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

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The Honorable James C. Greenwood
Panel Member, Blue Ribbon Study Panel on Biodefense

Statement for the Record

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee: Thank you for inviting me to discuss preparedness for biological threats on behalf of the bipartisan Blue Ribbon Study Panel on Biodefense. As former Chair of the Energy and Commerce Subcommittee on Oversight and Investigations, I am especially honored to be testifying here today.

This hearing is quite timely. Not because a catastrophic biological event has recently occurred but because one has *not* occurred. The kinds of events we are here to discuss today are health disasters we hope to never see on U.S. soil in our lifetime. Nonetheless, we must be prepared for these types of events. A dirty bomb in an urban center. The dispersion of anthrax in the metro system. The malevolent reintroduction of smallpox. The natural emergence of another Ebola-like disease or another pandemic influenza outbreak. As the Panel notes in our report, we are underprepared to respond to these threats and we must take immediate steps to address these gaps.

For the last year, it has been a privilege to join former Senator Joe Lieberman, former Governor Tom Ridge, former Department of Health and Human Services (HHS) Secretary Donna Shalala, former Senate Majority Leader Tom Daschle, and former Homeland Security Advisor Ken Wainstein on the Study Panel. Our goal was to assess U.S. capabilities with respect to potentially catastrophic biological events and to identify actions to advance our preparedness. We all decided to serve on this Panel, even before the global

events of the Ebola outbreak unfolded, because of concerns that the nation was insufficiently prepared.

Our report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts,* was released in October 2015. The report starts from the premise that the biological threat is real and growing. As you are quite aware, the federal government has undertaken many initiatives – especially since the anthrax attacks of 2001 – to fortify U.S. biodefense capabilities to address this threat. From fielding environmental detection units to stockpiling medical countermeasures (MCMs) to building public health capacity, we are better prepared today than we were a decade ago. But the fact is, we are still dramatically underprepared to respond to a biological event of truly disastrous proportions.

The reason for this is neither lack of interest nor of effort, but a lack of whole-of-government coordination required to achieve this goal. To date, many of the federal activities undertaken to improve our preparedness have been implemented in a strategic vacuum. There is no comprehensive national strategy for biodefense, and no corresponding unified budget for biodefense. As a result, Congress lacks the most important tools it needs for thorough biodefense oversight. Without them, the appropriation of funding for the enterprise is ultimately limited to discrete agency-by-agency visions for expenditures. Further, for biopharmaceutical companies that want to aid in our preparedness, a national strategy and unified budget are vital for defining the research and subsequent funding priorities that industry needs to plan their investments.

Consider a company that has a novel technology that could be applied to the bio-threats or emerging diseases identified by HHS as threats to the U.S. This company wants to partner with the government to address these urgent public health threats but there are so many uncertainties and unique market challenges. Unlike products with a viable commercial market, the market for most MCMs is defined and supported solely by the

federal government. Therefore, the federal government is often the only research funding source ***and*** the only purchaser of vaccines, therapies and diagnostics against these unique threats. Many companies begin their research at their own risk, conducting early R&D even before receiving government funds in order to better understand the pathogen and the disease. Over the last few years, government funding for R&D has been decreasing, just as the number of threats has been increasing. The investor community views these products as risky and a distraction from similar products that have a clear commercial value, making it almost impossible to raise the necessary R&D funds for MCMs in the private capital markets. The regulatory pathway is not always clear, especially for an emerging infectious disease, and so determining the clinical trial strategy can be complex. Lastly, industry has seen a precipitous drop in the level of funds for *purchase* of the final MCMs. For many companies the biggest risk is that they will invest significant internal funds and time developing a product only to find there is no clear procurement strategy from the U.S. government, foreign governments or non-governmental organizations due to sudden shifts in priorities or a dearth of funds.

Our report outlines 33 recommendations, but today I would like to focus on the recommendations related to strengthening the public-private partnership that supports the development of MCMs (Recommendations 28-29). Congressional leadership could have a powerful impact on the implementation of these recommendations, as well as others.

For example, we recommend that the medical countermeasure enterprise be prioritized, fully funded, and incentivized. As stated above, we strongly support the need for a comprehensive multi-year strategic plan and unified budget that clearly outlines the priorities for research, development and procurement of medical countermeasures, pandemic influenza and emerging infectious diseases. Such a strategic document would provide much needed transparency on government priorities and projected requirements, thus helping companies determine what products to pursue in the partnership. The unified

budget would help support the funding requests necessary for our national and global health security.

The Project BioShield Special Reserve Fund (SRF) was created by Congress in 2004 to provide companies with a guaranteed market for their medical countermeasure products by establishing a ten-year advanced appropriation of $5.6 billion. Paired with funding for early stage research support from the NIH and the Biomedical Advanced Research and Development Authority (BARDA), the SRF proved successful in attracting companies to invest in MCM R&D. BARDA reports that 12 MCMs against chemical, biological, radiological, and nuclear threats were procured during that ten-year authorization period. There are now more than 200 MCMs in the pipeline and[1] they expect to procure another 12 MCMs by 2018.[2]

But the progress made due to Congress' initial $5.6 billion investment is now in jeopardy. The SRF was reauthorized at $2.8 billion for the period of FY 2014 through 2018, but rather than a set-aside sum of money, the program has been funded through annual appropriations, and funded much lower than the authorization amount. Congress appropriated only $255 million in both FY 2014 and FY 2015. This year, the funding amount for the SRF was doubled to $510 million, and industry partners appreciate the commitment to the MCM enterprise that this increase demonstrates, especially in a tough fiscal climate. Unless funding continues to increase, though, we are risking a $600 million to $1 billion shortfall below the authorized level. Such a sustained deficit in funding endangers the progress we have made in building up the MCM enterprise and puts the 200 product candidates in the pipeline at risk of never being stockpiled for use in an emergency. I hope that all Members of Congress will make the Special Reserve Fund a priority by supporting its funding throughout the appropriations process each year and exercising oversight to ensure that the program is being funded and administered appropriately.

[1] R. Robinson. BARDA Industry Day. October 2015.
[2] U.S. HHS PHEMCE. *Multiyear Budget Fiscal Years 2014-2018.*

Similarly, pandemic influenza has been woefully underfunded the last few years considering the threat posed to Americans by this evolving virus year after year. The Centers for Disease Control and Prevention (CDC) estimates that the 2009 H1N1 pandemic infected 43 to 89 million people and killed between 8,000 and 18,000 people.[3] Unlike emerging infectious diseases, pandemic influenza is a known threat that is particularly challenging given the dynamic, versatile and persistent nature of these viruses. It is imperative that our pandemic preparedness capabilities keep up with the multiple strains that threaten us each year. Constant vigilance in vaccine development and stockpiling, as well as surveillance, is essential. We must not let the urgent threat of the moment overshadow our efforts to prepare against the long-term and continuous threats from pandemic influenza.

From FY 2004 through FY 2013, pandemic influenza activities at HHS included advanced development of vaccines, antivirals and diagnostics, pre-pandemic rapid response capability building, and the replenishment of pre-pandemic vaccine and antiviral stockpiles. These activities were primarily funded through supplemental appropriations of $6.23 billion in FY 2006 and $8.23 billion in FY 2009. It is our understanding that these supplemental balances have been nearly exhausted, yet only $72 million per year in FY 2015 and FY 2016 has been appropriated. The discrepancy in funding stems, in part, from the fact that pandemic influenza activities at HHS lack an explicit authorization. Recommendation 28 in our plan calls for Congress to provide a legislative authorization to define and guide pandemic influenza programs, in order to ensure that they receive the prioritization and the concomitant funding required to address this urgent and repeated threat.

The Report lists several excellent mechanisms that demonstrate the government's commitment to development and acquisition of MCMs. One of the most important incentives that the U.S. government can use is the priority review voucher (PRV) program

[3] Centers for Disease Control and Prevention. Pandemic Flu History. http://www.flu.gov/pandemic/history/

for pathogens designated as material threats. The PRV is a proven and valuable incentive that has helped to spur investment in other complex and neglected areas of R&D, such as rare pediatric diseases and neglected tropical diseases. An extension of the PRV program to include material treats is viewed by many companies as a way to offset the dramatic decline in procurement funding for MCMs. Adding MCM targets to the PRV program may help convince investors that the government is committed to this endeavor and provide increased certainty that MCMs can have value in the marketplace.

As we all learned during the recent Ebola outbreak, it is important to invest in MCMs *prior* to an outbreak. When we try to jumpstart R&D efforts while an outbreak is happening, we are already too late. And I would remind this Committee that Ebola had been on the material threat list for many years. The scientific process takes years, often decades, and science can only be sped up so much. So we must make our best attempts to prepare for the broadest possibilities by investing in novel technologies and supporting a strong private sector base in infectious diseases that can assist when needed. While we do not know what disease will emerge next, if we invest well now in the broader set of known threats, we will be better positioned to pivot and respond when faced with an unknown threat.

In addition to robust, sustained funding, the public-private partnership must be strengthened through improvements to the contracting process. Recommendation 29 calls for changes to the contracting process within BARDA to make it more efficient and predictable, as well as for better coordination between the government agencies who are partnering with companies on R&D. Streamlining processes to eliminate unnecessary red tape is key to ensuring that there are not preventable and excessive delays in the implementation of vital research. Furthermore, these reductions would help companies manage their business planning and decrease uncertainty.

While strong leadership is needed from all branches of government, Congress has an important role to play. Congress must exercise its authority on these issues in a more

proactive and coordinated manner. This Subcommittee can play an integral role in this process by exercising additional oversight over federal biodefense programs. I commend the Committee's recent attention to pandemic influenza preparedness and the letters the Committee sent to the Administration last year with questions about flu vaccine supply and development, healthcare system capacities and strategic plans. The Panel proposes a number of Congressional oversight hearings in Appendix A of our report, many of which fall into the Energy and Commerce Committee's jurisdiction, such as examining BARDA's mission space, the development of a unified biodefense strategy for the federal government, bio-surveillance programs, global health response, and MCM innovation, among others. I hope that the Energy and Commerce Committee and this Subcommittee continue to examine the issue of bio-preparedness further.

Finally, I'd like to close by specifically calling for the swift passage of H.R. 3299, the Strengthening Public Health Emergency Response Act of 2015, which has been introduced by Representatives Susan Brooks and Anna Eshoo. Passage of this bill would represent a strong initial step toward implementing the recommendations of the Blue Ribbon Study Panel. The bipartisan bill includes a number of the Panel's recommendations, including streamlining contracting processes, coordinating stockpiling plans, and increasing transparency around future MCM funding needs. H.R. 3299 also addresses our recommendation that the government identify and institute new, meaningful incentives for MCM development. The bill would do so by extending the tropical disease PRV program to biological agents included on the Department of Homeland Security's (DHS's) material threat list. I hope all the members of this Subcommittee will consider cosponsoring this important legislation and actively work to advance it.

The threats facing our nation are real and many. They are splashed across the headlines each day. ISIS has repeatedly threatened the use of biological weapons. In the last year, avian influenza has decimated Midwestern poultry flocks and posed the risk of

infecting humans. And a new infectious disease seems to emerge regularly, whether it is influenza, SARS, MERS, Ebola, chikungunya, or Zika. And we have already had several small-scale targeted attempts such as the 2001 anthrax mailings, which required $27 million just to decontaminate the Hart Senate Office Building.[4] Thus far we have been relatively lucky in terms of the impact to our society, economy, and public health, but when something happens on a catastrophic scale, the American public will expect the government to be ready to respond.

The good news is that the domestic policy challenges we face are not insurmountable and correcting these issues will put us on the road for success and accountability. Once the governance structure and the tools are in place, we believe that the entire enterprise will run more smoothly, that gaps will be easier to identify, that capabilities will improve.

Thank you again for the opportunity to testify on the work of the Blue Ribbon Study Panel on Biodefense. I commend the Subcommittee for examining the state of our national preparedness for biological threats. I look forward to your questions.

[4] U.S. GAO. *Capitol Hill Anthrax Incident: EPA's Cleanup was Successful; Opportunities Exist to Enhance Contract Oversight.* June 2003.