about 100 short-, medium-, and long-term programmatic, legislative, and policy actions. Collectively, they serve as a blueprint for biodefense. We highlight here the most important recommendations:

1. **Leadership:** First and foremost, we must instate 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 budget authority regardless of personalities or party in power, and with a person in a position with 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 aid in driving a coalition toward solutions.
2. **Biodefense Strategy:** The nature of those solutions will be dependent on a well-considered comprehensive strategy. The Vice President's top priority must be development of the National Biodefense Strategy of the United States of America. This strategy should be all-inclusive and harmonized, and should define all Executive Branch organizational structures and requirements, modernization and realignment plans, and resource requirements necessary for implementation. The White House staff must collate existing strategies and plans, identify requirements within extant policies, and assess spending history and value. They can then draft a comprehensive strategy, and policymakers can assess where we are falling short of meeting the strategic approach outlined therein. That will allow the President and the Congress to determine where to allocate resources. We strongly recommend that the President implement a unified biodefense budget to do this.
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. Early detection has been the goal of Department of Homeland Security (DHS) biodefense efforts since the Department was established. From the fielding of BioWatch detection machines in high-risk jurisdictions around the country, to the collection and integration of biosurveillance data by the National Biosurveillance Integration System, some limited progress has been made. But we are still incapable of truly rapid detection. 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 must coordinate with DHS on detection and biosurveillance, and we believe that this will only happen if someone at the White House is forcing the issue.
4. **Medical Countermeasures (MCM):** Senator Talent told us that policymakers should prioritize the development of MCM because we know that success is achievable in this specific area. The technological and resource challenges to taking threats off the table with MCM are tough, but surmountable. Innovative ideas within industry abound. We must reduce bureaucratic hurdles at the Department of Health and Human Services and increase efforts to incentivize and fund what is still a nascent MCM industry. 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.

- 5. One Health:** One Health is the glue that will hold all of these efforts together. 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, for example, came to humans through animals. And avian influenza spread from wild birds through their environment to reach farm animals. We were not and still are not prepared to deal with this. 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.

This short list does not diminish the importance of every other recommendation in our report. We submit that all thirty-three recommendations are necessary to advance our status as a prepared nation. Enhanced intelligence collection, protection of pathogen data and cybersecurity, overhaul of the Select Agent Program, support of hospital preparedness and public health preparedness grants, and U.S.-led international efforts in public health response and biological weapons diplomacy will lead us to a position of much greater strength – if executed efficiently, effectively, and in concert.

Last but not least, the role of Congress in conducting oversight and providing authorities regarding all of these recommendations cannot be overstated. Our report provides a number of recommendations to amend legislation and coordinate congressional oversight. It also provides an extensive list of suggested topics in need of oversight that we hope you and your colleagues on other committees and in the House will consider.

As we close, we ask you to keep in mind the concerns of our citizenry. They were far from apathetic when Ebola came to the United States and claimed lives here and abroad. Thousands are becoming sick and dying of Chikungunya, a disease for which – like Ebola – we do not have a cure. They were aghast to see chemical weapons used in the Middle East by the Islamic State of Iraq and the Levant earlier this year, especially given the proximity of our troops. They watch television shows and movies featuring diseases and their devastating effects on society. They are close to this issue and want us to do something about it, before biological weapons, accidental releases from laboratories, or new diseases kill their neighbors, their friends, or their families. It is too late to get ahead of this threat – it is already out there. But we can get ahead of its impact.

Once again, we thank you for this opportunity to hear our perspective. 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 financially and otherwise. 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.