Response of Dr. Steve Redd, Centers for Disease Control and Prevention,
to Questions for the Record:
June 6, 2018 hearing on the Pandemic and All Hazards Preparedness Act,
House Energy and Commerce Committee, Health Subcommittee

Rep. Bilirakis

Resiliency is vital to preparedness and ultimately response and recovery. The stockpile of drugs, vaccines, and other medical products and supplies, known as the Strategic National Stockpile is critical to our ability to respond and recover from catastrophic events. Reliable storage and delivery of these lifesaving medicines is also important in terms of patient safety and cost.

1. **In what ways is your agency working with industry to extend shelf life and improve resiliency of the Strategic National Stockpile?**

Response: Improving the resiliency of the Strategic National Stockpile by working with industry is a priority. CDC has engaged industry by forming partnerships with major industry trade associations specifically - Health Industry Distributors Association (HIDA), International Safety Equipment Association (ISEA), Healthcare Distribution Alliance (HDA), National Association of Chain Drug Stores (NACDS), and Healthcare Supply Chain Association (HSCA). These partnerships improve the resiliency of the Strategic National Stockpile through:

- Improved monitoring of commercial supply chain inventory and performance;
- Improved access to personal protective equipment (PPE);
- Improved public access to medical countermeasures; and
- Redundant distribution of medical countermeasures, information, and materiel.

The resiliency of the Strategic National Stockpile is closely linked to the resiliency of the commercial supply chain. Recognizing that private industry relies on accurate forecasting of demand when determining manufacturing priorities, CDC held three pre-solicitation conferences (or bidder conferences) for potential vendors and stakeholders in January 2018. These conferences, which focused on three requirements being developed for the SNS, were intended to improve the quality and accuracy of future requests for proposals in the requirement areas, as well as enabling the vendors to submit better proposals.

In addition to the important work done with private industry, CDC seeks to maximize the value of the SNS appropriation in collaboration with FDA through the Shelf Life Extension Program (SLEP). Some pharmaceuticals, if stored in accordance with the manufacturer's recommendations, may be viable beyond the manufacturer's labeled expiration date and allow for deferment of drug replacement costs. CDC works with FDA to test stability of drugs approaching labeled expiry through SLEP. If SLEP testing confirms that the product is viable and safe to use beyond the established expiration date, FDA will typically provide an additional 12 to 24 months of extended shelf life. For some products not eligible for the SLEP program, including biological products such as vaccines and immune globulins, SNS contracts with the manufacturers for annual potency testing to try to extend the shelf life of the stockpiled products.

Rep. Mullin:

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

    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?**

    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 anti-biotic and antimicrobial resistance?**

Defer to ASPR/BARDA

Rep. Carter:

1. **How can ASPR ensure that the transfer is not overly disruptive for state and local health departments?**

    Response: CDC has a 70-year history of working directly with public health agencies during public health responses as well as routine day-to-day operations, providing guidance, funding, and strategic direction for any public health threat. CDC will continue to work with state and local health departments to improve readiness to deploy SNS items by providing them with guidance, trainings, evaluation tools, performance metrics, and targeted technical assistance and subject matter expertise. Since 2004, CDC has provided dedicated medical countermeasure (MCM) funding via the Public Health Emergency Preparedness (PHEP) cooperative agreement to 72 of the largest metropolitan statistical area across the country— covering over 60% of the U.S. population. This funding supports the Cities Readiness Initiative, an initiative for these metropolitan areas to develop and exercise plans to rapidly dispense MCMs to their entire populations in response to large public health emergencies.

    The PHEP cooperative agreement sets requirements and standards for state and local public health preparedness and response programs. PHEP recipients develop and demonstrate operational capability across CDC's 15 public health preparedness capabilities critical for an effective public health response. MCM distribution and dispensing are two of the public health preparedness capabilities that must be integrated with the other 13 planning areas (including surveillance, responder safety and health, risk communication, public health emergency operations) to ensure a successful response. This work will continue after the SNS transfer.

    The Department is dedicated to improving the final distribution and dispensing of products contained in the SNS by providing robust operational support to states and locals. ASPR is working with CDC and other federal agencies to build upon the work CDC has done to date to continue to explore options.

    To ensure a smooth Strategic National Stockpile transition on October 1, 2018, with no degradation of operational capability, ASPR and CDC have set up several joint transition workgroups to evaluate and plan for all aspects of the program transition. CDC and ASPR also

have established a new senior CDC liaison who is working within the ASPR Immediate Office. CDC will continue to be a core member of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), which is led by ASPR and provides a venue for sharing information across HHS agencies with a role in medical countermeasures requirement setting, research, development, regulatory review, procurement, stockpiling, distribution and use. CDC subject matter experts will remain active participants in all PHEMCE workgroups and committees.

2. **This past year was a very serious flu season and we learned that the virus had not changed dramatically from the previous year. With a universal flu vaccine still years away, do you think that learning more about stopping the spread of infections in doctors' offices and hospitals would be a good step in reducing the impact of the flu and other serious communicable diseases?**

Response: Effective infection control and prevention practices require consistent and ongoing refresher training by the healthcare professional and the healthcare systems that they work in. Consistent infection control practices across all U.S. healthcare settings can help prevent future outbreaks of influenza/flu and other serious emerging infectious diseases like Ebola, MERS, and SARS. Since the 2014 Ebola outbreak, CDC has provided support to state health departments through the CDC Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement to perform infection control assessments and provide feedback and guidance to healthcare facilities across the country. CDC also provides educational resources, guidelines, and tools for healthcare professionals, healthcare facilities, and the public on CDC's infection control website: https://www.cdc.gov/infectioncontrol/index.html.
Healthcare-associated influenza infections can occur in any healthcare setting and are most common when influenza is also circulating in the community. Therefore, the influenza prevention measures outlined by CDC (https://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm) should be implemented in all healthcare settings. Supplemental measures may need to be implemented during influenza season if outbreaks of healthcare-associated influenza occur within certain facilities, such as long-term care facilities and hospitals. A combination of infection prevention and control strategies is recommended to decrease transmission of influenza viruses in healthcare settings. These include source control (immediately putting a surgical mask on patients being evaluated for respiratory symptoms), promptly placing suspected influenza patients in private rooms, ensuring that influenza vaccination is provided to all healthcare personnel, and having healthcare personnel wear personal protective equipment (PPE) when caring for patients with suspected influenza. Healthcare personnel should wear gloves, an isolation gown, and face protection (either a face shield, or eye protection and a mask) for entry into an influenza patient isolation room. A mask should be worn by infectious patients any time they leave the isolation room.

Through the CDC-funded Prevention EpiCenters Network, CDC collaborates with academic medical centers to address important scientific questions and find new ways to improve healthcare quality and patient safety. This work includes innovative research on preventing the transmission of viral and bacterial pathogens within healthcare settings, enhancing healthcare

worker safety, and understanding the role of the healthcare environment in disease transmission to further establish effective infection control strategies and novel interventions.

3. **The Ebola outbreak highlighted a successful public-private partnership between CDC and Emory University; all 4 patients that were treated in Emory's Serious Communicable Diseases Unit recovered from this highly contagious infectious disease. Building off this model partnership and the lessons learned by researchers and providers, would you be supportive of applying this knowledge to future pandemics that could affect thousands of Georgians like avian flu?**

   Response: CDC continues to learn from previous outbreak investigations and uses them to inform the science, data, and safe healthcare practices going forward. To prevent highly contagious infectious diseases and outbreaks from spreading widely, CDC works closely with state and local health departments, healthcare systems/facilities, and other state and local partners before, during and after an emergency to enhance infection control capacity and further identify gaps in infection control practices to help mitigate outbreaks, epidemics and pandemics in the future. CDC has also leveraged strategic partnerships with professional organizations, healthcare partners, and academic groups to provide infection control training to clinicians, patients and healthcare workers (HCWs) through live training events, web-based resources, webinars, conference calls, and mobile device apps. To better establish prevention strategies and improve infection control practices, CDC is supporting innovation and research through CDC cooperative agreements and collaboration via the CDC Prevention EpiCenters network and other professional groups. These groups continue to work with CDC to identify and validate infection control strategies and novel interventions that effectively prevent transmission of infectious viral or bacterial pathogens in healthcare settings.

   The linkages between CDC and Emory University, as well as with the University of Nebraska Medical Center and Bellevue Hospital Center, are effective public-private partnership models and have contributed to the development of the ten regional treatment facilities for Ebola and other highly infectious diseases to help prepare for future pandemics.

4. **The Hospital Preparedness Program is an important tool for our regional health care system preparedness. Emory University has been a recipient of funding to explore innovated ways to increase hospital readiness during local or national emergencies. In partnership with GA Tech, the have developed new tools including using virtual reality to keep healthcare workers trained and up to date on best practices to help improve patient outcomes and provider safety. Do you believe this program has been helpful in getting out nation more prepared for the next epidemic?**

   The $3 trillion healthcare delivery system in this country is a largely private sector, highly competitive enterprise. The Hospital Preparedness Program (HPP) helps to prepare the nation's health care system to save lives during emergencies and disasters by supporting the development of healthcare coalitions (HCCs) that facilitate collaboration before disaster strikes. It is the only source of Federal funding for health care system readiness. HCCs are groups of health care, emergency management and response organizations that collaborate to prepare for and respond to a large influx of injured or ill patients. HCCs incentivize diverse and often competitive health care organizations to work together.

HCCs have supported communities' health care systems—including hospitals, long term care facilities, emergency medical services agencies, public health departments and other health care partners. Specific to infectious disease preparedness, HPP used supplemental funding to establish a regional treatment network. This network balances geographic need and differences in institutional capabilities, and accounts for the potential risks of care. Through HHS investments, the U.S. health care system has achieved marked progress in the development of a regional network of tiered hospitals. HPP's collection and analysis of annual performance and impact data indicate that supplemental Ebola funding provided through the cooperative agreements has been instrumental in enhancing awardees' tactical facility- and system-wide capacity to respond to an Ebola-like threat. HPP's cooperative agreement funding strategy and performance measures for Ebola encouraged a rapid buildup of key response capabilities at each facility tier. HPP requires awardees to engage in operational planning, tactical coordination across states and regions, workforce training, intentional purchase of necessary equipment, and exercises that promote skill-building. From the purchase of personal protective equipment (PPE) by facilities on the frontline to acquiring incinerators to handle contaminated waste at regional Ebola and other special pathogen treatment centers, hospitals at each tier used HPP's year-one funds to purchase equipment and infrastructure required to fulfill their response roles moving forward. Also in the initial funding year, nearly 7,000 rostered staff in the Ebola treatment centers and regional Ebola and other special pathogen treatment center tiers were pre-identified and trained to provide Ebola patient care. Most importantly, the regional treatment network practiced its ability to activate improved response capabilities in each region; 100 percent of regional Ebola and other special pathogen treatment centers conducted quarterly exercises that incorporated unannounced first-person drills, patient transport, and patient care simulation. It is important to note that while the initial focus was on preparedness for Ebola, it is likely that preparedness for other novel, highly pathogenic diseases has also been enhanced through these Ebola preparedness grants.

As of June 30, 2017 (the most recent data available), over 31,000 health care facilities and community organizations were participating in 476 HCCs nationwide. This is an increase in HCC membership of 92 percent since June 2012. The diverse membership of HCCs also contributes to their success in preparing a community to respond to a wide variety of incidents that impact public health. Medical evaluation and treatment of incident victims require coordinated activities that extend beyond hands-on medical care. By building and sustaining HCCs, information can be collected, analyzed, and managed to support rapid patient distribution to appropriate facilities, patient tracking, family support, information coordination, and resource and transportation management. HCCs also disseminate knowledge of the range of injury and illness to inform response and timely requests for additional resources. The coordination processes and health care capabilities promoted by HPP's coalitions are designed to limit community morbidity and mortality after exposure to a hazard.

Rep. Pallone:

The Strategic National Stockpile (SNS) is a key line of defense against natural and manmade threats. The SNS is not just a stockpile of medications, antidotes, and medical supplies, but also consists of logistical infrastructure capable of deploying products in the event of a public health emergency. The proposed bill, H.R. ___, the Pandemic All-Hazards Preparedness Reauthorization Act of 2018 would transfer the SNS to ASPR from the Centers for Disease Control (CDC), expand the role of ASPR in responding to public health emergencies and our national response. The

transfer of the Strategic National Stockpile (SNS) from the Centers for Disease Control (CDC) and Prevention to the Assistant Secretary for Preparedness and Response (ASPR) raises a number of concerns about the stability and coordination of the SNS and ultimately, how the departmental changes could affect our national readiness and ability to respond to a public health emergency.

1. **Please describe the CDC's past role in leading the SNS, the range and type of deployments and the types of products the CDC has delivered through the SNS program?**

   Response: The SNS (formerly the National Pharmaceutical Stockpile) has an established record of responsible, scientifically informed product stewardship and a history of successful deployments of products since 1999. The first deployment from the SNS was completed in 2001, deploying portable mechanical ventilators to Houston in support of patients displaced by flooding related to Tropical Storm Allison. In response to the 9/11 attacks CDC deployed large quantities of personal protective equipment and 12 hour push packages of broad spectrum supplies for mass casualty treatment. Following the Anthrax attacks CDC deployed large quantities of treatment and prophylaxis countermeasures for individuals exposed to Anthrax. Since these initial deployments in 2001, CDC has directed more than 100 deployments of SNS supplies, including the largest deployment of medical countermeasures ever in response to the 2009 H1N1 pandemic. In addition, CDC has close, ongoing relationships with state and local health departments, broad clinical expertise, and deep laboratory capacity has been able to direct many SNS small scale deployments of life-saving products for treatment of botulism, anthrax exposures, and for complications of vaccinia (smallpox) vaccination, for which the SNS holds the nation's primary or only supply of approved treatments. These day-to-day emergency deployments ensure that systems and relationships are in place and ready to go when larger scale responses are required. Federal Medical Station sets or FMS sets are another asset CDC frequently deploys in hurricane responses. These FMS sets support the Office of the Assistant Secretary for Preparedness and Response's (ASPR) National Disaster Medical System (NDMS) teams and other trained medical staff involved in augmenting public health and medical needs in communities impacted by disaster. Each FMS set is comprised of medical supplies and pharmaceuticals sufficient to stand up a low acuity healthcare facility in open structures such as arenas, aircraft hangers or empty retail space. Each FMS set can provide a platform for NDMS and other trained medical staff to care for up to 250 patients with non-surgical healthcare needs for up to 3 days without resupply. These FMS sets were first deployed in response to Hurricane Katrina. Since their initial deployment, FMS sets have been used extensively to support the response to hurricanes, flooding and other natural disasters. FMS sets were most recently deployed in response to the 2017 Hurricanes Harvey, Irma, and Maria.

2. **How does CDC assist state and local health departments with the "last mile" deployment of SNS items in the event of a public health emergency?**

   Response: CDC works with state and local health departments to improve readiness to deploy SNS items by providing them with guidance, trainings, evaluation tools, performance metrics, and targeted technical assistance and subject matter expertise. Since 2004, CDC has provided dedicated medical countermeasure (MCM) funding via the Public Health Emergency Preparedness (PHEP) cooperative agreement to 72 of the largest metropolitan statistical area across the country— comprising approximately 60 percent of the U.S. population. This funding supports the Cities Readiness Initiative, an initiative for these metropolitan areas to develop and

exercise plans to rapidly dispense MCMs to their entire populations in response to large public health emergencies. The PHEP cooperative agreement sets requirements and standards for state and local public health preparedness and response programs. PHEP recipients must develop and demonstrate operational capability across CDC's 15 public health preparedness capabilities critical for an effective public health response. MCM distribution and dispensing are two of the public health preparedness capabilities that must be integrated with the other 13 planning areas (including surveillance, responder safety and health, risk communication, public health emergency operations) to ensure a successful response. This work will continue after the SNS transfer.

CDC also assesses state and local public health MCM programs through an Operational Readiness Review. CDC analyzes the Operational Readiness Review data to determine state and local MCM gaps and strengths, develops strategies for improvement, and works closely with state and local health departments to implement jurisdictional improvement plans.

CDC provides a variety of MCM trainings to improve state and local dispensing capabilities. Trainings range from monthly webinars to in-person point-of-dispensing training courses. CDC also has dedicated regional MCM field staff who work directly with 16 high-risk Urban Areas Security Initiative (UASI) cities to improve readiness for release of a Category A agent (Anthrax, Botulism, Plague, Smallpox, Tularemia, Viral hemorrhagic fever, pandemic influenza) and to provide assistance to other jurisdictions upon request. CDC works with PHEP awardees to identify potential state and local surge personnel solutions for MCM dispensing operations.

CDC will continue its direct day-to-day support of state, tribal, local and territorial jurisdictions in the planning and execution of MCM dispensing "last mile" activities. In addition to the funding, technical assistance, operational assessments and training described above, CDC provides expertise to ensure SNS assets are used in the best way possible. These activities, which are specific to and supported by the SNS, augment the "last mile" of a MCM response. Specifically:

- Scientific Research – CDC research seeks to optimize the effectiveness and use of SNS MCMs for smallpox, anthrax and other threat agents in a public health emergency. As one of only two laboratories in the world authorized to work with Variola, the virus that causes smallpox, CDC's high containment laboratory is the only place where smallpox research activities can be conducted.
- Operational Research and Tools- CDC conducts operational research to inform jurisdictions on how to best leverage private sector partnerships (for example with retail pharmacy partners) to augment their MCM dispensing activities, and has developed novel tools to support and augment state and local MCM access, dispensing, and medication compliance tracking.
- Surveillance - CDC's surveillance and epidemiological activities help identify when a threat happens and assess the impact. This helps to define the population that needs to receive SNS MCMs during a response.
- Lab –CDC's laboratory expertise provides surge capacity to better detect and identify a threat and to ensure that the MCMs released from the SNS are effective against the pathogen.

- Clinical Guidance - CDC develops and publishes clinical guidance and clinical tools to inform the use of SNS MCMs in all segments of the population, including the pediatric and other vulnerable populations.
- Regulatory Mechanisms - CDC works with FDA to develop and maintain the necessary regulatory mechanisms to allow for the safe and effective use of SNS MCMs. In addition, CDC assists in the development of post-marketing data collection required by FDA for certain MCMs.
- Communication – CDC is the trusted source for public health information every day and during responses. CDC is also the trusted source for the clinical community – this ensures that clinicians and the public trust and are willing to use the recommended SNS MCMs at the time of an event and in planning for an event.

In addition, CDC and ASPR are working closely with other senior leaders across government to develop federal solutions for specific strategies for improving MCM dispensing and distribution. Efforts are focused specifically on how the federal government can help states, localities, and territories with their MCM mission.

3. **What training programs does the CDC sponsor are funded through the SNS program? Will the funding from SNS continue to be used to pay for training activities?**

Response: CDC, through the Public Health Emergency Preparedness Cooperative Agreement, provides substantial training to prepare Federal, state, and local partners for effective response to public health emergencies. CDC provides MCM training to improve state and local dispensing capabilities. Trainings range from monthly webinars to in-person point-of-dispensing training courses. CDC also has dedicated regional MCM field staff who work directly with 16 high-risk Urban Areas Security Initiative (UASI) cities to improve readiness for release of a Category A agent (Anthrax, Botulism, Plague, Smallpox, Tularemia, Viral hemorrhagic fever, pandemic influenza) and to provide assistance to other jurisdictions upon request. CDC works with state and local health departments to identify surge personnel solutions for MCM dispensing operations. Training by CDC will continue after the SNS transitions to ASPR, with details currently under discussion between CDC and ASPR.

4. **The President's FY 2019 budget requested the transfer of the SNS from the CDC to ASPR. What is the main motivation behind the transfer of the SNS?**

At a time when the U.S. threat environment is becoming more complex and dangerous, the transition of the SNS to ASPR will strengthen and streamline the medical countermeasures enterprise and leverage synergies in supply chain logistics.

ASPR was established in 2006; the CDC first received appropriations to support the SNS in 1998, before ASPR was authorized. Operational authority for the SNS was subsequently split between HHS and DHS, but it was unified at HHS in 2004 and maintained in CDC. While placing the SNS at CDC made historical sense, the creation and maturation of ASPR provides an opportunity to align the direct oversight and management of SNS under ASPR.

When disasters occur, ASPR leads the National Response Framework, Emergency Support Function #8 as delegated by the Secretary, thereby coordinating Federal public health and medical responses, including assets from CDC as well as contents of the SNS.

ASPR has a robust medical logistics capability that supports the National Disaster Medical System (NDMS), moving medical personnel, equipment, and supplies across the nation within hours. ASPR works closely with state and local emergency management professionals, clinicians, healthcare facilities, and NDMS response teams who may be called upon to dispense SNS medical products. Shifting operational control of the SNS to ASPR, while continuing to leverage CDC's leadership role with public health agencies, will consolidate emergency response materiel under a single entity and improve the distribution during emergencies.

In addition, making this change will strengthen and streamline the entire medical countermeasures (MCM) enterprise. ASPR leads the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which includes senior representatives from all agencies involved in the medical countermeasures enterprise. The PHEMCE oversees setting MCM requirements, developing and procuring new products through the Biomedical Advanced Research and Development Agency (BARDA) and Project BioShield. Congress established BARDA and Project BioShield to encourage companies to develop medical countermeasures the government needs to keep Americans safe from national security threats, by creating a government market where there is usually not a commercial incentive and to enable public-private partnerships for such advanced research and development.

When MCMs for DHS-identified national security threats are in late stage development, BARDA can procure them using the Project BioShield Special Reserve Fund. After these MCMs are approved or licensed by FDA, procurement responsibility may then shift to SNS.

Having the right MCM is one part of the PHEMCE mission. To ensure that the use of MCMs continues to be coordinated with public health and disease threat experts, CDC will continue to play an important role in PHEMCE activities. In addition to participating in setting requirements as part of the PHEMCE interagency, CDC leads public health surveillance, epidemiologic, and laboratory investigation needed to know when a threat happens, who is impacted, and what MCMs to use. CDC also provides clinical guidance to ensure that clinicians and the public know how to use SNS MCMs, and leads and coordinates with state and local public health partners. These activities, along with CDC risk and health communications, will continue to support PHEMCE efforts to ensure the optimal use of SNS assets.

5. **What issues may be solved by this move and what challenges may be created by transferring the SNS from the CDC to ASPR?**

   Response: Transferring SNS from CDC to ASPR will increase operational effectiveness and efficiencies around the development and procurement of medical countermeasures, and enable nimble responses to public health emergencies.

   To ensure a smooth SNS transition with no degradation of operational capability, CDC and ASPR have set up several joint transition workgroups to evaluate all aspects of the program transition. The transition workgroups are devoting substantial effort to issues such as: 1) ensuring that CDC subject matter expertise continues to be involved in SNS work, especially developing guidance on when and how to use medical countermeasures in the SNS, including regulatory support; 2) ensuring that the interests of state and local health departments continue to be represented in SNS planning and operations; and 3) coordination in the distribution and dispensing of MCM.

6. **How will moving the SNS from CDC to ASPR affect programs that support the SNS and are run by CDC, such as the Public Health Emergency Preparedness (PHEP) awards, which support state and local capacity to receive, distribute and dispense medical countermeasures (MCMs)?**

Response: Ensuring ongoing successful utilization of SNS assets will require CDC's continued ability to provide, in a collaborative and transparent fashion, its expertise in the scientific, clinical, regulatory, laboratory, and state, tribal, local and territorial response coordination (including MCM distribution and dispensing) matters that are a critical part of this mission. SNS transition details are currently under discussion between CDC and ASPR.

CDC will continue to provide subject matter expertise in SNS MCM issues and in the decision-making process. SNS funding supports a portion of the PHEP program's MCM planning work. PHEP recipients must develop and demonstrate operational capability across CDC's 15 public health preparedness capabilities critical for an effective public health response. Two of these capabilities are contained within the Countermeasures and Mitigation domain, and relate to distribution and dispensing of MCMs. PHEP project officers are assigned to specific state and local jurisdictions to support their work in advancing the public health preparedness capabilities the jurisdiction considers priorities. In addition, regional project officers based in the field work directly with 16 high-risk Urban Areas Security Initiative (UASI) jurisdictions to improve readiness for release of anthrax or other Category A agents and provide assistance to other jurisdictions upon request. CDC will continue MCM work after the SNS is transferred to ASPR, with additional details currently under discussion between CDC and ASPR.

Beyond the PHEP grants, CDC provides expertise in multiple areas to ensure SNS assets are used in the best way possible. These activities are specific to, and supported by, the SNS program. Specifically:

- State, Local, Tribal, Territorial (SLTT) Coordination – CDC has over 70 years of experience working with STLT partners. CDC will continue its direct day-to-day support of SLTT jurisdictions in the planning and execution of MCM dispensing, as an integrated part of overall response capabilities that include epidemiologic and laboratory surveillance, communication strategies, and non-pharmaceutical interventions at the federal, state and local levels. CDC also routinely assesses state, local and territorial plans, with an emphasis on state and local operational response readiness; conducts operational research to inform jurisdictions on how to best leverage private sector partnerships (for example with retail pharmacy partners) to augment their MCM dispensing activities; and has developed novel tools to support and augment state and local medical countermeasure access, dispensing, and medication compliance tracking.
- Research – CDC research seeks to optimize the effectiveness and use of SNS MCMs for smallpox, anthrax and other threat agents in a public health emergency. As one of only two laboratories in the world authorized to work with Variola, the virus that causes smallpox, CDC's high containment laboratory is the only place where smallpox research activities can be conducted.
- Surveillance - CDC's surveillance and epidemiological activities help identify when a threat happens and assess the impact. This helps to define the population that needs to receive SNS MCMs during a response.

- Lab –CDC's laboratory expertise provides surge capacity to better detect and identify a threat and to ensure that the MCMs released from the SNS are effective against the pathogen.
- Clinical Guidance - CDC develops and publishes clinical guidance and clinical tools to inform the use of SNS MCMs in all segments of the population, including the pediatric and other vulnerable populations.
- Regulatory Mechanisms - CDC works with FDA to develop and to implement the necessary regulatory mechanisms for the safe and effective use of SNS MCMs. These critical activities include supporting emergency use of MCMs that are not yet FDA approved and the use of approved MCMs for unapproved indications through protocols in applications for Investigational New Drug (INDs), Emergency Use Authorizations (EUAs), and Emergency Use Instructions (EUIs), as appropriate. In addition, CDC assists in the development of post-marketing data collection required by FDA for certain MCMs.
- Communication – CDC is the trusted source for public health information every day and during responses. CDC is also the trusted source for the clinical community – this ensures that clinicians and the public trust and are willing to use the recommended SNS MCMs at the time of an event and in planning for an event.

7. How does the CDC and ASPR currently coordinate?

Response: CDC and ASPR have strong working relationships and will continue to collaborate closely to ensure that the expertise and resources of both agencies are most effectively leveraged to protect the health of the American people. CDC is part of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which defines and prioritizes requirements for public health emergency medical countermeasures. Created by HHS in 2006, PHEMCE is an interagency effort led by the ASPR to coordinate the research, development, procurement, and preparation for the effective utilization of medical countermeasures among the civilian population. CDC consults with ASPR on strategic policy decisions during a Public Health Emergency, such as deployment of SNS assets. SNS MCM needs are specific to the incident and the jurisdictional request, with the goal of protecting and saving lives. CDC and ASPR also work together on the Public Health Emergency Preparedness Program (PHEP) and the Hospital Preparedness Program (HPP) to support state and local jurisdictions during emergency responses.

8. What plan does the CDC and ASPR have to ensure PHEP-supported health departments continue coordination after the transfer of the SNS?

Response: CDC will continue to provide subject matter expertise in SNS MCM issues and in the decision-making process. SNS funding supports a portion of the PHEP program's MCM planning work. PHEP project officers are assigned to specific state and local jurisdictions to support their work in advancing the public health preparedness capabilities the jurisdiction considers priorities. In addition, regional project officers based in the field work directly with 16 high-risk Urban Areas Security Initiative (UASI) jurisdictions to improve readiness for release of anthrax or other Category A agents and provide assistance to other jurisdictions upon request. CDC is committed to continuing, to the maximum extent possible, its support of the overall MCM mission, which includes state and local capacity to receive, distribute, and dispense MCMs. This will ensure support to health departments after the transfer of the SNS.

ASPR and CDC have convened five working groups to oversee the details of the SNS transfer. One of those groups focuses on state and local coordination.

In addition, CDC and ASPR are working closely with other senior leaders across government to develop federal solutions for five specific strategies for improving MCM dispensing and distribution. Strategies include federal support for staffing, distribution support, residential delivery strategies, national partnerships with the private sector, and pre-positioning federal caches within several high-risk jurisdictions. Efforts are focused specifically on how the federal government can help states, localities, and territories with their MCM mission.

9. How does the CDC currently coordinate with state and local health departments? How will this relationship with state and local health departments continue if the SNS is transferred to ASPR?

Response: Since its creation, CDC has established strong relationships with state, tribal, local and territorial health officials and funded them to build and improve capacity, and therefore agency performance, agility and resilience in providing public health services. Whether through programs focused on obesity, environmental health, the opioid crisis, emergency preparedness, influenza, childhood immunization or heart disease, CDC support strengthens public health programs that state, tribal, local and territorial public health officials operate on a daily basis and their ability to effectively prepare for and respond to emergency situations. And, the established foundation of trust and personal relationships, avenues of communication and collaboration, and body of agency knowledge built over time with jurisdictions helps inform CDC's assistance every day and during emergencies. This support will continue after the SNS transfer.

As to the SNS, CDC provides expertise in multiple areas and coordination directly with state and local health departments to ensure SNS assets are used in the best way possible. Specifically:

- State, Tribal, Local and Territorial Coordination – The PHEP cooperative agreement sets requirements and standards for state and local public health preparedness and response programs. PHEP recipients must develop and demonstrate operational capability across CDC's 15 public health preparedness capabilities critical for an effective public health response including distribution and dispensing. CDC will continue its direct day-to-day support of STL jurisdictions in the planning and execution of MCM dispensing, as an integrated part of overall response capabilities that include epidemiologic and laboratory surveillance, communication strategies, and non-pharmaceutical interventions at the federal, state and local levels. CDC also routinely assesses state, local and territorial plans, with an emphasis on state and local operational response readiness. CDC also conducts operational research to inform jurisdictions on how to best leverage private sector partnerships (for example with retail pharmacy partners) to augment their MCM dispensing activities, and has developed novel tools to support and augment state and local medical MCM access, dispensing, and medication compliance tracking.
- Surveillance - CDC's surveillance and epidemiological activities in coordination with state and local partners help identify when a threat happens and assess the impact. This helps to define the population that needs to receive SNS MCMs during a response.
- Lab –CDC's laboratory expertise provides surge capacity for state and local health departments to better detect and identify a threat and to ensure that the MCMs released from the SNS are effective against the pathogen.

- Clinical Guidance - CDC develops and publishes clinical guidance and clinical tools to inform the use of SNS MCMs in all segments of the population, including the pediatric and other vulnerable populations.
- Communication – CDC is the trusted source for public health information every day and during responses. CDC is also the trusted source for the clinical community – this ensures that clinicians and the public trust and are willing to use the recommended SNS MCMs at the time of an event and in planning for an event.

10. Please describe how state and local public health departments were impacted by funding from the PHEP cooperative agreement being redirected for the Zika response?

Response: During the Zika response, $44.25 million in PHEP funding was redirected in March 2016 to support Zika response activities. This redirection impacted state and local staffing. After the funding was restored through a supplemental appropriation from Congress, some jurisdictions reported that they were not always able to rehire the staff or find new staff with similar expertise and preparedness experience.

11. In the opinion of CDC, could state and local health departments maintain operations and staffing if currently funding was cut or delayed?

Response: CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement funds 62 state, local, and territorial public health departments to create response-ready public health departments. PHEP funds support staff, enable exercises, provide for training, pay for equipment, and provide other services essential to maintaining preparedness for and readiness to respond to a public health emergency. CDC provides ongoing technical assistance to PHEP awardees and, at times, provides on-the-ground personnel to assist with a state`s response effort.

Funding cuts to PHEP would likely result in decreased awards to states, localities, and territories. Such reductions could lead to staff layoffs at the state and local levels, which could include public health emergency managers, laboratorians, epidemiologists, public health nurses, and risk/health communicators. Such reductions could also affect activities and functional areas, including:

- Training
- Developing plans and conducting exercises
- Purchasing and maintaining equipment and supplies
- Coordinating with partners
- Conducting community outreach and public engagement sessions

12. When funding cuts or delays occur, how does that impact the ability of state and local health departments to respond to public health emergencies?

Response: State and local health departments rely on the PHEP cooperative agreements to plan, train, and prepare for emergencies so that when disasters strike communities are prepared. Inconsistency in funding could lead to delays in hiring and procurement, and staff layoffs. Funding reductions could also erode an established state and local network of expertise, relationships, and trust built over time through shared responses, training, and exercises.

Funding cuts also could reduce CDC's activities that support state and local preparedness, such as:

- consultation to awardees
- placement of field staff in jurisdictions to address unmet state and local needs
- CDC monitoring and evaluation of awardees
- CDC support for medical countermeasure planning to ensure state and local health departments can distribute and dispense essential supplies during a public health emergency