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The Honorable Michael C. Burgess, MD
Chairman
Subcommittee on Health
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burgess:

Thank you again for the opportunity to testify at the hearing "Reauthorizing the Pandemic and All-Hazards Preparedness Act on June 6, 2018 on behalf of NACCHO and Harris County Public Health. Please find below answers to questions submitted for the record.

The Honorable Markwayne Mullin:

1. Do you all believe that current law puts some constraints on how BARDA is able to partner new companies and new technologies?

The current law has enabled BARDA to make important progress on curtailing the spread of emerging infectious diseases that threaten global health security when left unchecked. BARDA's implementation of the Broad Spectrum Antimicrobials (BSA) Program has helped to address the antimicrobial development gap by expanding engagement with industry partners to develop novel antimicrobials. While the scope of BARDA's efforts has encompassed the dual utility of antimicrobials, its focus on indications for biological threat agents likely limits the extent to which BARDA has been able to partner with certain new companies and technologies working to counter the spread pathogens that demonstrate drug resistance of primarily clinical and public health significance but have the potential to severely impact global and national security.

   a. Follow up: Can you explain to me the limits of BARDA's authority to work with companies developing non-therapeutic technologies to counter antibiotic and antimicrobial resistance?

   While BARDA's mission to develop and procure medical countermeasures includes diagnostics and non-pharmaceutical countermeasures against natural or deliberate threats, including those caused by emerging infectious diseases, the emphasis on qualified countermeasures and qualified pandemic or epidemic products for biodefense is rooted in the agency's purpose, as described in the legislation. Consequently, while a program such as the BSA allows for and facilitates the development of candidate

antimicrobials for their commercial and clinical applications, the program stipulates that partners concomitantly support the development of these products for biodefense threat agent indications. Companies developing non-therapeutic technologies to address antimicrobial resistance, particularly those with a primary or sole emphasis on commercial or clinical application, even if their product potentially benefits biodefense may, in some cases, be at a disadvantage or ineligible for participating in the BSA program.

b. Follow up: Do you believe giving BARDA the flexibility to work with companies more broadly would be beneficial to BARDA as they work to achieve their mission to counter antibiotic and antimicrobial resistance?

Giving BARDA the flexibility to work with companies more broadly may be beneficial in achieving the agency's mission to counter antimicrobial resistance. While it will require substantial time and effort to measure the impact of BARDA's efforts on curbing the spread of antimicrobial resistance, BARDA's successful increased engagement of industry partners in moving more candidate antimicrobials through the drug development pipeline was a critical step in the FDA's approval in 2017 of a new antibiotic against highly resistant pathogens. Expanding BARDA's mission and flexibility could help to further identify promising therapies and other non-pharmaceutical products for tackling the spread of drug-resistant pathogens and better protect the health – and thereby national security – of our country.

The Honorable Earl L. Buddy Carter:
In 2014, two American medical missionaries infected with the Ebola virus disease in Liberia were evacuated by air ambulance to Emory University Hospital in my home state of Georgia. At the time, Emory had 12 years of training to address highly communicable diseases, and was chosen by the U.S. State Department and the CDC as a result of the agencies confidence in their ability to treat the patients.

Following the successful discharge of the four patients, Emory has continued to disseminate best practice information and new knowledge about treatment, complications, and the clinical course of Ebola; serve as a national leader in education and training; create new university forums; develop education materials for residents, fellows and the general public; present clinical and research findings at scientific meetings and in journal articles; and engage in the broader policy issues of preventing and treating highly contagious diseases.

1. I had the opportunity to tour the unit where these patients were treated at Emory and was impressed with the contamination prevention efforts the staff employed to protect themselves and others from the spread of this disease. Can you discuss the lessons we have learned from Emory's use of personal protective equipment for healthcare workers?

In August 2015, NACCHO and the Association of State and Territorial Health Officials (ASTHO) conducted an in-progress review of the public health systems' response to Ebola in the United States. The review included over 90 stakeholders representing federal, state, and local government, healthcare, environmental health, and the private sector. While the review was primarily focused on the public health system, consideration was given to the intersection between healthcare and public health. Lessons learned from the review meeting included the following:

- Additional capacity and subject matter expertise in infection control and prevention are needed across the public health and healthcare system, particularly at the state and local level.
- Specific guidance from the federal government, in multi-media formats, such as training videos and graphic one-pagers that were tailored to the audience (e.g., healthcare, emergency management, law enforcement) were most effective for communicating PPE guidance.
- The federal government should take a lead role in coordinating with PPE manufacturers for the acquisition and distribution of PPE for Ebola and future highly pathogenic infectious diseases.

It should be remembered that what occurred with Ebola in 2015 will most likely be a guide to what would occur in a new Ebola outbreak today or in the future. However, given that emergencies are never the same, this guide should only serve as a roadmap for the future of Ebola type infectious disease response. It is clear that flexible, proactive capacity-building at the local (public health) level – in coordination with strong state and federal funding levels – must be a part of any consideration to ensure appropriate emergency response capabilities for the future. Finally, this is also an appropriate moment to emphasize the link between global health and domestic health – ensuring appropriate attention to both is necessary to assure the health, security, and well-being of all Americans.

2. I have toured the CDC a number of times and am consistently impressed by the work that occurs there on a daily basis. When the SNS is transferred from the CDC to ASPR - we need to make sure that public health response capabilities are not lost. What steps need to be taken during the transfer to ensure that state and local public health departments remain engaged?

To ensure that state and local health departments remain engaged in the SNS:

- Have representatives from State and Local health departments be a part of the transition decision making team as well as any follow up advisory group moving forward.
- Utilize national organizations such as ASTHO and NACCHO to facilitate acquiring additional recommendations from their members.

- Ensure frequent and constant communication and coordination between CDC and ASPR regarding SNS so that guidance to state and locals are consistent and clear.
- Have listening sessions and/or requests for feedback from state and local health department representatives. Coordination and communication should occur throughout the transition to ensure that the state and local health department perspective is included in major decisions that could impact state and local capacity and/or response strategies.
- Make available new processes and frameworks for state and local health department representative comment whenever possible.
- ASPR and CDC should remain transparent about the changes that will occur as a result of this transition and provide information and guidance to state and local health departments – as well as involve them in the transition planning itself – leading up to the transition and as the transition occurs. Mechanisms to achieve transparency may include press releases, web conferences, guidance documents, and frequently asked questions documents.

3. As you mentioned in your written testimony, you discussed the importance of reauthorizing the Hospital Preparedness Program. The HPP gives health systems the tools they need to save lives during emergencies that exceed the day-to-day capacity of hospitals and emergency response systems. Can you discuss ways that health systems have used these funds in order to establish preparedness infrastructure?

HPP has helped to improve emergency communication and coordination among hospitals, ancillary medical facilities and health officials; facilitate patient tracking in mass casualty events, such as the mass-shooting event that occurred in Las Vegas in 2017, or during the myriad of emergencies our nation has faced this past year such as hurricanes, wildfires, and infectious disease responses; sustain operations in the midst of an event; track medical resources and assets including available hospital beds; and establish systems to reunite family members following an event.

HPP Funds are used in the Harris County, Texas, region, for example, by the Southeast Texas Regional Advisory Council (SETRAC) to plan, train, exercise, and equip hospital systems for the catastrophic disasters they may have to respond to outside of their normal business operations. With the transition of employees every year, these trainings and exercises must continue annually to keep newer employees prepared.

To close, appropriate and sustained funding for both HPP and Public Health Emergency Preparedness (PHEP) programs is critical to the success of any public health emergency planning and response. These inter-connected programs are both necessary to ensure the health, security, and well-being of all Americans.

The Honorable Frank Pallone Jr.:

1. How do public health departments currently coordinate with the CDC, Division of Strategic National Stockpile, and ASPR to develop medical countermeasures in response to public health emergencies?

Public health departments have not historically been engaged in the development of medical countermeasures for response. State and local health departments should be involved in all phases of the medical countermeasures (MCM) enterprise including in initial investment; research and development of vaccines, medicines, diagnostics and equipment for responding to emerging public health threats; and distribution and dispensing of countermeasures.

Recently CDC announced that state and local health department representatives would be included in the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) to help inform decisions related to the SNS formulary. This has not yet been implemented and details regarding the nomination/application have not yet been released.

2. What issues or challenges do health departments currently face with response to public health emergencies in terms of interfacing with CDC, ASPR, and use of the SNS?

The federal system is the safety net for local public health when dealing with large-scale catastrophic events; however, in some cases the federal system does not always have a good understanding of what is actually happening at the local level. Emergency managers must be able to communicate effectively with state and federal partners, generally communication goes through a state conduit, which can cause a delay in rapid response communications. Local planning and response efforts do not always coincide with federal guidance during operational efforts. It is critical that federal agencies coordinate their activities across the federal government to ensure consistency of messaging and activities when interacting with local health departments engaged in a public health response.

While much progress has been made, the issues and challenges related to public health emergency response coordination very much centers around the fact that emergencies are unpredictable and chaotic. This was seen of course this past year during the myriad of emergencies this nation has faced and will continue to face in the years to come. Given such unpredictability, our nation must be prepared by ensuring that federal and state public health systems are strong and supportive of the work that happens in local communities where local public health departments are best-suited to respond to their community needs in emergencies.

3. Do you feel any issues will be resolved by transferring the SNS from the CDC to ASPR?

There are currently two sets of stockpiled assets housed separately - with the federal medical station assets managed and stockpiled by ASPR - and the SNS managed and stockpiled by CDC. This transfer under one entity could help streamline processes for requesting medical material and products from the Federal government. However, this transfer must be well-coordinated and details – that are still not known – must be made known so more specificity of what the implications of such transfer can be more clearly considered and articulated.

4. What problems may arise from the transfer of SNS from the CDC to ASPR?

Current funding, support, and expertise provided to state and local health departments for the SNS must be maintained regardless of the infrastructure or location of the SNS – it is too vital to this country's ability to respond in the midst of a variety of large-scale emergencies. However, there are potential vulnerabilities to this with the proposed transfer of authority for the SNS from CDC to ASPR at the beginning of FY2019. The Committee should include a provision that assures the maintenance of appropriate coordination and support for state and local public health departments. **Under no circumstance can public health response capabilities be lost in the sea of other health care system response capability needs.** This cannot and must not happen.

As proposed, operational and logistical functions that would be transferred to ASPR would essentially be separated from programmatic and support functions already in place at the CDC. If not handled well, such a transfer may introduce added complexity, poor coordination and less expediency as it pertains to the national, state and local operational readiness to distribute and dispense medical countermeasures from the stockpile where the healthcare-public health interface is critical. There needs to be clear communication and engagement between the federal level and state and local levels throughout the entire process to ensure state and local input is incorporated and state and local planners have the information that they need to update their plans in a timely fashion.

5. How can the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and medical countermeasure developers improve their response to health departments and distribution of medical countermeasures?

NACCHO supports the codification of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE Strategy and Implementation should require that state and local health departments be involved in all phases of the medical countermeasures (MCM) enterprise including in initial investment; research and development of vaccines, medicines, diagnostics and equipment for responding to emerging public health threats; and distribution and dispensing of countermeasures.

NACCHO recommends that state and local public health departments have a permanent place in the PHEMCE membership to ensure that all decisions that will affect state and local health

functions are vetted by public health authorities. Membership should include a state public health authority and a local public health authority.

6. What are the most urgent state and local public health emergency preparedness priorities?

Flooding, winter storms, and infectious disease remain among the top threats, but local health agencies feel more prepared to address these since we've been responding to these kinds of events over and over again. Though there is always the concern that even previous emergencies that have been seen over and over again will throw a "curve ball" in the future, even more attention must be paid to those types of emergencies that are large-scale and with potential for incredible loss of life and property. As such, there are large gaps in addressing critical infrastructure protection, medical supply chain disruption, and cybersecurity, NACCHO's 2018 Preparedness profile results show that opioids and mass casualty events such as large-scale loss of life from mass shootings are among the most concerning issues that health departments feel the least prepared to address. There is also concern that there remains a significant gap in the link between global health and domestic health – a gap that must continue to be paid attention to and be shored up.

7. The proposed bill, H.R. _, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2018, would expand the eligibility for the Hospital Preparedness Program beyond the current state and local grantees, how would this affect state and local public health emergency preparedness?

Expanding the eligibility for HPP is problematic. This is a program that has been cut by 50% over the last decade and is insufficiently funded to support the activities of current grantees and health care coalitions. Improving surge capacity, enhancing community and healthcare system preparedness, and implementing response actions is complex and requires state and local public health coordination. It is critical that public health continues to play this coordination role among the varied first responder and healthcare partners to ensure that the needs of the entire jurisdiction are met. SETRAC is a great asset to our community and surrounding counties.

8. How would the cybersecurity provisions in the proposed bill affect state and local health departments?

The bill highlights the importance of cybersecurity as part of national health security. As people use electronic health data more widely and increasingly rely on networked computer technology to deliver efficient healthcare and public health services, the need to protect public health information and public health infrastructure increases. A successful cyber-attack on public health information infrastructure could severely reduce both public health emergency responses and non-emergency public health functions. However, the Committee should be cautious in expanding the scope of PAHPA without the authorization of commensurate resources to carry out new activities and initiatives.

The manager's amendment adopted by the Health Subcommittee appropriately clarifies that the ASPR is the lead for continuity of health care in the event of a cybersecurity event and incorporates cybersecurity into the National Health Security Strategy.

9. What lessons did health departments learn from public health emergencies such as Zika and Hurricane Harvey? How can Congress improve state and local public health department efforts to respond to emergencies such as these?

Local health departments – including Harris County – have learned several lessons based on recent public health emergencies such as Zika and Hurricane Harvey. Public health requires a sustainable and long-term emergency public health funding source, and a sustainable capacity to plan for, train, exercise, and respond during emergency situations. Public Health is a first-responder during emergency situations and must be recognized as such. Public health has a large role in both public health and non-public health emergencies as either the lead or support role.

It should be noted that funding must reach the entirety of a community regardless of the jurisdictional line. For example, Harris County oversees mosquito control in the entirety of Harris County, including the city of Houston. However, the funding mechanism that was used to fund Zika-related response previously utilized a mechanism that essentially moved resources away from the very entity that was providing the mosquito control for Zika in our community. This has been a recurring issue and also one in play during Hurricane Harvey funding considerations. Ensuring that there is a focus on an "all-community" approach to funding is necessary and will most appropriately assure that such funding reaches both where the populations are located and the risks are in place.

Additionally, preparedness, response, and recovery requires the whole of a health department as well as the whole of the community (as above). Preparedness funding such as PHEP and HPP supports local health departments by helping build, train, and exercise with partners both internal to the health department (e.g., maternal and child health, environmental health), and external (e.g., public works, behavioral health, volunteers) so that all partners can respond effectively together. Congressional support for a public health emergency response fund and sustained investment in preparedness infrastructure are long-term keys to the promotion of public health for the nation.

10. Based on your experience with the Zika Response, could you describe how state and local public health departments were impacted by funding from the Public Health Emergency Preparedness (PHEP) cooperative agreement being redirected for the Zika response?

In 2016 during the Zika response, in the absence of supplemental funding CDC redirected $44 million in Public Health Emergency Preparedness funds from state and local health departments. NACCHO surveyed local health departments on the impact of the cuts to their preparedness programs and found that the cuts were disruptive impacting planning, staffing, exercising, and coordination with partners. It is also important for federal agencies to take an "all-community" approach so those dollars reach the entirety of a community based on population, bonafide risk, and/or actual response needs for all emergencies including those that have already occurred in a community (see above response to Zika funding in #9).

A standing rapid response fund to provide bridge funding between base preparedness funding and supplemental appropriations for acute emergencies and emerging threats is absolutely necessary. NACCHO appreciates that the bill strengthens existing authorities for the Public Health Emergency Fund (PHEF). However, there is concern about the 1% transfer authority to infuse the fund when a public health emergency is declared.

11. What types of coordination services did the South East Texas Regional Advisory Council (SETRAC) provide during hurricane Harvey?

SETRAC coordinated a wide arrange of medical activities including 1,544 patient movements, 24 hospital evacuations, and 20 nursing home evacuations. They established and coordinated ambulance staging areas (three ground assets and 2 air assets) and coordinated with the US Coast Guard Houston/Galveston Sector to run high acuity medical transfer. SETRAC provided mobile medical units into the area where healthcare services were unable to function, established an appointment/transportation process with dialysis centers, held daily conference calls with all hospitals and nursing homes in the region to provide situational awareness and mission priorities, managed surge capabilities in regional healthcare facilities, and coordinated across state lines (Louisiana/Texas) and through regulatory bodies to evacuate hospital and nursing home patients into Louisiana utilizing Louisiana EMS entering and practicing in Texas.

12. What is the impact of having an entity like SETRAC available during a disaster response?

SETRAC is a great asset to Harris County and the southeast Texas region. As the recipient of the HPP grant, they maintain constant communication and interaction with medical facilities and agencies and ensure they are prepared for any disaster response. They serve as the conduit between public health and hospitals, and respond directly to any medical needs during the response. They provide the professional and technical assistance and resources needed to address the complexities of the medical infrastructure and associated ancillary requirements and regulations.

13. How have funding cuts to the Hospital Preparedness Program (HPP) impacted local preparedness and response efforts?

Funding cuts have resulted in staffing reductions, forced staff to fill multiple roles and hindered the ability to maintain existing or build new partnerships between public health and the healthcare sector. It has also resulted in increased responsibilities for 16 other healthcare provider types that now fall under the new CMS EM rule. If funding were to commensurate with population, needs, and risk, SETRAC would be able to better maintain a basic level of preparedness through education, training, and exercising to address common issues such as surge capacity and disaster transfers.

As always, we remain ready alongside you to prepare and respond to ensure the health, security and well-being of our communities. Most importantly, thank you for your leadership in keeping our communities healthy and safe.

Sincerely,

Umair A. Shah, MD, MPH
Executive Director
Harris County Public HealtNACCHO Past-President

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health