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Strengthening our Nation's Public Health Security through Medical Countermeasures and the Strategic National Stockpile

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Introduction

Good afternoon, Chairman Bilirakis, Ranking Member Richardson, and Members of the Subcommittee. I am Dr. Ali Khan, an Assistant Surgeon General and Director of the Office of Public Health Preparedness and Response, at the Centers for Disease Control and Prevention (CDC). Thank you for the invitation to address the Subcommittee today. My remarks will discuss the role of medical countermeasures (MCM), including the CDC Strategic National Stockpile (SNS), in strengthening our nation's public health preparedness and response, and ultimately our nation's health security.

Background

Threats to the public's health are always present. These threats can range from a local food-borne disease outbreak to the tornadoes that devastated the southeastern United States two weeks ago to the anthrax attacks in the fall of 2001. We cannot control when or where an outbreak, pandemic, natural disaster, nuclear incident, or terrorist attack may occur and threaten the public's health, but we can control how we respond to it. Threats to public health are threats to the nation's health security.

Because of its unique abilities to respond to infectious, occupational, or environmental incidents, CDC plays a pivotal role in ensuring that state and local public health systems are prepared for public health emergencies. CDC provides funding and technical assistance for state, local, tribal, and territorial public health departments through the Public Health Emergency Preparedness (PHEP) cooperative agreement. PHEP cooperative agreement funding provides approximately $700 million annually to 50 states, four localities, and eight U.S. territories and freely associated states for building and strengthening their abilities to respond to public health threats.

The same systems that we use to meet everyday public health needs are at the core of public health preparedness and response for unforeseen and unpredictable public health threats. State and local surveillance and epidemiologic investigations allow us to detect an emerging health threat and assess its scope, and laboratories identify and characterize the biological, chemical, or radiological agent causing it. The public health workforce at the state, local, and federal levels uses information from these resources to make decisions about how to respond to a public health emergency. In some cases, responding involves the use of MCM to protect or treat people who have been exposed, infected, or injured, or to protect the healthcare workers and others responding to the incident such as first responders and critical infrastructure personnel.

The SNS is a national repository of MCM. It contains antibiotics, antiviral drugs, chemical antidotes, antitoxins, vaccines, life-supporting medications, and medical supplies that are available to state and local health departments during a public health emergency and when local supplies are depleted or unavailable. The specific MCM in the SNS formulary for response to CBRN events are based largely on assessments by HHS of the need for MCM to address material threats to national security identified by Department of Homeland Security (DHS).

The SNS is a vital and valuable resource for protecting the American people. Many threats against the public health component of national security are from chemical, biological,

radiological, or nuclear (CBRN) agents for which there are few, if any, commercially available lifesaving MCM. The SNS is, in many cases, the only viable purchaser and holder of necessary quantities of these scarce materials which are vital for a successful response to many incidents.

As important as the national capability to obtain and hold these MCM is, the success of health security interventions of the SNS depends on several factors. These include the detection and characterization of an event to the timely delivery of these assets to the site of an incident to the local plans for receiving, distributing, and dispensing them in the communities. The SNS has developed, tested, and used pathways to accomplish these goals. CDC's job is not finished, and the SNS continues to work towards more rapid, efficient, and cost-effective ways to accomplish this mission.

Importance of State and Local Partnerships

CDC is working to continually improve our capability to deliver SNS assets to affected areas during a public health emergency. This work has led to the recent reformulation of the 12 hour push packages—assets designed to provide a broad spectrum of potentially beneficial interventions in the early hours of an emergency when we do not have complete information—that expanded the capability of each 12 hour push package for use in response to a biological incident, such as an anthrax release. CDC has also increased the number of storage locations to allow for better and faster distribution across the country. The result is that the SNS can deliver large amounts of MCM anywhere in the United States and the U.S. territories in a very short window of time, and CDC continues to work to decrease that time window even further.

Getting these products to the people who need them during an emergency depends on sufficient infrastructure and planning at the state and local levels. CDC goes beyond stockpiling and delivering SNS MCM assets to supporting our partners at the state and local levels to develop and refine their abilities to effectively receive and utilize MCM delivered from the SNS. CDC is also exploring innovative ways to dispense them to communities by cultivating strong collaborative partnerships among planners, emergency responders, and businesses at the state and local levels. CDC supports these partners by providing funding through the PHEP cooperative agreement, technical assistance, distribution plans, and performance measurement consultation.

CDC provides technical assistance to state and local health departments on receiving and dispensing SNS and other medical assets. This assistance includes written guidance, on-site and video teleconference consultations, training and exercise support (e.g., workshops, national training summit, tools to design and test response plans), and direct assistance of CDC personnel at state health departments. Just as the nature and contents of the SNS have evolved over time, the guidance, assistance, and support CDC offers to states have also adapted to changing needs. SNS Program Services Consultants (Consultants) are CDC employees available to support states and localities that receive PHEP cooperative agreement funding to engage the SNS. SNS Consultants regularly provide direct, on-site technical assistance to state and local personnel on interpreting guidance, developing and refining plans, conducting training and exercises, and evaluating capabilities and performance. SNS Consultants are backed up by dedicated training,

exercise, and response teams from CDC that conduct regular training in Atlanta and provide on-site training and exercise support to states.

State and local public health responders depend on the implementation of emergency contracts and, in some cases, mobilization of volunteer workforces to distribute MCM during an event. CDC recognizes that volunteers are critical to the final dispensing of MCM and sponsors grant-funded pilot studies of innovative means to recruit volunteers. All of these functions feed into the ongoing development of the capabilities critical to the effective dispensing of MCM to the communities of each state.

Every state maintains plans to receive, distribute, and dispense MCM received from the SNS. These plans are all unique and account for the local infrastructure and supporting government and commercial partnerships at the state and local levels. These plans are evaluated and exercised by the SNS coordinators at the state and local levels and reviewed by the SNS Consultants as part of annual reviews. To facilitate the improvement of plans and aid in the development of new capabilities, CDC maintains several forums to actively share promising practices and innovative concepts and foster discussions among SNS Consultants and state and local staff. CDC has also developed several modeling tools that facilitate planning at the federal, state and local levels, providing officials with ways to evaluate plans without resource intensive drills or exercises.

To evaluate the effectiveness of each state's plans to use MCM, SNS Consultants conduct regular Technical Assistance Reviews (TARs) at least annually to ensure continued readiness. These reviews use an objective, quantitative scoring framework to assess plans for receiving, distributing, and dispensing SNS assets. CDC conducts these reviews at the state, local, and territorial levels and provides each level with a tool to help them identify gaps in their plans.

The purpose of this technical assistance and performance measurement consultation is to ensure that each state and local health department has the ability to utilize SNS MCM assets during the window where it would make a difference from a public health standpoint. Because different incidents require different modes of dispensing and different timelines for effective treatment, CDC has established a flexible framework for the delivery of MCM from the SNS, through partnerships with air and ground transportation providers, from a network of storage locations. Within this framework, CDC staff can ensure the best combination of location and method of transportation to support the delivery of MCM within the required timeframe.

During the 2009 H1N1 influenza pandemic response (April 2009 to spring 2010), there was a clear need to provide antiviral drugs and personal protective equipment to minimize illness and death. The SNS distribution planning and MCM holdings helped CDC to rapidly deploy large quantities of key medical assets, including 11 million regimens of antiviral drugs as part of the deployment of 25% of pro rata allocations of pandemic influenza MCM, including personal protective equipment to all U.S. states and territories. CDC also released 300,000 bottles of Tamiflu® oral suspension for pediatric use to fill production gaps and meet increasing demand. Later, SNS distributed 234,000 additional bottles of the suspension to all U.S. states and territories. HHS also authorized the release of 59.5 million N95 respirators from the SNS to all

U.S. states and territories that requested them. The SNS achieved all planned timelines for this distribution.

Lessons learned from real-world events such as the 2009 H1N1 influenza pandemic response and ongoing work with the SNS have been applied to a broad range of public health problems. For example, California relied on its extensive public health preparedness, planning, and training to distribute and dispense MCM to respond to an outbreak of pertussis, or whooping cough, in 2010.[1] Surveillance systems first brought the increase in the number of cases among pediatric hospital patients to the attention of the California Department of Public Health (CDPH) in early 2010. To prevent transmission of pertussis to vulnerable infants, CDPH offered free vaccine and encouraged hospitals and local health departments to support vaccination of new mothers and newborn caregivers. County public health departments across California applied elements of SNS planning and public health preparedness to develop and disseminate educational materials and clinical guidance, raise community awareness, and set up accessible and innovative vaccine dispensing points, from mobile clinics to grocery stores, to reach their communities. The success of this response can be attributed to not only prior SNS planning among CDC, state, local, and private partners, but also the capability of the public health workforce in counties across California to receive and administer the vaccine in a timely manner.

Federal Partner Collaboration

CDC collaborates with federal partners on several MCM efforts. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is a coordinated interagency effort to define and prioritize public health emergency MCM requirements, focus research, development, and procurement activities for identified requirements, and establish deployment and use strategies for MCM in the SNS. PHEMCE is led by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes key federal interagency partners, including DHS. Together, the PHEMCE partners work to optimize our preparedness for public health emergencies with respect to the creation, stockpiling, and use of MCM.

CDC also collaborates with ASPR and other federal partners on the interagency implementation of Executive Order 13527, "Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack." CDC is currently looking at ways to further reduce the time required to deploy assets at the federal level and to better understand the costs associated with these changes, particularly at the state and local levels, where resources are limited. CDC subject matter experts have participated in DHS- and ASPR-led interagency working groups to generate the planning documents required by the Executive Order. Through these working group interactions, CDC is addressing the public health issues associated with the implementation of the Executive Order. These collaborative efforts with DHS have resulted in plans to respond that will better protect the public's health.

CDC is also working with federal partners to optimize the use of MCM. For example, CDC is collaborating with DHS and the Food and Drug Administration (FDA) to establish a process to validate laboratory methods that will enable the public health community to respond effectively and appropriately. This process will be used in the Laboratory Response Network, which is

[1] CDC. Notes from the Field: Pertussis --- California, January--June 2010. MMWR June 9, 2010; 59(26):817

managed by CDC. CDC is also working with the Biomedical Advanced Research and Development Authority (BARDA) to enhance our abilities to rapidly test clinical specimens and determine who has been exposed to a biological agent in order to provide effective post-exposure prophylaxis. DHS and CDC are also working to develop rapid antimicrobial resistance testing to quickly identify agents that may be resistant to first-line MCM in the SNS, conduct anthrax-related exercises, and develop risk assessments for CBRN threats.

PHEMCE Recommendations Guide SNS Procurements

The contents of the SNS are determined by the PHEMCE, which assesses the SNS' formulary and makes recommendations based on current scientific evidence about future procurements. PHEMCE provides priorities to guide the allocation of funds to the most critical MCM requirements and the recommended MCM are added to the SNS as resources allow.

The current PHEMCE process for identifying MCM requirements includes activities to identify and assess CBRN threats through DHS threat prioritization; assess medical and public health consequences for a given threat scenario and use of MCM for each threat agent through HHS public health modeling; and consult with subject matter experts. ASPR then assesses MCM requirements by incorporating the DHS threat prioritization and medical and public health consequence assessments with evaluations of current levels of preparedness, concepts of utilization, and product specifications.

Maintaining the inventory of the SNS poses a significant challenge. All MCM stockpiled in the SNS are subject to FDA regulations. These regulations include a requirement to label products with expiration dates that are intended to protect the public from ineffective products. While some of these FDA-approved MCM are included in the FDA Shelf Life Extension Program, extension is not an option for the majority of MCM, and so all of the MCM will eventually expire. SNS appropriations must be used not only to procure new MCM, but also to replace items that have expired. Therefore, there are many resource demands for expanding capabilities to meet PHEMCE requirements.

Innovation is critical to ensuring that public health preparedness remains dynamic and responsive to changing needs. For example, we continue to examine the formulary to address new threats like multi-drug resistant anthrax. CDC is also seeking innovative ways to use the existing, limited supply of MCM in the SNS. For example, CDC is providing technical support to the National Institutes of Health (NIH) and BARDA to conduct anthrax vaccine dose sparing studies to explore the effectiveness of using smaller doses of anthrax vaccine for each person to potentially use the current product in the SNS to treat more individuals.

Optimizing the Use of MCM in the SNS

In addition to the previously mentioned federal partnership activities to optimize the use of MCM, CDC's ability to use the MCM provided by SNS during an event depends on the necessary regulatory mechanisms that allow for deployment, dispensing, and utilization of SNS MCM assets. In order to treat individuals at the state and local level with MCM that have not been approved, licensed, or cleared by FDA for their intended uses, Emergency Use

Authorization (EUA) or Investigational New Drug protocols must be in place for each product for the intended purpose. CDC also continues to prepare for potential deployment and use of MCM by preparing pre-EUA documents and working with FDA to streamline the process for obtaining an EUA at the time of an incident. For example, at the request of DHS and with FDA, CDC is assisting in the development of an EUA for certain MCM that could be pre-authorized, rather than waiting until an emergency occurs. This supports continuity of operations planning through implementation of Executive Order 13527 and would allow federal agencies to store and forward place caches of MCM to treat mission-essential personnel, thereby shortening the timeframe in which MCM would be made available for use and ensuring continuity of operations.

In addition, during an emergency, CDC must be able to provide clinical guidance for public health and medical professionals. Difficult allocation decisions should also be made in advance of an emergency to the extent possible. For example, prioritization policies are needed to identify populations at highest risk of exposure following an incident because the need for certain limited MCM would likely exceed supply. CDC is currently beginning the process of developing an anthrax vaccine policy that would provide guidance on priority populations for vaccination as well as those who should not be vaccinated, much like we do annually for influenza .

CDC is also working with state and local partners to identify ways and develop systems to better track MCM supply during a public health emergency response. During the 2009 H1N1 influenza pandemic, the federal government was able to distribute antiviral drugs and other MCM to the states, in accordance with pandemic influenza response plans. This activity ensured the availability of MCM at the state level. However, there was no standard mechanism to track distribution at the local level. While state and local partners cooperated in CDC's efforts to establish this level of visibility as the response progressed, the lack of detailed, accurate inventory tracking information was challenging for the decision making process for further SNS deployments. CDC is applying lessons learned from the response to understand the most effective and efficient means to distribute and track antiviral drugs during a pandemic.

The optimal use of MCM also requires rapid feedback on how well drugs and other interventions are working and how effectively individuals are able to use public health information to protect themselves and their families. As with other drugs, monitoring for adverse events related to the use of MCM is important to guide future recommendations. Providing decision makers and public health authorities with adverse event data is useful not only for identifying new concerns, but also for demonstrating that safety monitoring is a vital part of any emergency response.

Challenges to Maintaining a Strong, Flexible System

We have been successful in expanding CDC and public health resources for preparedness through federal interagency support and strong state and local collaboration, but there is still much work to do.

CDC staff and the interagency participants in PHEMCE diligently evaluate the SNS to ensure that the public receives the best value for the funding invested, and that the holdings of the SNS are scientifically reviewed and prioritized.

The result of this decoupled system for determining requirements and budgets is that CDC prioritizes the use of funds to meet the requirements.

Other challenges include professional shortages in State and local workforce and limited subject matter expert capacity for MCM data review. In addition, limited safety and efficacy data is available for many MCM for special populations such as children and pregnant women. CDC is working with HHS, FDA, and NIH to seek innovative ways to obtain critical data to improve the evidence base for use in these populations.

Conclusions

The SNS is a unique federal asset. Effectively using the SNS requires a collaborative effort by state, local, tribal, territorial, and federal partners on everything from MCM development to development of diagnostics to detection of an event to distribution and dispensing of MCM. CDC is seeking ways to ensure appropriate use of resources in the current fiscal environment. We see examples every day across the nation of how public health preparedness and planning to use MCM from the SNS are being incorporated into everyday public health systems.

CDC continues to work with federal partners, including DHS, to integrate federal capabilities in the overall effort to identify, develop, acquire, distribute, and dispense MCM—with the ultimate goal of getting MCM to the people who need them. Being prepared to protect the public's health is ultimately an issue of health security.

I thank you again for the invitation to testify before you today. I will be happy to answer any questions you may have.