

Questions for the Record

Robert Kadlec, MD

**U.S. Department of Health and Human Services
Assistant Secretary for Preparedness and Response**

House Energy and Commerce Subcommittee on Health

“Reauthorizing the Pandemic and All-Hazards Preparedness Act”

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Rep. Burgess:

- 1) It is my understanding that HHS established a goal to provide domestic manufacturing surge capacity that makes first doses of pandemic influenza vaccine available within 12 weeks of a pandemic declaration. This goal was profiled in HHA’s 2017 Pandemic Update and HHS investments to achieve this goal go back at least to 2011. Have HHS and private sector investments yield that capacity? Does HHS maintain this timeline as a goal?**

Rapid, large scale domestic manufacturing capacity for pandemic influenza vaccines is a critical component of pandemic preparedness to make vaccine available for everyone as soon as possible after emergence of a pandemic virus. Using previous supplemental appropriations, ASPR, through BARDA, has made significant gains in pandemic influenza vaccine preparedness over the last 10 years. For example, BARDA’s partnerships with industry have led to the licensure of faster, more flexible cell-based, recombinant and adjuvanted influenza vaccines, as well as modernized and expanded domestic manufacturing capabilities. Specifically, these partnerships have increased domestic influenza vaccine projected manufacturing capacity – from 60 million dose capacity a decade ago to up to 600 million bulk antigen dose capacity, which can now be produced within 6 months after a decision is made to begin large scale manufacturing. However projected timelines for vaccine (finished product) availability depend on many factors, including manufacturing yields and fill/finish capacity.

Building on these successes, and to ensure vaccine is available within 12 weeks of a pandemic declaration, BARDA has established a multifaceted strategy.

- First BARDA is partnering with companies to support the development of novel technologies that rely less on viral growth properties (e.g. eggs) to improve the speed and robustness of vaccine production. For example, BARDA supported the development of the first FDA licensed recombinant influenza vaccine (Flublok®, manufactured by Protein Sciences), and BARDA continues to fund other recombinant vaccine-related technologies, moving away from the production of vaccine in eggs.

- Second, BARDA is supporting domestic production capabilities to ensure vaccines are available for everyone across the country if necessary.
- Third, BARDA is supporting further development of recombinant and cell-based vaccines through comparative efficacy clinical studies to demonstrate and validate the expand use indications of these vaccines for a broad range of high-risk and vulnerable populations.
- Fourth, BARDA is continuing to improve adjuvant capabilities and capacity which is crucial for a rapid response. BARDA continues to support efforts to obtain licensure and expand the approved age ranges for influenza adjuvanted vaccines. In addition, BARDA is supporting development of new adjuvants for pandemic influenza vaccines that will have improved characteristics, such as improved effectiveness, decreased sustainability costs, or are faster to produce, and could also improve seasonal vaccine efficacy.

2) As biological threats arise internationally, it creates a domestic risk and surveillance is necessary in the United States to provide a warning and an opportunity for an early intervention to prevent the transmission of disease. Is there a mechanism to detect infected persons entering the country that may be a risk? What authorities and protocols does ASPR, in coordination with CDC have to detect and detain infected patients?

Early warning and detection of an infectious disease entering a community is critical for mounting a rapid, effective response. ASPR relies heavily on other parts of HHS and the federal government, such as CDC and Department of Homeland Security, to provide this early warning.

Under the Public Health Service Act (42 U.S.C. 264) and regulations at 42 CFR parts 70 and 71, CDC's Division of Global Migration and Quarantine (DGMQ) has broad authority to undertake public health measures to prevent the introduction, transmission, and spread of communicable disease into and within the United States. DGMQ uses a number of risk mitigation strategies to address public health risks posed by ill travelers entering the United States, such as:

- With federal and local partners, evaluating sick travelers arriving at US Ports of Entry and, when necessary, doing contact investigations to determine if public health follow-up is required for ill and for exposed travelers
 - For example, the Ebola entry risk assessment and risk management program evaluated all travelers arriving from countries with Ebola outbreaks in West Africa during 2014-2016.
- Regulatory requirements for airlines and other conveyances coming to the United States to report travelers (passengers or crew) with certain signs and symptoms of illness and deaths.
- If an individual presents at a port of entry and is known to be infected with, or suspected of having been exposed to, a communicable disease for which federal public health orders are authorized, by statute CDC may apprehend, detain (i.e.

isolate or quarantine), or conditionally release individuals to prevent introduction, transmission, or spread.

- This list of diseases is provided by Executive Order of the President (Executive Order 13295: Quarantinable Communicable Diseases April 4, 2003, amended by 13375 on April 1, 2005 and by 13674 on July 31, 2014).
- CDC strives to use the least restrictive means to achieve public health goals, and generally individuals voluntarily comply with public health recommendations for further medical assessment or movement restrictions, so issuance of federal public health orders are rare.

CDC and the Department of Homeland Security (DHS) operate the Public Health Do Not Board/Border Lookout tool. If an individual meets certain criteria, CDC works with DHS Transportation Security Administration (TSA) to include the individual on the Do Not Board list, which prevents an individual who presents a public health risk during travel from being able to obtain a boarding pass for air travel to or from the United States. Simultaneously, a Border Lookout record is created with DHS Customs and Border Protection (CBP) to prevent an individual from trying to enter the United States via land or sea.

Rep. Bilirakis:

- 1) As I mentioned in my opening statement, Florida is bracing for the “next big one” each hurricane season and its implications—especially with significant population growth over the last few years, a sizable portion aged 55 and older. Disaster Medical Assistance Teams (DMATs) are tremendously important to states like mine because medical care stemming from disasters can quickly overwhelm our healthcare system. To what extent does ASPR ensure that DMAT members are mission-ready?**

DMATs are a component of ASPR’s National Disaster Medical System (NDMS). ASPR ensures all DMAT members have up to date credentials. This year, ASPR began increasing the training provided to NDMS members – increasing frequency of training for personnel from once every five years to once every three years, and ensuring the training they receive includes information on treating chemical, biological, radiological and nuclear injuries. In addition, when DMAT teams are activated for national special security events, such as the State of the Union, Peace Officer Memorial, or 4th of July celebration, they participate in just-in-time trainings to refresh skills.

Specific NDMS training includes DMAT 101 and DMAT 201. DMAT 101 provides training and practice on fundamental knowledge and skills to ensure NDMS personnel are able to provide basic healthcare needs to a community impacted by disaster. Specifically, the course includes basic training on use of equipment (e.g. ventilators, defibrillators, etc.), providing a controlled environment where personnel are able to practice with equipment that is configured and organized as it would be deployed during a public health and medical emergency.

In DMAT 201, teams simulate a deployment and are required to set up their Base of Operations (Western Shelter canvas tent and supporting components to include ventilation system, water purification system, generator power, etc.) while simultaneously providing care to patients using only the equipment and supplies that would be deployed with them during an actual event. This training requires the team to function independently, similar to how they operate on an actual deployment.

1.b) Last season, DMATs experience a staffing shortage. What barriers still exist to filling this gap and does this bill provide ASPR with the necessary authority to address this challenge?

The standard U.S. government hiring process, to which NDMS is subject, takes an estimated 6-9 months from start to finish. The Bipartisan Budget Act of 2018 provided NDMS with 270 days of direct hiring authority. Direct hire authority means the usual hiring process can be expedited – reducing the 6-9 month timeline significantly.

Using this direct hire authority, NDMS is working to fill as many vacancies as possible before the authority expires in November, 2018. Currently, there are approximately 4000 vacancies within the NDMS system. ASPR projects 1000 vacancies will be filled by November, leaving 3000 vacancies. Included in the Department's PAHPA reauthorization technical assistance was a request for direct hire authority for a one to two year period to ensure NDMS is fully staffed and ready for future public health emergencies. The bill introduced in the House for PAHPA reauthorization includes direct hire authority for three years (expiring September 30, 2021).

1.c) What barriers still exist for recruiting the best medical professionals into DMATs?

NDMS personnel deploy and support public health and medical emergencies side-by-side other responders. Currently, NDMS personnel are not eligible for death benefits paid out through the Public Safety Officer Benefit (PSOB) Program, yet other responders, like FEMA personnel, are eligible should they die while supporting a response operation. Limiting coverage for NDMS personnel may have impacted recruitment and retention for NDMS.

Included in the Department's PAHPA reauthorization technical assistance was a request to align NDMS benefits with the same coverage afforded to other federal responders under the PSOB Act. Expanding this program to include NDMS personnel could support recruitment and retention of qualified personnel. The bill introduced in the House for PAHPA reauthorization includes PSOB coverage for NDMS personnel.

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

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?**

Included in the Department's PAHPA reauthorization technical assistance was a request to authorize a 10 year advance appropriation for the Project BioShield Special Reserve

Fund, consistent with the FY 2018 Addendum to the President's Budget, which supports advanced development and initial procurement of medical countermeasures, which often have no commercial market.

BARDA utilizes many of the innovative authorities authorized by the Pandemic and All-Hazards Preparedness Act of 2006 to support advanced development of medical countermeasures. Authorities like Other Transaction Authorities mean BARDA can enter into innovative, more flexible agreements with companies. In addition, direct hire authority allows BARDA to recruit and hire personnel with the specific expertise to ensure medical countermeasure development initiatives are efficient and scientifically sound.

1.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?

BARDA has utilized its authority to establish flexible Other Transaction Authority (OTA) agreements with companies for portfolios of products to address many threats, including antimicrobial resistant pathogens. The first BARDA OTA agreement was within the broad spectrum antimicrobial program and currently three out of six BARDA OTA agreements are focused on development of antimicrobial products. BARDA has also utilized CARB-X – an innovative public-private partnership – to address the threat of antibiotic resistant bacteria. CARB-X involves seven partners in the U.S. and U.K. and is backed with \$500 million in funding from several different organizations. In addition, CARB-X funded companies have been able to leverage that investment to secure significant additional private equity funding. A total of \$70 million in BARDA CARB-X investment resulted in nearly \$500 million in private equity follow on investment. The partnership has 28 different companies making novel antibacterial drugs, vaccines, and diagnostics, including eight new classes of antibiotics.

Existing statutory authorities do not prevent BARDA from working with companies to develop medical countermeasures to counter the increasing threat of antibiotic/antimicrobial resistant pathogens.

1.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?

Existing statutory authorities do not prevent BARDA from working with companies to develop medical countermeasures to counter the increasing threat of antibiotic/antimicrobial resistant pathogens.

Rep. Carter

- 1) I recently met with Dr. Redfield and am very confident in his leadership and the work of all the experts at the CDC. Given their deep technical knowledge and expertise, how will you ensure that the CDC experts have the opportunity to stay involved in medical countermeasure development and employment after the Strategic National Stockpile (SNS) is moved to ASPR in October? How will you continue to engage CDC state-based mechanisms in this process and ensure that the transfer is not overly disruptive for state and local agencies?**

ASPR recognizes and appreciates the tremendous expertise of CDC subject matter experts including on infectious diseases, other public health threats, epidemiological surveillance, as well as working directly with state and local public health departments. To increase collaboration between ASPR and CDC, ASPR has invited and instituted a new senior CDC liaison who is working within the ASPR Immediate Office.

CDC is 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 Federal agencies with a role in medical countermeasures requirement setting, research, development, regulatory review, procurement, stockpiling, distribution and use. CDC subject matter experts will remain an active participant in all PHEMCE workgroups and committees.

In order 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. We would be pleased to provide a full briefing for your staff at any time before the end of the fiscal year.

There will be no changes to the CDC's relationship with state and local public health agencies. Additional transition details are still under discussion between CDC and ASPR.

ASPR is dedicated to improving federal support in the final distribution and dispensing of products contained in the SNS by providing robust operational support to states and locals.

- 2) Your extensive experience has given you a rare look into the classified threat assessments facing our country. Do you think the United States government is doing enough to prevent and mitigate the threat of a biologic attack here at home or to our key interests abroad? In your view, will the reforms laid out in this reauthorization bill work to improve the biodefense enterprise?**

ASPR believes more can be done to prevent and mitigate the threat of biological as well as chemical and radiological threats here at home. As outlined in the Administration's technical assistance with respect to reauthorization of PAHPA, encouraging ASPR to coordinate with the Director of National Intelligence and Department of Homeland Security to assess current national security threats would further strengthen our emergency preparedness and response framework. ASPR's priorities for building readiness for 21st century health security threats are:

1. Providing strong leadership,
2. Building a regional disaster health response system,
3. Sustaining robust and reliable public health security capabilities, and
4. Advancing an innovative medical countermeasures enterprise.

All of the Administration's PAHPA reauthorization proposals will assist in improving our biodefense capabilities.

3) How will the transition from the SNS to ASPR occur and what will that mean for changes in staffing in Atlanta?

The SNS Director will report to ASPR leadership in Washington, DC, but all Division of SNS staff in the Atlanta area will remain there, and staff employed at warehouse locations across the country will also not be physically moved.

In order to ensure a smooth Strategic National Stockpile transition with no degradation of operational capability, ASPR and CDC have set up several joint transition workgroups to evaluate all aspects of the program transition. We would be pleased to provide a full briefing for your staff at any time before the end of the fiscal year.

4) What is the estimated cost of the transition from SNS to ASPR?

SNS transition details are currently under discussion between CDC and ASPR.

5) Will any of the regional stockpiles be moved to the Washington region as a result of the transition?

There are no plans to relocate or move any of the existing stockpile warehouses from their current locations.

6) Will any personnel be shifted from Georgia to the Washington area?

7) ASPR has no plans to shift SNS staff from Georgia to Washington, DC. Have you reviewed the possibility of having ASPR co-located in Atlanta with the CDC to ensure that HHS and the CDC can build off existing knowledge and ensure increased efficacy? If so, what would be required, regarding staffing and financing, to make that a reality?

The transition of the Strategic National Stockpile from CDC to ASPR will not result in staff physically moving from Atlanta to Washington, or vice versa.

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. Currently, the Prevention to the Assistant Secretary for Preparedness and Response (ASPR) is primarily responsible for managing the Hospital Preparedness Program (HPP), the Biomedical Advanced Research and Development Authority (BARDA), Project BioShield, and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). ASPR is required to carry out drills and operational exercises to identify, inform, and address gaps in and policies related to all-hazards medical and public health preparedness and response. ASPR is required to develop, and update each year, a five-year budget plan for medical countermeasures based on the priorities established by the public health emergency medical countermeasures enterprise strategy and implementation plan. The proposed bill, H.R. ____, the Pandemic and All-Hazards 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 ASPR's past role in responding to public health emergencies and how ASPR coordinates with the CDC in preparation for and deployment of SNS items?

ASPR's mission is to save lives and protect Americans from 21st century health security threats. ASPR was created by PAHPA to lead and coordinate the Department's medical and public health emergency preparedness activities and to collaborate across the federal government, including with CDC, to bring unified medical and public health response capabilities to support state and local authorities during public health emergencies, in accordance with the National Response Framework, Emergency Support Function (ESF) #8 (Public Health and Medical Services).

Since ASPR was established in 2006, there have been 39 declared public health emergencies. For example, ASPR coordinated the response across the Department to the unprecedented 2017 hurricane season and the 2015-2016 Zika Virus Outbreak. During the 2017 hurricane season, ASPR's National Disaster Medical System (NDMS) deployed thousands of medical professionals from across the country to aid communities in Texas, Florida, Puerto Rico and the U.S. Virgin Islands. Collectively, HHS medical responders – from NDMS and the U.S. Public Health Service Commissioned Corps – saw more than 36,000 patients between the three major hurricanes and spent months deployed. Through daily ESF-8 coordination calls, ASPR maintained situational awareness of the impact of the storms, the health needs of the impacted communities, and coordinated the federal medical and public health assets deployed to assist those communities, including deployment of SNS contents such as Federal Medical Stations. During the Zika virus outbreak, ASPR supported development of medical countermeasures (MCM), augmented community preparedness via the Hospital Preparedness Program, supported interagency coordination calls and meetings, and provided consolidated reporting and situational awareness to senior leaders on a daily basis.

In addition to response capabilities, BARDA has partnered with the private sector to develop medical countermeasures (MCM) to protect Americans from chemical, biological, radiological, and nuclear threats; pandemic influenza; and emerging infectious diseases, leading to 38 FDA approvals, licenses or clearances.

2) What training, drills and operational exercises does ASPR conduct to ready the national response for public health emergencies?

ASPR plans, conducts and supports annual training and exercises for National Disaster Medical System (NDMS) Teams, Incident Response Coordination Teams, Federal Health Coordinating Elements, and the ASPR Emergency Management Group.

This year, ASPR began increasing the training provided to NDMS members – increasing frequency of training for personnel from once every five years to once every three years, and ensuring the training they receive includes information on treating chemical, biological, radiological and nuclear injuries. In addition, when DMAT teams are activated for national special security events, such as the State of the Union, Peace Officer Memorial, or 4th of July celebration, they participate in just-in-time trainings to refresh skills.

Specific NDMS training includes DMAT 101 and DMAT 201. DMAT 101 provides training and practice on fundamental knowledge and skills to ensure NDMS personnel are able to provide basic healthcare needs to a community impacted by disaster. Specifically, the course includes basic training on use of equipment (e.g. ventilators, defibrillators, etc.), providing a controlled environment where personnel are able to practice with equipment that is configured and organized as it would be deployed during a public health and medical emergency.

In DMAT 201, teams simulate a deployment and are required to set up their Base of Operations (Western Shelter canvas tent and supporting components to include ventilation system, water purification system, generator power, etc.) while simultaneously providing care to patients using only the equipment and supplies that would be deployed with them during an actual event. This training requires the team to function independently, similar to how they operate on an actual deployment.

In addition to the annual NDMS trainings, ASPR conducts a series of exercises designed to test and assess capabilities and readiness to respond to a variety of public health emergencies. These drills and exercises include:

- HHS Noble Lifesaver Exercises designed to test our capability to evacuate and move patients from health facilities;
- HHS Nimble Challenge and Nimble Response exercises designed to focus on an identified capability or need and include both announced and no-notice exercises and/or drills;
- HHS Plan Validation Exercises designed to test and validate new or updated plans before they are finalized; and,

- HHS Emergency Management Group exercises designed to test and evaluate the HHS response to various public health emergency scenarios.

3) Will the transfer of the SNS to ASPR affect the funding and conduction of these preparatory sessions?

The transfer of the SNS to ASPR will not affect funding or conduct of trainings, drills, or exercises.

4) The President's FY 2019 budget requested the transfer of the SNS from the CDC to ASPR.

Yes, the FY19 President's Budget proposes to transfer the SNS from CDC to ASPR. At a time when the U.S. threat environment is becoming more complex and dangerous, this change will improve the efficiency of emergency responses, strengthen and streamline the medical countermeasures enterprise, and leverage synergies in supply chain logistics.

5) 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 improve the efficiency of emergency responses, 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, such as Federal Medical Stations (FMSs) which are 250-bed medical centers set up during a disaster to care for an affected community.

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, public health officials 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 established relationships with public health agencies, will increase the effectiveness and efficiency of emergency responses.

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.

6) What issues may arise by moving the SNS from CDC to ASPR?

To support a smooth transition 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.

7) Will any issues the ASPR currently faces be resolved by this transfer?

As mentioned in question 5, at a time when the U.S. threat environment is becoming more complex and dangerous, the transition of the SNS to ASPR will improve the efficiency of emergency responses, and strengthen and streamline the medical countermeasures enterprise.

8) How does ASPR and the CDC currently coordinate on SNS and other public health emergency response efforts?

ASPR and CDC coordinate regularly in a number of areas, for example:

- On behalf of the Secretary, ASPR leads the federal medical and public health responses to emergencies and disasters under the National Response Framework ESF #8. CDC is a key public health component of a coordinated federal response.
- ASPR manages the Secretary's Operations Center (SOC) in Washington, DC, which coordinates communication flow with the CDC's Emergency Operations Center in Atlanta.
- ASPR's Regional Emergency Coordinators collaborate with CDC field staff located in the 10 HHS Regional Offices, as well as with state and local health officials in their respective regions.

- ASPR's Hospital Preparedness Program coordinates regularly with CDC's Public Health Emergency Preparedness Program on grant requirements, timelines, capabilities, and communications with state and local health officials.
- ASPR leads the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which includes senior representatives from all agencies involved in the medical countermeasures enterprise. CDC is an active participant in all PHEMCE working groups and executive committees.

9) How does ASPR and the CDC plan to ensure continued coordination after the transfer of the SNS?

ASPR recognizes and appreciates the tremendous expertise of CDC subject matter experts including on infectious diseases, other public health threats, epidemiological surveillance, as well as working directly with state and local public health departments. All of the methods of coordination identified in question 8 will continue to happen after the SNS transfer. To further increase collaboration, ASPR has invited and instituted a new senior CDC liaison who is working within the ASPR Immediate Office.

10) How does ASPR 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?

ASPR's Regional Emergency Coordinators currently coordinate with state and local health officials. ASPR also maintains extensive coordination with state and local emergency management officials, as well as public and private healthcare and emergency medical services leaders. With the transfer of the SNS, all previous relationships with state and local officials at ASPR and CDC will be maintained. State and local officials will continue to engage and communicate with their existing points of contact.

11) How does the Hospital Preparedness Program (HPP) improve local and state health system preparedness and public health emergency response systems?

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 healthcare 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 healthcare system readiness. HCCs are groups of healthcare, 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 healthcare organizations to work together.

HCCs have supported communities' healthcare systems—including hospitals, long term care facilities, emergency medical services agencies, public health departments and other healthcare partners— throughout the nation during past response operations. For example, as Hurricane Harvey made landfall in Houston Texas, the Southeast Texas

Regional Advisory Council (SETRAC), an HPP-supported HCC, coordinated all of the Houston region's healthcare response for Hurricane Harvey. SETRAC support, in part, enabled the 9,600-bed Texas Medical Center to remain operational throughout the storm and the flooding that ensued. The HCC also ensured that patients from other facilities that needed to be evacuated were transported to appropriate facilities safely. To do so, they utilized response equipment and communications and emergency management systems, financed by HPP, to coordinate across the entire region's healthcare delivery system.

Other recent examples where HCCs were successful in supporting community healthcare system needs during emergencies include responses to the Ft. Lauderdale airport shooting and to Hurricane Matthew in Georgia. When a shooter opened fire on January 6, 2017, at the Fort Lauderdale-Hollywood International Airport, killing five people and injuring many more, the Broward County HCC was ready to respond. The HCC and the airport have been close partners since 2007, conducting multiple disaster drills together every year. Thanks to years of exercising together, the HCC and airport have formalized plans, placing representatives at both the airport's Emergency Operations Center (EOC) and in local hospitals, greatly enhancing information sharing during a response. This shared coordination enabled effective, real-time communication between healthcare responders, transit authorities, and law enforcement as the incident unfolded. Within seven minutes of shots being fired, the HCC EOC liaison at the airport was coordinating patient distribution with first responders on the scene, while providing real-time updates to local hospitals and HCC members. As a result, local hospitals were able to suspend scheduled surgeries and accommodate over 50 incoming patients. One HCC member reflected that "...the response felt like an organized symphony. Without our HCC, we would not have had the established relationships or communication channels that enabled us to efficiently transport and treat so many unexpected patients and, ultimately, save lives."

Related to Hurricane Matthew, the HCC in coastal Georgia had a strong coastal evacuation plan developed from lessons learned through years of HPP-funded exercises, as well as numerous agreements with healthcare and other partners essential for moving patients across Georgia. These formalized, cross-functional partnerships enabled shared understanding of staffing, capacity, and resource availability before and during the response. Five days before hurricane landfall, the HCC began coordinating situational awareness among members and partners, allowing ample time for collaborative, informed decision-making. In the critical 24 hours before landfall, the HCC evacuated over 1,200 patients – some just out of surgery – without any loss of life. The HCC turned to its strong partnerships, including with law enforcement, to ensure all patients were relocated around the state using appropriate transportation, which included helicopters from neighboring states to evacuate the most critical patients to safety. One HCC member shared that "HPP enables critical partnerships to be formed and tested before a disaster. By exercising and planning together, our HCC ensured that everyone knew their role during the response. We would not have successfully evacuated over a thousand patients – some in extremely vulnerable condition – in 24 hours without our HCC and HPP." HCCs are critical in supporting communities before, during, and after emergencies and are proving their ability to support needs during disaster.

As of June 30, 2017 (the most recent data available), over 31,000 healthcare 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 healthcare capabilities promoted by HPP's coalitions are designed to limit community morbidity and mortality after exposure to a hazard.

12) Specifically, how could the HPP be improved?

As included in the Department's PAHPA reauthorization technical assistance, there are four key modifications that could strengthen HPP to better support preparedness and response efforts and capabilities at the local level and better utilize existing resources. These include:

- Expand the use of HPP awards from preparedness to preparedness, response, and medical surge activities. This change helps ensure HPP funds can also be used to respond to local emergencies.
- Making clear that HPP partnerships can include coalitions and other entities in addition to those currently listed in the statute, and that such partnerships must include emergency medical service organizations and emergency management organizations.
- Add the option to deviate from 62 formula-based cooperative agreement awards, in order to make awards to jurisdictions with the highest risk (based on risk scores).
- Expand the withholding period for failure to reach certain benchmarks and performance metrics from one year to two years.

Further, combating modern threats requires innovative solutions to train, equip, organize, and incentivize our healthcare systems in ways that make our local communities, and our nation, more resilient. ASPR is developing two demonstration projects that address healthcare preparedness challenges, establish best practices for improving disaster readiness across the healthcare delivery system, and show the potential effectiveness and viability of a Regional Disaster Health Response System (RDHRS).

The proposed system aims to leverage established investments in healthcare preparedness and trauma systems, including HPP. The proposed regional disaster health response system aims to expand the involvement of trauma centers, burn centers, pediatric hospitals, public health labs, outpatient services, and Federal facilities like Veterans Affairs clinics to better meet the healthcare needs of the public in a disaster.

13) What level of funding is required to enable the HPP to achieve its mission and respond to a regional disaster?

The President's FY19 Budget requests \$255 million, which is \$2 million above the FY 2018 Appropriations Act, for ASPR's Hospital Preparedness Program. The healthcare delivery system across the country is a \$3 trillion, highly competitive industry.

14) How does ASPR plan to improve HPP-supported healthcare coalitions into integrated entities capable of responding to severe public health emergencies such as that caused by Hurricane Harvey?

Combating modern threats requires innovative solutions to train, equip, organize, and incentivize our healthcare systems in ways that make our local communities, and our nation, more resilient.

In addition to the PAHPA reauthorization technical assistance submitted by the Department, and utilizing a portion of the increase in appropriations in FY18 for HPP, ASPR released a funding opportunity announcement, inviting applicants to develop demonstration projects that address healthcare preparedness challenges, establish best practices for improving disaster readiness across the healthcare delivery system, and show the potential effectiveness and viability of a regional disaster health response system.

15) How does ASPR currently address cybersecurity threats within the healthcare industry and public health emergency system?

The healthcare and public health systems of the U.S. rely on a complex network of staff, supplies, systems, and space to provide care. Americans rely on that critical infrastructure every day. ASPR's Critical Infrastructure Protection (CIP) program enhances the security and resilience of the nation's healthcare and public health (HPH) critical infrastructure through a voluntary public-private partnership between all levels of government and the private sector. ASPR's partners work together to mitigate risk from all hazards, including physical and cyber threats. The program analyzes infrastructure risks; prioritizes actions to mitigate those risks; and shares information related to risk management with private sector, state, local, tribal, and territorial partners during steady-state and incident response periods.

In December 2015, the Cybersecurity Act of 2015 (P. L. 114-113, Div. N) was enacted. The Act, as well as PPD-21 ("Critical Infrastructure" which designates the Department of Homeland Security and Resilience") and PPD-41 ("United States Cyber Incident Coordination") as the central point for cyber threat information sharing into the government, recognizes the unique challenges facing cybersecurity across the nation's critical infrastructure. These authorities, include provisions on HPH Sector preparedness reporting and information-sharing protocols that are led by the Department of Homeland

Security. The Act called for the creation of a federal advisory committee, the Healthcare Industry Cybersecurity Task Force, to make recommendations on HPH cybersecurity issues. In 2016, CIP established the Task Force, and supported it through the release of the Task Force's report to Congress in June 2017. The Task Force developed recommendations on cybersecurity challenges and barriers in the Sector, and how to achieve near real-time sharing of actionable threat information at no cost to businesses. On June 29, 2018, ASPR convened a workshop to highlight progress made on healthcare cybersecurity and initiated a set of public and private sector task groups to address the recommendations of the Task Force.

16) What best practices or guidance does ASPR provide regarding cybersecurity of electronic health records (EHRs) and medical devices?

ASPR defers to the relevant HHS components to address specific technical, programmatic, and/or regulatory issues related to cybersecurity. In the case of medical devices, ASPR defers to the guidance developed by the Center for Devices and Radiological Health at the Food and Drug Administration. For electronic health records, ASPR defers to the guidance developed by the HHS Office for Civil Rights and Office of the National Coordinator for Health Information Technology. ASPR promotes materials from these organizations and others in the cybersecurity and electronic health records space on the ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) website.

17) Does ASPR coordinate with the Department of Homeland Security or any other departments or agencies on cybersecurity threats?

Under Presidential Policy Directive 21, Critical Infrastructure Security and Resilience, DHS provides strategic guidance, promotes a national unity of effort, and coordinates the overall Federal effort to promote the security and resilience of the Nation's critical infrastructure. HHS is the Sector-Specific Agency for the healthcare and public health (HPH) sector. The HHS Critical Infrastructure Protection (CIP) program within ASPR coordinates HHS's role as the Sector-Specific Agency. The healthcare and public health systems of the U.S. rely on a complex network of staff, supplies, systems, and space to provide care. Americans rely on that critical infrastructure every day. The CIP program enhances the security and resilience of the nation's HPH critical infrastructure through a voluntary public-private partnership between all levels of government and the private sector. ASPR's partners work together to mitigate risk to the HPH sector from all hazards, including physical and cyber threats. The program analyzes HPH infrastructure risks; prioritizes actions to mitigate those risks; and shares HPH information related to risk management with HPH private sector, state, local, tribal, and territorial partners during steady-state and incident response periods.

In 2017, the healthcare and public health critical infrastructure sector continued to be a target for cyber-attacks with two major international cyber incidents. In May and June 2017, the WannaCry and NotPetya ransomware incidents brought together a coordinated federal effort across all sectors to respond to the attacks. As the SSA, HHS assessed

impacts to the Sector's ability to provide continuity of care across the country. Because of the foresight of HHS and HHS/ASPR leadership, the full resources of HHS's ESF 8 response capabilities were brought to bear in the response to the ransomware attacks, in partnership with HHS and DHS cybersecurity leadership. As a result, HHS, in coordination with DHS, was able to assist the overall Federal incident response effort by engaging with its private sector partners and providing them with vital guidance for remediation and information from DHS on the cyber attacks.

18) What lessons did ASPR learn from the Wannacry attacks and how can HHS' cybersecurity response be improved?

The coordinated Federal Government response to WannaCry validated the importance of the public-private sector partnership structure for responding to nationally significant cyber threats under the guidance of Presidential Policy Directive 41. Early alerting and regular communication with private sector partners helped them have the information they needed to take steps to keep their systems secure. It also allowed HHS to understand better the impact of WannaCry on the private sector and their needs. WannaCry also demonstrated the importance of coordination throughout the Department and the rest of the Federal Government. ASPR relied on subject matter experts throughout the Department and the Federal Interagency to provide the technical information and analysis.

In response to the lessons learned from WannaCry, ASPR has coordinated a series of exercise and planning activities with HHS partners. Through these activities ASPR and HHS partners have addressed issues such as assessing the significance of individual cyber incidents, coordinating communication with private sector partners, and coordinating incident management activities.

19) What resources does ASPR currently have to be successful in addressing cybersecurity risks in the health system?

The healthcare and public health systems of the U.S. rely on a complex network of staff, supplies, systems, and space to provide care. Americans rely on that critical infrastructure every day. ASPR's Critical Infrastructure Protection (CIP) program enhances the security and resilience of the nation's healthcare and public health (HPH) critical infrastructure through a voluntary public-private partnership between all levels of government and the private sector. ASPR's partners work together to mitigate risk from all hazards, including physical and cyber threats. The program analyzes infrastructure risks; prioritizes actions to mitigate those risks; and shares information related to risk management with private sector, state, local, tribal, and territorial partners during steady-state and incident response periods.

20) Given that it is FDA that approves medical devices, how does ASPR foresee leading cybersecurity guidance related to medical devices?

ASPR does not lead development of medical device cybersecurity guidance. ASPR does however work in close coordination with FDA on medical device cybersecurity matters. FDA currently serves as co-chair of the Healthcare Sector Government Coordinating Council, which is the primary organization for coordinating ASPR's critical infrastructure protection activities with government partners.

Rep. Engel:

- 1) In regard to Dr. Kadlec's response on AMR and specifically drug resistant TB, BARDA, and CARB-X have unfortunately never offered funding opportunities to product developers working on MDR-TB medical countermeasures, including drugs, diagnostics or vaccines, and while NIAID does some work on TB research, it is not focused on product development for new TB tools, which is really what we need now to address a potential epidemic. Will BARDA and CARB-X include MDR-TB – the world's leading infectious killer and a rising global health security threat – in the scope of its funding opportunities in 2019 beyond?**

ASPR, through BARDA, invests in the development of products to address antimicrobial resistance. BARDA has largely focused on the research and development of novel antibiotics to stem the tide of antimicrobial resistant infections in both hospitals and in communities across the United States. These antibiotics are typically derivatives of existing classes of antibiotics that overcome known drug resistance mechanisms while also targeting one or more of the bioterrorism agents BARDA is tasked with addressing as part of its core mission. Additionally, the overall strategy is to leverage the development of products for routine clinical use as a means of having products "at the ready" in the event of a bioterrorism event.

Unfortunately, many of the products that would be developed to prevent or treat TB do not possess the dual purpose of also addressing a bioterrorism pathogen. For example, bedaquilin, the most recently approved TB drug, is not predicted to have any activity against the five bioterrorism bacteria (anthrax, plague, tularemia, glanders, melioidosis) for which BARDA is tasked with developing medical countermeasures.

In regard to CARB-X, TB is not currently in the scope of CARB-X. However, in addition to substantial research investments by NIAID, there are other important groups with particular expertise addressing this challenge, including the Bill and Melinda Gates Foundation and TB Alliance.

Rep. Matsui:

- 1) One of the main issues that we will be discussing is the Strategic National Stockpile—a stockpile of supplies that can be deployed in case of a variety of types of emergencies. One of the conversations we will be having is about whether it is appropriate and necessary to transfer some SNS functions from CDC to the Assistant Secretary for Preparedness and Response (ASPR). I am interested to hear your thoughts on this topic.**

However, I want to ask a specific question related to safety of products stored in the stockpile. I understand that vaccines and other injectable drugs can be contaminated by glass because their glass containers may break, crack, delaminate, or contain glass particles. In some cases, these glass failures have resulted in recalls because they pose a potential threat to patient safety. Do you have concerns about the impact of these glass failures on the safety, security, or sterility of countermeasures in the stockpile?

FDA works closely with the CDC and manufacturers to ensure that the Strategic National Stockpile is managed very carefully and that products stored there are safe, effective, and ready for use. FDA did issue an advisory to drug manufacturers regarding the potential formation of glass lamellae (i.e., tiny glass particles that shed from the surface of glass) in injectable drugs filled in small-volume glass vials in 2011. Along with the advisory, FDA issued guidance to industry which includes recommendations to help prevent the formation of glass lamellae.¹ A subsequent analysis (using surveillance data from FY 2008 – FY 2017) by FDA did not identify any new or increasing safety signals since the advisory was issued. For glass lamellae, the number of recalls has dropped substantially since FDA issued the advisory and guidance in 2011. Glass containers are a very stable and often preferable container type for long-term storage, particularly for sterile products. Manufacturers can choose from a variety of glass container compositions depending on suitability for their specific product and storage conditions.

FDA will continue to monitor drug quality, evaluate and assess incidents involving quality issues, and respond with appropriate actions when information suggests a need to correct an issue with drug safety or availability.

- 2) Cyberattacks represent an immediate and growing threat to public health, especially when attacks involve health care providers or health care devices. While ASPR has some role in cybersecurity preparedness, cybersecurity has not traditionally been a part of the PAHPA conversation. I think Congress and HHS both need to pay more attention to cybersecurity and health care. Big hospital systems and other health care stakeholders make efforts to ensure that their health care data is protected, but that is not always possible for smaller entities. And, the more that our health data is connected...as it should be to enhance patient care..the more vulnerable we are. That is why I work with my colleague Rep. Billy Long on the HHS Cybersecurity Modernization Act, as a first step in the direction of enhancing agency leadership on cybersecurity. Can you speak to ASPR's current role in cybersecurity preparedness?**

¹ <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124780.htm#11>

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3) Are there ways that we can better coordinate across HHS and other agencies to ensure health data both within the agency and in the health care sector is protected?

ASPR coordinates on cybersecurity matters with HHS partners through the HHS Cybersecurity Working Group. This working group reports to the Deputy Secretary of HHS, who is the identified lead official within the Department for cybersecurity. ASPR also coordinates on cybersecurity matters with government partners outside of HHS through the Healthcare and Public Health Sector Government Coordinating Council. This Council, established by the Department of Homeland Security's Critical Infrastructure Partnership Advisory Council. This Council, which convenes under DHS authorities, includes HHS, Federal Interagency, and state and local government partners.

Rep. Dingell:

The National Health Security Preparedness Index has found that our healthcare delivery readiness lags behind our preparedness in other areas. Despite this fact, the Hospital Preparedness Program has received about half the funding it once did. Given the growing threats, it seems that we need to provide more resources not less.

- 4) How could increasing funding for the Hospital Preparedness Program improve preparedness across the health care system? At its highest level the HPP program was appropriated at \$515 million, yet today the program has eroded to about half of what it once was. From climate change and extreme weather events to pandemic influenza and cybersecurity, now is the time to robustly fund this important preparedness program.**

The nation's healthcare delivery infrastructure is a \$3 trillion, highly competitive enterprise. ASPR's Hospital Preparedness Program (HPP) has supported over 31,000 healthcare facilities and community organizations participating in 476 healthcare coalitions (HCCs) nationwide. HCCs are groups of healthcare, 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 healthcare organizations to work together.

HCCs have supported communities' healthcare systems—including hospitals, long term care facilities, emergency medical services agencies, public health departments and other healthcare partners— throughout the nation during past response operations. For example, as Hurricane Harvey made landfall in Houston Texas, the Southeast Texas Regional Advisory Council (SETRAC), an HPP-supported HCC, coordinated all of the Houston region's healthcare response for Hurricane Harvey. SETRAC support, in part, enabled the 9,600-bed Texas Medical Center to remain operational throughout the storm and the flooding that ensued. The HCC also ensured that patients from other facilities that needed to be evacuated were transported to appropriate facilities safely. To do so, they utilized response equipment and communications and emergency management systems, financed by HPP, to coordinate across the entire region's healthcare delivery system.

Other recent examples where HCCs were successful in supporting community healthcare system needs during emergencies include responses to the Ft. Lauderdale airport shooting and to Hurricane Matthew in Georgia. When a shooter opened fire on January 6, 2017, at the Fort Lauderdale-Hollywood International Airport, killing five people and injuring many more, the Broward County HCC was ready to respond. The HCC and the airport have been close partners since 2007, conducting multiple disaster drills together every year. Thanks to years of exercising together, the HCC and airport have formalized plans, placing representatives at both the airport's Emergency Operations Center (EOC) and in local hospitals, greatly enhancing information sharing during a response. This shared coordination enabled effective, real-time communication between healthcare responders, transit authorities, and law enforcement as the incident unfolded. Within seven minutes of shots being fired, the HCC EOC liaison at the airport was coordinating patient distribution with first responders on the scene, while providing real-time updates to local hospitals and HCC members. As a result, local hospitals were able to suspend scheduled surgeries and accommodate over 50 incoming patients. One HCC member reflected that "...the response felt like an organized symphony. Without our HCC, we would not have

had the established relationships or communication channels that enabled us to efficiently transport and treat so many unexpected patients and, ultimately, save lives.”

Related to Hurricane Matthew, the HCC in coastal Georgia had a strong coastal evacuation plan developed from lessons learned through years of HPP-funded exercises, as well as numerous agreements with healthcare and other partners essential for moving patients across Georgia. These formalized, cross-functional partnerships enabled shared understanding of staffing, capacity, and resource availability before and during the response. Five days before hurricane landfall, the HCC began coordinating situational awareness among members and partners, allowing ample time for collaborative, informed decision-making. In the critical 24 hours before landfall, the HCC evacuated over 1,200 patients – some just out of surgery – without any loss of life. The HCC turned to its strong partnerships, including with law enforcement, to ensure all patients were relocated around the state using appropriate transportation, which included helicopters from neighboring states to evacuate the most critical patients to safety. One HCC member shared that “HPP enables critical partnerships to be formed and tested before a disaster. By exercising and planning together, our HCC ensured that everyone knew their role during the response. We would not have successfully evacuated over a thousand patients – some in extremely vulnerable condition – in 24 hours without our HCC and HPP.” HCCs are critical in supporting communities before, during, and after emergencies and are proving their ability to support needs during disaster.

However, combating modern threats requires innovative solutions to train, equip, organize, and incentivize our health care systems in ways that make our local communities, and our nation, more resilient. ASPR is developing two demonstration projects that address healthcare preparedness challenges, establish best practices for improving disaster readiness across the healthcare delivery system, and show the potential effectiveness and viability of a Regional Disaster Health Response System (RDHRS). The proposed system aims to leverage established investments in healthcare preparedness and trauma systems, including HPP. The proposed regional disaster health response system aims to expand the involvement of trauma centers, burn centers, pediatric hospitals, public health labs, outpatient services, and federal facilities like Veterans Affairs clinics to better meet the healthcare needs of the public in a disaster.