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Preparing the Nation for Radiation and Nuclear Terrorist Events

Statement of
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Good morning Chairmen Akaka and Pryor, and Ranking members Voinovich and Sununu. I am Kevin Yeskey, MD, Deputy Assistant Secretary and Director of the Office of Preparedness and Emergency Operations in the Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services (HHS). Thank you for the opportunity to discuss the domestic preparations HHS has made for radiation and nuclear terrorist incidents. The Office of the Assistant Secretary for Preparedness and Response (ASPR) was created by the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006. Our office is less than one year old, but in conjunction with the Operating and Staff Divisions of HHS, we have made considerable progress in preparing the Nation for public health emergencies, including a radiation or nuclear incident. ASPR has adopted an "all-hazards" approach to our preparedness and response activities. We have collaborated and coordinated closely with our federal interagency partners and have provided States and municipalities with funding to enhance their public health and medical preparedness.

My comments today will cover an overview of our all-hazards preparedness; the preparations specific to radiation and nuclear events; and the lessons learned by HHS through its participation in the Top Officials 4 exercise which involved several simulated attacks involving radiological dispersal devices.

HHS Preparedness

The Pandemic and All Hazards Preparedness Act created the ASPR and focused the leadership for all federal public health and medical preparedness and response functions in that office. As directed in the statute, the National Disaster Medical System

and National Bioterrorism Hospital Preparedness Program were transferred to ASPR. NDMS has over 6000 medical and public health responders to provide early support of an overwhelmed or damaged medical system. It also has over 1500 participating hospitals that offer definitive care services to those affected by a disaster. Over the past five years, the hospital preparedness program has provided over $2.0 billion in funding for development of surge capacity at the State and local level. ASPR also coordinates closely with the Medical Reserve Corps which includes over 700 local teams and over 160,000 citizen volunteers who support community resilience at the local level and who can be asked to help support the Federal response to large scale events.

HHS has implemented an incident command system that is complementary to and consistent with the National Response Plan and the National Incident Management System. We have trained and equipped response personnel who include not only the NDMS teams, but also Public Health Service Commissioned Corps Officers. ASPR has written and exercised playbooks based on the 15 National exercise scenarios. The process of developing these playbooks provides opportunities for input from our Emergency Support Function (ESF) #8 federal partners. The operational command of personnel deployed under our auspices is fully consistent with and supportive of the Department of Homeland Security's role as overall incident manager, including liaisons in the National Operations Center, National Response Coordination Center, and the Joint Field Office. HHS recognizes and supports the overall lead of DHS in coordinating the federal response and we take seriously our role as the lead federal agency for

Public Health and Medical Services through Emergency Support Function #8, of the National Response Plan.

In the area of medical countermeasure development and acquisitions, ASPR has stood up the Biomedical Advanced Research and Development Authority (BARDA) and established the Enterprise Governance Board (EGB), which oversees the strategic and operational aspects of medical countermeasures from development to delivery platforms. The EGB oversees development and acquisition of medical countermeasures based on known vulnerabilities and threats. Membership on the EGB consists of senior HHS officials, including the ASPR, Food and Drug Administration (FDA) Commissioner, National Institutes of Health (NIH) Director, and the Centers for Disease Control and Prevention (CDC) Director with advisory status for other federal partners.

ASPR has worked diligently to partner with State, Tribal, Territorial, and local officials to enhance their level of preparedness and to ensure they can see how HHS will respond to disasters. We have accomplished this in several ways. For example, our Regional Emergency Coordination (REC) program has been enhanced. In the past year, we have increased the number of RECs from 10 to over 30. The REC's role is to work with the States and local jurisdictions to coordinate and enhance preparedness within the region. The ASPR has been to each of the 10 HHS regions to participate in local exercises and meet with State and local health leadership to discuss the level of preparedness and how HHS can support them. Additionally, HHS playbooks, starting with the hurricane playbook, will be placed on the HHS web site to facilitate their

examination and use by State, Tribal, Territorial, and local officials. We will make additional playbooks, including the Radiological Dispersal Device playbook, available as they become ready for release.

HHS Preparations for a Radiation/Nuclear Incident

Planning

I would now like to address the preparations HHS is making for the public health and medical consequences resulting from a radiation dispersal device (RDD). HHS has worked with its operating and staff divisions as well as its federal partners to develop our plans, based on the national planning scenarios. As noted above, we have developed a comprehensive framework to respond to any type of radiological event. There is one playbook focused on RDDs. This playbook was successfully used during the recent TopOff 4 exercise. We will take the lessons observed from this exercise and through a corrective action process, revise the playbook. There is also another separate playbook for Improvised Nuclear Devices. Improvised nuclear devices pose challenges of a different order of magnitude than RDDs. The framework includes a response system that considers radiation exposure to the victims and the time limitation that responders may stay within the locations to avoid exceedance of the Environmental Protection Agency (EPA) Protective Action Guidelines. The response framework includes the potential locations for medical triage, transportation, on-site treatment and collection points for displaced people. We are in the process of mapping medical resources and infrastructure around the country so that we can produce Geographic Information Systems (GIS) maps highlighting such resources on a moment's notice (we are calling this the MEDMAP project).

Few medical providers have experience treating patients with radiation injury. To remedy these gaps in most practitioners' knowledge base, ASPR, in collaboration with the National Library of Medicine, has developed a web-based site for physicians and nurses with just-in-time information on the medical management of radiation injuries. The site, called Radiation Event Medical Management or REMM is now live and can be accessed at www.remm.nlm.gov. The site has been widely acclaimed as an effective way to provide clinical information for education and training as well as concise medical management algorithms for use in any radiation event. In the event of an incident, clinicians at all levels could refer to this web site or to a downloadable file on their own computer for the most current treatment protocols for patients exposed to radiation or contaminated with radioactive materials.

We are also defining the requirements for medical countermeasures for radiation incidents. Two Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) working groups have estimated the medical requirements that would emerge after a radiological or nuclear incident. The Radiological/Nuclear Medical Countermeasures Working Group has provided estimates of the number and type of radiation injuries that would be expected after the detonation of an improvised nuclear device, while the Blood and Tissue Working Group has estimated the requirements for blood products and skin grafts in the immediate aftermath of such an event. Requirements have also been established for two medical countermeasures used in treatment of internal contamination with radionuclides (exposure of greatest concern after an RDD). Once a countermeasure is procured for inclusion in the Strategic National Stockpile, working groups are established to look at deployment and utilization

issues, working in close coordination with the Division of Strategic National Stockpile (DSNS).

BARDA and the National Institute of Allergy and Infectious Diseases (NIAID) at NIH, and the CDC collaboratively support research and development of new and improved medical countermeasures and diagnostics for radiation victims. The development, licensure, and procurement of such countermeasures contribute to our strategy to mitigate the medical and public health consequences of a radiological or nuclear event. Some of these countermeasures may have the potential to enhance supportive care for cancer patients receiving radiation therapy, potentially improving the long-term outcomes and quality of life for millions of cancer survivors, so we believe our investments in this area will likely have value even if radiological and nuclear attacks never occur.

Response Operations

HHS maintains an operations center 24/7/365. The Secretary's Operations Center (SOC) is directly connected to the DHS National Operations Center and the FEMA National Response Operations Center. It serves as the focal point for situational awareness, information management and response coordination for HHS. HHS has established relationships with subject matter experts from within HHS Operating and Staff Divisions such as NIH, CDC, FDA, and ASPR.

The response steps are preplanned and prescripted in the preparation of the playbooks I mentioned earlier. The treatment of radiation casualties is greatly facilitated by knowledge of radiation dose and individual has received. After an RDD, HHS will depend on the Federal Radiological Monitoring and Assessment Center (FRMAC) of the Department of Energy (DOE) and the Interagency Modeling and Atmospheric Assessment Center (IMAAC) to provide both models and on-site information regarding the radionuclide involved and the distribution pattern of radiation. This information, in conjunction with radiation biodosimetry information gathered from individual patients will guide medical treatment decisions for individuals in the early hours and days after an event.

HHS also has representatives on the Advisory Team for Environment, Food, and Health (sometimes referred to as the A-Team), a collection of experts from a variety of federal agencies that advise state, local, and territorial governments on ways to protect people and the environment following a radiological incident.

For all disasters, systems are needed to rapidly expand or surge capabilities to meet the needs of the event. The DSNS can deploy medical countermeasures rapidly after notification to deploy. In addition to medical countermeasures that can be tailored to meet the event's specific needs, the DSNS inventory contains supplies and materiel required in the medical management of burns, trauma, injuries that will likely be seen in conjunction with radiation exposure. As for personnel, NDMS response teams can deploy to provide acute care to the victims. NDMS hospitals can provide surge beds for victims who require in-patient clinical care. The NDMS counts beds bi-monthly and the last count identified approximately 34,000 hospital beds immediately available for

patient care. HHS also works with the American Burn Association to assess burn bed availability and we have developed a burn nurse program which trains nurses in the care for burn patients. To facilitate the delivery of expert care to radiation casualties, we are also participating in the Radiation Injury Treatment Network (RITN) in collaboration with the National Marrow Donor Program and the National Cancer Institute Cancer Centers. This voluntary network includes centers that have concentrations of experts in oncology and hematology who are used to caring for patients with bone marrow suppression and other types of injury that may be expected after a radiological or nuclear incident. RITN is in its early stages of development but actively participated in TopOff 4.

TOPOFF 4, Lessons learned

HHS was fully engaged in TopOff 4, from the Secretary to HHS response staff. The SOC was staffed around the clock and we had liaisons in partner operations centers at the state, regional, and federal levels. HHS deployed response teams to Portland, the site of the largest simulated activities. HHS took the opportunity to exercise a number of functions that included: exercising the ESF#8 RDD playbook; Secretarial declaration of a public health emergency; issuance of an emergency use authorization for Prussian Blue in children under the age of 2 years; and deployment of our Incident Response Coordination Team. Many successes were observed from our participation in TopOff 4. The RDD playbook provided a comprehensive guide for managing HHS operations. HHS felt well integrated into the overall federal response and had very good communications at the local, State, and Federal levels. HHS communications staff

worked with the interagency partners on getting public messages out proactively and rapidly. HHS staff participated in the regular National Incident Communications Conference Line, which facilitates the coordination of public communications across the federal interagency. HHS also produced several public service announcements that aired on the Virtual News Network.

Despite the successes, we also identified areas for improvement. Efforts are already underway to take the lessons learned in TopOff 4 and incorporate them into the RDD playbook. For example, in the area of surge capacity, HHS needs to continue to work with federal and State partners on patient movement away from the incident site. While protocols exist and we have made improvements, there is still a need to refine the protocols and standard operating procedures that guide patient movement.

Laboratory capacity to determine whether members of the public may have received internal contamination is limited. As a result, the demand for Prussian Blue was far greater than the projected need. Many people might be treated needlessly if rapid diagnosis of internal contamination is not possible. Estimating the dose of radiation that patients have received ("radiation biodosimetry") is also critical but limited. The current gold standard for radiation biodosimetry requires cytogenetic analysis of blood samples from victims.

To address this acknowledged gap in our lab capacity, subject matter experts within HHS have discussed with their interagency partners the concept of a Radiation Laboratory Network (Rad-LN) that is comparable in many ways to the Laboratory

Response Network developed by CDC for the diagnosis of biological threats. The Rad-LN would provide four major improvements in our medical response capability:

1. Radionuclide bioassay capability for all radionuclides of concern,
2. Enhanced cytogenetic biodosimetry assay throughput,
3. Hematology surge capacity, and
4. A testbed for assessment and interlaboratory comparison of novel high-throughput approaches to measuring molecular markers of radiation exposure.

NIAID is supporting research and development of high throughput approaches to biodosimetry and identification of biomarkers of radiation exposure through its Centers for Medical Countermeasures against Radiation (CMCR). The preliminary data and proof-of-concept studies for these approaches and biomarkers are very exciting but few if any of these techniques will be ready for field use in the next 3-5 years.

Other approaches to improving our national capabilities include partnering with allied nations. At the recent Global Health Security Action Group ministerial meeting, there was some consideration paid to the possibility of establishing international laboratory networks among the member nations. Links with Canada would be particularly useful given the geographic proximity. Informal discussions among the scientists and subject matter experts have been ongoing for a few years but no formal arrangements have been made. We continue to explore possibilities that serve the national interest.

HHS has made progress in developing the plans and surge capacity to deal with the public health and medical consequences resulting from the use of a radiological or nuclear device. We have used exercises like TopOff 4 to identify gaps and

vulnerabilities that need to be addressed. We continue to work closely with our local, State and Federal partners on improving our responses. While our progress is considerable, there is still much more to accomplish.

This concludes my testimony and I will be glad to answer any questions.