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House Committee on Homeland Security
Subcommittee on Emergency Preparedness, Response and Communications
"Taking Measure of Countermeasures (Part 2): A Review of Efforts to Protect the Homeland Through Distribution and Dispensing of CBRN Medical Countermeasures"
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Chairman Bilirakis, Ranking Member Richardson, and members of the Subcommittee: My name is Jeffrey Levi, and I am Executive Director of Trust for America's Health (TFAH), a nonprofit, nonpartisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. I am grateful for the opportunity to testify before the Subcommittee today on the distribution and dispensing of medical countermeasures (MCM) for chemical, biological, radiological, and nuclear (CBRN) threats.

I have two major points to make in my testimony today:

First, our nation faces continuing natural and man-made threats that require an ongoing commitment to public health preparedness. This is a national security threat – as direct as any we face abroad. The death of Osama Bin-Laden does not erase that threat; there are still very creative terrorists out there and our guard cannot be let down.

Second, we must fund public health preparedness with the same level of commitment as we have made to other national security priorities. This means: (a) we must assure reliable, predictable funding for public health preparedness, in contrast to the 27 percent decline faced over the last several years; (b) we must assure that state and local health departments are given flexibility to use all employees supported with federal funds during an emergency and not be hamstrung by categorical restrictions; (c) and we must fully embrace the spirit of "all hazards" in the Pandemic and All-Hazards Preparedness Act (PAHPA) by recognizing that almost every public health program contributes to preparedness. As our health care system modernizes – especially with regard to health information technology – we must be sure public health programs, such as biosurveillance, adapt as well, including by leveraging existing resources in more creative ways.

As you know, research and development of medical countermeasures are only half of the battle in our capacity to quickly respond to a public health disaster. These medicines, diagnostics, vaccines, and devices must also reach the potential victims. That is why we need a well-staffed, well-trained, and well-funded public health system to ensure these drugs reach the mouths or arms of every impacted individual.

The public health system has always been integral in our response to natural disasters and terrorist attacks. Public health was on the frontlines of the response to 9-11 and to the anthrax attacks. It is as fundamental to the nation's security as our military and as fundamental to local protection as fire and rescue. Passage of PAHPA codified and expanded the federal

government's support for this role. As a result of this legislation, and the investments that followed, our nation is more prepared than ever. We saw this in the response to the H1N1 outbreak in 2009, when nearly every state and jurisdiction implemented its pandemic influenza plan in response to the H1N1 outbreak, with activities including disease surveillance, ongoing communication updates, carrying out vaccination campaigns and the coordination of response efforts with partners.[1]

Since 2003 TFAH has been tracking our nation's progress in improving our preparedness through our annual report entitled *Ready or Not: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism.* In our 2010 report, we found that states had made enormous progress since the events of 2001 in planning for and responding to disasters. The Public Health Emergency Preparedness and Hospital Preparedness Programs, federal, state, and local attention to the role of public health in emergency preparedness, and real-world experiences such as the H1N1 outbreak have helped us bring preparedness to the next level. However, the report also found that the economic crisis is putting almost a decade of gains at serious risk. While emergency H1N1 and stimulus funds may have helped states weather the storm of the pandemic, we cannot continue to fund preparedness on a disaster-by-disaster basis.

Our report laid out several remaining public health gaps that need to be addressed, each of which impacts our ability to distribute and dispense medical countermeasures: A workforce and infrastructure gap, a surge capacity gap, a surveillance gap, a gap in community resiliency support, and gaps in medical countermeasure development. I'll address these in turn.

Workforce and Infrastructure Gap: The economic recession has led to cuts in public health staffing and eroded the basic capabilities of state and local health departments. Our report found that 33 states and D.C. cut public health funding from fiscal years 2008-09 to 2009-10, with 18 of these states cutting funding for the second year in a row. In addition, federal support for public health preparedness was cut by 27 percent between FY2005 and FY2010 (adjusted for inflation). We also expect to see major cuts to federal public health preparedness programs in both FY2011 and 2012. The National Association of County and City Health Officials reports that we have lost roughly 19 percent of the local health department workforce since 2008. This loss of experience has a staggering impact on preparedness, as workers cannot simply be hired and trained once a disaster strikes. Strengthening the public health preparedness infrastructure is critical to ensuring the health protection of our nation through distribution and dispensing of medical material. It also requires adequate funding and human resources to recruit and train personnel, stockpile life saving countermeasures, develop and exercise plans to distribute assets, and identify and engage partners to support the public health mission. The resources required to truly modernize public health systems must be made available to bring public health into the 21st century and improve preparedness.

During the 2009-2010 H1N1 influenza outbreak, state and local health departments were on the front lines responding to the pandemic, though many were limited in their efforts as a result of federal and state budget cuts, particularly those that have occurred over the past five years. These

[1] Centers for Disease Control and Prevention, *Public Health Preparedness: Strengthening the Nation's Emergency Response State by State, September 2010.* Available from: http://emergency.cdc.gov/publications/2010phprep/pdf/complete_PHPREP_report.pdf

budget crises demonstrated, among other things, the need to build in mechanisms to allow more flexibility in how staff, funded by federal grant programs, are used during emergencies. In the H1N1 influenza response, the ability to re-assign staff from other funded projects in health departments could have improved the financial and human resource efficiencies of that agency's response to the influenza pandemic, especially during the earlier response phases when additional funding was not yet available and jurisdictions needed to mobilize "all hands on deck."

The Department of Health and Human Services (HHS) and Department of Homeland Security (DHS) have been working to align grant programs that aim to build our nation's emergency preparedness capacity, including the Public Health Emergency Preparedness (PHEP) grants, Hospital Preparedness Program (HPP), and FEMA grants. Currently the PHEP and HPP grants, both of which are often distributed through public health departments, have separate application and reporting requirements, overarching goals, and in some cases conflicting performance metrics. We believe the alignment process should include coordinating grant priorities and goals, grant cycles, and streamlining application and reporting mechanisms to achieve maximum efficiency. We hope this Committee works with your counterparts in Energy & Commerce to ensure the alignment process continues.

Surge Capacity Gap: Surge capacity, the ability of the medical system to care for a massive influx of patients, requires ongoing planning, funding, and coordination across healthcare, public health, first responder, and private sectors. The medical system will be an integral partner in distributing medical countermeasures, as we saw during H1N1, so we must prepare them to triage and identify targeted recipients. We believe efforts currently underway to build regional collaboration into the Hospital Preparedness Program are essential to leverage the capacity of the inpatient and ambulatory healthcare system for medical asset dispensing.

Surge planning must also take into account the important role of volunteers in mass dispensing. The Medical Reserve Corps (MRC) is a national network of community-based groups which include volunteers from public health, medicine, nursing, and non-medical support fields. During the H1N1 outbreak, MRC units across the country participated in 2,500 response activities, including vaccination clinics, significantly augmenting the capacity of local public health to implement the immunization strategy.[2] However, in a survey conducted during the outbreak, MRC units reported that fear of liability was a significant barrier to full participation. [3] HHS has also acknowledged that a patchwork of federal liability laws is confusing and frustrating to other healthcare providers.[4] HHS should clarify federal volunteer liability laws to implement one, blanket liability that applies to all volunteer health professionals and entities volunteering under a nationally-declared public health emergency or disaster. There should also

[2] Office of the Civilian Medical Reserve Corps, Report on the Medical Reserve Corps Response to the H1N1 Influenza Pandemic April – December 2009." http://www.medicalreservecorps.gov/file/PandemicFlu/MRC-H1N1-2009-final.pdf

[3] Office of the Civilian Medical Reserve Corps, "Medical Reserve Corps Units and H1N1 Influenza Related Activities: September 2009." http://www.medicalreservecorps.gov/file/SwineFlu/MRC_Units_H1N1_Flu_Activities.pdf

[4] DHHS, Office of the General Counsel, "Public Health Emergencies and Federal Health Law." Presentation at 2010 Public Health Preparedness Summit, February 2010. http://www.phprep.org/2010/Agenda/upload/Interactive-145.pdf

be Federal Tort Claims Act protection for MRC volunteers year-round, as these personnel participate in public health drills and training during times of non-disaster.

Surveillance Gap: The nation still lacks an integrated, national approach to biosurveillance, the gathering and analysis of data related to threats to human health to achieve early warning, detection, and situational awareness.[5] An interoperable, coordinated national biosurveillance system would significantly improve the country's capability to quickly detect an outbreak or attack and thus target our medical countermeasures appropriately. The lack of an overarching federal biosurveillance strategy has led to fragmentation, multiple separate surveillance systems, and barriers to relevant agencies prioritizing and synthesizing data.[6, 7] We urge HHS to lead the development of a national strategy, which should examine means to achieve interoperability and transparency among various surveillance systems.[8]

The national strategy should also call for leveraging of new epidemiological data that may become available as a result of the development of health information technology (IT) and electronic health records (EHRs). There is no overarching coordination between public health surveillance efforts at HHS and the work of the Office of the National Coordinator (ONC). For example, as ONC develops new standards for meaningful use of health IT, it should incorporate the preparedness and biosurveillance implications of such technologies. Interoperability between public health and EHRs could not only help with early detection of an emerging disease outbreak or bioterror attack, but could also help with identification of targeted populations or geographic regions to receive medical countermeasures and tracking the post-dispensing impact of medical interventions.

Community Resiliency Support Gap: We continue to face challenges in preparing communities to recover from a disaster, especially at-risk people. Without an ability to reach these populations, such as home-bound individuals or those with limited-English proficiency, we face significant barriers in distributing medical countermeasures to them. Public health must work with the private sector, community-based and faith-based organizations, healthcare organizations, and community leaders to develop trust and communication with at-risk communities before a disaster occurs. We also must address ongoing vaccine access issues during times of non-disaster, especially in high-risk communities. For example, according to 2008 data, 70 percent of older non-Hispanic whites received the seasonal influenza vaccination, compared to only 51 percent and 56 percent of older African-Americans and Hispanics,

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[5] Centers for Disease Control and Prevention, "Biosurveillance: A Definition, Scope, and Description of Current Capability for a National Strategy," Presentation before International Society for Disease Surveillance, 2008. http://www.syndromic.org/conference/2008/presentations/Track%203/ISDS%20Presentation_Fleischauer_Biosurveillance_2008.ppt

[6] Nuzzo, Jennifer, Center for Biosecurity of UPMC. "Developing a National Biosurveillance Program," *Biosecurity and Bioterrorism*. Volume 7, Number 1, 2009. http://www.upmc-biosecurity.org/website/resources/publications/2009/biomemo/2009-03-27-develop_natl_biosurveillance.html

[7] Vinter, S. et al, Trust for America's Health, *Ready or Not? 2009: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*. December, 2009. http://healthyamericans.org/reports/bioterror09/pdf/TFAHReadyorNot200906.pdf

[8] Nuzzo, 2009.

respectively.[9] This indicates a systemic problem with access, acceptance, and education that must be addressed before the next mass-dispensing campaign occurs.

Gaps in Medical Countermeasure Enterprise: As you explored in your April hearing, although we are miles ahead of where we were during the 2001 anthrax outbreak, our ability to spur innovation in limited-use technologies has been hampered by a lack of stable funding and some breakdowns in program administration. As the nation revamps its approach to research and development of vaccines, medicines, diagnostics and equipment to respond to emerging public health threats, policymakers must ensure public health is involved throughout the process, from initial investment through distribution and dispensing.

We believe a federal MCM strategy should lead to: 1) increased coordination between all of the involved agencies within HHS, DHS, and state and local public health, from initial investment through dispensing; 2) improved transparency of the development and distribution process; and 3) an end-to-end approach – not just focused on initial investments, but on advance development, procurement, distribution, and surveillance.

There should also be a plan for stocking the Strategic National Stockpile (SNS) and for ongoing replacement of expiring product, especially vaccines,[10] pediatric doses of antimicrobials, antivirals and other products, and restocking materiel used as a result of the H1N1 outbreak. This plan should also include a professional judgment budget for replacing product expiring over the next several years.

Success at Risk: The Urban-Rural Experience

Urban and rural areas face very different challenges in capacity to distribute and dispense medical countermeasures. For all jurisdictions, adequate workforce and resources are a continuing obstacle to effective dispensing.

The Cities Readiness Initiative (CRI) is a federal program that directly funds the largest metropolitan statistical areas (MSA) and provides technical assistance to develop capacity to receive and distribute medical countermeasures. Fifty percent of the U.S. population is covered by the 72 jurisdictions in the CRI program.[11] The program requires each area to demonstrate plans to be able to distribute antibiotics to the entire population within 48 hours. An analysis by RAND in 2009 found that CRI had helped cities develop the workforce, partnerships, planning, and purchasing capacity to dispense medical assets, but evaluation of the real capacity of cities to carry out these plans was limited due to the nature of the data collected.[12] We hope CDC continues to refine these measures to enable evaluation of the actual capacity and capabilities of

[9] HHS Office of Minority Health, Immunizations Data/Statistics, April 20, 2010. http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=3&lvlid=60.

[10] Testimony of Robert Kadlec Before House Homeland Security Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology. June 15, 2010. http://hsc.house.gov/SiteDocuments/20100615131640-79968.pdf

[11] Centers for Disease Control and Prevention, "Cities Readiness Initiative," May 20, 2010. http://www.bt.cdc.gov/cri/

[12] Willis, H.H., et al. RAND Corp, *Initial Evaluation of the Cities Readiness Initiative*, 2009. http://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR640.pdf

each jurisdiction, rather than just the adequacy of plans, and we urge CDC to release this data at the local level.

The impact of CRI in urban areas was demonstrated during the H1N1 outbreak. In Los Angeles County, for example, 200,000 people received free H1N1 vaccines at 109 points-of-dispensing (PODs) in a six week period.[13] And the county has in place plans to distribute medical assets to 10 million people within 48 hours, as required by CRI. L.A. is also in the process of developing partnerships with schools and child care facilities to serve as alternative dispensing sites. These kinds of partnerships are key to achieving coverage of an at-risk population (during H1N1, children), and ensuring that income, language, and transportation are not barriers to receipt of the product.

The rural perspective varies based on whether the area is part of a CRI. Those rural areas within a CRI's MSA have the benefit of additional resources and technical assistance from the federal program, with fewer people to serve. However, in truly rural areas, additional creativity is required. For example, one rural Virginia health department pursued agreements with fast food establishments and banks to serve as drive-thru PODs.[14] Rural areas also face different challenges due to the limitations of communications. In many areas, land-lines are the only consistent form of telecommunication, while cities can depend more reliably on internet and cell phone use.[15]

In both rural and urban areas, local health departments have had to rely on public-private partnerships to achieve maximum coverage of dispensing planning. During H1N1, health departments depended on big box stores, retail pharmacies, schools, and private physician offices to serve as distribution points. These partnerships are an acknowledgement that public health does not have the personnel to reach everyone in a community, but also demonstrates that the private sector and other community-level organizations often have better access to the population. Federal assistance, both before and during an emergency, should embrace and grow these partnerships. This is one of the reasons we support expansion of the mission of the Hospital Preparedness Program to include the entire medical system of a region.

Thank you for this opportunity to weigh in as the Subcommittee considers the end-to-end realities of a medical response to a disaster. I look forward to your questions.

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[13] Plough, A. et al, "Pandemics and Health Equity: Lessons Learned From the H1N1 Response in Los Angeles County," *Journal of Public Health Management & Practice*: January/February 2011 - Volume 17 - Issue 1 - p 20–27.

[14] McMorrow, Julie, National Association of County and City Health Officials, personal communication, May 10, 2011.

[15] Ibid.