



**Written Testimony  
Senate Homeland Security and  
Government Affairs Committee**

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**The Federal Perspective on the State of Our Nation's  
Biodefense**

*Statement of*

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Good morning Chairman Johnson, Senator Carper, and other distinguished members of the Committee. I am Rear Admiral Stephen Redd, Director of the Centers for Disease Control and Prevention's (CDC) Office of Public Health Preparedness and Response.

I am pleased to appear before the Committee today to discuss the state of public health preparedness and health security in the United States, and CDC's current level of preparedness for biological and other natural and manmade, domestic and international threats, including recent progress made in ensuring our preparedness and response capabilities. I am also happy for this opportunity to provide an update on CDC's ongoing response to the Zika virus outbreak.

CDC advances the health security of the Nation by helping communities prepare for, respond to, and recover from all hazards, including chemical, biological, radiological, and nuclear threats; natural disasters; and epidemics. Whether the hazard is naturally occurring (Zika and Ebola viruses, and hurricanes), unintentional (the 2014 West Virginia chemical spill) or intentional (anthrax attacks), effective public health emergency management and response depends on building, maintaining and constantly improving the capability of state and local health departments to prepare for and respond to public health emergencies. We have to be ready to respond to any threat: this approach to public health preparedness and response fosters development of emergency-ready public health departments that are flexible and adaptable to the needs of responding to a particular incident.

### ***Role of State and Local Public Health Agencies***

State and local public health agencies are the front lines of public health preparedness and response. CDC provides ongoing technical assistance and, where requested, on-the-ground personnel and materials to assist with response efforts. For example, CDC personnel are providing laboratory testing surge capacity and training, vector control, and surveillance support to Puerto Rico in response to the current Zika virus outbreak.

Investments in preparedness since 2001 have greatly increased the Nation`s public health preparedness for any threat. One of the lessons learned as a result of responding to the 9/11 and anthrax attacks was that state and local health departments lacked critical capabilities needed to mount an emergency response, and the Nation`s public health system also was not consistently able to provide essential public health services during an emergency. Health departments lacked laboratory networks, electronic disease surveillance systems, expertise in risk communication, and emergency operations centers.

Successful state and local response to public health emergencies depends upon many factors, including a capable state and local public health and healthcare system. To support our state, local, and territorial partners, CDC established the Public Health Emergency Preparedness (PHEP) cooperative agreement program. In the 14 ½ years since 9/11 CDC has awarded an average of \$766 million dollars per year to improve preparedness at the state, local, and territorial levels. However, current funding for the PHEP cooperative agreement program is approximately \$300 million dollars lower than funding amounts from 2001-2003.

The PHEP cooperative agreement program currently funds 62 awardees -- including all 50 states, eight territories and freely-associated states, and four directly-funded localities (New York City; Washington, D.C.; Chicago; and Los Angeles County) -- according to a base-plus population formula prescribed by statute, which ensures a minimum amount of funding to each awardee.

These funds support staff, pay for equipment, provide for training, enable exercises, and provide other services essential to maintaining preparedness. In addition, CDC personnel help PHEP awardees improve their performance by sharing knowledge, useful practices and lessons learned along with the tools and resources needed to identify and address gaps in preparedness capabilities.

Cooperative agreements under CDC`s PHEP program and the Hospital Preparedness Program (HPP), overseen by the Assistant Secretary for Preparedness and Response (ASPR), are aligned and managed jointly with a single funding opportunity announcement, funding application, and grant award. This

collaboration reduces the administrative burden on the awardees through a single application process for both cooperative agreements. PHEP and HPP also aligned the program capabilities, framework, and reporting requirements to streamline operations and strengthen public health and healthcare preparedness synergies.

State and local health departments have greatly increased their capacity to respond to an array of hazards, which is evidenced through states' proven success in responding to critical events without requesting direct federal support (such as a 2015 oil spill in Montana).

### ***Lessons learned from exercises and real-life incidents***

While training and skill development are important, exercises and real-life events provide opportunities to put those skills to work. PHEP awardees are required to demonstrate their capabilities at least once a year by conducting an exercise and evaluating their performance through an after-action review process.

Oftentimes, jurisdictions are able to use real incidents in their communities to test operational readiness to respond to public health emergencies.

After-action reviews collect data about successes and areas for improvement identified during unexpected incidents, exercises, and real events such as festivals or concerts that draw large crowds. Data from these reviews are used to identify strengths for sustainment and gaps for future capability development. Use of this information is key to improving performance for the next incident or event. For example, the after-action review of the 2010 cholera outbreak response in Haiti recommended that CDC institutionalize the use of permanently assigned in-country CDC staff to act as Incident Managers, to better prepare staff to lead emergency response operations within the country. As a result, additional in-country staff around the world have observed and been trained on managing emergency operations in the event the country activates its Emergency Operations Center. More effective in-country response operations will reduce the geographic spread of an outbreak and help protect the U.S. against domestic cases.

CDC recently concluded emergency response operations for the 2014 Ebola outbreak in West Africa (Guinea, Liberia, and Sierra Leone) and will be identifying and addressing lessons learned in the coming months. To date, CDC has already recognized three key lessons learned:

- The need for every country to have systems in place to prevent, detect, and respond to health threats;
- The need for other countries and international support groups to be prepared to respond swiftly and effectively in a coordinated fashion when a country is overwhelmed by an incident; and
- The need to improve infection control practices with respect to health care facilities.

In response to these lessons learned, CDC is working with certain countries in Africa to help build their capacity to respond to health threats. Domestically, to improve infection control CDC is partnering with state and local public health preparedness and healthcare-associated infection control programs to develop common processes for management of persons under investigation for potential diseases. Through these partnerships CDC is also developing and sharing protocols for notification of and response to cases of emerging or re-emerging, highly contagious diseases in healthcare facilities.

### ***A strong laboratory response network***

Rapid identification of disease is critical to addressing public health threats before they become a crisis. CDC's Laboratory Response Network (LRN) maintains an integrated system of state and local public health, Federal, and international laboratories that can respond to biological, chemical, and other public health threats. The linking of state and local public health laboratories, veterinary, agriculture, and water- and food- testing laboratories over the last 15 years the LRN represents a significant advance in our preparedness capabilities and provides for rapid testing, timely notification and secure communication of laboratory results.

The LRN is a scalable and flexible asset to address public health threats. In response to the Zika virus outbreak, CDC collaborated with the Food and Drug Administration (FDA) to quickly equip LRN

laboratories around the United States with the ability to quickly test specimens for the outbreak strain of Zika virus. In recent weeks, the FDA has issued two Emergency Use Authorizations (EUA) for CDC-developed diagnostic tools. One, the CDC Trioplex Real-time (RT)-PCR Assay, allows doctors to tell which, if any, of three similar viruses (chikungunya, dengue, or Zika) has infected an individual, instead of having to perform three separate tests to determine which infection one might have. Fifty states and Washington, D.C. have been provided with materials to conduct the RT-PCR test. The second test called the CDC Zika IgM Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA), can detect antibodies that the body makes to fight a Zika virus infection; presence of such antibodies indicates that there was a recent infection. Results of this test will help patients (particularly pregnant women) and physicians determine the best approach to monitoring patient health. Both the RT-PCR and Zika MAC-ELISA tests require specialized equipment and skills and can only be done by qualified laboratories capable of performing “high-complexity tests,” as that phrase is used in the Clinical Laboratory Improvement Act. As of April 5, 2016, 14 labs in 11 states were verified to conduct the RT-PCR test and 16 labs across 15 states have the capability to perform the Zika MAC-ELISA test. We expect more labs to come on line in the near future.

***Medical countermeasures for public health responses***

CDC’s Strategic National Stockpile (SNS) manages and delivers life-saving medical countermeasures during a public health emergency. In addition to stocked products, SNS has many capabilities that can be rapidly brought to bear to respond to threats to public health and thus the nation’s health security.

Holding more than \$7 billion in assets, SNS is authorized to maintain a stockpile of drugs, vaccines, and medical equipment to provide for the emergency health security of the United States. These supplies and SNS capabilities are designed to support response to public health emergencies of all types. If a chemical, biological, radiological, or nuclear incident occurred anywhere in the United States or its territories tomorrow, SNS capabilities and supplies are available to respond immediately. SNS also is positioned to

support response to emerging infectious disease threats such as Ebola and Zika viruses, through personal protective equipment and other supplies to prevent infection.

CDC works with HHS's ASPR and with other Federal agencies, through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), to prioritize Federal investments in medical countermeasures based on analysis of risk and support of critical markets. SNS procurements and the advanced development and procurement mechanisms managed through ASPR are critical to assuring the United States' health security with a ready stock of medicine and medical supplies to respond. The continued purchase of products which are vital for response and have no regular commercial market assures that manufacturer capabilities are maintained and product continues to be produced. And, sustained purchasing of commercially available medical supplies assures there is a ready stock for a response that might exceed normal market operations and potentially assures a more robust supply chain capability.

Just as important as having the right medical countermeasure on the shelf in the SNS is knowing our public health partners at the state and local levels will be able to effectively and efficiently receive those assets from the SNS and get them in time to the end users, individuals in need of treatment or protection.

For this reason, CDC offers training programs to ensure that our partners have the knowledge and skills they need to distribute and dispense SNS assets in a timely manner, and CDC supports exercises to test the skills of trained responders and evaluate plans for possible improvements. These trainings and exercises help our partners improve their preparedness and establish confidence in their ability to respond.

In FY 2015, CDC trained 1,661 individuals at the federal, state, and local level through 66 training opportunities. Additionally, expanded offerings of three self-paced online courses provided training to another 1,776 federal, state, and local planning and response personnel. CDC also supported and participated in 20 realistic objective-based exercise events at CDC and around the country, to assess the readiness of CDC and its state, local and territorial partners.

Jurisdictions face ongoing challenges when planning to dispense medical countermeasures to large populations. Decreased funding availability impacts both staffing and infrastructure. Fewer state and local public health staff are available to protect or treat large populations of affected individuals and the infrastructure (i.e., warehouses, transportation, systems) critical to the management of a public health response requiring medical material is increasingly unfunded. These two gaps challenge state and local capacity to maintain and advance public health preparedness. CDC constantly works to develop and improve partnerships that can help support responses to health threats by filling these gaps.

These partners—who range from healthcare material trade associations to nationwide retail, pharmacy and hospital chains to faith based and community organizations—all help expand capability for delivery and dispensing of countermeasures in the communities and business sectors they serve. These partnerships improve response efficiency, provide additional means to deliver medical countermeasures to healthcare providers and populations within the community, and reduce the burden on local public health responders during times of urgent need.

CDC is currently working with Costco and Walgreens to develop medical countermeasure dispensing capabilities. Costco successfully conducted a dispensing exercise in a Virginia retail store last year to test these capabilities. As a direct result of this exercise and the planning that led up to it, Costco expressed willingness to consider requests from any local health jurisdiction to allow any of their retail stores in the United States to serve as public points of dispensing during a public health emergency. CDC has partnered with Walgreens for almost two years to develop dispensing capability, and Walgreens supports numerous local jurisdictions throughout the U.S. in their dispensing capability. This partnership continues to explore the potential use of Walgreens retail stores to not only support dispensing, but also use of trucks and drivers to support distribution, and Walgreens clinical staff to support public health operated dispensing sites.

### ***Zika Virus Update***



As of April 5, 2016, 41 countries and U.S. territories, including Puerto Rico, the U.S. Virgin Islands, and American Samoa, have reported local transmission of the Zika virus. CDC's key priority at this point is to reduce the risk of Zika virus infection to pregnant women. The virus can be transmitted through infected mosquitoes and infected sexual partners. Given the risks associated with maternal Zika virus infection, prevention is key. Therefore, CDC is taking action based on what we know now, and seeking to learn more so that we can better prevent adverse health outcomes in the future. For example, during the same week we identified Zika in brain tissue specimens from affected infants, we issued a warning to advise pregnant women not to travel to affected areas. We are working intensively with Puerto Rico and other areas to offer prevention tools to women who are or who may become pregnant. We also are engaging in studies with international partners so that we can more fully understand the magnitude of risk and the range of outcomes associated with Zika virus infection during pregnancy.

While we are working to better understand these health outcomes and the risk of transmission of Zika virus, we have developed diagnostic tests and are working to implement mosquito control measures. CDC has also been responding quickly. On January 22, 2016, we activated our Emergency Operations Center and on February 8, 2016, we elevated our Emergency Operations Center response efforts to the highest level to further enhance our activities in areas with current local transmission and to accelerate preparedness efforts in anticipation of local transmission in the continental United States and Hawaii.

For Puerto Rico, the U.S. Virgin Islands, and American Samoa, a surge in resources is urgently needed. The population of *Aedes aegypti* mosquitoes (key Zika virus transmitters) is widespread on these islands, protective environmental factors such as window screens are not in wide use, and high population density puts people there at greater risk for transmission. All three areas have already reported local Zika virus transmission, with Puerto Rico alone reporting over 300 hundred cases. Furthermore, recent outbreaks of dengue and chikungunya viruses, which are spread by the same mosquito species, suggest that Zika virus may spread extensively and rapidly in these areas. CDC has deployed staff to the U.S. Virgin Islands, American Samoa, and Puerto Rico to support response activities and provide technical assistance to

health departments there. CDC and the CDC Foundation are also partnering to create and distribute Zika Prevention Kits. Containing educational materials and initial supplies of prevention tools such as insect repellent and treated bed nets, the purpose of these kits is to help pregnant women in areas with local Zika transmission protect themselves from infection. Five thousand of these kits have been dispatched to Puerto Rico, the U.S. Virgin Islands, and American Samoa; and CDC plans to distribute approximately 50,000 kits to these areas in the future.

We have not yet seen transmission of the Zika virus by mosquitoes within the continental United States or Hawaii, but we know we are not doing enough to prepare the state public health system. More than 320 returning travelers have already been diagnosed with Zika infection. As a potential benchmark, we received reports of 3,270 travelers from 49 states with laboratory confirmed cases of chikungunya infection in 2014 and 2015. There are about 40 million people travelling between the continental U.S. and Zika-affected areas each year. Therefore, all U.S. jurisdictions must be prepared to evaluate, test, and manage patients potentially infected with Zika virus, particularly pregnant women. Furthermore, *Aedes aegypti* mosquitoes are found in many areas of the United States, raising the risk of local transmission. The most recent data available suggest that *Aedes aegypti* are found in 30 states and *Aedes albopictus* (mosquitoes also known to transmit Zika virus) are found in 40 states and the District of Columbia. Recent experience with chikungunya and dengue virus infections in the United States were relatively small outbreaks localized to the southernmost locations. Zika virus may follow this pattern as well. However, any local cases or clusters of cases will be of deep concern to the people living in areas with the *Aedes aegypti* and *albopictus* mosquitoes, and we must be prepared for different scenarios including more extensive transmission risk.

CDC is working with health departments across the country to ensure coordination and to expand capacity for detecting and responding to Zika virus. Surveillance is essential to monitor and quickly identify areas with local transmission. We conduct multi-faceted surveillance for arboviruses, including Zika, through ArboNET, an integrated network which, through our Epidemiology and Laboratory

Capacity cooperative agreements, funds staff in 49 states, Puerto Rico, and six large municipalities to conduct human case investigations, collect and test mosquitoes, and perform laboratory analysis on arboviruses including Zika. Zika virus is now a nationally notifiable disease, meaning states voluntarily report instances of the virus to CDC, a critical step in Zika surveillance. CDC also is working with several states and Puerto Rico to determine a baseline prevalence of microcephaly so that any increase, should it occur, can be quickly and accurately identified. Finally, on April 1, CDC hosted a Zika Action Plan Summit focused on ensuring that states, territories, and localities coordinate planning and apply best practices – from federal and other state and local subject matter experts -- to strengthen Zika Action Plans and identify gaps in readiness or resource needs.

CDC is also collaborating in its Zika response efforts with other components of HHS, including ASPR and its Biomedical Advanced Research and Development Authority (BARDA), the National Institutes of Health, and the FDA. We are also working with partners across the U.S. Government to communicate with travelers and health care providers, update travel alerts and clinical guidance, and develop improved mosquito-control methods.

### ***Conclusion***

Public health threats are everywhere. From imported measles cases, which have led to large outbreaks in the United States where it had been eliminated for years, to the Ebola virus, a threat from the other side of the world, to an earthquake that can strike without warning, the public health system must remain vigilant to protect U.S. residents.

Preparedness is not a destination. It is a process of skill development, and honing our abilities to adapt to the current environment and better prepare us to address future threats. CDC will continue to work with Federal, international, state, tribal, territorial, and local partners to ensure necessary capabilities are maintained to keep the public safe. I look forward to our continued partnership with the Congress and would be glad to answer any questions you may have.