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Committee on Homeland Security and Governmental Affairs
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HHS Radiological/Nuclear Preparedness

Statement of

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Good morning, I am RADM W. Craig Vanderwagen, MD, the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services. I appreciate the opportunity to present to the Committee on Homeland Security and Governmental Affairs the HHS plans and programs for public health and medical preparedness for and response to an improvised nuclear device or IND.

Earlier this year, in March, the Committee received a detailed response from HHS and other agencies addressing specific questions about readiness to respond to a nuclear terrorism incident. In my testimony today, I will provide a broad perspective on the HHS response to an IND incident while pointing out that the HHS response to an IND incident is part of ASPR's overall comprehensive all-hazards planning for all public health and medical emergencies resulting from natural or man-made causes. I should note that, while an IND event is the focus of my remarks today, HHS radiological/nuclear response planning also includes plans for responding to radiological dispersal devices (often known as dirty bombs) or other catastrophic events involving radiation. HHS responsibilities are included in the National Response Framework's Emergency Support Function #8, Public Health and Medical Services, and in Homeland Security Presidential Directives #18, Medical Countermeasures against Weapons of Mass Destruction, and #21, Public Health and Medical Preparedness. To address the breadth of resources and expertise and coordination needed for all of our medical countermeasure missions, the HHS Secretary has established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The Enterprise Governance Board, made up of myself, the Directors of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), and the Commissioner of the Food and Drug Administration (FDA), coordinates programs within the NIH, the CDC, and within two ASPR offices – the Biomedical Advanced Research and Development Authority, or BARDA, and the Office of Preparedness and Emergency Operations.

Through this Enterprise-wide effort, we are able to ensure that Federal activities with respect to needed medical countermeasures are coordinated effectively from research and development to acquisition and deployment.

Recent presentations to this Committee from Drs. Ashton Carter, William Bell, and Cham Dallas provided scenarios indicating the magnitude of disaster that could result from the detonation of an IND. The detonation of a large-scale IND will result in a catastrophic event. Many factors, however, will determine the number and type of casualties, including the size, type, and location of the device, time of day, and meteorological conditions.

During the Cold War, the magnitude of a state-sponsored nuclear event and the potential for multiple simultaneous detonations led to a sense of futility in mustering a civilian response. Over the last four years, HHS has approached planning for an IND with the goal of reaching as many people as possible, in a timely manner, to provide medical care as well as comfort and support. We recognize that few countries have attempted to undertake the detailed response planning that we, along with our other Federal, state, local, regional, and international partners, have undertaken. While there are certainly gaps remaining in our IND response plan, we have made substantial progress upon which we continue to build.

The basis for response and preparedness planning involves specific event scenarios. These scenarios are prepared by the Department of Homeland Security working with BARDA's public health and medical consequence modeling group, which includes modeling efforts from the Defense Threat Reduction Agency (DTRA) and the Agency for Healthcare Research and Quality (AHRQ). Models are refined continuously from the open desert models of a nuclear detonation to current models that take into account more accurately, though still not entirely, an urban setting.

While our medical and public health response plans are time-oriented, our new models describe the post-detonation time course in smaller increments to help planners better understand the rapidly changing situation on the ground. Radiation exposure rates in some locations can change significantly over a matter of hours, which is important for planners as they think about where the initial responders can and cannot enter. Similarly, certain areas will have radioactive fallout while some nearby areas will have little or no radiation and will be suitable for responders. The complex blast, thermal and flash blindness effects are now added to the models so victims at distances from the detonation site who have injury but no radiation exposure can also be estimated.

HHS prepares playbooks for the different scenarios of man-made and natural disasters. For radiological/nuclear response there are separate IND and Radiological Dispersal Devices (RDD) playbooks. These two playbooks have a good deal in common. They are internal documents for use by HHS during an event and include sections for the:

- Scenario;
- Concept of operations, or CONOPs, for the response ;
- Action steps;
- Briefing and decision papers; and
- Essential elements of information.

The Action Steps are time-oriented, and include pre-event steps should there be credible intelligence that the risk of an event is high. The Action Steps include a trigger for each step, a recommended strategy to follow, and specific actions to take. For example, should there appear to be a need to use drugs not currently approved by the FDA to treat Acute Radiation Syndrome (ARS), HHS can request an Emergency Use Authorization for a medical countermeasure [per PL 108-276, the Project BioShield Act of 2004] so the FDA Commissioner can rapidly consider an application to authorize the use of these drugs. This request

and authorization process would involve a series of actions by DHS, HHS (including FDA, NIH, and CDC), and DOD.

HHS response plans are based on models, scientific data, and clinical experience from radiation incidents. Recognizing that very few medical providers have experience in managing the consequences of a radiological or nuclear event and that these are very low probability events for the average medical responder, ASPR partnered with the National Library of Medicine to produce a tool called Radiation Event Medical Management, or REMM, that includes algorithms for just-in-time medical management. This tool has been produced with input from a wide range of international experts and is publicly available on the Internet. It can be downloaded to a home computer and PDA so that the information would be available, even following damage to the civil infrastructure.

The CDC has also produced an array of excellent educational materials and tools that are available on the Internet, as have other agencies including the Armed Forces Radiobiology Research Institute within the Department of Defense.

Depending on the type of event, the magnitude of an IND could result in tens of thousands of fatalities and severe casualties, resulting in the possible placement of over a hundred thousand people at risk for developing acute radiation syndrome (ARS) and of hundreds of thousands of people concerned about radiation exposure, not to mention the temporary displacement of hundreds of thousands of others. This type of event requires a response involving the entire nation. While the initial response is, of course, local, an event of this size will require rapid activation of regional partnerships and the influx of Federal resources.

Following an event, the HHS response will be coordinated under the National Response Framework, Emergency Support Function # 8, by the Emergency Management Group (EMG) through the Secretary's Operations Center (SOC).

The SOC will coordinate response activities with FEMA's National Response Coordination Center, the operational component of the Department of Homeland Security's (DHS) National Operations Center (NOC). Shortly after the event occurs, the Interagency Modeling and Atmospheric Assessment Center (IMAAC) will have gathered information on high altitude wind direction, which will carry the upper level fallout; however, it is recognized that wind patterns shift and that the lower altitude winds and urban canyons will have different airflow than the upper level atmosphere. The initial blast will create a mixture of injuries, some of which will involve radiation, while others will not, including those injuries from broken glass, burns, trauma, and vehicular injuries from the flash blindness. For the victims whose radiation exposure comes from the fallout and not the initial blast, the duration of radiation exposure determines who is at risk for developing ARS. The presence of radiation also limits the time that responders will be allowed to spend treating and rescuing victims.

HHS will work in close collaboration with state and local response efforts and the Federal Emergency Management Agency to implement its responsibilities under the National Response Framework to rapidly provide Federal public health and medical support in response to an IND event. The full-time U.S. Public Health Service (USPHS) responders include the Rapid Deployment Force (RDF) Teams, Applied Public Health Teams (APHT), Mental Health Teams (MHT) and additional USPHS Officers. Volunteer healthcare professionals are available through the Medical Reserve Corps, which has over 160,000 members in approximately 700 teams. The Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) ensures the availability of volunteers for quick exchange between jurisdictions.

The HHS Federal Medical Station (FMS) is a deployable healthcare platform that can provide non-acute hospital bed surge capacity and special medical needs sheltering. A standard FMS can house approximately 250 patients and is staffed by the Rapid Deployment Force teams.

In the event of an IND, local and regional hospital capacity will be quickly overwhelmed. The National Disaster Medical System (NDMS) is a critical component of the response. NDMS field teams include the Disaster Medical Assistance Teams (DMAT), Disaster Mortuary Operational Response Teams (DMORT), National Medical Response Teams (NMRT), and International Medical and Surgical Response Teams (IMSRT).

Specialty care will be required and, nationwide, there is limited capacity for burn care and for general emergency care. In collaboration with the American Burn Association (ABA), HHS is training nurses to be able to support burn surge capacity. We have also worked with ABA to develop a burn bed tracking system that provides a national snapshot of available burn beds.

To specifically address the treatment of acute radiation syndrome, ASPR has helped establish the Radiation Injury Treatment Network in partnership with the National Marrow Donor Program and the National Cancer Institute's Cancer Centers. The Network continues to grow in size and scope. In this way, we are effectively tapping into the expertise found in oncology and hematology care as there are significant similarities observed in bone marrow failure caused by acute radiation syndrome.

HHS has developed a response system called the RTR system for Radiation Treatment, Triage and Transport that takes into account the radiation exposure in determining medical response. HHS is developing an interactive geographic information system (GIS)-based mapping system, called MEDMAP, which will include the potential medical care sites and assembly centers in the U.S. so that up-to-date information will be immediately available by which to organize the response. Determining which local medical care and assembly center facilities are functional or not in the radiation plume is essential, as is having information on what regional and nationwide resources are available.

Victim decontamination and transportation capability for victims and displaced individuals will most likely be overwhelmed. Key to directing the assets to those in immediate need will be public messaging regarding who should evacuate, when they should do so, who should shelter in place, who is well outside any risk zone, and where displaced people should go. Those not requiring immediate life-saving medical care can go to assembly centers to prevent the filling up of medical care facilities. Determining radiation exposure and locations where responders and victims can go will depend on IMAAC modeling, the Federal Radiological Monitoring and Assessment Center (FRMAC) measurements, and consultation with the multi-agency Advisory Team for Environment, Food, and Health (A-Team). As information becomes available from responders, state and local decision makers can make sheltering versus evacuation recommendations. Federal public communications support will be coordinated by DHS, using the National Incident Communications Conference Line (NICCL).

The triage of individuals will be based on medical evaluation including where they were during and shortly after the event with particular attention to special needs that they may have. The initial triage will attempt to separate people into three broad categories:

- those needing immediate medical attention, which would include those with major injury and/or high radiation exposure;

- those without traumatic injury but at high risk of developing ARS; and

- those with minimal or no radiation exposure and no significant trauma who do not require immediate medical care.

Transportation will be a major challenge, and to mitigate this challenge, a FEMA ambulance contract is in place. Upon HHS request, FEMA is prepared to activate the ambulance contract to support patient evacuation. Presently, the contract covers all Gulf and East Coast States. The contract will ultimately be expanded to provide coverage for all 48 contiguous states. Although coverage is targeted to the Gulf and East Coast States, ambulances may be deployed to any area in the United States. The contract provides support for up to 300 ALS/BLS ground ambulances, 25 medical evacuation helicopters, and Para-transit seats, which can be either a van or bus, at least equipped with a wheel chair lift, to move up to 3,500 patients within 72 hours.

More definitive evaluation for the risk of ARS will require establishing a Radiation Laboratory network which will provide standardized testing methods for conducting routine blood counts and specialized tests called cytogenetics. Assessing internal contamination will not be a major component of an IND event, as opposed to an RDD event, where it is essential to determine the need for and type of therapy required to remove internal radioactive burdens. There is a well-developed plan for a biodosimetry and bioassay network, and initial funding to support the Radiation Laboratory Network has been requested in the President's FY09 CDC budget. NIAID and BARDA are currently investing in the development of novel, rapid, high-throughput biodosimetry to assist in triage and medical management decisions.

Medical care for an IND event will require medical products including those needed for trauma and burns, blood products, and medical countermeasures to address the various symptoms of acute radiation exposure. There are currently no licensed products to treat the acute radiation syndrome. Medical countermeasures to be used include agents such as the hematological growth factors that can potentially mitigate bone marrow syndrome, thereby saving lives and reducing the burden on the healthcare system. The growth factors currently available are those used for low white blood counts in hematology and oncology.

Other agents are under evaluation for low platelet count. BARDA, working closely with NIAID, provides an integrated, systematic approach to the development and purchase of these necessary countermeasures and diagnostic tools for public health emergencies.

Current medical planning includes providing intervention as soon as possible for those at high risk for ARS. For those in whom exposure is uncertain and for those who do not receive countermeasures in the time window for mitigation, serial evaluation of blood counts and possibly cytogenetic studies will determine who needs to receive treatment with the hematological growth factors. For many of those with ARS, the clinical manifestations might not occur for three to four weeks, so our plan is to refer patients to experts for observation and management using the Radiation Injury Treatment Network. Much of the management of ARS could be done as outpatient care.

The Federal supply of medical countermeasures will come from the Strategic National Stockpile (SNS). In addition to hemapoietic growth factors, the SNS currently holds large quantities of supplies for treating the burns and blast injuries that will accompany an IND event. The HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats published in Spring 2007 stated HHS interest in obtaining additional medical countermeasures for ARS. A BARDA Request for Proposals to acquire medical countermeasures using BioShield Special Reserve Funds to specifically address the neutropenia component of ARS recently closed; submitted proposals are currently being evaluated. Additional countermeasures for acquisition will be considered as the scientific progress indicates. To this end, BARDA also is currently reviewing proposals sent in response to a Broad Agency Announcement and hopes to fund the advanced development of multiple products aimed at the various blood-related defects involved with ARS in addition to neutropenia.

HHS is also coordinating its research and development efforts closely with the Department of Defense (DOD) to allow the most effective utilization of federal resources. Moreover, DOD recently launched a program addressing ARS gastrointestinal syndrome. The NIAID has a Medical Countermeasures Research and Development Program to develop improved and novel countermeasures for ARS, compounds for decorporating internal radionuclides, and rapid approaches to biodosimetry. Although these candidate products are years away from clinical application, knowing what is in the pipeline informs the current acquisition and future replacement plans for medical countermeasures.

In addition to investigating new agents and technologies, HHS is investigating new models of deployment and distribution for medical countermeasures that would enhance and improve the capabilities of the SNS and potentially incorporate other partners into a national network, including the Radiation Injury Treatment Network, Department of Veterans Affairs, and hospital and pharmaceutical distribution systems.

HHS continues to expand the network of subject matter experts to whom we reach out for knowledge and advice and with whom we consult should an event occur. Experts from the Federal government are members of requirements-setting working groups organized under the Enterprise Governance Board to address both radiological and nuclear medical countermeasure needs and the large quantities of blood and tissue products that will be required in an IND event. There are ongoing efforts in collaboration with academic partners, as exemplified by the Centers for Medical Countermeasures Against Radiation of NIAID, and with international partners such as the Global Health Security Action Group.

Over the last six years, there has been an increase in basic science research on normal tissue injury, including work specifically on radiation injury by radiation biologists, and also on general wound repair, including research by experts in regenerative medicine.

As you can see, there has been significant progress in developing our medical responses to an IND, including the development of novel system networks and medical countermeasures. Given the many variables that would determine the effect of an IND event on physical infrastructure and individual health, and the complex multi-faceted response required in the face of catastrophic numbers of affected individuals, we depend heavily on a systems-based approach exemplified by the Radiation Event Medical Management system, the playbooks, and medical treatment networks. The more we can prepare our response beforehand, and the more innovative we can be in integrating these various components, the better our response will be.

We view this complex response as a Radiation Event Management System and are working to integrate and pre-script as much of the response as possible. We communicate and coordinate with responders through our Regional Emergency Coordinators, and we inform the public through publications in medical literature, information on the Internet, and participation in national conferences. Certainly, there remains much to be done. An IND event could be a catastrophic event and we continue to develop expertise, products, and processes to provide an ever-improving response among Federal, regional, state, local and tribal responders and healthcare providers.

I recognize that there is much detail behind these various components that time does not permit me to present. Nevertheless, I thank you for the opportunity to provide this information to you and appreciate your interest in having the United States as prepared as possible.

I will be happy to answer any questions.