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Formerly the Blue Ribbon Study Panel on Biodefense

# HOLDING THE LINE ON BIODEFENSE

STATE, LOCAL, TRIBAL, AND TERRITORIAL  
REINFORCEMENTS NEEDED

BIPARTISAN REPORT OF THE  
BLUE RIBBON STUDY PANEL ON BIODEFENSE

*October 2018*

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SPECIAL FOCUS

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**BLUE RIBBON  
STUDY PANEL**  
ON BIODEFENSE

#### CITATION UPDATE

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## EXECUTIVE SUMMARY

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The US Census Bureau counts a staggering 89,004 local governments in the United States. Among them are 3,031 counties, 19,522 municipalities and 16,364 townships.<sup>1</sup> There are 573 tribes,<sup>2</sup> 14 territories, and thousands of other special districts across America—each with a responsibility to serve the people who call those places home. Sometimes that service is in response to an emergency.

Our hometown heroes – emergency medical services, police, firefighters, doctors, nurses, pharmacists, lab technicians, public health professionals – are on the front lines keeping us safe. Maybe it's from a flash flood from a stalled rainstorm. Perhaps it's from a derailed train carrying hazardous liquids. These types of incidents can be handled with resources provided by local and state governments, but when events are severe - widespread in scope and damage – they may require intervention by our federal government. Whether it's a terrorist attack (e.g., September 11, 2001) or a natural disaster (e.g., Hurricane Katrina), the nation will quickly step up and respond, offering additional support and funding.

Unfortunately, there is grave concern that a large-scale biological event will prove to be the exception to this rule. Devastation could be vast and swift, and local resources would be very quickly depleted. The thousands of state, local, tribal, and territorial (SLTT) governments that are the backbone of our nation will have to fend for themselves for far too long until federal assets arrive, and Congress can provide emergency supplemental funding to support response and recovery.

In October 2015, the Blue Ribbon Study Panel on Biodefense issued its first report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*. The majority of the report's recommendations focused on our national government, touching only briefly on SLTT needs. The Panel promised to return to them later and revisited these issues during a special focus meeting on the campus of the University of Miami in January 2018. The Panel explored needed SLTT emergency medical services, hospital, pharmacy, laboratory, and public health department capabilities and capacities necessary to respond to large-scale biological events.

The Panel found that basic biological preparedness, response, and recovery infrastructure varies widely throughout the United States, placing the entire

nation at risk. If one community, for example, does not have access to a laboratory in their state that can quickly identify a biological threat, then they are immediately vulnerable and so are those who live in bordering states. It reminds us that states, localities, tribes, and territories play a huge role in national security. We would like to see state governors, territorial governors and administrators, tribal leaders, mayors, borough council presidents, and township supervisors make biodefense a greater priority before biological attacks, accidents, outbreaks, epidemics, and pandemics place the lives of their constituents at risk.

In the pages that follow, the Panel recommends key steps that will increase the capability of SLTT to share with the federal government the burden of preparedness for, response to, and recovery from large-scale biological events. These eight recommendations are:

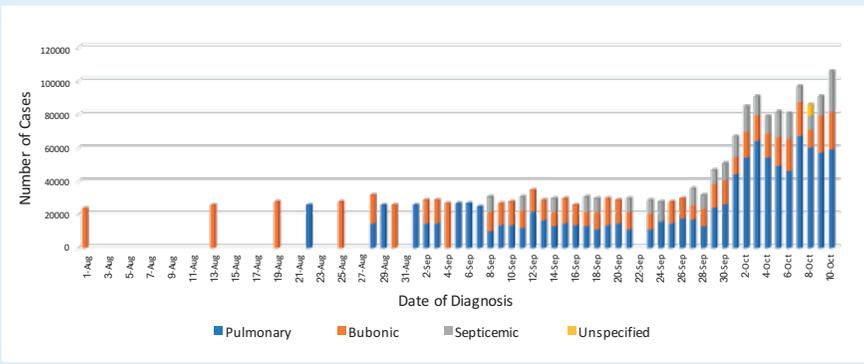
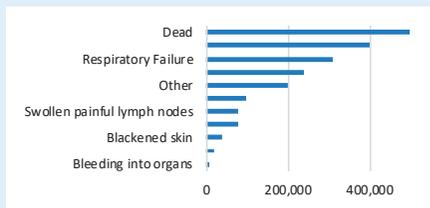
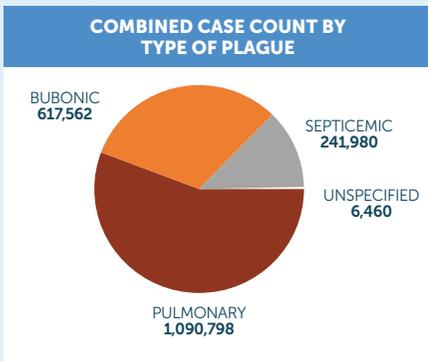
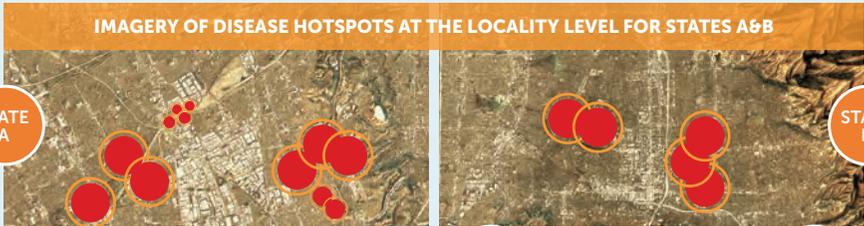
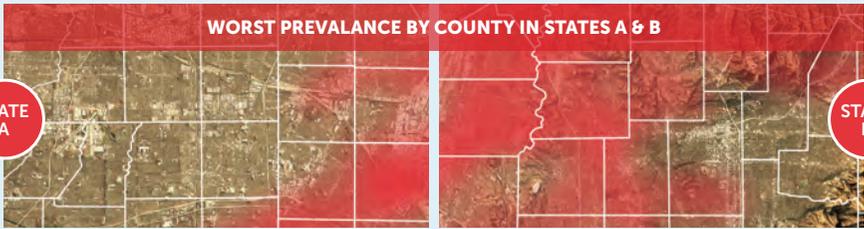
- Unify and establish a new National Emergency Medical Services system, including the creation of a National Emergency Medical Services Agency at the Department of Health and Human Services.
- Improve distribution of the Strategic National Stockpile and other stores of pharmaceuticals, equipment, and essential medical supplies, with enhanced training and assured access to pharmacy readiness data.
- Layer health care delivery across the nation and plan for when hospitals and other facilities are overwhelmed and overrun.
- Authorize all laboratory response networks to test for biological agents.
- Allow federally recognized tribes to enter into their own Public Health Emergency Preparedness cooperative agreements with the Centers for Disease Control and Prevention.
- Strengthen biosurveillance in, and eliminate burdensome transportation requirements for, the territories.
- Allocate response funding before biological crises occur with a credible Public Health Emergency Fund and sufficient assistance under the Stafford Act.
- Address public expectations by making biodefense a priority for all elected leaders throughout the nation.

## **HYPOTHETICAL SCENARIO FOR MULTIPLE UNEXPLAINED OUTBREAKS OF PLAGUE**

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*Plague has broken out in two states and the initial response is slow. The public health departments in both states are on their own until the case counts make it obvious that what these states are experiencing is not normal. It does not take long until the governors are involved. They want to know what is going on and they are looking for answers quickly, but information is only trickling in from hospitals and local government health departments. Eventually, the federal government offers some preliminary support, but only after they make two frightening discoveries: the disease has been genetically engineered and aerosolized, and two terrorist groups are claiming that they have successfully attacked the United States with plague. Outbreaks are expected to continue for months. A hypothetical governors' dashboard, along with a reporter's notes, follow.*

# HYPOTHETICAL GOVERNORS' DISEASE DASHBOARD



## SITUATION UPDATE: DAY 7

**STATE A** Cumulative total of antibiotic resistant *Yersinia pestis* (plague) = 652,267 cases (including 166,023 deaths). 4,720,962 samples (multiple per person) tested by the state public health lab, 98% of which tested positive for plague. Most recent lab-confirmed cases occurred today. Unclear as to whether transportation is exacerbating spread. Approximately 300,000 cases traveled from or through State B.

**STATE B** Cumulative total of antibiotic resistant *Yersinia pestis* (plague) = 1,304,533 cases (including 332,047 deaths). 2,749,003 samples (multiple per person) tested by the state public health lab, 85% of which tested positive for plague (15% deemed inconclusive). Most recent lab-confirmed cases occurred today. Insufficient numbers of epidemiologists available to investigate suspected cases throughout the state.

# HYPOTHETICAL REPORTER'S NOTES FROM INTERVIEWS

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**Governor, State A:** "We continue to see hundreds of cases of antibiotic-resistant plague. I urge our citizens to seek immediate treatment at your local hospitals."

**Governor, State B:** "We have been stricken with plague and cannot deny the serious implications of this disease. I'm asking our citizens to shelter in place. I've called the National Guard to assist with medical treatment and maintain lawful order."

**Director, Public Health Laboratory (BSL-3), State B:** "We heard that the CDC is developing a new testing protocol for this strain of plague, but does it matter? At this point, we're using the tests we have for plague and determining whether these organisms are antibiotic resistant ourselves."

**CEO, major hospital coalition, State A:** "This disease is antibiotic resistant, and unusual, in that it appears to be highly transmissible from person-to-person. We ran out of the supplies for palliative care days ago. We have no more to provide."

**Secretaries of Agriculture and Health, State B:** "We keep sending requests to get the national stockpiles sent here. The feds have always promised us they could get at least part here in 48 hours, but we haven't received anything in four days."

**Superintendent, State Police, State A:** "We have the authority to enforce a quarantine, but the Governor hasn't ordered one. I have no problem with that. What I do have a problem with are the folks coming over the border from State B, where their Governor has told his citizens to shelter in place."

**President, University of State B:** "I have almost 100,000 students, faculty, and other staff here at my university. We're sheltering in place but running out of food. I won't prevent parents from coming here to get their kids. I can't take care of them."

**Commanding General, State B National Guard:** "I've been told to maintain order. We'll do whatever it takes to maintain that order."

**President, cross-border Tribal Nation:** "I'm pretty sure we're on our own. We've got our own hospital, some medical supplies, and a couple of Indian Health Service doctors. That's about it. But who knows? We may be better off than the others. We know how to get along without medicines."

**Chief, Emergency Medical Services, State A:** "We're sending our personnel into harm's way, to bring sick people out of their homes and to the hospitals. Every day, some of my folks get sick, too. What are the communities going to do when there aren't any more of us to help? It's not like the doctors and nurses can come out of the hospitals and bring people in."

**Special Agent in Charge, FBI Field Office, State A:** "All I can tell you is that two terrorist groups have claimed responsibility for these attacks and that some sort of aerosolized agent may have been used. Anything else requires clearance. We'll share information with the Governors and both fusion centers when we can."

**Director, Centers for Disease Control and Prevention:** “The CDC confirms that the strain of *Yersinia pestis* affecting State A and State B is antibiotic resistant. At this time, we are not sending contents of the Strategic National Stockpile to these states because we have received warnings about other impending attacks throughout the Nation.”

**President, United States of America:** “Today, I declared major disasters in State A and B. I have ordered federal aid to supplement state and local response efforts in the areas affected by the plague. I expect the entire federal government to provide all of the assistance they can.”

**Administrator, Federal Emergency Management Agency:** “We are working to determine whether we can provide assistance and are deferring to the Department of Health and Human Services to address this rapidly escalating emergency in accordance with Emergency Support Function 8. FEMA may not duplicate assistance provided or available under the authority of another federal agency or from insurance. We have to wait and see what sort of support HHS is going to provide.”

**Secretary of Health and Human Services:** We are working to transfer funds from other accounts to help these states and save lives. Unfortunately, Congress never put enough money into the Public Health Emergency Fund. The last time I checked, there was about \$30,000 in there. It might as well be zero. I can’t do anything with that to help the millions in those two states.”

**Secretary of Agriculture:** “Our National Veterinary Stockpile is far smaller than the human stockpile. We’ll send what we think will help, but I have to be honest, it won’t help much.”

**Administrator, Environmental Protection Agency:** “This is a biological event. It is not the responsibility of the EPA to contain or clean this up.”

**Secretary of Defense:** “The nation has been attacked. The Governor of State B has activated the National Guard. Most of the National Guard for State A is deployed to the Middle East. We are sending some of the Reserves to State A, but our first priority is to defend the nation against further attacks and keep our enemies from taking advantage of this situation to attack us with other weapons. We will not pull back from our current deployments throughout the world. We have to maintain national security.”

**Doctor, local hospital, State A:** “We’re doing the best we can with what we’ve got, but it’s not enough. And we’re being overrun by the worried well. The situation is impossible.”

**Director, Wildlife Agency, State B:** “We have been working with the US Geological Survey’s National Wildlife Health Center and our colleagues in State A’s wildlife agency. We are trying to monitor where the rodents are, so that we can identify and control the spread of this disease. We can’t afford to ignore these reservoirs. If we do, we are not going to be able to eliminate this disease.”

**Citizen, home-bound, State A:** “Who knows? Maybe I’m safer here.”

**Director, Department of Health, State B:** “I have more bad news. We are going to see cases for months after we get these outbreaks under control.”

# INTRODUCTION

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Shortly after the 2001 anthrax attacks, in which five Americans were killed and 17 were sickened in what is widely considered the worst biological attack in United States (US) history, the Executive and Legislative Branches of our government made significant investments to improve America's ability to respond to bioterrorism. The government also invested in the development of SLTT response capability and capacity. Some of the newly established federal and SLTT programs were successful, but many subsequently languished as recurring budget cuts and declining awareness of the biological threat rendered them ineffective.

Eight years later, in 2009, political interest once again focused on a biological incident, only this time it was pandemic influenza. That is when H1N1 cases first appeared in Mexico and the United States, despite the prevailing assumption that an influenza pandemic would begin in Asia. The United States scrambled to manage H1N1 outbreaks. Increased congressional interest resulted in several hearings, and the US House of Representatives Committee on Homeland Security issued a report entitled, *Getting Beyond Getting Ready for Pandemic Influenza*.<sup>3</sup> Despite this additional attention, Congress added little to existing legislation at the time. While governors, mayors, and other locally elected officials throughout the country expressed serious concern, they concentrated most of their efforts on managing the spread of the disease and communicating to their constituents. Then-Governor of Maryland Martin O'Malley and former Representative (now Senator) Chris Van Hollen launched a summit of federal and non-federal stakeholders on the campus of the National Institutes of Health to address pandemic influenza,<sup>4</sup> but aside from vocally supporting the need for vastly improved national preparedness and response, they directed most of their attention to Maryland's response to the H1N1 pandemic.

Elected officials set priorities in their SLTT budgets to address hazards that occur frequently in their jurisdictions or that place their jurisdictions at risk. For some hazards (e.g., energy grid blackouts, hurricanes, tornadoes), combinations of voluntary SLTT and federally mandated programs contribute to preparedness. The infrequency of epidemics and pandemics means they rarely attract enough political attention to produce the proactive legislation

and sustained funding needed to support SLTT and national preparedness, response, and recovery. The public and its elected officials tolerate far more disease (e.g., the thousands of cases of Chikungunya still prevalent in Florida, New York, and Puerto Rico) than they should.

How we respond to biological events—especially those large in scale and impact— is now out of balance with how we prepare. Currently, SLTT entities respond immediately to these events, only to wait for federal support to follow. In January 2018 at the University of Miami, the Panel held a special focus meeting to examine the situation. Co-chaired by former Secretary of Health and Human Services Donna E. Shalala and former US Representative James C. Greenwood, this daylong meeting allowed current and former SLTT officials, academics, and private sector experts to describe the difficulties they face on the front line of biodefense. They made it clear that although the country has made progress since 2001, SLTT personnel require additional support from the federal government to ensure that the states, localities, tribes, and territories are better prepared for large-scale biological events. Based on the input received during the meeting and additional research, the Panel developed the following policy recommendations to improve preparedness, response, and recovery by SLTT emergency medical services (EMS), pharmacies, hospitals, laboratories, and public health departments. These recommendations build on those found in the Panel's 2015 report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts (Blueprint for Biodefense)* and other Panel publications.

# FORTIFY EMERGENCY MEDICAL SERVICES

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Local EMS, firefighters, and police will be among the first to respond to a biological event. In most cases, they will not know which disease they are dealing with. It will be too early for anything but cursory, preliminary diagnosis and identification.

During the late 1990s, some EMS and other first responders received training and participated in exercises based on several biological (and chemical) scenarios as part of the Nunn-Lugar-Domenici Domestic Preparedness Initiative.<sup>5</sup> However, the anthrax events of 2001 resulted in a narrow policy perspective—that the nation should prepare mostly for anthrax. This perspective was based on some false assumptions which included: (1) if we could not prepare for anthrax, we could not prepare for any other biological agent; and (2) the use of anthrax once meant that using anthrax again would be easier and more likely than an attack with any other biological agent. Subsequently, support for even anthrax preparedness declined in favor of funding all-hazards preparedness, making biological hazards just one of many threats to consider. Today, many of those previously trained under the Domestic Preparedness Initiative have retired, and current EMS and other first responders receive little or no training in how to deal with biological agents and those infected with them.

In November 2016, the Obama Administration updated the National Response Framework, assigning responsibility for the management and direction of emergency medical response assets (including EMS) to the Secretary of Health and Human Services during large-scale emergencies and disasters.<sup>6</sup> This policy is in keeping with the other emergency medical responsibilities of the Department of Health and Human Services (HHS) during such events,

Recognizing the critical role that emergency service providers play in preparing for, responding to, and recovering from biological events, the Panel issued the following recommendation in its 2015 *Blueprint for Biodefense*:

**Recommendation 15:** Provide emergency service providers with the resources they need to keep themselves and their families safe.

## ACTION ITEMS

- a. Provide vaccines to responders who request them.
- b. Provide medkits to emergency service providers and their families.
- c. Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.

but the federal government's role in this area has largely been limited to the Federal Emergency Management Agency (FEMA) national ambulance contract, implemented by HHS to coordinate patient transportation. The Department of Transportation (DOT) has historically been the most active federal department with regard to EMS and has shared responsibility for it with the Department of Defense (DOD), DHS, HHS, and Federal Communications Commission. HHS and DOT have not yet developed coordinated plans and policies, leaving deployed EMS assets without equipment, support, and direction when they need it most—during disaster response.

EMS providers receive inadequate funding and reimbursements for the pre-hospital emergency health care that they provide. While SLTT governments, DHS, and HHS provide some operational funding through grant programs, medical reimbursements fall under the sole domain of HHS via the Centers for Medicare and Medicaid Services (CMS). CMS and commercial insurance do reimburse EMS for transportation services (i.e., when EMS transports patients to hospitals), in keeping with the transportation priority placed on EMS more than 50 years ago. Today, however, EMS professionals are also responsible for pre-hospital health care, and in some rural areas are also considered part of the public health community. Despite the dependence of patient survival and other outcomes on high-quality and immediate treatment well before entering a hospital or other health care establishment, EMS professionals receive very few additional reimbursements or payments for the health care they deliver. Reimbursement-based funding requires EMS to provide services in routine and disaster situations before reimbursement occurs and does not pay for readiness activities beforehand to do so.

To rectify this, the Panel believes it is necessary to:

**Unify and establish a new National EMS System. Current demands far exceed requirements for rapid transportation and limited treatment that Congress originally envisioned for EMS more than 50 years ago. It is time to provide a federal home for EMS that is responsible for developing policy and serving as an advocate for preparedness, quality, funding, and reimbursement.**

## ACTION ITEMS

- a. **Assess SLTT EMS capability to respond to biological terrorism and warfare.** Congress should amend the Defense Against Weapons of Mass Destruction Act of 1996 (Title XIV, Public Law 104-201) to require the Secretary of Defense, Secretary of Health and Human Services, Secretary of Homeland Security, and Secretary of Transportation to submit a report to Congress containing: (1) an assessment of the ability of SLTT EMS and the federal government to provide emergency medical services in response to domestic terrorist incidents involving biological weapons; (2) needed improvements; (3) measures to achieve such improvements (including additional resources and legislative authorities required); and (4) federal support of SLTT EMS preparedness, response, and recovery efforts.
- b. **Establish a biological emergency response assistance program.** Congress should amend the Defense Against Weapons of Mass Destruction Act of 1996 (Title XIV, Public Law 104-201) to require the Secretary of Defense, Secretary of Health and Human Services, Administrator of the FEMA, and Administrator of the Environmental Protection Agency (EPA) to provide SLTT EMS and other first responders with training and expert advice regarding emergency response to the use or threatened use of biological weapons, including biological weapons of mass destruction, biological agents, and related materials. Assistance available under this program should include training in the use, operation, and maintenance of equipment for: (1) detecting biological agents; (2) monitoring the presence of such biological agents; (3) protecting emergency personnel and the public; and (4) decontamination.
- c. **Review extent and quality of EMS.** Congress should direct the Secretary of Health and Human Services, in collaboration with the Secretary of Defense, Secretary

of Homeland Security, and Secretary of Transportation, to conduct a national EMS assessment, and periodic, comprehensive, and independent reviews and evaluations regarding the extent and quality of EMS provided throughout the nation. Congress should direct the Secretary of Health and Human Services to prepare and submit annually to Congress a report on EMS that includes: (1) an evaluation of the adequacy of EMS in the United States during the period covered by the report; (2) an evaluation of the extent to which such services are adequately reimbursed by CMS, other health insurance programs, and all federal EMS grant programs; (3) an evaluation of the alignment of preparedness grant funds across all grantmaking federal agencies; and (4) recommendations for legislation needed to provide adequate SLTT EMS.

- d. Inform the delivery of EMS during large-scale biological events, mass casualty events, disasters, and other national emergencies.** The Secretary of Health and Human Services, in coordination with the Secretary of Defense and Secretary of Transportation, and in consultation with the Administrator of FEMA, should provide criteria, guidance, and instructions to inform the delivery of EMS during large-scale biological events, mass casualty events, disasters, and other national emergencies, in keeping with ESF-8. The Secretary of Health and Human Services should direct the Assistant Secretary for Preparedness and Response (ASPR) to provide technical assistance, subject matter expertise, and direct program services to help SLTT EMS prepare for, respond to, and recover from disasters, large-scale biological events, mass casualty events, and other national emergencies.
- e. Expand medical necessity rules for EMS reimbursement regarding pre-hospital health care.** Congress should direct the Administrator of CMS, in collaboration with the ASPR and EMS providers, to expand medical necessity rules for EMS reimbursement, ensuring comprehensiveness

without reimbursing unnecessary ambulance trips, while also providing necessary pre-hospital health care to all patients requiring such services without prior inquiry as to the ability to pay. This may include mechanisms such as amending the Social Security Act to make EMS a provider type, as recommended previously by the National Academies of Science, Engineering and Medicine.<sup>7</sup>

- f. **Establish a National EMS Agency.** Congress should amend the Public Health Service Act of 1944 (P.L. 78-410, 58 Stat. 682, 42 U.S.C. ch. 6A, § 201 et seq.) and the Highway Safety Act of 1966 (P.L. 89-564, 80 Stat. 731) to create a cohesive national EMS program under the purview of HHS, in coordination with DHS, DOD, and DOT, and in consultation with FEMA. Congress should direct the Secretary of Transportation to transfer EMS responsibilities of the National Highway Traffic Safety Administration Office of Emergency Medical Services to the Secretary of Health and Human Services regarding federal coordination and collaboration, federal planning, development of curricula standards and training guidelines, and the development and imposition of other EMS standards responsibilities. Congress should transfer relevant appropriations from DOT to HHS for this purpose. The Secretary of Health and Human Services should establish the National EMS Agency within the Office of the ASPR.

# IMPROVE STOCKPILE DISTRIBUTION AND PHARMACY READINESS

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The CDC is not responsible for distributing the contents of SNS pallets when they arrive at a locality. The CDC trains SLTT personnel (with an emphasis on the Urban Area Security Initiative jurisdictions) to execute this responsibility and establish point(s) of distribution in advance of SNS deployments. Many SLTT personnel feel that this training is inadequate and that training pallets should contain more than just contents to respond to anthrax. The CDC also reports dissatisfaction with SLTT training performance. While all levels of government recognize the need for and value of training, the program has yet to yield broadly acceptable results.

Public bystanders are often the first to respond to emergencies in their immediate vicinity. Recognizing this, the Red Cross increased its efforts to train the public in first aid, cardiopulmonary resuscitation, and automated external defibrillation. As a result, more people know how to respond in a variety of emergencies, and many workplaces and public spaces possess first aid kits and automated external defibrillators. Charlotte Douglas Airport in North Carolina also emplaced public access bleeding control kits in areas where shootings and other events could cause excessive blood loss. While helpful, previous training is not necessary to use these first aid kits, defibrillators, or bleeding control kits. Easy-to-follow directions are provided, and the public has neither stolen nor destroyed these openly available medical supplies and equipment. The public must be similarly prepared to take reasonable steps to care for themselves, their families, and their neighbors as a critical element of national preparedness for biological events.

Recognizing the pressing need for life-saving medicines and medical supplies when biological events exceed SLTT resources, and the benefit of prepositioning some medical countermeasures (MCM) and other contents of the Strategic National Stockpile (SNS) in or near high-risk localities, the Panel issued the following recommendation in its 2015 *Blueprint for Biodefense*:

**Recommendation 23:** Allow for forward deployment of Strategic National Stockpile assets.

## ACTION ITEMS

- a. Determine logistics and funding needs.
- b. Implement forward deployments.

The pharmaceutical distribution and sales systems in the United States are pervasive and familiar to the public. The public already obtains over-the-counter and prescription drugs, as well as essential medical supplies, from their local pharmacies. The government has worked with health care distributors and pharmacy chains to distribute medicines during crises. Delays occurred without formal agreements in place ahead of time, but otherwise, this public-private partnership worked well during recent emergencies.

The CDC Division of Strategic National Stockpile works with industry partners to improve SNS resiliency by monitoring commercial supply chain inventory, increasing access to personal protective equipment and MCM, and allowing for redundant distribution of MCM, information, and material. However, to ensure that the public can obtain the medicines, medical equipment, and other essential medical supplies they need (whether or not the contents of the SNS are deployed), the federal government requires data regarding pharmacy readiness, operational status, and capacities so that it can assist SLTT response to and recovery from large-scale biological events and disasters. Healthcare Ready, a private sector 501(c)(3) organization, gathers these data and helps the private sector communicate that information to the public sector (i.e., HHS, SLTT departments of health).<sup>10</sup> Private sector funding makes this information sharing possible. Should Healthcare Ready be unable to obtain enough private sector funding to support itself, SLTT and federal governmental entities will lose access to these data, leaving the US government without the information upon which it has come to depend during disasters.

To rectify and address these issues, the Panel believes it is necessary to:

**Improve distribution of pharmaceuticals, medical equipment, and other essential medical supplies needed to treat those affected by large-scale biological events.**

#### **ACTION ITEMS**

- a. **Improve, expand, enhance, and sustain SLTT training to receive and distribute SNS contents.** Congress should amend the Public Health Service Act (P.L. 78-410) to require the ASPR and the CDC Division of State and Local Readiness to work with SLTT stakeholders to improve

existing SNS training offerings, taking into consideration current limited SLTT abilities to distribute SNS pallets upon receipt. In executing this directive, the ASPR and CDC should build on previous experiences working with private sector entities (e.g., pharmacy chains) to distribute pharmaceuticals for public health purposes, include this option in plans, and train accordingly. Congress should also amend the Public Health Service Act (P.L. 78-410) to direct the CDC to immediately develop and make available training pallets for some naturally occurring infectious diseases and biological agents that would require SNS contents that are different from or in addition to those deployed for anthrax.

- b. Ensure availability and access to pharmacy readiness data.** The ASPR cannot assume that Healthcare Ready will always receive enough funding from industry to gather and provide these data to HHS. A cooperative agreement recognizes that both the federal government and a non-federal organization should work together to achieve outcomes that support society. The ASPR should enter into a cooperative agreement to ensure that public (including HHS) and private sector entities know whether pharmacies are still capable of operating in areas stricken by large-scale biological events and disasters.

# INCREASE HEALTH CARE SURGE CAPACITY

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Many hospitals and other health care entities operate at and often beyond capacity, trying to meet the needs of the communities they serve. They do not possess the excess capacity needed to respond to large-scale biological events. In the absence of government-issued quarantine and isolation orders confining the ill and those possibly exposed to specific geographic areas, the public will flood their local hospitals. The usual actions taken when they reach capacity (e.g., temporary diversion of patients from an emergency room when it is full) will not be an option since health care deliverers in surrounding areas will also be affected.

Some health care professionals insist that regardless of scale, hospitals and other health care entities will respond to biological events by surging their regular activities the same way they already frequently do. They will seek to maintain the standard of care for every patient, until their facilities' resources disappear. Many health care and public health disaster response professionals disagree—they believe that surging regular activities will be insufficient to respond adequately to large-scale biological events and that regular surge experience will prove no match

Recognizing that hospitals and other health care entities (e.g., medical clinics, community health centers, long-term care facilities) across the nation lack adequate guidance and resources to respond to large-scale biological events, the Panel issued the following recommendations in its 2015 *Blueprint for Biodefense*:

**Recommendation 18:** Establish and utilize a standard process to develop and issue clinical infection control guidelines for biological events.

## ACTION ITEMS

- a. Standardize the development of clinical infection control guidelines before biological events occur.
- b. Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events.
- c. Require training based on these guidelines.

**Recommendation 19:** Minimize redirection of Hospital Preparedness Program funds.

## ACTION ITEMS

- a. Cap Hospital Preparedness Program management and administration costs at three percent.
- b. Assess the impact of the Hospital Preparedness Program.

for thousands of patients seeking medical treatment simultaneously, over a prolonged period. The health care and public health communities will only be able to provide what care they can to the largest number of people, not the highest quality of care to each individual in every circumstance. There is little in the law, however, that allows for altered health care delivery requirements, even in such resource-constrained circumstances.

Health care leaders also often assume that: (1) biological emergencies affecting health care entities either do not occur or occur rarely; and (2) biological events that exceed capability to deliver patient care are and will not be the norm. Unfortunately, the impact of a poor medi-

cal response to a critical incident can be enough to ruin reputations, close departments, lose funding, and shutter health care institutions.<sup>11</sup> Many lives need not be lost for the public to lose confidence in the ability of a hospital or other health care entity to provide health care. Administrators, chief executive officers, and board members acknowledge the negative impact on profit and attendant loss in revenue if biological emergencies occur and biological events exceed health care response capabilities. They may also recognize that biological events threaten the communities in which they operate, but they consistently underestimate the biological risk faced by their institutions.

Current federal programs and directives to fund and require preparedness for biological terrorism and other biological events that could affect national security (e.g., Hospital Preparedness Program, Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers<sup>12</sup>) do not provide hospitals and other health care entities with enough financial incentive to pay for and maintain unused capability. Reactionary grants, hurried transfers of funds from one program to another,

**Recommendation 20:** Provide the financial incentives hospitals need to prepare for biological events.

**ACTION ITEMS**

- a. Adopt a disaster preparedness portfolio.
- b. Link Centers for Medicare and Medicaid Services incentives and reimbursement to new accreditation standards.

**Recommendation 21:** Establish a biodefense hospital system.

**ACTION ITEMS**

- a. Stratify hospitals.
- b. Develop accreditation standards for each stratum.
- c. Associate Centers for Medicare and Medicaid Services funding.

and emergency supplemental funding also demonstrate that the nation does not provide enough advance funding to help the health care community respond to disease events that exceed normal crisis thresholds.

Business priorities also place health care entities and alliances at odds with health care coalitions. With alliances, health care organizations affiliate with each other, augmenting individual member offerings and allowing members to leverage other institutional brands. On the other hand, coalitions of health care entities work together, sharing resources within the geographic bounds associated with their accreditation and addressing the needs of those they strive to serve. While coalitions take a softer view on the profit orientation of competition, they realize greater profits and sustain fewer losses during those emergencies that exceed the capacity of independent health care institutions and alliances. Unfortunately, coalitions composed of interdependent health care entities can also be difficult to manage because what affects one member of such a group affects them all. It may be that a weak link brings down the entire enterprise and that a significant stressor to the system causes the entire system to fail at once.

To rectify and address these issues, the Panel believes it is necessary to:

**Establish a national stratified health care delivery system capable of surging medically to respond to large-scale biological events. Hospitals in any region in the United States must be able to surge medically to respond to and recover from large-scale biological events.**

#### **ACTION ITEMS**

- a. **Establish medical surge capability and capacity for large-scale biological events.** The Administrator of CMS should make planning to surge medically part of accreditation requirements for hospitals that receive CMS funding. In addition to CDC, other HHS agencies (e.g., Agency for Health Research and Quality) and offices, the Occupational Safety and Health Administration, and by extension, the Department of Labor, should issue guidelines and performance standards for medical surge.

Congress should amend the Public Health Service Act (P.L. 78-410) to allow for more flexible treatment options when biological events rapidly drain and eventually deplete available resources and require the Secretary of Health and Human Services to undertake a national assessment of infection control resources and infrastructure.

- b. Communicate the business case for a stratified biodefense health care delivery system.** The Administrator of CMS and ASPR should work together with the American Hospital Association to develop and communicate a comprehensive business case for a national stratified biodefense health care delivery system. This business case should, at a minimum, address the potential for increasing or maintaining profit margins, decreasing losses, and reducing risk to reputation when hospitals are called upon to treat patients infected with dangerous pathogens.
- c. Assess risk to reputation.** Regardless of disease type or assessment of potential exposure of patients who may be treated in the future, hospitals and other health care entities should assess risk to their reputation by: (1) learning from the negative experience of other health care entities who dealt with disease events previously; and (2) surveying the communities they serve to determine how poor management of a disease event would impact patient utilization of their facilities.

# AUGMENT LABORATORY RESPONSE

Public health and public safety officials need to identify the organism they are dealing with in order to respond effectively and efficiently to a biological event. Quick and geographically close laboratory testing is critical for effective decision-making, disease management, and law enforcement. Not all laboratories, however, possess the same capabilities, biosafety, or biosecurity. As with hospitals, they lend themselves naturally to stratification and the creation of networks.

Laboratory networks exist that test for biological agents and infectious diseases that could affect national security. President William J. Clinton issued Presidential Decision Directive 39: US Policy on Counterterrorism in 1995. Four years later, the CDC worked with the Federal Bureau of Investigation (FBI) and Association of Public Health Laboratories (APHL) to establish the Laboratory Response Network for Bioterrorism (LRN) (now called the LRN for Biological Threats) in 1999, partially fulfilling the requirement for HHS to identify biological agents and provide health care, pharmaceutical, and public health support to counter biological terrorism. As the first among laboratory networks (many of which are still in nascent developmental stages twenty years later) established by federal departments and agencies, the LRN proved its mettle by testing thousands of white powder specimens during the anthrax events of 2001. It continues to test many specimens suspected of containing anthrax and other biological agents, as well as additional dangerous pathogens such as severe acute respiratory syndrome (SARS), influenza, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Ebola, and Zika. LRN

Recognizing the value of a laboratory network regarding animal and zoonotic diseases, the Panel issued the following recommendation in its 2015 *Blueprint for Biodefense*:

**Recommendation 14:** Improve surveillance of, and planning for, animal and zoonotic disease outbreaks.

## ACTION ITEMS

**b. Fund the National Animal Health Laboratory Network at a level that allows it to achieve success.**

The Panel reiterated this recommendation in its 2017 report, *Defense of Animal Agriculture*, stating that:

Congress should continue to fund the National Animal Health Laboratory Network in [Fiscal Year] 2018 and thereafter at no less than authorized levels, leaving open the possibility that additional funds may be required to fulfill the Network's mission as the need to rapidly diagnose outbreaks grows.

laboratories use standardized protocols, providing valid and reliable results to decision makers and discoverable information for legal proceedings.

Despite the remarkable success of the LRN and its stellar partnerships with non-traditional public health agencies (e.g., law enforcement) and private institutions (e.g., clinical laboratories, universities), Congress has never authorized the LRN. This poses a problem for congressional oversight, especially since the LRN is composed of several types of laboratories (both public and private sector) that receive funding from a variety of governmental sources. Dedicated funding for the LRN is also at risk whenever Congress decreases or changes appropriations for the CDC (which provides funding to state and local health departments via the Public Health Emergency Preparedness Cooperative Agreement, and to APHL to support the operations and management of the LRN through a cooperative agreement).

In addition to the LRN, other laboratory networks have been established and are in various stages of development. These are the: DOD Laboratory Network, Environmental Response Laboratory Network (funded by EPA), Food Emergency Response Network (funded by the Department of Agriculture (USDA) and the Food and Drug Administration (FDA)), NAHLN (funded by USDA), National Plant Diagnostic Network (funded by USDA), and the Veterinary Laboratory Investigation and Response Network (funded by FDA).<sup>13</sup> Of these, only the NAHLN has been authorized by Congress. Each of these networks is organized differently, with varying component laboratories. All are stratified to some extent, and all but the DOD Laboratory Network claim some non-federal governmental laboratories as members. Federal departments and agencies provide varying levels of support to these networks and do not place equal priority on the development of needed laboratory capability and capacity. The resultant patchwork is weak, with insufficient congressional oversight and inadequate appropriations.

To rectify and address these issues, the Panel believes it is necessary to:

**Authorize all laboratory networks that test for biological agents. Laboratory networks provide critical data in support of preparedness for, surveillance and detection of, response to, attribution of, and recovery from biological events.**

## ACTION ITEMS

- a. **Authorize and fund the Laboratory Response Network for Biological Threats.** While the LRN is well regarded and supported, the complicated nature of its membership and dependence on CDC for funding via cooperative agreements put the Network at risk. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services to enter into cooperative agreements, contracts, grants, or other legal instruments with eligible laboratories to formalize the LRN. Congress should require those territories with public health laboratories to join the LRN. Congress should authorize and appropriate \$200,000,000 annually to carry out these requirements.
  
- b. **Authorize and fund the Environmental Response Laboratory Network, Food Emergency Response Network, National Plant Diagnostic Network, and Veterinary Laboratory Investigation and Response Network.** Congress should amend the: (1) Farm Bill (P.L. 113-79) to authorize the National Plant Diagnostic Network under the auspices of USDA; (2) Farm Bill (P.L. 113-79) and Federal Food, Drug, and Cosmetic Act (P.L. 75-717) to authorize the Food Emergency Response Network under the auspices of USDA and FDA; (3) National Environmental Policy Act (P.L. 91-190) to authorize the Environmental Response Laboratory Network under the auspices of EPA; and (4) Federal Food, Drug, and Cosmetic Act (P.L. 75-717) to authorize the Veterinary Laboratory Investigation and Response Network under the auspices of FDA. Congress should direct each of these departments and agencies to enter into cooperative agreements, contracts, grants, or other legal instruments with eligible laboratories to formalize these networks. Congress should require those territories with public health laboratories to join these networks.

- c. **Establish requirements for all laboratory networks that test for biological agents.** Congress should direct the Secretary of Agriculture, Secretary of Health and Human Services, Administrator of EPA, and Commissioner of FDA, to better defend against novel, emerging, reemerging, or existing intentionally introduced, naturally occurring, and accidentally released biological threats to public health in a timely manner by establishing: (1) standards and interoperable data formats; (2) necessary capacity and capability to utilize standardized test procedures, reference materials, and equipment; (3) laboratory biosafety and biosecurity positions and requirements; (4) quality management system requirements; (5) chain-of-custody and other evidentiary requirements as established and communicated by the FBI; (6) rapid electronic reporting, exchange, and transmission of data; and (7) evaluation requirements for emergency preparedness, detection, response, attribution, and recovery. To the extent practicable and to the extent capacity and specialized expertise may be necessary, priority should be given to existing state, local, and territorial laboratory facilities that are already executing these responsibilities.

<b>Managing Department/Agency</b>	<b>Laboratory Network</b>
DOD	DOD Laboratory Network
CDC	Laboratory Response Network for Biological Threats
USDA	National Animal Health Laboratory Network
USDA	National Plant Diagnostic Network
USDA and FDA	Food Emergency Response Network
EPA	Environmental Response Laboratory Network
FDA	Veterinary Laboratory Investigation and Response Network

# RECTIFY SHORTFALLS IN TRIBAL PUBLIC HEALTH EMERGENCY PREPAREDNESS

American Indian and Alaska Native (AI/AN) tribes are sovereign entities with inherent authority to govern themselves and their own governance structures. As such, the tribes are entities separate from states, localities, and territories. Furthermore, AI/AN tribes have a unique relationship with the federal government that is shaped by the federal Indian trust responsibility—which is in turn constructed by federal law, legal precedence, and treaties entered into with the tribes. The federal trust responsibility embodies the promise that the federal government made to support the prosperity and health of the tribes.

Federally recognized AI/AN tribes are not eligible to enter into their own PHEP cooperative agreements with the CDC. Instead, tribes are forced to work with state and local public health entities to receive PHEP support, sometimes as part of a pass-through arrangement. The CDC encourages, but does not require, states to work with or fund tribes within their jurisdictions as a component of their respective PHEP cooperative agreements.

With hundreds of federally-recognized tribes and tribal entities, tribal public health needs and the appropriate funding and structures to address those needs understandably vary. Current funding to the states, however, does not adequately take the emergency preparedness needs of the tribes into account. Without direct allocations from the PHEP, tribes are only able to

The CDC Public Health Emergency Preparedness Cooperative Agreements currently makes funds available to 50 state, 4 local,<sup>14</sup> and 8 territorial<sup>15</sup>—but no tribal—public health departments to strengthen their ability to respond to a variety of threats and associated emergencies. Many heavily rely on these funds to support their public health emergency preparedness efforts. Without this funding, they would not have sufficient resources for necessary staffing, supplies, planning, training, and exercises.<sup>16</sup> Various Administrations and Congresses have repeatedly cut funding for the Public Health Emergency Preparedness (PHEP) program. To rectify this issue, the Panel issued the following recommendation in its 2015 *Blueprint for Biodefense*:

**Recommendation 17:** Fund the Public Health Emergency Preparedness cooperative agreement at no less than authorized levels.

## ACTION ITEMS

- a. Appropriate PHEP funding to authorized levels or the President’s Budget Request, whichever is higher.

dialogue with states about how preparedness funds could be utilized for the benefit of the tribes. Without direct funding, tribes lack the ability to direct their own planning and determine for themselves the best approach to invest preparedness resources.

In recognition of the need for dedicated resources for AI/AN tribes, CDC recently issued separate funding opportunities to bolster tribal public health infrastructure, providing limited funding relative to the need and to no more than 25 tribes. This program focuses on building and implementing basic public health infrastructure. It does not incorporate the emergency preparedness and response capabilities required by the PHEP.

To rectify and address these issues, the Panel believes it is necessary to:

**Give federally recognized American Indian and Alaska Native tribes the opportunity to enter into their own Public Health Emergency Preparedness cooperative agreements and obtain technical assistance. Congress and the Administration must make public health emergency preparedness part of the federal Indian trust responsibility to support the health of the tribes. The tribes, as sovereign entities, have the right to decide for themselves how to direct and shape public health emergency preparedness for their communities. They deserve to apply for and utilize PHEP funding directly.**

## ACTION ITEMS

a. **Make PHEP funding available directly to the tribes.**

Congress should amend the Public Health Service Act (P.L. 78-410) to authorize and fund the CDC to make PHEP tribal cooperative agreements directly available to the 573 federally-recognized tribes,<sup>17</sup> establish eligibility criteria, and increase CDC PHEP program funding and operations accordingly. Not every tribe will choose to receive their funding directly from CDC, but all tribes should be afforded the opportunity to make their own determination. This approach should offer flexibility to those tribes that cannot or do not want to support their own, separate

public health emergency preparedness programs, allowing them to continue to enter into agreements with states and localities to support these activities.

- b. Proactively bolster tribal public health emergency preparedness.** The Director of CDC, in collaboration and coordination with the Director of the Indian Health Services (IHS), should provide annual guidance and technical assistance to help tribal health departments with strategic planning and emergency public health preparedness. Through its Center for State, Tribal, Local, and Territorial Support, and Office of Tribal Affairs and Strategic Alliances, the CDC should utilize permanent tribal liaisons to conduct regular outreach and education to tribal governments (including direct consultations and site visits when requested) regarding funding opportunities and use of public health preparedness funds. CDC should also place tribal liaisons in each of its other centers, to ensure that they consider tribal needs. Federal technical assistance should address tribal public health emergency preparedness and response, the conduct of exercises, and how to establish and meet preparedness and response-oriented performance goals.
- c. Strengthen tribal epidemiology.** Congress should increase appropriations to the IHS for the purpose of strengthening tribal epidemiology centers (TECs) with additional funding. The IHS should develop criteria for allocating resources to the TECs, in consultation with tribal representatives and the National Indian Health Board.

# OVERCOME BARRIERS TO TERRITORIAL BIOSURVEILLANCE AND EMERGENCY RESPONSE

The federal government recognizes the value of SLTT biosurveillance efforts and has invested resources through grants and cooperative agreements to further enhance non-federal vigilance for biological threats. Unfortunately, the federal government has not always issued guidance along with this funding to ensure that those monies are effectively utilized to prepare for major public health emergencies.

Recognizing the gulf between federal biosurveillance activities and those of their SLTT counterparts, the Panel issued the following recommendation in its 2015 *Blueprint for Biodefense*:

**Recommendation 12:** Empower non-federal entities to become equal biosurveillance partners.

## ACTION ITEMS

- a. Create an interagency biosurveillance planning committee.

Planning and training must also take into consideration the specific needs of US insular areas (i.e., US territories and the freely associated states)<sup>18</sup> that receive direct public health preparedness assistance from the federal government. These areas face different logistical and resource challenges than the rest of the United States. Even with the funds provided through programs like PHEP, insular areas often do not have enough public health infrastructure or plans in place to respond to biological threats on their own. The quality of biosurveillance programs varies among insular areas, and they find it difficult to produce and obtain data. Despite their locations and the ease with which to travel through them to other areas in the United States, the federal government has yet to establish the robust biosurveillance needed to ensure national security.

Territories and other insular areas continue to find it very difficult to scale up their response to large public health emergencies, partly because geographical and policy constraints prevent them from obtaining needed medical supplies. For example, in September 2017, Hurricane Maria devastated Puerto Rico, including much of its public health infrastructure. In the aftermath of the storm, long-standing federal shipping policies prevented the territory's officials from obtaining basic supplies and other essential medical resources. Section 27 of the Merchant Marine Act (P.L. 66-261), also known as the Jones Act, requires that only US vessels carry goods shipped to Alaska, Hawaii, and Puerto Rico

from any other US port. Oftentimes, the other US territories are also impacted, as their shipping routes include these two states or Puerto Rico. Though not the primary cause of the slow public health response, the Jones Act did inhibit the ability of the US mainland to send supplies to Puerto Rico in the days and weeks after Hurricane Maria made landfall.

To rectify and address these issues, the Panel believes it is necessary to:

**Provide US insular areas with robust public health preparedness and response tools. The federal government must increase its engagement with the territories and freely associated states and share its expertise to assist them in fully leveraging public health resources.**

## ACTION ITEMS

- a. **Provide enhanced planning and technical assistance.**  
The Director of CDC should provide insular areas with the technical assistance necessary to plan for large-scale biological events, focusing on tailored and generally applicable preparedness goals and regular exercises to test the capabilities of their public health systems. Plans should take existing resource limitations into account and maximize available assets to help the territories and freely associated states better prepare for, respond to, and recover from public health crises and large-scale biological events.
- b. **Strengthen biosurveillance and data collection.** Congress should amend the Public Health Service Act (P.L. 78-410) to require the Secretary of Health and Human Services, in coordination with the Secretary of State, Secretary of Defense, and Secretary of Homeland Security, to develop and enhance the biosurveillance capabilities of each US territory and freely associated state. This includes close collaboration with the insular governments to establish permanent monitoring systems with technical and diagnostic reachback to the CDC. The Department of

State, DOD, DHS, and HHS should also develop a platform for sharing and integrating data obtained from these biosurveillance efforts.

- c. **Reduce barriers to transporting resources during a public health emergency.** Congress should amend Section 27 of the Merchant Marine Act of 1920 (P.L. 66-261) to allow automatic, emergency exemptions from Jones Act shipping requirements whenever the Secretary of Health and Human Services declares a public health emergency, or when there has been a declaration made under the Stafford Act that applies to Alaska, Hawaii, or the insular area in question. Congress should also direct the Secretary of Homeland Security, acting through the Administrator of FEMA, in coordination with the Secretary of Health and Human Services, the Secretary of Defense, the Secretary of State, and other relevant federal agencies, to: (1) evaluate challenges to transporting supplies and personnel to US insular areas immediately before and during public health emergencies; (2) develop recommendations to address those challenges; and (3) produce a deployment strategy that assigns roles and responsibilities throughout the federal government. As part of this evaluation, FEMA should consult with the territories and freely associated states, US states that may be called upon to support insular emergency response, associations with territorial members or interests, and the American Red Cross.

# ALLOCATE RESPONSE FUNDING BEFORE BIOLOGICAL CRISES OCCUR

Existing statutory language for the Public Health Emergency Fund (42 U.S. Code § 247d (b)) inadequately describes how the Fund can be used. On the few occasions where the account was previously funded and utilized, congressional appropriations only addressed specific threats. This leaves Congress with little information regarding how well the Fund would work as originally conceived. There is also no consensus regarding how much funding would be needed, or how use of the Fund could improve response to public health emergencies. As a result, Congress has been reluctant to provide additional appropriations for the PHEF.

Congress must examine the utility of the Fund and clearly identify triggers, eligible activities, and accountability. Currently, funds can only be dispensed when the Secretary of Health and Human Services makes a public health emergency declaration. However, funding may be needed to get ahead of biological threats before they reach the nation's borders—well before the Secretary declares a public health emergency. Congress has yet to consider additional triggers (e.g., presidential declaration) to release resources from the PHEF.

Not all response activities should wait until after biological events occur. Success greatly depends upon the commitment of readily available funding before such events occur, and at levels exceeding those currently available for public health emergency preparedness, response, and recovery activities. Waiting for supplemental appropriations could leave the nation's public health

The Panel addressed domestic public health emergency funding in its 2018 report, *Budget Reform for Biodefense: Integrated Budget Needed to Increase Return on Investment*. In this report, the Panel stated that the nation requires:

**A rapid response fund triggered not only by a declared public health emergency, but also, at times, in advance of any such declaration to preempt a major problem. Congressional proposals to seed such a fund have ranged from \$300 million to \$5 billion.**

## ACTION ITEMS

- a. Infuse no less than \$2 billion into the Public Health Emergency Fund (PHEF).
- b. Commit to regular annual appropriations for the PHEF.
- c. Provide guidance on triggers for PHEF.
- d. Update criteria for events covered by PHEF.

community without the emergency funding it needs to address large-scale biological events. Other emergency funding sources (e.g., the Commodity Credit Corporation, the Disaster Relief Fund) may also be applicable should a catastrophic biological event occur, keeping in mind that they are not intended to replace or augment appropriations made for other federal departments and agencies. FEMA previously considered pandemic influenza and the possibility of providing assistance to states and territories under the Stafford Act.<sup>19</sup> Although current FEMA policy and guidance allows for direct federal assistance to state, tribal, and territorial governments under a Stafford Act emergency declaration,<sup>20</sup> further clarification is needed regarding eligibility for this assistance.

To rectify and address these issues, the Panel believes it is necessary to:

**Ensure consistent, adequate response funding and guidance for public health emergencies. Even with a robust, preparedness-oriented public health system in place, the need for sustained, reliable response funding to address biological threats will always exist. Dedicated funding, combined with support from existing response funds, will reduce response times and save lives during large-scale biological events.**

## ACTION ITEMS

- a. **Reform the PHEF to ensure clarity of use, transparency, and accountability.** Congress should amend the Public Health Service Act (42 U.S. Code § 247d(b)) to clarify the structure of the PHEF and the categories of activities eligible to receive assistance. Congress should determine eligibility criteria for assistance, include robust accountability mechanisms, and consider circumstances for distribution of funding outside of public health emergency declarations made by the Secretary of Health and Human Services. Although Congress should allocate funding primarily for immediate emergency response to biological threats, Congress should also make funding available for certain other activities (e.g., time-sensitive

research, development of medical countermeasures) that could assist in responding to future outbreaks, events for which appropriations are not otherwise already available.

- b. Clarify SLTT eligibility for biological disaster assistance under the Stafford Act.** Large-scale biological events in the United States would drive the governors to declare states of emergency, request presidential emergency and disaster declarations, and apply for disaster assistance. FEMA should clarify eligibility for direct federal assistance under the Stafford Act to states, localities, tribes, and territories during declared emergencies involving pandemic influenza and other biological agents with large-scale consequences.
- c. Delineate HHS and FEMA assistance to SLTT governments for public health emergency response.** Congress should require HHS and FEMA to provide: (1) a report on the assistance they will offer states, localities, tribes, and territories;<sup>21</sup> (2) an action plan for future coordination; and (3) additional guidance for SLTT officials regarding federal public health emergency response assistance and coordination. In addition to the information regarding federal responsibilities found in the National Response Framework, HHS and FEMA should establish a memorandum of understanding to better define the SLTT assistance they each would provide during large-scale biological events.

# ASSUME BROADER LEADERSHIP OF BIODEFENSE

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The US system of federalism affords states a great deal of autonomy. The state governors, territorial governors and administrators, mayors, and other elected officials are powerful and responsible for setting goals and objectives for their own jurisdictions. They can and must set their own requirements for preparedness, response, and recovery well before biological events occur.

Political leaders will find themselves in situations where they must make tough decisions, particularly in the face of potentially catastrophic consequences. This makes the need for accurate biological risk assessments even more important. For example, poor understanding of the real risk of Ebola to New Jersey in 2014 resulted in the unnecessary quarantine of a nurse returning from Sierra Leone. New Jersey Governor Chris Christie based his decisions, at least in part, on an inaccurate assessment of biological risk.

While often informed only by what they watch and read in works of fiction, the public expects the health care community to treat patients in all circumstances. While the public may hope for the best care in all situations, it understands the concept of doing the best job possible with limited resources. They expect more than an all-or-nothing approach to health care delivery and public health management, especially in response to and recovery from public health emergencies and disasters.

Recognizing the need for national leadership to eliminate weaknesses at every interface during disaster response between the federal and SLTT governments, and the public and private sectors, the Panel issued the following recommendations in its 2015 *Blueprint for Biodefense*:

**Recommendation 1:** Institutionalize biodefense in the Office of the Vice President of the United States.

#### ACTION ITEMS

- a. Empower the Vice President with jurisdiction and authority.
- b. Empower the Vice President with budget authority.

**Recommendation 2:** Establish a Biodefense Coordination Council at the White House, led by the Vice President.

#### ACTION ITEMS

- a. Require broad federal participation.
- b. Invite broad non-federal stakeholder participation.
- c. Structure the Council for consensus and accountability.

To rectify and address these issues, the Panel believes it is necessary to:

**Make biodefense a priority for all elected leaders throughout the nation. Leadership of the biodefense enterprise is not only the responsibility of the Administration, but the responsibility of all elected leaders at every level of government. Each will find themselves belatedly managing biological events that occur in their jurisdictions if they do not recognize biological threats and take steps in advance to address them. They must assume that for large-scale biological events affecting huge regions of the United States, if not the entire nation, federal assets may not be readily or continuously available to send to every affected area. All SLTT leaders should make biodefense a high priority for their governance and act accordingly.**

#### ACTION ITEMS

- a. Establish health care and public health emergency preparedness, response, and recovery expectations in the states, localities, tribes, and territories. State, local, tribal, and territorial leaders do not have to wait for Congress or the federal government to act before establishing health care and public health expectations in their jurisdictions. As Hurricane Katrina so clearly demonstrated, repeated requests and demands of the federal government to provide assistance may not come to fruition completely or quickly. Taking this into consideration, SLTT government officials must establish their own requirements for health care entities and public health departments in their jurisdictions to prepare for large-scale biological events, and to demonstrate the capacity and capability to respond to and recover from them. To fulfill these requirements, SLTT personnel with biodefense responsibilities should obtain leadership training to ensure that they can provide the necessary guidance and structure needed to effectively guide non-federal biodefense activities.

- b. **Add biological risk management to agendas.** It behooves elected officials and other politicians to add the need to manage health care and public health risks to their agendas. This is a politically critical issue, known to destroy political careers when poorly addressed. Elected officials and political appointees must take up medical surge, public health emergency and related issues, commit to drafting and passing meaningful legislation to address them, hold responsible parties accountable via strong oversight, make site visits to hospitals, and demonstrate to the public that they are aware of the biological events which may befall them. Elected officials and political appointees should include questions regarding the risk of high-impact diseases in the polls they conduct, and use this information to inform their health care and public health agendas.
- c. **Address public expectations.** Politically, our elected officials must address public expectations. Ignoring the public fails to protect elected officials and political appointees when crises occur and affect public health. Informing public expectations now, with more than the entertainment industry's view of health care and public health readiness and response, is the most beneficial way to serve the public and achieve political success.

## CONCLUSION

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The United States is unaccustomed to responding to events that exceed resources available within the nation. With time and additional appropriations, the nation eventually responded extensively to terrorist events (e.g., September 11, 2001) and naturally occurring disasters (e.g., Hurricanes Irma and Maria). Unfortunately, the Panel expects that large-scale biological events will prove to be the exceptions. States, localities, tribes, and territories will have to fend for themselves while the federal government puts what assets it has available towards ensuring national security and societal stability.

We can describe scenarios in which fast-moving and deadly diseases spread throughout the nation and the world. We can zero-out resource availability in inventories and spreadsheets, and accurately describe the impact on patient management, waste management, disposition of the dead, public safety, and public health. Despite the predictability these afford, each level of the government has yet to develop sufficiently comprehensive plans for addressing the need to provide for public health, safety, and security during and after large-scale biological events.

Public health takes a population approach to health and health care delivery. Public health officials make decisions based on population data and statistics, and in a highly resource constrained environment, they make decisions that favor the greater good, doing the best they can for the most people. Beyond a certain point during a biological catastrophe, everything will become public health. Leaders will then have to do the best they can with the resources they have at their disposal to ensure the survival of the constituents for whom they are responsible.

We can take steps now to reduce the impact large-scale biological events will have on our states, localities, tribes, and territories. By rectifying shortfalls in EMS, improving SNS distribution and pharmacy readiness, increasing hospital surge capacity, augmenting laboratory response capacity, rectifying shortfalls in tribal emergency preparedness, overcoming barriers to territorial biosurveillance and response, delineating response funding before biological crises occur, and assuming broader leadership of biodefense, we can enable all levels of government and the private sector to defend the nation against biological threats and their potentially large-scale consequences.

# APPENDIX A: ALL PANEL SLTT RECOMMENDATIONS TO-DATE

## RECOMMENDATIONS TO INCREASE STATE, LOCAL, TRIBAL, AND TERRITORIAL ABILITY TO PREPARE FOR, RESPOND TO, AND RECOVER FROM LARGE-SCALE BIOLOGICAL DISASTERS

	<b>Recommendations in the 2015 <i>Blueprint for Biodefense, 2017 Defense of Animal Agriculture, and 2018 Budget Reform for Biodefense</i></b>	<b>Additional Recommendations in the 2018 SLTT <i>Reinforcements Needed for Biodefense</i></b>
<b>Fortify Emergency Medical Services</b>	<p><b>Recommendation 15:</b> Provide emergency service providers with the resources they need to keep themselves and their families safe. (<i>2015 Blueprint for Biodefense</i>)</p> <ol style="list-style-type: none"> <li>Provide vaccines to responders who request them.</li> <li>Provide medkits to emergency service providers and their families.</li> <li>Establish reasonable personal protective equipment guidelines and requirements in advance of a biological event.</li> </ol>	<p>Unify and establish a new National EMS System.</p> <ol style="list-style-type: none"> <li>Assess SLTT EMS capability to respond to biological terrorism and warfare.</li> <li>Establish a biological emergency response assistance program.</li> <li>Review extent and quality of EMS.</li> <li>Inform the delivery of EMS during large-scale biological events, mass casualty events, disasters, and other national emergencies.</li> <li>Expand medical necessity rules for EMS reimbursement regarding pre-hospital health care.</li> <li>Establish a National EMS Agency.</li> </ol>
<b>Improve Stockpile Distribution and Pharmacy Readiness</b>	<p><b>Recommendation 23:</b> Allow for forward deployment of Strategic National Stockpile (SNS) assets. (<i>2015 Blueprint for Biodefense</i>)</p> <ol style="list-style-type: none"> <li>Determine logistics and funding needs.</li> <li>Implement forward deployments.</li> </ol>	<p>Improve distribution of pharmaceuticals, medical equipment, and other essential medical supplies needed to treat those affected by large-scale biological events.</p> <ol style="list-style-type: none"> <li>Improve, expand, enhance, and sustain SLTT training to receive and distribute SNS contents.</li> <li>Ensure availability and access to pharmacy readiness data.</li> </ol>

	<b>Recommendations in the 2015 Blueprint for Biodefense, 2017 Defense of Animal Agriculture, and 2018 Budget Reform for Biodefense</b>	<b>Additional Recommendations in the 2018 SLTT Reinforcements Needed for Biodefense</b>
<b>Increase Health Care Surge Capacity</b>	<p><b>Recommendation 18:</b> Establish and utilize a standard process to develop and issue clinical infection control guidelines for biological events. <i>(2015 Blueprint for Biodefense)</i></p> <ol style="list-style-type: none"> <li>a. Standardize the development of clinical infection control guidelines before biological events occur.</li> <li>b. Institute a process for obtaining and incorporating feedback regarding clinical infection control guidelines during biological events.</li> <li>c. Require training based on these guidelines.</li> </ol> <p><b>Recommendation 19:</b> Minimize redirection of Hospital Preparedness Program (HPP) funds. <i>(2015 Blueprint for Biodefense)</i></p> <ol style="list-style-type: none"> <li>a. Cap HPP management and administration costs at three percent.</li> <li>b. Assess the impact of the HPP.</li> </ol> <p><b>Recommendation 20:</b> Provide the financial incentives hospitals need to prepare for biological events. <i>(2015 Blueprint for Biodefense)</i></p> <ol style="list-style-type: none"> <li>a. Adopt a disaster preparedness portfolio.</li> <li>b. Link Centers for Medicare and Medicaid Services (CMS) incentives and reimbursement to new accreditation standards.</li> </ol> <p><b>Recommendation 21:</b> Establish a biodefense hospital system. <i>(2015 Blueprint for Biodefense)</i></p> <ol style="list-style-type: none"> <li>a. Stratify hospitals.</li> <li>b. Develop accreditation standards for each stratum.</li> <li>c. Associate CMS funding.</li> </ol>	<p>Establish a national stratified health care delivery system capable of surging medically to respond to large-scale biological events.</p> <ol style="list-style-type: none"> <li>a. Establish medical surge capability and capacity for large-scale biological events.</li> <li>b. Communicate the business-case for a stratified biodefense health care delivery system.</li> <li>c. Assess risk to reputation.</li> </ol>

	<b>Recommendations in the 2015 Blueprint for Biodefense, 2017 Defense of Animal Agriculture, and 2018 Budget Reform for Biodefense</b>	<b>Additional Recommendations in the 2018 SLTT Reinforcements Needed for Biodefense</b>
<b>Augment Laboratory Response</b>	<p><b>Recommendation 14:</b> Improve surveillance of, and planning for, animal and zoonotic disease outbreaks. <i>(2015 Blueprint for Biodefense)</i></p> <ul style="list-style-type: none"> <li>a. Fund the National Animal Health Laboratory Network (NAHLN) at a level that allows it to achieve success.</li> </ul> <p>Congress should continue to fund the NAHLN. <i>(2017 Defense of Animal Agriculture)</i></p>	<p>Authorize all laboratory networks that test for biological agents.</p> <ul style="list-style-type: none"> <li>a. Authorize and fund the Laboratory Response Network for Biological Threats.</li> <li>b. Authorize and fund the Environmental Response Laboratory Network, Food Emergency Response Network, National Plant Diagnostic Network, and Veterinary Laboratory Investigation and Response Network.</li> <li>c. Establish requirements for all laboratory networks that test for biological agents.</li> </ul>
<b>Rectify Shortfalls in Tribal Public Health Emergency Preparedness</b>	<p><b>Recommendation 17:</b> Fund the Public Health Emergency Preparedness (PHEP) cooperative agreement at no less than authorized levels. <i>(2015 Blueprint for Biodefense)</i></p> <ul style="list-style-type: none"> <li>a. Appropriate PHEP funding to authorized levels or the President’s Budget Request, whichever is higher.</li> </ul>	<p>Give federally recognized American Indian and Alaska Native tribes the opportunity to enter into their own PHEP cooperative agreements and obtain technical assistance.</p> <ul style="list-style-type: none"> <li>a. Make PHEP funding available directly to the tribes.</li> <li>b. Proactively bolster tribal public health emergency preparedness.</li> <li>c. Strengthen tribal epidemiology.</li> </ul>
<b>Overcome Barriers to Territorial Biosurveillance and Response</b>	<p><b>Recommendation 12:</b> Empower non-federal entities to become equal biosurveillance partners. <i>(2015 Blueprint for Biodefense)</i></p> <ul style="list-style-type: none"> <li>a. Create an interagency biosurveillance planning committee.</li> </ul>	<p>Provide US insular areas with robust public health preparedness and response tools.</p> <ul style="list-style-type: none"> <li>a. Provide enhanced planning and technical assistance.</li> <li>b. Strengthen biosurveillance and data collection.</li> <li>c. Reduce barriers to transporting resources during a public health emergency.</li> </ul>

	<b>Recommendations in the 2015 Blueprint for Biodefense, 2017 Defense of Animal Agriculture, and 2018 Budget Reform for Biodefense</b>	<b>Additional Recommendations in the 2018 SLTT Reinforcements Needed for Biodefense</b>
<b>Allocate Response Funding Before Biological Crises Occur</b>	<p>Rapid response fund triggered not only by a declared public health emergency, but also, at times, in advance of any such declaration to preempt a major problem. <i>(2018 Budget Reform for Biodefense)</i></p> <ol style="list-style-type: none"> <li>Infuse no less than \$2 billion into the Public Health Emergency Fund (PHEF).</li> <li>Commit to regular annual appropriations utilizing a consistent methodology and no-year funding for the PHEF.</li> <li>Provide guidance on triggers for PHEF use.</li> <li>Update criteria for events covered by the PHEF.</li> </ol>	<p>Ensure consistent, adequate response funding and guidance for public health emergencies.</p> <ol style="list-style-type: none"> <li>Reform the PHEF to ensure clarity of use, transparency, and accountability.</li> <li>Clarify SLTT eligibility for biological disaster assistance under the Stafford Act.</li> <li>Delineate HHS and FEMA assistance to SLTT governments for public health emergency response.</li> </ol>
<b>Assume Broader Leadership of Biodefense</b>	<p><b>Recommendation 1:</b> Institutionalize biodefense in the Office of the Vice President of the United States. <i>(2015 Blueprint for Biodefense)</i></p> <ol style="list-style-type: none"> <li>Empower the Vice President with jurisdiction and authority.</li> <li>Empower the Vice President with budget authority.</li> </ol> <p><b>Recommendation 2:</b> Establish a Biodefense Coordination Council at the White House, led by the Vice President. <i>(2015 Blueprint for Biodefense)</i></p> <ol style="list-style-type: none"> <li>Require broad federal participation.</li> <li>Invite broad non-federal stakeholder participation.</li> <li>Structure the Council for consensus and accountability.</li> </ol>	<p>Make biodefense a priority for all elected leaders throughout the nation.</p> <ol style="list-style-type: none"> <li>Establish health care and public health emergency preparedness, response, and recovery expectations in the states, localities, tribes, and territories.</li> <li>Add biological risk management to agendas.</li> <li>Address public expectations.</li> </ol>

# APPENDIX B: PROPOSED GUBERNATORIAL HEARINGS

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The State Governors and Territorial Governors and Administrators must ensure that their subordinate agencies and personnel meet legislative and other mandates, and do so in a coordinated fashion. These proposed hearing topics reflect major recommendations outlined in this report, and additional ideas for consideration.

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## Issue

### EMS Requirements and Shortfalls

#### Summary

The origin of EMS lies with the National Highway Safety Act (P.L. 89-564) in 1966. What started as a means for providing preliminary first-aid and rapid transportation from high-speed accidents to nearby hospitals has become a major health care and public safety asset, upon which every community in the nation depends. EMS is now out of alignment with its federal sponsor, DOT, and inadequately informed by the department responsible for health care certification and guidance, HHS. Within the state or territory, which agency(s) should take responsibility for EMS? Do they need additional funding? How can local EMS benefit from lessons learned by DOD (medics and others) and vice versa—especially when DOD medics are based within the state or territory?

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## Issue

### Distribution of the SNS and other Pharmaceuticals, Equipment, and Essential Medical Supplies

#### Summary

The CDC provides training to states and localities to help prepare them to be able to distribute the contents of the SNS. Some state recipients of this training do not believe this training is adequate. Within the state or territory, has the department of health received training? What do they think of it? What are their recommendations to improve it? What plans do they and local pharmacies throughout the state or territory have in place to distribute needed pharmaceuticals, medical equipment, and essential medical supplies? Does the state or territory have a way to determine pharmacy readiness during and after biological disasters?

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## Issue

### Medical Surge and Hospital Accreditation and Reimbursement

#### Summary

Hospitals throughout the nation are operating at or beyond capacity every day. Additionally, every hospital in the state or territory cannot be expected to treat every patient exposed to biological agents, especially during significant, difficult to control outbreaks. How well have hospitals in the state or territory met CMS hospital accreditation requirements? Do any of these hospitals receive HPP funding? Do they think they will receive sufficient reimbursement from CMS and commercial health insurance if they had to treat thousands of patients infected during a large-scale biological event? Which hospitals made investments to increase their ability to treat novel infectious diseases (especially in response to Ebola)? How do they feel about not getting reimbursed for those investments? What plans (if any) do they have in place to deal with the worried well?

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## **Issue**

### **Laboratory Response**

#### **Summary**

State public health laboratories are members of the LRN and other laboratory networks. How does the state public health laboratory director feel about the testing protocols put out by the CDC? What recommendations do the public health laboratories have to improve these protocols? How would they characterize the relationship they have with local FBI field offices in the state? For the territories, why are the territorial public health laboratories not part of the LRN and other networks? What plans do they have in place to send specimens to state public health laboratories that are LRN and other network members?

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## **Issue**

### **Territorial Roles and Requirements in Biodefense**

#### **Summary**

How can the territory, associated state, or area in which the US exercises extraterritorial jurisdiction overcome weaknesses in biosurveillance and biodetection? What do they need from the federal government to increase their biodefense?

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## **Issue**

### **Tribal Public Health**

#### **Summary**

The Bureau of Indian Affairs, Indian Health Service, and Centers for Disease Control and Prevention all have roles to play in helping to improve tribal public health, but seem to lack goals for outcome-focused assistance. Funding opportunities for tribes to improve their own public health infrastructure and programs is also lacking. What is the current state of tribal public health emergency preparedness? How can we better integrate the tribes into mutual aid agreements? How should the governors and administrators ensure that the tribes are included in PHEP cooperative agreements? What role could the Tribal Epidemiology Centers (TECs) play in tribal, state, and national biosurveillance efforts? What can the federal government do to bring other TECs up to the same level as that of the Navajo Nation?

## APPENDIX C: PROPOSED CONGRESSIONAL HEARINGS

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Congress must ensure that federal departments and agencies meet congressional and other mandates, and do so in a coordinated fashion. These proposed hearing topics reflect major recommendations outlined in this report, and additional ideas for consideration.

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### Issue

#### Federal Responsibility for EMS

##### Summary

The origin of EMS lies with the National Highway Safety Act (P.L. 89-564) in 1966. What started as a means for providing preliminary first-aid and rapid transportation from high-speed accidents to nearby hospitals has become a major health care and public safety asset, upon which every community in the nation depends. EMS is now out of alignment with its federal sponsor, DOT, and inadequately informed by the department responsible for health care certification and guidance, HHS. Should all or some responsibility for EMS shift from DOT to HHS? What funding shortfalls exist, and which department should be responsible for providing it? How can local EMS benefit from lessons learned by DOD (medics and others) and vice versa?

**House Committee(s):** Armed Services • Energy and Commerce • Transportation and Infrastructure

**Senate Committee(s):** Armed Services • Health, Education, Labor, and Pensions • Commerce, Science, and Transportation

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### Issue

#### Management of the Strategic National Stockpile

##### Summary

The National Pharmaceutical Stockpile (NPS) was created in 1999. The Homeland Security Act of 2002 made DHS responsible for the NPS in 2003, and the NPS was renamed the Strategic National Stockpile (SNS) that same year. HHS assumed control of the SNS after the Project BioShield Act became law in 2004. The CDC has been in charge of the SNS since then. The Trump Administration would like the HHS ASPR to take over management of the SNS. How would the HHS ASPR manage the SNS differently than the CDC? Would the ASPR need additional personnel to manage the SNS? How would ASPR management change SNS program performance and improve state and local support? How will CDC and ASPR work together?

**House Committee(s):** Energy and Commerce

**Senate Committee(s):** Armed Services • Health, Education, Labor, and Pensions

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### Issue

#### Medical Surge and Hospital Accreditation and Reimbursement

##### Summary

Hospitals throughout the nation are operating at or beyond capacity every day. Additionally, every hospital cannot be expected to treat every patient exposed to biological agents, especially during significant, difficult to control outbreaks. While CMS reimburses health care for disease treatment, it has issued few preparedness and response requirements to hospitals. Given the limitations of the HPP, how can CMS better incorporate emergency preparedness into its hospital accreditation requirements and health care reimbursement schema? How should the HHS ASPR and CMS Administrator work together to improve hospital preparedness?

**House Committee(s):** Energy and Commerce

**Senate Committee(s):** Health, Education, Labor, and Pensions

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## Issue

### Diagnostics

#### Summary

While laboratory testing (performed by the LRN, NAHLN, and other laboratory networks) remains the gold standard for disease identification, the nation needs diagnostics as well, for use in both laboratory and patient care settings. How have CDC-produced diagnostics performed in state and local laboratory settings? What is the role of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) in addressing diagnostics and how has PHEMCE interacted with other HHS agencies to increase the number of diagnostics available to the nation? What is the state of research in this regard? What contributions can DOD and other departments make?

**House Committee(s):** Agriculture • Armed Services • Energy and Commerce • Homeland Security

**Senate Committee(s):** Agriculture • Armed Services • Health, Education, Labor, and Pensions • Homeland Security and Governmental Affairs

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## Issue

### Territorial Roles and Requirements in Biodefense

#### Summary

US territories are subnational administrative divisions directly overseen by the federal government. Unlike the states and tribes, territories are not sovereign. How do biodefense requirements vary with unincorporated organized, incorporated and unincorporated unorganized, inhabited and uninhabited territories, and associated states? How can the US overcome weaknesses in biosurveillance and biodetection in the territories, associated states, and areas in which the US exercises extraterritorial jurisdiction? What role can the federal government play in biodefense in this area and on behalf of the nation as a whole?

**House Committee(s):** Armed Services • Energy and Commerce • Foreign Affairs • Homeland Security • Natural Resources

**Senate Committee(s):** Armed Services • Energy and Natural Resources • Foreign Affairs • Health, Education, Labor, and Pensions • Homeland Security

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## Issue

### Tribal Public Health

#### Summary

The Bureau of Indian Affairs, Indian Health Service, and Centers for Disease Control and Prevention all have roles to play in helping to improve tribal public health, but seem to lack goals for outcome-focused assistance. Funding opportunities for tribes to improve their own public health infrastructure and programs is also lacking. What is the current state of tribal public health emergency preparedness? How can we better integrate the tribes into mutual aid agreements? How should Congress modify the PHEP to address cross-border tribes? What role could the TECs play in tribal, state, and national biosurveillance efforts? What can the federal government do to bring other TECs up to the same level as that of the Navajo Nation?

**House Committee(s):** Natural Resources • Energy and Commerce

**Senate Committee(s):** Indian Affairs • Health, Education, Labor and Pensions

## APPENDIX D: METHODOLOGY

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The Blue Ribbon Study Panel on Biodefense was established in 2014 to inform US biodefense and to provide recommendations for change. The Panel is supported by a suite of ex officio members, fiscal sponsorship by Hudson Institute, and funds from foundations and industry.

### RESEARCH QUESTIONS

In order to address SLTT ability to prepare for, respond to, and recover from large-scale biological events, and gaps in the related biodefense enterprise and biodefense body of knowledge, the Panel developed the following research questions:

- 1) Are our priorities correct?
- 2) Are our investments commensurate with the challenge?
- 3) Can we benefit from rebalancing investments or is new funding required?
- 4) What have we done that has brought a significant return on investment?
- 5) What else should we be doing that we are not?

### PRELIMINARY RESEARCH

The Panel reviewed previous research efforts, scientific studies, reports by congressional and presidential commissions (including the US Commission on National Security/21st Century, Commission on Terrorist Attacks on the United States, Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction, and Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism); presidential directives; statute and proposed legislation; Government Accountability Office reports; and federal strategies, plans, budgets, organizational constructs, and programs related to defense against deliberately introduced and naturally occurring biological events with catastrophic potential. This review: (1) allowed for an assessment of the comprehensiveness of efforts to address the postulated and actual SLTT preparedness, response, and recovery challenges they were intended to meet; and (2) determined how the understanding of

the threat, knowledge base, and elements of the biodefense enterprise should change in light of this assessment. This review also informed the structure and topics of the formal meeting of the Panel.

## FORMAL PANEL MEETING

The Panel organized its formal meeting on this subject in accordance with national and SLTT policy. During this day-long meeting, Panel members, ex officios, and staff received: (1) information regarding current relevant national policy, legislative issues, and federal departmental and agency programmatic activities; and (2) statements from current and former federal and SLTT officials, thought leaders, and subject matter experts. Panel staff summarized major insights, areas for improvement, and recommendations articulated by meeting speakers, and conducted preliminary high-level analysis of this meeting for Panel and ex officio review.

## ANALYSIS

Panel staff used qualitative methods to analyze this information. The Panel examined the oral and written statements provided by meeting speakers and mapped their findings and recommendations to the capabilities required. Panel staff further evaluated each finding and recommendation, including additional policy research and interviews with subject matter experts and former high-level officials, as well as considering the Panel's own experience. Throughout the process, the five questions defined previously provided the basis for assessment. This approach allowed the Panel, ex officios, and staff to identify organizational, legal, policy, and programmatic issues and to recommend specific solutions. Panel staff did not use statistical and other quantitative methods for this study. This study is not considered pseudo-qualitative/quasi-quantitative.

## STUDY LIMITATIONS

Funding and other resource constraints prevented the Panel from performing site visits. In addition, a number of biodefense programs and policies; intelligence, raw data, and documents; appropriations and budget documents; and other sensitive pieces of information are classified or otherwise unavailable, and were not reviewed by the Panel as this was a wholly unclassified endeavor.

## APPENDIX E: MEETING AGENDA AND SPEAKERS

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Meeting held at the University of Miami, Coral Gables, FL

### SPECIAL FOCUS MEETING: SLTT ABILITY TO RESPOND TO LARGE-SCALE BIOLOGICAL EVENTS

JANUARY 17, 2018

#### Opening Remarks

- Former Secretary of Health and Human Services Donna E. Shalala, Blue Ribbon Study Panel on Biodefense
- Former Representative James C. Greenwood, Blue Ribbon Study Panel on Biodefense

#### Political Perspective

Need to ensure that states, localities, tribes, and territories possess the resources, capabilities, and capacity to respond to large-scale biological events.

- Richard Serino, Distinguished Senior Fellow, Harvard School of Public Health; former Deputy Administrator, Federal Emergency Management Agency; former Chief, Boston Emergency Medical Services

#### Panel One – Community and Pre-Hospital Assets and Resources

Use of SLTT pre-hospital assets and resources, and the ability of communities to respond to large-scale biological events.

- Nicolette A. Louissaint, PhD, Executive Director, Healthcare Ready
- Jimmy Mynatt, AAE, Assistant Aviation Director, Operations, Charlotte Douglas International Airport
- James Robinson, Assistant Chief, Denver Health Paramedic Division

#### Panel Two – Hospital Preparedness and Response

SLTT leadership in hospital preparedness, training, and response; the recent Centers for Medicare and Medicaid Emergency Preparedness Rule; and the need for a stratified biodefense hospital system.

- David Zambrana, PhD, DNP, MBA, RN, Senior Vice President and CEO of Jackson Memorial Hospital
- David Marcozzi, MD, MHS-CL, FACEP, Associate Professor, Co-Director of the Program in Health Disparities and Population Health, University of Maryland School of Medicine; Assistant Chief Medical Officer for Acute Care, University of Maryland Medical Center
- Alexander P. Isakov, MD, MPH, Executive Director, Office of Critical Event Preparedness and Response, Emory University

### **Panel Three – Public Health Response and Population Management**

Public health roles and responsibilities when responding to biological events affecting large groups, and how the public health community must interface with the health care delivery and public safety communities.

- Celeste Philip, MD, MPH, Surgeon General and Secretary, Florida Department of Health
- Scott J. Zimmerman, DrPH, Director, Division of Public Health, North Carolina State Laboratory of Public Health
- Tina Batra Hershey, JD, MPH, Assistant Professor, Health Policy and Management; Assistant Director for Law and Policy, Center for Public Health Practice, University of Pittsburgh Graduate School of Public Health

### **Lunch Keynote – Local Response, Global Perspective**

Local response to a large-scale biological event placed into global context.

- Julio Frenk, MD, PhD, MPH, President, University of Miami

### **Panel Four – Working the Interfaces**

Federal support of local response requirements and the need for federal agencies to work with SLTT officials.

- Michael Fraser, PhD, MS, Executive Director, Association of State and Territorial Health Officials
- Joseph M. Henderson, MPA, Director, Office of Safety, Security and Asset Management, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, Department of Health and Human Services; Faculty, National Preparedness Leadership Initiative, T.H. Chan School of Public Health and Kennedy School of Government, Harvard University

### **Closing Remarks**

- Former Representative James C. Greenwood, Blue Ribbon Study Panel on Biodefense
- Former Secretary of Health and Human Services, Donna E. Shalala, Blue Ribbon Study Panel on Biodefense

# ACRONYMS

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<b>AI/AN</b>	..... American Indian and Alaska Native
<b>APHL</b>	..... Association of Public Health Laboratories
<b>ASPR</b>	..... Assistant Secretary for Preparedness and Response, Department of Health and Human Services
<b>CDC</b>	..... Centers for Disease Control and Prevention
<b>CMS</b>	..... Centers for Medicare and Medicaid Services, Department of Health and Human Services
<b>DHS</b>	..... Department of Homeland Security
<b>DOD</b>	..... Department of Defense
<b>DOT</b>	..... Department of Transportation
<b>EMS</b>	..... emergency medical services
<b>EPA</b>	..... Environmental Protection Agency
<b>FBI</b>	..... Federal Bureau of Investigation
<b>FDA</b>	..... Food and Drug Administration
<b>FEMA</b>	..... Federal Emergency Management Agency
<b>HHS</b>	..... Department of Health and Human Services
<b>HPP</b>	..... Hospital Preparedness Program, Department of Health and Human Services
<b>IHS</b>	..... Indian Health Service, Department of Health and Human Services
<b>LRN</b>	..... Laboratory Response Network for Biological Threats (previously known as the Laboratory Response Network for Bioterrorism)
<b>MCM</b>	..... medical countermeasure(s)
<b>MERS-COV</b>	..... Middle East Respiratory Syndrome Coronavirus
<b>NAHLN</b>	..... National Animal Health Laboratory Network
<b>NPS</b>	..... National Pharmaceutical Stockpile
<b>PHEF</b>	..... Public Health Emergency Fund
<b>PHEMCE</b>	..... Public Health Emergency Medical Countermeasures Enterprise
<b>PHEP</b>	..... Public Health Emergency Preparedness program (cooperative agreements)
<b>SARS</b>	..... Severe Acute Respiratory Syndrome
<b>SLTT</b>	..... state, local, tribal, and territorial
<b>SNS</b>	..... Strategic National Stockpile
<b>TEC</b>	..... Tribal Epidemiology Center
<b>US</b>	..... United States
<b>USDA</b>	..... Department of Agriculture

## ENDNOTES

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1. US Census Bureau. (2012). Census of Governments. Washington, DC: US Census Bureau. See: <https://www.census.gov/programs-surveys/cog.html>.
2. Bureau of Indian Affairs. (2018). Mission Statement. Washington, DC: US Department of the Interior. See: <https://www.bia.gov/bia>.
3. Majority Staff, US House of Representatives. (2009). Getting Beyond Getting Ready for Pandemic Influenza. Washington, DC: US House of Representatives. See: <https://www.hsdl.org/?view&did=232395>.
4. National Institutes of Health. (2009). NIH Hosts H1N1 Flu Summit. See: [https://nihrecord.nih.gov/newsletters/2009/08\\_07\\_2009/story1.htm](https://nihrecord.nih.gov/newsletters/2009/08_07_2009/story1.htm).
5. National Defense Authorization Act of 1997 (Public Law 104-201), Title XIV, Subtitle A.
6. Federal Emergency Management Agency. (2016). Emergency Support Function #8 – Public Health and Medical Services Annex. Washington, DC: Federal Emergency Management Agency. See: [https://www.fema.gov/media-library-data/1470149644671-642ccad05d19449d2d13b1b0952328ed/ESF\\_8\\_Public\\_Health\\_Medical\\_20160705\\_508.pdf](https://www.fema.gov/media-library-data/1470149644671-642ccad05d19449d2d13b1b0952328ed/ESF_8_Public_Health_Medical_20160705_508.pdf).
7. National Academy of Science, Engineering, and Medicine. (2016). A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury. Washington, DC: The National Academies Press. See: <http://www.nationalacademies.org/hmd/Reports/2016/A-National-Trauma-Care-System-Integrating-Military-and-Civilian-Trauma-Systems.aspx>.
8. Or the ASPR, if Congress transfers the SNS in accordance with the President’s Budget Request for Fiscal Year 2019.
9. Or the ASPR, if Congress supports transfer of the SNS, in accordance with the President’s Budget Request for Fiscal Year 2019.
10. For more information about Healthcare Ready, see: <https://www.healthcareready.org/>.
11. For instance, the brand of the Texas Health Presbyterian Hospital in Dallas is now associated with its faltering response to Ebola.
12. Centers for Medicare and Medicaid Services. (2016). Medicare and Medicaid Programs: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, Final Rule (81 FR 63860). Washington, DC: Department of Health and Human Services. See: <https://www.regulations.gov/document?D=CMS-2013-0269-0377>.
13. For more information on these laboratory networks, see: <https://www.icln.org>.

14. Localities receiving PHEP awards are Chicago, IL; Los Angeles County, CA; New York, NY; and Washington, DC. See: <https://www.cdc.gov/phpr/readiness/phep.htm>.
15. Territories and freely associated states receiving PHEP awards are American Samoa, Guam, US Virgin Islands, Northern Mariana Islands, Puerto Rico, Federated States of Micronesia, Republic of Marshall Islands, and Republic of Palau. See: <https://www.cdc.gov/phpr/readiness/phep.htm>.
16. PHEP funding is intended to build upon jurisdictional efforts, not replace them. Recipients must provide at least 10% in matching funds.
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18. For definitions of insular areas, see: <https://www.doi.gov/oia/islands/politicatypes>.
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20. Regardless of any FEMA recommendation, the President retains sole authority to approve requests for Stafford Act emergency declarations.
21. Prior documentation, including most recently FP-104-009-001 lists Pre-Scripted Mission Assignments that provide detailed examples of potential assistance and cost-share requirements in responding to biological events. These do not overlap with assistance that Congress has authorized HHS to provide. FEMA assistance would be limited to Direct Federal Assistance and would not reimburse SLTT costs for protective measures.



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