

Written Testimony of the Department of Homeland Security
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Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology

Chairwoman Clarke, Ranking Member Lungren and members of the Committee. The Department of Homeland Security (DHS) thanks you for taking the time today to discuss the national response to 2009 H1N1 flu. The DHS Office of Health Affairs (OHA), the Federal Emergency Management Agency (FEMA) and Immigration and Customs Enforcement (ICE) are key players in DHS efforts to ensure the nation is prepared for the effects of 2009 H1N1 influenza.

At this time, the nation has a solid idea of the scope and severity of the outbreak. However, we are still watching to see what changes will occur during regular flu season, if any, as the seasonal flu strains circulate concurrently with the 2009 H1N1 virus. DHS has worked in close collaboration with the Department of Health and Human Services (HHS) and other agencies to lead a strong response since the initial appearance of 2009-H1N1 flu in the spring, and we have implemented changes to continually improve our response now and in the future.

Lessons Learned and Accomplishments

As a result of what we learned in the spring about H1N1, the federal government has updated its response plans, enhanced our community mitigation planning and guidance, and improved a range of our abilities. We have effectively pre-deployed antiviral medications, and we have created and disseminated messages that help the public understand what the nation is facing. These improvements are not only critical to our H1N1 response, but are also critical to responding to future pandemics when they occur.

Specifically, the Department and other federal agencies had been planning for an influenza pandemic for many years, and especially since 2005. However, we learned this past spring that much of what actually occurred in the H1N1 outbreak did not align with prior avian flu planning. Since the spring, DHS has led interagency efforts to develop and implement H1N1-specific preparedness and response planning activities. On Aug. 25, 2009, the Secretary of Homeland Security signed the *DHS 2009-H1N1 Influenza Implementation Plan*, which identifies specific component roles and responsibilities, and directs all DHS components to develop plans that address key preparation and response actions, performance of mission essential functions, workforce protection, continuity of operations, and communications with key stakeholders during the H1N1 influenza outbreak. We also worked with the Department of State to clarify the status of international border operations under provision of the Security and Prosperity Partnership of North America's Plan for Avian and Pandemic Influenza.

Interagency Coordination

Throughout the response to H1N1, DHS has engaged closely with federal interagency partners, including the Department of Health and Human Services (HHS) and its Centers for Disease Control and Prevention (CDC), the Department of Education, the Department of State, and the White House. DHS has also worked with state, local, tribal, and territorial governments and with the private sector to help mitigate and monitor the spread of this illness.

Our partnerships with HHS, including the HHS Assistant Secretary for Preparedness and Response (ASPR), and other federal departments and agencies continue to play a critical role in our efforts. The National 2009 H1N1 Summit, held on July 9, 2009, brought together the Secretaries of DHS, HHS and Education, other federal officials and experts, staff from governors' offices, state, tribal and territorial health, education, and emergency management/homeland security officials, and national organizations to discuss H1N1 response realities and potential fall scenarios. The summit was condensed into a webcast for city, county, and local officials and released on Aug. 4, 2009, to update local officials on the status of H1N1, resources available and expectations going forward.

In addition, DHS, HHS, and CDC to provide updated guidance to help multiple segments of the private sector and academic community prepare for and respond to 2009 H1N1. DHS, HHS, and the Department of Education released updated guidance for the K-12 education community on Aug. 7, 2009; updated business guidance from DHS, HHS, and the Department of Commerce followed on Aug. 19, 2009; and guidance for higher education institutions came the following day. In conjunction with the business guidance, DHS, HHS, and the Small Business Administration also produced a small business guide on H1N1 preparedness.

Guidance to DHS Employees

DHS has one of the largest operational workforces in the federal government. The health and safety of this workforce continues to be a primary priority of DHS leadership. Therefore, OHA stockpiled personal protective equipment (PPE) and antivirals in advance of any influenza outbreak. Currently PPE is pre-positioned at over 120 DHS locations and field offices nationwide. Our antivirals are stored in a pharmaceutical warehouse, fielded across the operational workforce sites, and are prepared to be deployed as required by DHS components.

Throughout the H1N1 response, the Management Directorate and OHA provided DHS employees with new and updated guidance on a number of topics. This guidance has been disseminated to components, is available to all employees on the DHS intranet, and includes information on seasonal influenza and 2009 H1N1 vaccines, influenza antiviral medications, low- and medium-exposure risk occupations, mandatory use of respirators for high and very high exposure risk occupations, fit testing and fit checking of respirators, and human resources flexibilities for employees as well as supervisors and managers. We will continue to provide our employees with guidance based on the best science available.

The Office of Health Affairs

For the past three years, OHA has led the Department's pandemic preparedness activities, placing it in a position to assume a appropriate leadership role when the pandemic occurred. OHA stood up a Decision Support Cell at the first reports of an outbreak, and worked directly with our interagency partners to provide information needed by DHS leadership to coordinate the federal response. OHA also serves as the DHS representative to interagency coordinating bodies focused on 2009 H1N1.

OHA is co-leading the DHS 2009 H1N1 planning effort in cooperation with the DHS Office of Operations Coordination (OPS). The office also plays a critical role in protecting the DHS workforce, particularly higher-risk employees. OHA provides health and medical guidance to operational components, and has stockpiled PPE and antivirals for DHS employees. To test our internal coordination for workforce protection, OHA conducted an Assistant Secretary level 2009 H1N1/Pandemic table top exercise on Sept. 10, 2009. The exercise was designed to provide an opportunity for DHS offices and components to identify how they will continue to meet their essential functions while protecting employees during an influenza pandemic event. The forum validated operational relationships, the soundness of Secretarial decision-making processes, and roles and responsibilities of DHS components, confirming that DHS must continue to confront long-term pandemic-related continuity issues head on.

Biosurveillance

OHA, through the National Biosurveillance Integration Center (NBIC), integrates and analyzes biological surveillance information from multiple federal, state, local and private sector partners. NBIC provides senior DHS leaders a clear, comprehensive picture of ongoing incidents and/or outbreaks, both domestically and overseas, and provides the continuing capability to maintain cross-domain analysis and impact assessments of the novel 2009 H1N1 influenza pandemic.

Recognizing the potential consequences of 2009 H1N1 infections on multiple critical infrastructure areas of the United States, NBIC engaged with the National Infrastructure Simulation and Analysis Center (NISAC) to assess potential outbreak characteristics and infrastructure impacts of a resurgent novel-H1N1 virus. The results of the assessment effort were analyzed and reviewed by an aggressive and thorough interagency process that engaged all NBIC Member Agencies and additional federal participants (including the departments of Energy, Education, and Labor). The assessment was based on the best scientific snapshot of the outbreak in June and assumed no mitigation efforts. NBIC is now working with HHS and other departments and agencies to conduct an updated assessment that takes into account updated assumptions and mitigation strategies. DHS will use this information to continue to inform federal government planning and preparedness.

Incident Management

DHS has taken an aggressive, proactive approach to 2009 H1N1 incident management operations. FEMA has staffed and trained 56 Incident Management Assistance Teams-Advance (IMAT-As) to provide direct federal support to any state or territory upon a governor's request.

The primary mission of an IMAT-A is to rapidly deploy to an incident or at-risk venue, provide leadership in the allocation and provision of federal assistance, and to coordinate and integrate an inter-jurisdictional response in support of the affected state(s) or U.S. territory(s). The IMAT-As will support efforts to meet the emergent needs of state and local jurisdictions; possess the capability to provide initial situational awareness for federal decision-makers; and support the initial establishment of a unified command. In addition, last month, FEMA activated the National IMAT East to provide a dedicated coordination cell for the 2009 H1N1 national response. This cell coordinates with the DHS National Operations Center and the HHS Secretary's Operations Center, facilitates information collection and dissemination; is prepared to receive and evaluate requests for assistance from states and other federal agencies; and is ready to expand as needed.

For the 2009 H1N1 influenza pandemic, Secretary Napolitano elected to replace the National Pandemic Influenza Principal Federal Official (NPI-PFO) field teams with reconfigured 2009 H1N1 Regional Coordination Teams (RCTs). Secretary Napolitano has outlined clear missions for the 2009 H1N1 RCTs, which will:

- Serve as a conduit between the many federal agencies engaged in the 2009 H1N1 response efforts and our various partners in the States;
- Identify and, through the established incident management architecture, respond to the Secretary's critical information requirements, enabling the Secretary to make decisions related to her role as the Principal Federal Official for the 2009 H1N1 Pandemic;
- Serve as the Secretary's primary source in the field for awareness of strategic issues related to the 2009 H1N1 pandemic and help broker resolution of significant disputed issues;
- Report through the FEMA Regional Administrator and the Federal Coordinating Officer (FCO). This will ensure that the FEMA Regional Administrators can focus on emergency management and regional administration functions and the FCOs can focus on and lead the administration and coordination of relief at the operational and tactical levels as required by law;
- Assist DHS Component and other federal interagency leaders in the field to coordinate and collaborate to achieve nationally directed strategic objectives, including those related to entry and exit screening, quarantine, isolation, vaccination, continuity of operations, and continuity of government.

Federal Emergency Management Agency Activities

In addition to establishing the IMAT-A teams, FEMA is identifying and addressing potential gaps in federal response plans, and is providing critical preparedness and response assistance to states and localities.

As a proactive measure at the federal level, FEMA has shared with HHS a number of Pre-Scripted Mission Assignments (PSMAs) to expedite potentially necessary support to states. In the absence of a declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, P.L. 93-288, the PSMAs provide an advance architecture for the scope and cost of federal support that HHS can use to develop Interagency Agreements (IAAs) between HHS

and the Emergency Support Function Departments and Agencies. For example, PSMA's have been established to outline how HHS will seamlessly integrate with the IMAT-A teams, FEMA's Regional Response Coordination Centers and the National Response Coordination Center.

FEMA is also taking the lead in the effort to ensure that the federal government can continue operating in the event of significant absenteeism in a major outbreak. The agency's National Continuity Programs (NCP) Directorate has developed and tested its Continuity of Operations for Pandemic to ensure the relevant federal departments and agencies have the capability to continue supporting disaster activities if pandemic conditions warrant social distancing. NCP has developed planning guidance to address differences in pandemic continuity planning and traditional continuity planning. For example, unlike more traditional continuity planning scenarios, pandemic influenza may be widely dispersed geographically and could arrive in waves that could last several months at a time.

To ensure that all of these federal planning efforts are well coordinated across all agencies, FEMA has incorporated lessons learned in the Common Operating Picture (COP), within the Homeland Security Information Network (HSIN). The COP is a web-based tool that collects information and provides data to our partners in the government and in the private sector. To continue updating and improve planning efforts, FEMA provides the DHS Deputy Secretary status updates on a select number of action items, which are included in the Department of Homeland Security Weekly Situation Report. The DHS Situation Report (SitRep) is uploaded to the COP by DHS OPS each week. The DHS weekly SitRep, which provides updated information from responding Federal Departments and Agencies, including HHS, specifically highlights information such as:

- Stafford Act emergency declarations and requests for federal assistance (to date, there have not been any Stafford Act declarations or requests of DHS pertaining to H1N1.)
- Status of federal-state coordinating elements (e.g. RCTs, ESFs, and IMAT)
- Status of reported school closings
- Updates from all federal departments and agencies
- Impacts, if any, on critical infrastructure and key resources (i.e. absenteeism, operational impact, 7-10 day concerns, mitigation measures, and unique concerns)
- Any specific department or agency updates regarding planning or operational capacity within the four national framework pillars: mitigation, surveillance, communication and vaccination.

FEMA is also playing a key role in proactively assisting state and local governments with their H1N1 preparedness and response efforts. For example, the agency's Mass Care Unit is working with state, regional, and other federal agencies and non-governmental organization partners in the development of a Mass Care (ESF6)/Emergency H1N1 Planning Guidance Template that will assist states with planning for sheltering, feeding operations and donations management within an H1N1 environment. The Mass Care/Emergency Assistance Planning Guidance Template provides guidelines for the FEMA regions to support states in their planning efforts for either a pandemic or a pandemic combined with a natural or man-made disaster. Some of the functions included in the template are sheltering, feeding, providing emergency supplies, supporting mass evacuations, facilitating unification, and supporting household pets.

FEMA's National Preparedness Directorate's Center for Domestic Preparedness (CDP) revised the Pandemic Influenza Planning and Preparedness (PIPP) course to reflect new information about the 2009 H1N1 strain along with updated planning considerations. This course is available to state, territory, local and tribal homeland security and emergency management professionals.

FEMA's Individual Assistance's Crisis Counseling Program (CCP) is also working with HHS' Single State Medicaid Agencies (SMSA) to develop a contingency plan for administering CCP technology in the event of a mass infectious disease outbreak.

Finally, FEMA's Disaster Assistance Directorate has developed procedures and criteria, under the authority provided in the Stafford Act for requesting assistance from the federal government. The President approves all Stafford Act emergency and disaster declaration requests (DAP 9523.17). The Disaster Assistance Directorate has developed guidance titled "Procedure for Evaluating State Requests for Emergency Disaster Declarations for Pandemic Influenza," which is designed to provide states information on factors considered in evaluating state requests for emergency assistance declarations for a pandemic influenza. In addition, FEMA Public Assistance is developing a Disaster Assistance Fact Sheet, entitled "2009 H1N1 Influenza Frequently Asked Questions."

ICE National Intellectual Property Rights Coordination Center

Immigration and Customs Enforcement places a significant emphasis on reducing the threat to health and safety posed by the trafficking of counterfeit, unapproved, and substandard pharmaceuticals. Due to the current 2009 H1N1 threat, this emphasis now includes efforts to identify and interdict counterfeit 2009 H1N1 vaccines and other influenza treatment products, such as counterfeit antiviral medications. In addition to the investigative resources of the ICE Office of Investigations, and the Office of International Affairs, ICE spearheaded the establishment of a new National Intellectual Property Rights Coordination Center (IPR Center). The IPR Center now includes representation from all federal agencies with enforcement jurisdiction over intellectual property (IP)-related crime, including U.S. Customs and Border Protection (CBP), the Federal Bureau of Investigation (FBI), the Food and Drug Administration (FDA) - Office of Criminal Investigations, the U.S. Postal Inspection Service (USPIS), the Department of Commerce, and the Department of Justice Computer Crimes and Intellectual Property Section (CCIPS). Of particular significance is the recent inclusion of Mexico Customs as a partner agency, providing ICE and the IPR Center with the ability to more effectively address cross-border commercial fraud issues between our two countries.

With the reorganization and restructuring into the IPR Center, we have created a true task force environment, bringing together the statutory authority of the partner agencies for a more focused approach to addressing pharmaceutical-related IP crime. The IPR Center develops and receives actionable leads; generates intelligence, seizures, investigations and initiatives; and conducts outreach and training. One of the primary missions of the IPR Center is the analysis, deconfliction, and coordination of leads received from private industry, counterpart law enforcement agencies, and public avenues. This is accomplished through the sharing of all lead information with agency partners for review and vetting, and is vital to the identification and

coordination of existing investigative or interdiction overlaps. To maximize its investigative capabilities, the IPR Center is conducting ongoing investigations of subjects, organizations, and networks exploiting the Internet to facilitate the sale and distribution of counterfeit, tainted and substandard products.

As previously noted, ICE places specific focus on products that present a threat to the health and safety of the U.S. public, which currently include 2009 H1N1 and antiviral medication counterfeit pharmaceuticals. In 2004, ICE developed and implemented Operation Apothecary, which specifically focuses on international mail and express courier services that facilitate the importation of counterfeit and unapproved pharmaceuticals. Operation Apothecary generates information about, and conducts investigations of, subjects and websites involved in the sale and importation of suspect pharmaceuticals.

With the outbreak of 2009 H1N1 earlier this year, ICE and its partners at the IPR Center projected a potential influx of counterfeit influenza products. In response, the IPR Center proactively initiated undercover activity targeting individuals and websites that were offering potential counterfeit influenza treatment products for sale. Even with heightened vigilance, close attention and thorough investigation, to date ICE has found no evidence of the illicit production or dissemination of counterfeit antiviral medications in the United States. While we have not encountered any counterfeit vaccines or medicines to date, we recognize the potential for the emergence of this threat. ICE will remain diligent in coordinating with our domestic and foreign partners and counterparts on this issue, and will continue to conduct investigative and interdiction activity targeting counterfeit 2009 H1N1 vaccines and other associated pharmaceuticals.

Conclusion

In closing, DHS is continuing to address 2009 H1N1 influenza aggressively, as it has since the first appearance of this virus in the spring. Since that time, we have strengthened our plans and our response capacity as we have learned more about 2009 H1N1, and we have built a strong, coordinated, and effective response. Again, thank you for inviting us to testify on this important issue, and we are happy to answer any questions you have.