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OCTOBER 24, 2014

EBOLA CRISIS: COORDINATION OF A MULTI-AGENCY RESPONSE

U.S. HOUSE COMMITTEE ON OVERSIGHT & GOVERNMENT REFORM

ONE HUNDRED THIRTEENTH CONGRESS, SECOND SESSION

HEARING CONTENTS:

WITNESSES

Hon. Nichole Lurie, MD *[view pdf]*
Assistant Secretary, U.S. Department of Health and Human Services

Hon. Michael Lumpkin *[view pdf]*
Assistant Secretary of Defense, U.S. Department of Defense

Major General James M. Lariviere *[pdf unavailable]*
Deputy Director, Political-Military Affairs (Africa), U.S. Department of Defense

Hon. John Roth *[view pdf]*
Inspector General, U.S. Department of Homeland Security

Deborah Burger, RN *[view pdf]*
Co-President, National Nurses United

Mr. Rabih Torbay *[view pdf]*
Senior Vice President, International Operations, International Medical Corps

AVAILABLE WEBCAST

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https://www.youtube.com/embed/kk265H-lacc?feature=player_embedded

Part Two
https://www.youtube.com/embed/_Y555EYoTWk?feature=player_embedded

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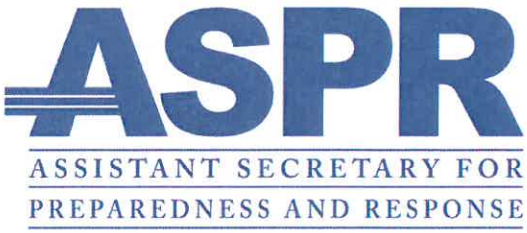
Written Testimony
House Committee on Oversight and Government Reform

"The Ebola Crisis: Coordination of a Multi-Agency Response"

Statement of
Nicole Lurie, MD, MSPH
Assistant Secretary For Preparedness and Response



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Good morning, Chairman Issa, Ranking Member Cummings, and other distinguished Members of the Committee. I am Dr. Nicole Lurie and I serve as the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS).

I appreciate the opportunity to talk to you today about the aggressive steps that HHS and other Federal Agencies have taken since the first cases of Ebola were identified in West Africa. By all accounts, the spread of this deadly disease in West Africa is unprecedented and we continue to work diligently, as part of the global community, to support the response and make necessary preparations in this country. The likelihood of a significant Ebola outbreak in the United States is remote, but ASPR, other HHS components, and other agencies are moving forward with preparedness planning to be ready for any contingency.

As the ASPR, I serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies. Since my confirmation as the ASPR in 2009, I have created cross-Department policy group, the Disaster Leadership Group, which is comprised of leadership from my HHS counterparts at the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA), to advise on critical preparedness matters, address ongoing response activities, and mitigate lasting effects of disasters. I also led the modernization of the medical countermeasure enterprise; created opportunities for new coordination among state and local health care systems; strengthened our systems for response; and advanced a science base to strengthen decision-making processes before, during, and after emergencies. Our all-hazards approach, a shift from individual planning efforts to a more comprehensive approach to all

public health and medical emergencies, allows us to be flexible and nimble to both known and unknown threats, including the current Ebola crisis in West Africa that has challenged the entire global response capacity.

As part of the HHS leadership team responding to Ebola, I lead coordination activities supporting the HHS policy team managing critical issues including: international engagement for HHS; establishing technical assistance for state and local health care providers; the development of medical countermeasures, vaccines, and treatments for Ebola as well as testing and possible use; and preparation of Federal personnel. I coordinate daily with the Secretary and other key HHS leadership to address Ebola. I engage on an ongoing basis with the Departments of Transportation (DOT), State, Defense (DOD), and Homeland Security (DHS), as well as the Department of Labor's Occupational Safety and Health Administration (OSHA), the U.S. Agency for International Development, and others, to share information and align activities. I also communicate regularly with the Assistant to the President for National Security Affairs and other White House leadership. My staff and I work aggressively to keep leadership well-informed of ASPR's engagement, needs, and priorities related to the ongoing Ebola epidemic in West Africa and our Nation's domestic preparedness. For HHS to be successful, each element of the Agency must be fully engaged in its mission space.

Recognizing the potential impact of the many threats we face, ASPR has sought to build relationships within and outside the Federal Government and internationally to enhance coordination; make improvements in planning, logistics, and personnel management for responses to emergencies within the United States; maximize coalition building under the

Hospital Preparedness Program; and coordinate efforts within the Public Health Emergency Medical Countermeasures Enterprise. Over the past five years, we have worked to create an infrastructure capable of developing, testing, producing, and deploying medical countermeasures for the range of threats we face. Even as we continue to learn from the outbreak in West Africa and the current situation in the United States and to make adjustments, that infrastructure serves us well as we develop Ebola countermeasures, ensure that our health care system is prepared, and make decisions based on the best available science.

As you know, three cases of Ebola have been detected in the United States—an individual who was infected in Liberia and two nurses who attended to him. Our hearts go out to them and their families. Mr. Duncan's death is a tragic loss. We wish the health care workers a speedy recovery as they fight this terrible illness. I understand why you and your constituents are concerned. We are extremely serious in our focus on protecting America's health security. The best way to do that is to support the response to the Ebola epidemic in West Africa to get infection and spread under control as quickly as possible. At the same time, thanks to the preparedness work and planning that has taken place over the past several years, we are speeding the development of medical countermeasures and preparing our public health and health care systems to deal with any further cases in the United States.

Let me pause here and provide an assessment of where we are today thanks to past investments. Thanks to the support of the Congress and feedback from critical stakeholders at all levels of government, we have made significant improvements in preparedness, response, and recovery at the Federal, state, and local levels. We have strengthened our medical countermeasures

enterprise to respond to chemical, biological, radiological, or nuclear (CBRN) threats. State and local partners are more prepared than ever before due to enhanced response capabilities, improved coordination, and enhanced awareness among the public health and medical communities.

HHS has made progress in preparing the Nation for the range of CBRN threats we face by creating a flexible capacity capable of developing and producing novel safe and effective medical countermeasures faster than ever before. Elements of this infrastructure are being used right now to develop countermeasures against the Ebola virus. In 2012, HHS established the Centers for Innovation in Advanced Development and Manufacturing, public-private partnerships that provide a significant domestic infrastructure in the United States to produce medical countermeasures to protect Americans. These Centers are now positioned to expand the production of Ebola monoclonal antibodies, like those in ZMapp, into tobacco plants and mammalian cells. The Fill Finish Manufacturing Network established last year will be used to formulate and fill Ebola antibody and vaccine products into vials for studies and other uses. With respect to vaccines, HHS is working to scale-up to commercial scale the manufacturing of promising investigational Ebola vaccine candidates with funds provided by the FY 2015 continuing resolution.

The Congress provided critical authorities and appropriated billions of dollars for development and procurement of CBRN medical countermeasures that have been turned into real products by the combined efforts of ASPR's Biomedical Advanced Research and Development Authority, NIH, FDA, and CDC. Despite some of the challenges that dealing with a serious illness such as

Ebola can have on even the most advanced health care system, I can say with certainty that we are now more prepared for the range of CBRN threats and other emerging infectious diseases, such as pandemic influenza, than at any point in our Nation's history. We have gone from having very few products in the medical countermeasure pipeline to funding over 80 candidate products. If successfully transitioned to procurement contracts and inclusion in the Strategic National Stockpile, we anticipate having the following new medical countermeasures available in the next five years: an entirely new class of antibiotics; anthrax vaccine and antitoxins; smallpox vaccine and antivirals; radiological and nuclear countermeasures, including candidates to address the hematopoietic, pulmonary, cutaneous, and gastrointestinal effects of acute radiation syndrome; pandemic influenza countermeasures; and the first set of chemical antidotes to chemical threats. Furthermore, in demonstration of our end-to-end approach to development, we have successfully moved a product through all phases of the medical countermeasure pipeline—from discovery to procurement—and have begun manufacturing a new smallpox vaccine (Modified Vaccinia Ankara).

Related to state and local preparedness, HHS has also utilized and strengthened two critical tools to support community preparedness and resilience. Both the ASPR-led Hospital Preparedness Program (HPP) and the CDC-led Public Health Emergency Preparedness (PHEP) cooperative agreement grant programs have advanced our preparedness agenda within the health care and public health infrastructure as well as throughout a number of communities. HPP and PHEP support efforts at state and local public health departments and medical facilities to ensure that communities are prepared to respond to public health emergencies. With HPP grants, we made great strides in the ability of the predominantly private-sector health care system to surge to

provide medical care to a large number of patients. PHEP funding has fostered an increased level of preparedness throughout communities and contributed to state and local governments' decreased reliance on Federal aid following disasters. Specifically, since 2002, state and local health departments have used HPP grants to allow hospitals and health care coalitions to purchase equipment and supplies; exercise and train for a number of different emergency scenarios, including highly infectious diseases; and develop partnerships and coalitions across regional health care systems to address situations like Ebola. More recently, HPP has moved towards a community-based preparedness approach to build resiliency and encourage the creation of health care coalitions. Health care coalitions are collaborative networks of hospitals, health care organizations, public health providers, emergency management, emergency medical services, and other public and private sector health care partners within defined regions. The HPP program seeks to build capabilities for hospitals and health care coalitions, such as the ability to surge and manage infectious diseases.

Building on past successes, these programs are proving critical in preparedness activities for Ebola. HHS has a number of specific activities underway to support national health security and preparedness. These efforts benefit and support broader preparedness initiatives and will strengthen the national health care infrastructure going forward. CDC, in coordination with OSHA, has issued updated infection-control guidance for health care workers caring for patients with Ebola in the United States to ensure there is no ambiguity with respect to the use of personal protective equipment (PPE). In addition, HPP began informing awardees on October 1, 2014, that funds may be used to prepare for suspected or known Ebola patients. This includes developing action plans, purchasing supplies for health care facilities, including PPE, and

training personnel. Also, in emergency circumstances, HPP awardees may request, and in some cases already have requested, approval to use grant funds for activities outside the currently approved scope of work. HHS is also using these networks to disseminate educational materials on awareness and response regarding potential Ebola patients, such as checklists to prepare health care providers, hospitals, emergency medical services, and community health care coalitions. The checklists provide practical and specific suggestions to ensure health care workers, facilities, and coalitions are able to detect possible Ebola cases, protect their employees, and respond appropriately.

HHS has also organized a number of training opportunities, in coordination with other Federal partners, to ensure quick and accurate identification of persons with Ebola, including training to support ongoing screening activities at domestic airports. HHS is also supporting efforts to develop protocols for waste management, something that has been a key concern for health care providers, hospitals, and political leadership at state and local levels. For example, HHS developed Ebola Medical Waste Management guidelines with input from DOT, the Environmental Protection Agency, and OSHA. These guidelines provide hospitals and health care providers with key information about the safe handling, transport, and disposal of waste generated from the care of persons diagnosed with or suspected of having Ebola. CDC also will be coordinating with OSHA and other Federal Agencies to develop guidance that is relevant to other occupations—such as employees of the transportation industries—to address potential exposure to persons with Ebola.

Thanks to a number of new authorities provided by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), ASPR stands ready to support a response to such events as the current Ebola incidents. One specific provision of that Act allows the Secretary to authorize a state or Indian Tribe to temporarily reassign health personnel funded through HHS programs under the Public Health Service Act to augment resources for a declared public health emergency. In addition, PAHPRA gave the Secretary the authority to declare that circumstances exist to justify the authorization of emergency use of certain medical products, which, under certain circumstances, enables FDA to issue an Emergency Use Authorization (EUA) when appropriate. The Secretary issued a declaration for in vitro diagnostic devices for detection of Ebola virus on August 5, 2014, which was based on an existing Ebola virus Material Threat Determination issued by DHS. The HHS EUA declaration was then used to support FDA issuance of an EUA for an Ebola diagnostic test developed by DOD and two EUAs to permit distribution and use of Ebola diagnostic tests developed by CDC.

Understanding today's global community, HHS has strengthened international partnerships. HHS now has a number of international relationships designed to better support information sharing, leverage critical assets, and help one another in times of need. Through a variety of initiatives, plans, and strategic capacity building programs, in response to the current Ebola outbreak, HHS—in coordination with other Federal Departments and Agencies—has been able to rapidly engage with international partners in communications and collaborations, including the Ministers of Health of the G7 countries, Mexico, the European Commission, the World Health Organization (WHO), the Institute Pasteur and its affiliates in West Africa, to discuss countries' domestic preparedness activities and policies. These activities include border protocols, mutual

notifications of imported cases, support for medevac capabilities, and coordination of activities to develop and manufacture medical countermeasures among developed countries (mainly Canada, UK, and France) and the WHO, and overall support for West African countries. In its coordination role for the medical portion of the U.S. response effort, HHS convenes weekly U.S. Government and WHO clinical conference calls with physicians in developed countries who treat patients with Ebola to facilitate information-sharing and diffusion of best practices. In addition to coordinating with international partners, HHS is working to support the deployment of U.S. Public Health Service (PHS) officers to West Africa.

Throughout the Federal Government, we are all working together to ensure we are safer going forward and protecting against the growing number of threats to public and medical health. Mr. Chairman and Members of the Committee, I understand why you and your constituents are anxious and concerned. There is good reason for concern. Ebola is a dangerous disease, but there is hardly a reason for panic. There is an epidemic of fear, but not of Ebola, in the United States. We always can, and do, learn from experience, and we are making adjustments moving forward based on the first U.S. cases. I can assure you that my team, HHS, and our interagency partners have worked long hours to prepare our Nation for threats like Ebola. We are making efficient use of the investments provided and we are far better off than we were ten years ago following the anthrax attacks and the Hurricane Katrina response. As a result, HHS stands ready to provide health and medical support to our states and communities. I thank you again for this opportunity to address these issues and welcome your questions.

STATEMENT FOR THE RECORD

HONORABLE MICHAEL D. LUMPKIN

ASSISTANT SECRETARY OF DEFENSE

SPECIAL OPERATIONS AND LOW-INTENSITY CONFLICT

BEFORE THE 113TH CONGRESS

UNITED STATES HOUSE OF REPRESENTATIVES

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

OCTOBER 24, 2014

Introduction

Chairman Issa, Ranking Member Cummings, and distinguished Members of the Committee – thank you for the opportunity to testify today regarding the Department of Defense's role in the United States' comprehensive Ebola response efforts. As President Obama noted last month, the Ebola epidemic in West Africa is growing at an alarming rate. It is not only a global threat, but a national security priority for the United States. Due to the U.S. military's unique capabilities, specifically speed and scale, the Department has been called upon to provide interim solutions in support of USAID's efforts that will help give other U.S. Government departments and agencies the time necessary to expand and deploy their own capabilities. Additionally, U.S. military efforts may also galvanize a more robust and coordinated international effort, which is urgently needed to contain this threat and reduce human suffering in West Africa.

Before addressing the specific elements of the Department of Defense's (DoD) Ebola response efforts, I would like to share my observations of the evolving crisis and our increasing response. At the beginning of this month, United States Agency for International Development (USAID) Assistant Administrator Nancy Lindborg and I visited Liberia. Meeting with the country's civilian and military leaders, United Nations officials, nongovernmental organizations, and our civilian and military responders already operating in the region, I was left with a number of overarching impressions that are shaping the Department's role in our comprehensive, interagency response.

First, the United States Government (USG) has deployed a top-notch team with vast experience in dealing with disasters and humanitarian assistance. The USAID Disaster Assistance Response Team is leading the USG effort to address the Ebola epidemic abroad, and

the Joint Force Commander is in direct support of USAID's leading role. This collaborative effort is already making a difference. The interagency team has received a warm welcome from the Liberian government, and is synchronizing its activities with the local and international response efforts.

Second, the Liberian government, although significantly overburdened by this crisis, is doing what it can with every resource available at its disposal.

Third, there is little transportation or health infrastructure outside Liberia's capital, Monrovia. Moreover, the existing infrastructure is in disrepair and dangerously overstressed. With almost 200 inches of rain each year, the roads in many locations are impassible for any movement beyond foot travel and – concomitantly – the Ebola virus.

Fourth, the international response is increasing due to the USG response efforts. The USG, led by the Department of State's diplomatic efforts and USAID's engagement with international healthcare organizations, continues to see an upswing in international efforts, particularly in the wake of President Obama's remarks last month and with the advent of the United Nations Mission for Ebola Emergency Response (UNMEER).

Fifth, I traveled to the region thinking we faced a healthcare crisis with a logistics challenge. In reality, we face a logistics crisis focused on a healthcare challenge. The shortage of local transportation, passible roadways, and inadequate infrastructure to facilitate the movement of essential supplies and equipment are hindering the overall global community response to contain and combat the Ebola outbreak. This global threat, with increased international response efforts and contributions, can be overcome.

Sixth, the four lines of effort requested by USAID's Disaster Assistance Response Team (DART) – Command and Control, Training Assistance, Logistics Support, and Engineering

Support – are well within DoD's capabilities. With the proper precautions established and followed, our personnel can safely deploy to the region.

Seventh, speed and scaled response matter. Incremental responses will be outpaced by an epidemic growing exponentially.

Finally, the Ebola epidemic we face is a national security issue – one that requires coordinated domestic and international efforts. Neither the U.S. nor the international community can build a moat around this issue in West Africa, and DoD's efforts in the region are an essential component to contain and reduce the epidemic. Absent a USG response in West Africa, the virus' increasing spread brings the risk of more cases in the U.S.

Before summarizing DoD's role in the USG's USAID-led Ebola response efforts, I would like to thank the defense oversight committees for their recent decision to authorize obligation of up to $750 million of the $1 billion reprogrammed from Overseas Contingency Operations funding to DoD's Overseas Humanitarian, Disaster, and Civic Aid Program. As many are aware, deployment funding is required immediately in order to establish support contracts, move forces, and create logistics networks. This obligation authority provides DoD the latitude it needs to undertake its response in support of USAID activities necessary over the next six months.

The Department of Defense's Role in United States Government Ebola Response Efforts

In mid-September, President Obama ordered DoD to undertake military operations in West Africa to support USAID-led Ebola response efforts. The comprehensive USG response is predicated upon a strategy with four pillars: (1) control the outbreak, (2) mitigate second-order

impacts of the crisis, (3) foster coherent international leadership and response operations, and (4) improve mechanisms for global health security.

As Secretary Hagel noted at the September 26th meeting of the Global Health Security Agenda, DoD is operating in support of USAID as part of the USG's coordinated response to the Ebola Virus Disease (EVD) outbreak. The Secretary directed that U.S. military forces undertake a two-fold mission – first, support USAID in the overall USG efforts to contain the spread and reduce the threat of EVD; and, second, respond to Department of State requests for security or evacuation assistance if required. Direct patient care of Ebola-exposed patients in West Africa is not a part of the DoD mission.

In support of the mission's first element, Secretary Hagel approved military activities falling under four lines of effort: Command and Control, Logistics Support, Engineering Support, and Training.

Our first line of effort is Command and Control. On September 15th, Secretary Hagel approved a named operation, OPERATION UNITED ASSISTANCE (OUA), for U.S. military efforts in response to EVD. United States Africa Command identified Major General Darryl Williams, the Commander of U.S. Army Africa, as UNITED ASSISTANCE's initial commander. On October 25th, OUA command will transition to Major General Gary Volesky, the Commander of the Army's 101st Airborne Division.

Major General Volesky and the deploying elements of his command bring not only significant operational capabilities to support the mission's other lines of effort, but also the command-and-control structure necessary to coordinate U.S. military efforts with other entities. These include: other USG departments and agencies; the Government of Liberia and – in particular – the Armed Forces of Liberia; the United Nations, other intergovernmental

organizations, and nongovernmental organizations providing relief in the region; and bilateral partners providing a military response to the epidemic.

Our second line of effort is Logistics Support. DoD logistics activities are primarily improving transportation capabilities regionally and immediate care capabilities in Liberia. To support transportation efforts, the U.S. military has worked with regional and international partners to establish an intermediate staging base in Dakar, Senegal. U.S. military aircraft are providing strategic airlift into West Africa and tactical airlift within Liberia to move supplies and personnel. To support immediate care capabilities, U.S. military forces constructed a 25-bed hospital in Monrovia as a treatment facility for Liberia-based, non-U.S. military healthcare providers exposed to Ebola. This hospital will be manned by United States Public Health Service healthcare professionals, some of whom are already in-country. The rest will arrive in early November.

Our third line of effort is Engineering Support. In this effort, we are establishing our joint force headquarters in Monrovia, a training facility proximate to the headquarters, and up to 17 Ebola Treatment Units (ETUs) in Liberia at which non-U.S. military healthcare professionals can effectively provide care to Ebola-infected patients. U.S. military engineers are facilitating site selection and construction of the ETUs, and are working closely with Armed Forces of Liberia engineers who are committing their efforts to ETU construction.

The operation's fourth line of effort will be Training. U.S. military personnel will train up to 500 healthcare support personnel at a time, enabling the healthcare workers to serve as the first responders in ETUs throughout Liberia. Again, U.S. military personnel will not provide direct care to Ebola patients in West Africa.

In addition to OUA's four lines of effort, the Department continues two enduring programs in the region. In Liberia, OPERATION ONWARD LIBERTY, consisting of approximately 60 U.S. military personnel, partners with the Armed Forces of Liberia to improve the professionalization and capabilities of Liberia's military.

Regionally, we are expanding the efforts of DoD's Cooperative Biological Enhancement Program (CPEB) to provide robust enhancements to biosafety, biosecurity, and biosurveillance systems in West Africa. The program will also seek to leverage existing partnerships with South Africa, Kenya, and Uganda to bolster regional capacities to mitigate threats associated with the current and potential future outbreaks. As an example of these efforts, CPEB has deployed two mobile labs to Liberia that provide diagnostic capabilities essential to containing and reducing EVD. These labs augment the capacity of the Liberian Institute for Biomedical Research lab, at which CBEP has funded the work of three experts. DoD plans to deploy four additional mobile labs to Liberia the first week of November.

Throughout all of our planning and operations, the safety and well-being of our deployed forces remain of particular importance. The Department recently disseminated new policy regarding the training, screening, and monitoring DoD personnel will undergo prior to, during, and after deployments to West Africa. Before deployment, all personnel will receive a medical threat briefing covering all health threats and countermeasures. In addition, they will receive information on EVD and safety precautions, prevention/protection measures, personal protective equipment use, and symptom recognition and monitoring. DoD medical personnel will receive advanced Ebola-related training, in the unlikely event they must treat our personnel possibly exposed to the virus.

During the operation, DoD personnel will be equipped based on their mission requirements and the likelihood of interacting with local personnel. At a minimum, DoD members will have advanced protective masks, gloves, personal protective suits, and sanitizer immediately available. DoD supervisors and healthcare workers will monitor personnel for early detection of possible symptoms.

To treat DoD personnel who are injured or fall ill while deployed, we have advanced medical care capabilities deployed in Liberia, and are deploying additional capabilities to Liberia and Senegal. Should the unfortunate occur and a DoD member be exposed to Ebola, we have procedures in place to evacuate DoD patients to CDC-designated advanced care facilities in the United States.

When the mission is complete, DoD will continue to monitor the health of our personnel. Within 12 hours of departure from West Africa, trained DoD healthcare personnel will interview and assess DoD personnel to determine possible exposure. After returning from deployment, our personnel will undergo twice-a-day medical monitoring for 21 days – the maximum incubation period of EVD. In all circumstances, the protection of our personnel and the prevention of any additional transmission of the disease remain paramount planning factors for U.S. military response efforts.

Conclusion

West Africa's Ebola epidemic remains dangerous, but we have a comprehensive United States Government response and – increasingly – a coordinated international response to contain the threat and mitigate its effects. The Department of Defense's interim measures are an essential element of the U.S. response, without which it will be extremely difficult to block the

epidemic's rapid expansion. As President Obama has noted, this global threat requires a global response. He has committed U.S. leadership to international Ebola response efforts, but the United States cannot unilaterally address the situation. Now is the time to devote appropriate U.S. resources – military and civilian – necessary to contain the threat, to reduce and mitigate the suffering of the afflicted, and to establish the mechanisms and processes for better future responses.

STATEMENT OF JOHN ROTH

INSPECTOR GENERAL

DEPARTMENT OF HOMELAND SECURITY

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

CONCERNING

DHS' MANAGEMENT OF PANDEMIC PREPAREDNESS SUPPLIES

October 24, 2014

Good morning Chairman Issa, Ranking Member Cummings, and Members of the Committee. Thank you for inviting me to testify about the Department of Homeland Security's (DHS) management of pandemic preparedness supplies.

DHS must have the ability to continue its operations in the event of a pandemic. In 2006, Congress appropriated $47 million in supplemental funding to DHS to train, plan, and prepare for a potential pandemic. As a result, that year DHS began efforts to develop contingency plans and preparedness to be able to protect DHS personnel who may become exposed in a pandemic. Using the appropriated supplemental funding, DHS has acquired, stockpiled, and maintained protective equipment and antiviral drugs at departmental and component levels in preparation for a pandemic response.

DHS' Office of Health Affairs (OHA) and the Directorate for Management are responsible for organizing the Department's pandemic preparations. These offices provide guidance to DHS components to enable mission readiness and protect DHS personnel during a pandemic.

My statement today will focus on the results of our August 2014 audit of the Department's management of personal protective equipment and antiviral drugs as well as DHS' progress in addressing our recommendations.[1] Our audit focused on the Department's preparations to continue operating and achieving its mission should a pandemic occur. In short, our audit concluded that DHS did not adequately assess its needs before purchasing pandemic preparedness supplies and then did not adequately manage the supplies it had purchased. We made 11 recommendations to help improve the efficiency and effectiveness of the Department's pandemic preparedness.

DHS Did Not Adequately Assess Its Needs or Plan Its Acquisition of Supplies

During our audit, we found that DHS did not adequately conduct a needs assessment before purchasing protective equipment and antiviral drugs. DHS reported spending $9.5 million on pandemic protective equipment beginning in 2006, yet did not identify its needs for protective equipment. Moreover, DHS spent $6.7 million for antiviral drugs, but did not have clear and documented methodologies for determining the types and quantities of medication it should purchase. In other words, we could not determine the basis for DHS' decisions on how much or what types of pandemic preparedness supplies to purchase, store, or distribute. The balance of the funds was spent on pandemic research, exercises, and storage.

By not identifying its needs, the Department cannot be sure its protective equipment stockpiles are adequate or determine whether it has excess supplies on hand. For example:

- The DHS National Capital Region (NCR) pandemic stockpile contains about 350,000 white coverall suits. Yet DHS had no justification or related documentation to support that this quantity and type of protective equipment was necessary for pandemic response.

[1] *DHS Has Not Effectively Managed Pandemic Personal Protective Equipment and Antiviral Medical Countermeasures*, OIG-14-129, August 2014.

- The Department has a reported inventory of approximately 16 million surgical masks but did not demonstrate a need for that quantity of masks.
- The Department's NCR and component pandemic protective equipment stockpiles include expired hand sanitizer. Out of 4,982 bottles, 4,184 (84 percent) are expired, some by up to 4 years.
- TSA's stock of pandemic protective equipment includes about 200,000 respirators that are beyond the 5-year usability guaranteed by the manufacturer. TSA is sampling these to determine any specific problems with usability.

In fiscal year 2009, OHA added approximately 240,000 courses of antiviral drugs to the Department's stockpile, again without first determining the Department's pandemic needs. Only after its initial purchases did OHA prepare an acquisition management plan for antiviral drugs, which estimated its requirements, but it did not follow this plan. Instead, OHA acted on a senior-level decision to cover the DHS workforce in the event of a pandemic, but it did not provide any documentation demonstrating how the current stockpile of about 300,000 courses aligned with its pandemic needs. Without sufficiently determining its needs, the Department has no assurance it will have enough antiviral drugs to maintain critical operations during a pandemic.

DHS Does Not Adequately Manage Pandemic Preparedness Supplies

DHS did not effectively manage and oversee its inventory of pandemic preparedness supplies, including protective equipment and antiviral drugs. DHS did not keep accurate records of what it purchased and received and did not implement sufficient controls to monitor its stockpiles. More specifically, the Department did not develop and implement stockpile replenishment plans, establish sufficient inventory controls to monitor stockpiles, conduct adequate contract oversight, or ensure compliance with departmental guidelines. As a result, the Department may not be able to provide pandemic preparedness supplies that are adequate to continue operations during a pandemic.

DHS did not readily know how much protective equipment it had on hand or where the equipment was being stored. The Department also cannot be assured that the protective equipment on hand is still effective. For example, the Department's entire respirator stockpile has reached, or will soon reach, the manufacturer's date of guaranteed usability. In fact, the Department's own assessment is that the entire protective equipment stockpile will not be usable after 2015.

DHS also did not keep records of the protective equipment it purchased and received, and it has not accurately accounted for how much protective equipment it currently has in stock. There is departmental guidance on inventory management, but the Department and components did not establish and maintain accurate inventories in accordance with that guidance. This may have occurred because it did not use an inventory system to track and monitor protective equipment or perform periodic inventories of its protective equipment stockpiles. During site visits to several components, we identified inaccurate protective equipment inventories.

The Department's management of protective equipment has not been effective because it has not clearly designated department-level responsibility. For example, OHA and the Directorate for

Management interpret roles and responsibilities for administration and oversight of DHS' NCR stockpile differently. Both offices acknowledged the responsibilities were not clearly delineated to guarantee coordinated management and oversight of protective equipment.

DHS has also not effectively managed its antiviral drug stockpile. DHS decided to preposition some of its stockpile to component offices in response to the 2009 H1N1 influenza pandemic. OHA prepositioned approximately 32,000 courses of antiviral drugs to U.S. Customs and Border Protection, U.S. Immigration and Customs Enforcement (ICE), the U.S. Secret Service, and Federal Emergency Management Agency locations. OHA did not maintain complete or accurate records of the quantity and destination of antiviral drugs distributed from the stockpile, and components did not document receipt of antiviral drugs.

Based on our analysis of antiviral drugs sent to components, OHA and components did not have complete or accurate inventories of prepositioned antiviral drugs. For example:

- OHA sent more than 1,500 courses of antiviral drugs to Secret Service headquarters. OHA did not have records of any antiviral drugs at the Secret Service because it did not maintain shipment documentation.
- At three ICE field office locations, 720 courses of antiviral drugs were incorrectly reported to ICE headquarters as destroyed; yet, we identified they were still in possession of these antiviral drug courses.

Component headquarters did not issue guidance for their field offices or ensure proper controls were in place to account for the antiviral drugs after they were prepositioned. Specifically, components did not ensure antiviral drugs were consistently stored at the correct temperatures. For example, at multiple sites we visited, officials said the buildings where antiviral drugs were being stored were not temperature controlled during evenings and weekends. Antiviral drugs stored incorrectly may lose effectiveness. OHA spent about $600,000 on the antiviral drugs sent to component field offices, but because it cannot be assured that the prepositioned antiviral drugs have been properly stored, it is recalling about 32,000 courses for possible destruction because of safety and efficacy concerns.

DHS' Progress in Addressing Audit Recommendations

DHS concurred with all 11 of our recommendations and 1 recommendation has been fully implemented. The Department has agreed to make the Chief Readiness Support Officer responsible for the management and accountability of pandemic protective equipment. The Department is taking action to implement the remaining 10 recommendations. We will continue to keep the Committee informed about the Department's progress.

Mr. Chairman, this concludes my prepared statement. I welcome any questions you or other Members of the Committee may have.

Department of Homeland Security

Office of Inspector General

DHS Has Not Effectively Managed Pandemic Personal Protective Equipment and Antiviral Medical Countermeasures

OIG-14-129

August 2014

OFFICE OF INSPECTOR GENERAL
Department of Homeland Security

Washington, DC 20528 / www.oig.dhs.gov

August 26, 2014

MEMORANDUM FOR: The Honorable Alejandro Mayorkas
Deputy Secretary
Department of Homeland Security

Dr. Kathryn Brinsfield
Acting Assistant Secretary and Chief Medical Officer
Office of Health Affairs

FROM: John Roth
Inspector General

SUBJECT: *DHS Has Not Effectively Managed Pandemic Personal Protective Equipment and Antiviral Medical Countermeasures*

Attached for your action is our final report, *DHS Has Not Effectively Managed Pandemic Personal Protective Equipment and Antiviral Medical Countermeasures.* We incorporated the formal comments from the Department in the final report. The report contains 11 recommendations aimed at improving the efficiency and effectiveness of the Department's pandemic preparations. Your office concurred with the intent of all 11 recommendations. We consider Recommendation 9 resolved and closed. Based on information provided in your response to the draft report, we consider the remaining recommendations resolved and open. Once your office has fully implemented the recommendations, please submit a formal closeout letter to us within 30 days so that we may close the recommendations. The memorandum should be accompanied by evidence of completion of agreed-upon corrective actions.

Please email a signed PDF copy of all responses and closeout requests to OIGAuditsFollowup@oig.dhs.gov. Until your response is received and evaluated, the recommendations will be considered open and resolved.

Consistent with our responsibility under the *Inspector General Act*, we will provide copies of our report to appropriate congressional committees with oversight and appropriation responsibility over the Department of Homeland Security. We will post the report on our website for public dissemination.

Please call me with any questions, or your staff may contact Anne L. Richards, Assistant Inspector General for Audits, at (202) 254-4100.

Attachment

Table of Contents

Executive Summary 1

Background 2

Results of Audit 3

Needs Assessment for Pandemic Preparedness Supplies 3
Personal Protective Equipment Planning 4
Antiviral Medical Countermeasures Planning 7
Management of Pandemic Preparedness Supplies 8
Personal Protective Equipment Oversight 9
Antiviral Medical Countermeasures Inventory Management 10
Interagency Agreement Oversight 11
Antiviral Medical Countermeasures Guidance and Monitoring 11
Additional Observation 12
Recommendations 13
Management Comments and OIG Analysis 15

Appendixes

Appendix A: Objectives, Scope, and Methodology 21
Appendix B: Management Comments to the Draft Report 24
Appendix C: Major Contributors to This Report 32
Appendix D: Report Distribution 33

Abbreviations

CBP	U.S. Customs and Border Protection
CDC	Centers for Disease Control and Prevention
COR	contracting officer's representative
DHS	Department of Homeland Security
ECD	Estimated Completion Date
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FY	fiscal year
HHS	Department of Health and Human Services
IAA	interagency agreement
ICE	U.S. Immigration and Customs Enforcement

MCM	medical countermeasures
NCR	National Capital Region
NPPD	National Protection and Programs Directorate
OHA	Office of Health Affairs
OIG	Office of Inspector General
PPE	personal protective equipment
SLEP	Shelf-Life Extension Program
TSA	Transportation Security Administration
USCG	United States Coast Guard
USCIS	U.S. Citizenship and Immigration Services
USSS	United States Secret Service

Executive Summary

The Department of Homeland Security (DHS) supports efforts to develop and execute pandemic contingency plans and preparedness actions as part of the United States Government's pandemic preparedness strategy. A severe influenza pandemic presents a tremendous challenge, which may affect millions of Americans, cause significant illnesses and fatalities, and substantially disrupt our economic and social stability. It is DHS' responsibility to ensure it is adequately prepared to continue critical operations in the event of a pandemic.

In 2006, Congress appropriated $47 million in supplemental funding to DHS for necessary expenses to plan, train, and prepare for a potential pandemic. DHS reported that it spent this funding on personal protective equipment, pandemic research, exercises, and medical countermeasures. The Department and components purchased personal protective equipment and medical countermeasures (specifically, antiviral medical countermeasures) to reduce potential effects of a pandemic and ensure the workforce can continue operations. We conducted an audit of the DHS pandemic preparedness efforts to determine if DHS effectively manages its pandemic preparedness supply of personal protective equipment and antiviral medical countermeasures.

DHS did not adequately conduct a needs assessment prior to purchasing pandemic preparedness supplies and then did not effectively manage its stockpile of pandemic personal protective equipment and antiviral medical countermeasures. Specifically, it did not have clear and documented methodologies to determine the types and quantities of personal protective equipment and antiviral medical countermeasures it purchased for workforce protection. The Department also did not develop and implement stockpile replenishment plans, sufficient inventory controls to monitor stockpiles, adequate contract oversight processes, or ensure compliance with Department guidelines. As a result, the Department has no assurance it has sufficient personal protective equipment and antiviral medical countermeasures for a pandemic response. In addition, we identified concerns related to the oversight of antibiotic medical countermeasures.

We made 11 recommendations that when implemented should improve the efficiency and effectiveness of the Department's pandemic preparations. The Department concurred with the intent of all 11 recommendations.

Background

DHS pandemic preparedness strategy includes efforts to develop and execute pandemic contingency plans and preparedness actions. As new threats emerge, DHS must plan and prepare for possible disasters—both natural and manmade. One of these threats is a pandemic resulting from a new influenza virus. A severe influenza pandemic presents a tremendous challenge, which may affect millions of Americans, cause significant illnesses and fatalities, and substantially disrupt our economic and social stability.

According to the Centers for Disease Control and Prevention (CDC), an influenza pandemic can occur when a nonhuman influenza virus is able to transmit efficiently and sustainably from human to human and spread globally.

In the event of any emergency, Federal employees will be expected to continue operations to sustain agency functions. An influenza pandemic is not a singular event, but may come in waves that last weeks or months. It may also pass through communities of all sizes across the Nation and world simultaneously, as demonstrated with the 2009 H1N1 influenza pandemic. The mounting risk of a worldwide influenza pandemic poses numerous potentially devastating consequences for critical infrastructure in the United States.

DHS is responsible for ensuring it is adequately prepared to continue critical operations in the event of a pandemic. The Office of Health Affairs (OHA) serves as DHS' principal authority for all medical and public health issues. OHA provides medical, public health, and scientific expertise in support of DHS' mission to prepare for, respond to, and recover from all threats. OHA leads the Department's workforce health protection and medical oversight activities and provides medical and scientific expertise to support the Department's preparedness and response effort. The Directorate for Management is responsible for implementing the Departmental occupational safety and health program, as well as procurement, property, equipment, and human capital for the Department. Within the Directorate, the Departmental Occupational Safety and Health office integrates safety and health principles into the management of DHS operations, and provides direction and advice to DHS management for occupational safety and health matters.

Both OHA and the Directorate for Management are responsible for organizing pandemic preparations for the Department. These offices provide guidance to DHS components to enable mission readiness and the protection of DHS personnel during a pandemic event. Mission readiness for a pandemic includes having pandemic personal protection equipment (PPE) and antiviral medical countermeasures (MCM) to distribute and dispense during a pandemic. Pandemic PPE is a workplace control measure the DHS

workforce may use to prevent infection and reduce the spread of disease. In addition, the distribution and dispensing of antiviral MCM may protect DHS personnel, as well as critical contractors and those within DHS' care and custody who are potentially exposed in a pandemic.

In 2006, Congress appropriated $47 million in supplemental funding to DHS for necessary expenses to train, plan, and prepare for a potential pandemic. DHS reported that it spent this funding on PPE, pandemic research, exercises, and MCM. The Department and components purchased PPE and medication (antiviral MCM) to reduce potential effects of a pandemic and ensure the workforce can continue operations.

Using the appropriated supplemental funding, DHS has maintained PPE and antiviral MCM stockpiles at both the departmental and component levels in preparation for a pandemic response. Specifically, DHS has a PPE stockpile held at a Federal Emergency Management Agency (FEMA) distribution center and multiple component locations. Stockpiles of antiviral MCM are held at a Department of Health and Human Services (HHS) facility and multiple component locations.

We conducted an audit of the DHS pandemic preparedness efforts to determine if DHS effectively manages its pandemic preparedness supply of PPE and antiviral MCM. As part of this audit, we also identified concerns related to oversight of antibiotic MCM, which was outside our audit scope.

Results of Audit

DHS did not adequately conduct a needs assessment prior to purchasing PPE and MCM for pandemic preparedness. DHS did not effectively manage the inventory of pandemic preparedness supplies it purchased. Specifically, it did not have clear and documented methodologies for the types and quantities of PPE and MCM purchased for workforce protection. The Department also did not develop and implement stockpile replenishment plans, sufficient inventory controls to monitor stockpiles, adequate contract oversight processes, or ensure compliance with Department guidelines. As a result, the Department has no assurance that it has sufficient PPE and MCM for DHS employees to continue operations. DHS also has no assurance that the supplies on hand remain effective. As part of our audit work, we also identified concerns related to oversight of antibiotic MCM.

Needs Assessment for Pandemic Preparedness Supplies

DHS did not effectively determine its need for pandemic preparedness supplies prior to purchasing those supplies. Specifically, it did not identify its PPE needs or

its needs for antiviral MCM, have clear and documented methodologies for the types and quantities of equipment purchased, have stockpile replenishment plans for either PPE or MCM, or implement sufficient inventory controls to monitor the stockpiles. Much of the PPE DHS purchased is past the manufacturers' date of guaranteed usability and most of the MCM purchased is now nearing the manufacturers' expiration date.[1] As a result, DHS and components may not have sufficient PPE or MCM to provide to the workforce during a pandemic.

Personal Protective Equipment Planning

Prior to purchasing PPE, the Department did not identify the type and quantity needed to continue operations during a pandemic. DHS reported spending $9.5 million on pandemic PPE beginning in 2006 for its headquarters and components, yet did not develop a life cycle management plan.[2] PPE purchases included respirators, surgical masks, gloves, goggles, hand sanitizer, and coverall suits. DHS and components did not have clear and documented methodologies for determining the types and quantities of equipment they needed. By not identifying its needs, the Department cannot be sure its PPE stockpiles are adequate or determine if it has excess supplies on hand. For example:

- The DHS National Capital Region (NCR) pandemic stockpile contains about 350,000 white coverall suits. No justification or related documentation was available to support that this quantity and type of PPE was necessary for pandemic response.

[1] Based on the manufacturer's experience, the filter media in the respirators retains its filtration performance in accordance to stated National Institute for Occupational Safety and Health certification for 5 years from the date of manufacture.
[2] A life cycle management plan is a documented process to acquire, maintain, and ultimately dispose of a product or service.

Source: OIG photo
One of 432 pallets of coverall suits at the DHS NCR PPE stockpile.

- The Department has a reported inventory of approximately 16 million surgical masks without demonstrating a need for that quantity of masks.

Source: OIG photo
An aisle of the DHS NCR PPE stockpile containing nitrile gloves, surgical masks, respirators, and coverall suits.

The Department also did not develop alternative use or rotation plans for headquarters and component PPE stockpiles. The Department's entire respirator

stockpile has reached, or will soon reach, the manufacturer's date of guaranteed usability. In fact, the Department's own assessment is that the entire PPE stockpile will not be usable after 2015. During site visits, we identified the following:

- The Transportation Security Administration's (TSA) stock of pandemic PPE includes about 200,000 respirators that are beyond the 5-year manufacturer's guaranteed usability. TSA is conducting sampling of its PPE to identify any specific problems with its usability. However, TSA officials said they will maintain existing stock and may use it for "employee comfort."

Source: OIG photo
There were 62,000 surgical masks designated for pandemic use at a TSA warehouse.

- The Department's NCR and component pandemic PPE stockpiles include expired hand sanitizer. Out of 4,982 bottles, 4,184 (84 percent) are expired, some by up to 4 years.

Source: OIG photo
Pallet in DHS NCR stockpile of hand sanitizer that expired in February 2010.

Antiviral Medical Countermeasures Planning

In fiscal year (FY) 2009, OHA purchased approximately 240,000 courses of antiviral MCM on behalf of the Department, without first determining the Department's pandemic needs.[3] After its initial purchases, OHA prepared an acquisition management plan for antiviral MCM, which estimated its requirements. However, OHA did not follow this plan. Instead, OHA acted on a senior-level decision establishing 110 percent coverage of the DHS workforce.[4] The Department has not provided any documentation demonstrating how the current stockpile of approximately 300,000 courses aligns with its pandemic needs.

Since FY 2009, OHA has purchased additional antiviral MCMs without reevaluating the stockpile quantity for reasonableness. OHA conducted periodic data calls to components to identify mission-critical employees. However, OHA did not document how the information was used to ensure its stockpile of antiviral MCM would be sufficient to meet its needs.

[3] A course is a series of doses administered to a single individual over a designated period. The DHS antiviral MCM stockpile contains Tamiflu and Relenza.
[4] The DHS workforce includes critical contractors and people under DHS' care and custody. It does not include the United States Coast Guard (USCG) because the USCG maintains its own MCM program and stockpile.

Without sufficiently determining its needs, the Department has no assurance it will have an adequate amount of antiviral MCM to maintain critical operations during a pandemic. Also, it cannot ensure previous and future purchases of antiviral MCM are an efficient use of resources. DHS acquired most of its stockpile of antiviral MCM in FY 2009, but did not implement an acquisition management plan that included a strategy for replenishment. Having an acquisition management plan would ensure its stockpile continued to meet its needs. As a result, about 81 percent of its stockpile will expire by the end of 2015 (shown in table 1). DHS recently spent about $760,000 on an additional purchase of 37,000 antiviral MCM courses, yet had still not demonstrated how that purchase met its needs.

OHA is applying for a shelf-life extension with the Food and Drug Administration (FDA) to extend the expiration dates on the antiviral MCM expiring in 2015, specifically Tamiflu, in the DHS stockpile. We applaud their effort and encourage this process, as it reduces the resources needed to replace expiring drugs and would extend their Tamiflu stockpile expiration until 2018. However, OHA has not yet been granted an extension. Even with the extension, this may not fulfill the DHS requirements if a pandemic event occurs.

Table 1. Courses of DHS Antiviral Medical Countermeasures Expiring in 2015

Antiviral MCM	Current Antiviral MCM Stockpile	Antiviral MCM Expiring in 2015	Percent of Antiviral MCM Expiring in 2015
Tamiflu	192,272	192,272	100%
Relenza	103,734	47,472	46%
Totals	**296,006**	**239,744**	**81%**

Source: OIG analysis

Management of Pandemic Preparedness Supplies

DHS did not effectively manage and oversee its inventory of pandemic preparedness supplies, including PPE and antiviral MCM. Specifically, DHS did not keep accurate records of what it purchased and received and did not implement sufficient controls to monitor its stockpiles. As a result, DHS may not be able to provide sufficient pandemic preparedness supplies to its employees to continue operations during a pandemic.

Personal Protective Equipment Oversight

DHS did not have proper oversight of its pandemic PPE supplies. It did not keep records of what it purchased and received, and it has not accurately accounted for how much PPE it currently has in stock. There is departmental guidance on inventory management; however, the Department and components did not establish and maintain accurate inventories in accordance with that guidance. This condition may have existed because the Department and components did not use an inventory system to track and monitor PPE or perform periodic inventories of their PPE stockpiles. For example, the Department lost a secondary PPE stockpile, once located in Washington, DC, containing 25,000 surgical masks and hand sanitizer. A Federal Government office building in Washington, DC received this stockpile in 2009, but officials were unable to locate the stockpile for this audit and reported it as lost. Additionally, at a site visit to the DHS NCR stockpile at a FEMA distribution center, we found inventory discrepancies as seen in table 2.

Table 2. Analysis of DHS National Capital Region Stockpile

Personal Protective Equipment Item	FEMA Distribution Center Inventory Aug. 2013	OIG Verified Count Aug. 2013	Discrepancy
Model 9210 Respirators	Not on Inventory	4,800	4,800
Model 1860 Respirators	919,080	928,320	9,240
Coverall Suits	367,800	356,400	-11,400
Hand Sanitizer (8 oz.)	Not on Inventory	784	784
Protective Goggles	23,214	20,312	-2,902

Source: OIG analysis

We also identified inaccurate inventories at component offices. United States Immigration and Customs Enforcement (ICE), National Protection and Programs Directorate (NPPD), and TSA did not establish an inventory of the initial stock they received from the Department. Subsequent attempts to inventory their pandemic PPE were not accurate. ICE and TSA officials reported unknown quantities of PPE may have been disposed of, but we could not verify this report since the components had not performed an earlier inventory. In fact, at some ICE and United States Secret Service (USSS) locations, PPE was distributed to employees without any tracking or record keeping.

Management of the Department's pandemic PPE has not been effective because responsibility at the departmental level has not been clearly designated. The Directorate for Management and OHA have different interpretations regarding

the roles and responsibilities for administration and oversight of DHS' NCR stockpile. Both offices acknowledged that there is no clear delineation of responsibilities necessary to guarantee successful coordination of the management and oversight of pandemic PPE. They have agreed to clarify their roles. Without delineated roles, proper management, accountability, and oversight of the Department's pandemic PPE cannot occur.

Antiviral Medical Countermeasures Inventory Management

DHS decided to pre-position some of its stockpile to component offices in response to the H1N1 influenza pandemic in 2009. OHA pre-positioned approximately 32,000 courses of antiviral MCMs to U.S. Customs and Border Protection (CBP), ICE, USSS, and FEMA locations. OHA did not maintain complete or accurate records of the quantity and shipped location of MCM distributed from the stockpile, and components did not document receipt of MCM.

In 2010, OHA requested component inventories, but did not validate the reported information. OHA cannot account for nearly 6,200 courses of antiviral MCM pre-positioned with the components (see table 3). During our review, we were able to locate more than 4,000 courses of antiviral MCM; however, more than 2,000 courses remain missing.

Table 3. Analysis of OHA and Component Antiviral Medical Countermeasures Inventories

Component	Courses Shipped by HHS	Courses Reported to OHA by Components	Net Adjustments from OIG Validation	Courses Missing
CBP	24,192	20,275	2,040	1,877
FEMA	144	144	0	0
ICE	6,240	5,496	696	48
USSS	1,536	0	1,406	130
Grand Total	**32,112**	**25,915**	**4,142**	**2,055**
Total Unknown to OHA			**6,197**	

Source: OIG analysis

Based on our analysis of antiviral MCM sent to components, OHA and components did not have complete or accurate inventories of pre-positioned antiviral MCM. Specifically, we identified the following:

- OHA sent more than 1,500 courses of antiviral MCM to the USSS headquarters. OHA did not have records of any MCM at USSS because it did not maintain shipment documentation.
- OHA sent 590 courses of antiviral MCM to eight CBP field offices, of which CBP headquarters was unaware because it did not monitor antiviral MCM until 2012.
- At two CBP locations, we found inventory discrepancies including one location that reported 90 courses, but actually had 1,344; and another location reported 330, but actually had 528.
- At three ICE field office locations, 720 courses of antiviral MCM were incorrectly reported to ICE headquarters as destroyed; yet, we identified they were still in possession of these MCM courses.

Interagency Agreement Oversight

OHA had interagency agreements (IAA) with HHS for the storage and logistics of the majority of its antiviral MCM. However, OHA did not ensure proper contract administration and oversight. Specifically, there was no documentation that the contract performance was routinely monitored. Only one inspection was documented during the entire contract period. The most recent contracting officer's representative (COR) was unaware of his appointment and did not fulfill his duties for more than 7 months. This occurred because the program office responsible for designating the COR did not notify the COR of his appointment and responsibilities.

COR oversight is essential to ensuring that goods are received and services are performed in accordance with the statement of work. However, OHA has paid HHS without ensuring it received goods and services. We notified OHA of this problem, and OHA has since designated a COR and issued an appointment letter outlining COR duties and responsibilities.

Antiviral Medical Countermeasures Guidance and Monitoring

OHA issued guidance that pre-positioned antiviral MCM was to be securely stored in remote locations with limited or no immediate access to medical care, properly dispensed, and kept in a temperature-controlled environment. However, CBP, ICE, and USSS did not follow OHA's guidance on pre-positioning antiviral MCM in remote locations, and OHA did not enforce this requirement. Instead, OHA allowed components to store antiviral MCM in major metropolitan areas like Boston, MA; Chicago, IL; Denver, CO; Miami, FL; and Washington, DC. For example, ICE requested that OHA send an equal amount of antiviral MCM to

locations nationwide, regardless of the size of the office or of its remote location.

Neither OHA nor components provided documented guidance regarding how to properly secure the antiviral MCM. This contributed to the ineffective management of the antiviral MCM and diminished the Department's ability to continue critical operations during a pandemic. For example, ICE was missing 48 courses of antiviral MCM at two of its locations. ICE headquarters cannot account for what happened to the missing courses of antiviral MCM. We visited one of these offices and found that the medication was in an unsecured office storage room.

In addition to missing antiviral MCM, USSS may have improperly dispensed 130 courses of antiviral MCM to its employees to treat influenza in 2009. USSS could not provide any documentation, as required, to show they were dispensed. OHA officials said components were not authorized to dispense the antiviral MCM. OHA did not maintain records of MCM at USSS, and it may not have provided guidance on proper dispensing protocols to USSS.

OHA also had no assurance that components stored antiviral MCM at the proper temperature and did not monitor components to ensure MCMs were stored in continuously temperature-controlled environments. OHA's 2009 guidance for antiviral MCMs outlined the requirements for storage temperature, but it did not have monitoring requirements for components to ensure the antiviral MCM were stored properly.

Additionally, component headquarters did not issue guidance for their field offices or ensure proper controls were in place to account for the antiviral MCM after it was pre-positioned. Specifically, components did not ensure antiviral MCM were consistently stored at the correct temperatures. For example, at multiple sites we visited, officials said the buildings where antiviral MCM were being stored were not temperature controlled during evenings and weekends. OHA spent approximately $600,000 on the antiviral MCM sent to component field offices. OHA does not have assurance that the pre-positioned antiviral MCM have been properly stored. Therefore, it is in the process of recalling approximately 32,000 courses of antiviral MCM for possible destruction due to concerns about safety and efficacy.

Additional Observation

Although antibiotic MCM was outside the scope of our audit, we have similar concerns regarding the effectiveness of CBP's monitoring of its antibiotic MCM.

During four of our CBP site visits, we observed antibiotic MCM stored alongside antiviral MCM. CBP MCM monitoring relies on the self-reported inventories, which do not contain storage conditions at field offices. This monitoring is insufficient to ensure pre-positioned antibiotic MCM are being stored according to requirements. As a result, the usability of its stockpile of more than 88,000 courses of antibiotic MCM, valued at $5 million, may be questionable.

OHA has agreements in place with most components giving them the responsibility to properly store antibiotics and outlining requirements to maintain the antibiotics. During our audit, we observed inadequate monitoring of storage conditions only at CBP. However, we urge OHA to ensure there is proper management and oversight of the Department's pre-positioned antibiotic MCM and that components comply with all storage requirements.

Recommendations

We recommend that the Deputy Secretary:

Recommendation #1:

Identify and designate an office responsible for the management and accountability of pandemic PPE.

We recommend the office designated for the management and accountability of pandemic PPE:

Recommendation #2:

Develop a strategy for management, storage, and distribution of pandemic PPE.

Recommendation #3:

Implement an inventory system for the current inventory and future inventories of pandemic PPE.

Recommendation #4:

Work with components to establish a methodology for determining sufficient types and quantities of pandemic PPE to align with the department-wide pandemic plan.

Recommendation #5:

Have components implement inventory control procedures for pre-positioned pandemic PPE to monitor stockpiles, track shipments, and ensure compliance with departmental guidance.

We recommend the DHS MCM Working Group and OHA:

Recommendation #6:

Determine requirements of antiviral MCM for the Department to maintain critical operations during a pandemic.

We recommend OHA:

Recommendation #7:

Create an antiviral MCM Acquisition Management Plan to include:

a) a methodology for determining the ideal quantity of antiviral MCM OHA will stockpile and how frequently it will be reevaluated;
b) a replenishment plan; and
c) inventory tracking, reporting, and reconciliation procedures for existing stockpile and new antiviral purchases.

Recommendation #8:

Revise procedures to ensure proper contract oversight by government employees for management of its MCM support service contracts and ensure the contracting officer's representatives follow procedures.

Recommendation #9:

Finalize and issue antiviral MCM guidance on the storage conditions, security, and distribution for antiviral MCM for all components.

Recommendation #10:

Finalize the antiviral MCM recall it has initiated on the CBP, ICE, FEMA, and USSS inventories.

Recommendation #11:

Collaborate with CBP to determine the safety and effectiveness of the antibiotic MCM that have been stored alongside their antivirals.

Management Comments and OIG Analysis

In its response to our draft report, the Department concurred with the intent of all 11 recommendations. It identified issues it believed were not appropriately characterized, which are addressed below. The Department expressed concern that we overemphasized the role of PPE and MCM, which they view as the last in a hierarchy of controls. During the audit, we did review the hierarchy of controls including engineering controls, administrative controls, PPE, and MCM. The audit focuses on PPE and MCM due to the extensive governmental resources dedicated to purchasing materials and drugs in both areas. In addition, according to the DHS Chief Medical Officer, "the MCM Program plays a vital role in protecting our workforce and ensures that the Department's operational and headquarters components have the capability and the resources to continue to fulfill our mission during a major incident." We were unable to include information on engineering controls because the Department could not provide documentation to demonstrate this control was used. According to DHS officials, no funding has been allocated for engineering controls, such as physical barriers. We also considered the potential impact of administrative controls, specifically telework. At the time of our audit, less than 5 percent of DHS employees actually teleworked and approximately 30 percent of DHS employees were in positions that are capable of telework. Many of DHS employees conduct operations, such as passenger screening, that are not suitable for telework. Therefore, while there are alternative controls, we chose to focus on where DHS has invested its resources and on the controls within the hierarchy that would be critical in allowing DHS operations to continue during a pandemic.

In auditing PPE and MCM, the OIG relied on HHS, FDA, CDC, manufacturer information, and DHS's medical, safety and health professionals as outlined in the report. The Department headquarters' entire respirator stockpile has reached, or will soon reach, the manufacturer's date of guaranteed usability. According to a Departmental safety and health official, "although periodic sampling by DHS professional occupational safety and health personnel could establish whether it remained usable, Management has determined the best alternative is to standardize the pandemic PPE supply chain and discontinue headquarters' reliance on current stockpiles and dispose of them by the end of 2015." At the time of the audit, DHS provided no documentation on plans to replace their current PPE stockpile by 2015 and the funding to accomplish such a

task. The audit found that DHS and components do not know where PPE is located, how much it has, and the usability of the stockpiles that exist. Although DHS has identified PPE and MCM as the least effective controls, it has invested millions in purchasing these resources without determining the quantities needed for a pandemic response. According to DHS, it is not required under the Occupational Safety and Health Administration to provide PPE supplies to its personnel; however, it has elected to do so in its own planning requirements. DHS should ensure it has sufficient supplies to fulfill its requirements and that the supplies are in working condition.

In addressing MCM, OHA has taken steps with the FDA to use the Shelf-Life Extension Program (SLEP), which can save valuable resources by extending expiration dates on drugs still found to be effective. We applaud their effort and encourage this process, as it reduces the resources needed to replace expiring drugs. However, OHA needs to ensure that it properly identifies the drugs that receive such an extension. OHA improperly identified in its response that it had been granted an FDA extension for its antiviral MCM. The FDA has not approved the specific drugs OHA has in its strategic stockpile that are due to expire next year. During meetings with the Department, they confirmed they did not have an FDA extension for their stockpile.

The plans in place when the audit was initiated were the 2009 H1N1 plans for both the Department and the components. The Department was in the process of updating its pandemic plans, so we were unable to review those as part of this initial audit. The Department's pandemic planning efforts will be addressed in an upcoming audit.

Recommendation #1: Concur. The Office of the Under Secretary for Management designated the DHS Office of the Chief Readiness Support Officer as being responsible for the management and accountability of pandemic PPE effective January 2014. We request that OIG consider this recommendation resolved and closed.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. This recommendation is resolved and will remain open until the Department provides evidence that the Chief Readiness Support Officer has been designated as being responsible for the management and accountability of pandemic PPE effective January 2014. The Department should also provide a copy of the new policy memo, once implemented.

Recommendation #2: Concur. The DHS Chief Readiness Support Officer issued a Pandemic Logistics Support Plan Charter on May 30, 2014. This charter

establishes the framework for the development of a Department pandemic logistics support plan for pandemic PPE. A Pandemic Logistics Integration Team (iTeam) has also been established with representation from DHS Components and pandemic PPE requirements have been drafted. Estimated Completion Date (ECD): September 30, 2014.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. This recommendation is resolved and will remain open until the Department provides a copy of the strategy for management, storage, and distribution of pandemic PPE developed by the Pandemic Logistics Integration Team. We will close this recommendation upon determining that the evidence provided meets the intent of this recommendation.

Recommendation #3: Concur. Members of the Pandemic Logistics iTeam are reviewing the application of the Department's existing personal property inventory management systems for establishing management and inventory controls for pandemic PPE. The current pandemic PPE inventories are being distributed within DHS where operational requirements can be augmented; remaining items will be surplused in accordance with Federal and Department requirements and standards. ECD: September 30, 2014.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. This recommendation is resolved and will remain open until the Department provides a copy of the implementation plan including the inventory system for the current inventory and future inventories of pandemic PPE developed by the Pandemic Logistics Integration Team. We will close this recommendation upon determining that the evidence provided meets the intent of this recommendation.

Recommendation #4: Concur. Work is underway. A workgroup has been established under the Pandemic Logistics iTeam to develop PPE requirements using an employee risk based approach supporting work place controls. ECD: September 30, 2014.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. This recommendation is resolved and will remain open until the Department provides a copy of the workgroup's plan establishing a methodology for determining sufficient types and quantities of pandemic PPE to align with the department-wide pandemic plan. We will close this recommendation upon determining that the evidence provided meets the intent of this recommendation.

Recommendation #5: Concur. This is in the planning stage. A policy and standards workgroup is being established under the Pandemic Logistics iTeam to establish PPE control procedures and standards. ECD: September 30, 2014.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. This recommendation is resolved and will remain open until the Department provides a copy of the workgroup's plan implementing inventory control procedures for pre-positioned pandemic PPE to monitor stockpiles, track shipments, and ensure compliance with departmental guidance. We will close this recommendation upon determining that the evidence provided meets the intent of this recommendation.

Recommendation #6: Concur. Concur. OHA continues to solicit, receive, and address DHS component MCM needs and requirements as a standing agenda item during the monthly MCM Working Group meeting, and as a key element of the MCM Quarterly Reports, OHA prepares and distributes as part of the MCM program. Additionally, DHS is working with CDC on an interagency process to define antiviral stockpiling needs on behalf of the entire Federal Government. We request that OIG consider this recommendation resolved and closed.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. This recommendation is resolved and will remain open until the Department provides a copy of the workgroup's plan outlining the determination of requirements of antiviral MCM for the Department to maintain critical operations during a pandemic. We will close this recommendation upon determining that the evidence provided meets the intent of this recommendation.

Recommendation #7: Concur. An MCM Integrated Logistics Support Program has been drafted and is currently in DHS clearance. Completion of the MCM Integrated Logistics Support Program will address all three elements of this recommendation. ECD: September 30, 2014.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. This recommendation is resolved and will remain open until the Department provides a copy of the Integrated Logistics Support Program addressing all three elements of this recommendation. We will close this recommendation upon determining that the evidence provided meets the intent of this recommendation.

Recommendation #8: Concur in principle. Existing procedures as described in the Homeland Security Acquisition Regulation, Homeland Security Acquisition

Manual, the DHS Office of Procurement Operations contracting officer's representative guidebook and component-specific procedures addressing contracting officer's representative duties and responsibilities are adequate for ensuring proper contract oversight, but these procedures were not followed consistently in the administration of MCM support service contracts. Since OIG identified findings concerning inadequate oversight, OHA has taken steps to ensure that highly qualified contracting officer's representatives are assigned to all MCM support service contracts. These employees provide direct and comprehensive oversight of each aspect of the MCM project including detailed governance over all related contract support. We request that OIG consider this recommendation resolved and closed.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. This recommendation is resolved and will remain open until the Department provides a copy of the revised procedures to ensure proper contract oversight by government employees for management of its MCM support service contracts and ensure the contracting officer's representatives follow procedures. We will close this recommendation upon determining that the evidence provided meets the intent of this recommendation.

Recommendation #9: **Concur.** Storage and security guidance MCM standard operating procedures initially released in 2010 have been updated and expanded, and provided to component MCM planners. They have also been posted to the DHS Connect Intranet MCM page. We request that OIG consider this recommendation resolved and closed.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. The Department provided supporting documentation on storage and security guidance MCM standard operating procedures that have been updated and expanded, and provided to component MCM planners. This documentation was sufficient to close this recommendation. This recommendation is resolved and closed.

Recommendation #10: **Concur.** The recall is complete. OHA recently received a confirmation letter, dated July 7, 2014, from the HHS storage facility advising that all antiviral lots had been returned. We request that OIG consider this recommendation resolved and closed.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. This recommendation is resolved and will remain open until the Department provides a copy that all antiviral MCM shipped to the

field locations has been returned. There are still 1,071 courses of antiviral MCM sent from the field that have not been returned to the HHS facility. There were five locations that did not return any of the antiviral MCM they were shipped, and there were eight locations that did not return the full amount of the MCM that was originally shipped. This recommendation cannot be closed until OHA locates the remaining courses or documents that those courses have been lost and provides documentation in either case. We will close this recommendation upon determining that the evidence provided meets the intent of this recommendation.

Recommendation #11: Concur. OHA continues to collaborate with all DHS Components to include U.S. Customs and Border Protection, through the MCM Working Group, to validate the safety and effectiveness of MCM. DHS employs the approved SLEP in close coordination with the FDA and the U.S. Department of Defense. To date, ten lots of antibiotic MCM have been submitted to SLEP for testing and of those for which testing has been completed all have been found to remain efficacious resulting in a cost avoidance of $5.1 million to the Department.

In addition to extending the shelf life, the SLEP testing verifies the safety/efficacy of MCM that may have been stored improperly (outside of the manufacturer's temperature range). In one instance, 5,450 bottles of antibiotics were exposed to a temperature spike over 100 degrees Fahrenheit for an unknown duration. The lot was submitted to SLEP to test for continued efficacy. It was found to be still safe and effective for use, and it was returned to the DHS stockpile.

Additionally, on July 7, 2014, OHA provided procedural guidance to DHS Components regarding MCM on measures to ensure the safety and effectiveness of medications, including antibiotics, in the MCM Program. We request that OIG consider this recommendation resolved and closed.

OIG Analysis: The Department's response to this recommendation addresses the intent of the recommendation. This recommendation is resolved and will remain open until the Department provides documentation on how it is validating the safety and effectiveness of the MCM. We will close this recommendation upon determining that the evidence provided meets the intent of this recommendation.

Appendix A
Objectives, Scope, and Methodology

The DHS OIG was established by the *Homeland Security Act of 2002* (Public Law 107-296) by amendment to the *Inspector General Act of 1978*. This is one of a series of audit, inspection, and special reports prepared as part of our oversight responsibilities to promote economy, efficiency, and effectiveness within the Department.

We conducted an audit of the DHS pandemic preparedness efforts to determine if DHS effectively manages its pandemic preparedness supply of PPE and antiviral MCM. To achieve our audit objective, we identified and reviewed applicable Federal laws, regulations, and DHS policies and procedures regarding pandemic preparedness. The audit covered DHS pandemic efforts from FY 2006 through April 2014.

We interviewed DHS officials within the Directorate for Management, the Office of Operations Coordination and Planning, OHA, and some components responsible for pandemic preparedness planning, administration, oversight, and management. Specifically, we met with component officials from CBP, FEMA, ICE, TSA, USCG, NPPD, U.S. Citizenship and Immigration Services (USCIS), and USSS. We also interviewed personnel at HHS.

We met with Department officials to determine which offices were responsible for pandemic preparedness planning, management, and oversight to ensure workforce protection. We interviewed DHS officials within the Directorate for Management, the Office of Operations Coordination and Planning, and OHA responsible for pandemic preparedness planning, administration, oversight, and management. We also met with HHS personnel who conduct the storage and logistics of the DHS antiviral MCM stockpile as part of the IAA. Finally, we interviewed DHS employees from component headquarters and field offices of CBP, FEMA, ICE, TSA, the USCG, NPPD, USCIS, and USSS.

To determine if DHS effectively manages its pandemic PPE, we reviewed what plans and guidance DHS had for the types and quantities of PPE, for the alternative use or rotation of the equipment, and for distribution of PPE to components. We assessed the accuracy of DHS inventories by conducting a judgmental sample of site visits and a physical verification of onsite equipment. Specifically, we visited pandemic PPE stockpiles for the NCR at a FEMA distribution center and at ICE, USSS, TSA, and NPPD locations and documented storage conditions and discrepancies between inventories and quantities onsite. We assessed DHS oversight of its pandemic PPE stockpile by determining how DHS tracked and monitored PPE, conducted periodic inventories of their PPE stockpiles,

and delineated the roles and responsibilities between DHS offices. See table 4 for the offices we visited that possessed PPE.

Table 4. Personal Protective Equipment Site Visits

Component	Number of Locations
FEMA	4
ICE	5
NPPD	2
TSA	5
USSS	3

Source: OIG

To determine if DHS effectively manages its pandemic preparedness supply of antiviral MCM, we determined whether OHA created plans for its acquisition and inventory management. We evaluated the guidance OHA issued on appropriate storage and distribution of antiviral MCM. We assessed OHA oversight of its antiviral MCM stockpile by determining how OHA tracked and monitored antiviral MCM, conducted inventories of the antiviral MCM stockpiles, and ensured performance of COR responsibilities. We assessed the accuracy of OHA and component antiviral MCM inventories by comparing their inventories with the shipping data from HHS. In addition, we reviewed the accuracy of component headquarters' inventories of antiviral MCM stockpiled at their offices by conducting a judgmental sample of site visits and a physical verification of the medication on site. Specifically, we visited antiviral MCM stockpiles at an HHS storage facility and at ICE, CBP, NPPD, and USSS locations, and documented storage conditions and discrepancies between inventories and quantities on site. See table 5 for the offices and locations we visited.

Table 5: Medical Countermeasures Site Visits

Component	Number of Locations
CBP	14
FEMA	1
ICE	12
NPPD	1
TSA	1
USCG	1
USCIS	1
USSS	2

Source: OIG

We relied on components and DHS headquarters to provide us counts of their pandemic PPE and antiviral MCM stockpiles, which were not complete and accurate. We

performed physical verification by sampling inventories at the headquarters level, as well as at component headquarters and field office locations selected. We also compared original order and shipment information for antiviral MCM with OHA and component inventories and were able to identify quantities that were in undocumented locations or missing. The evidence from testing the inventories through our physical verification during site visits and analysis of data was sufficient and adequate for the purposes of meeting our audit objective and supporting our audit findings.

We conducted this performance audit between July 2013 and April 2014 pursuant to the *Inspector General Act of 1978*, as amended, and according to generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based upon our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based upon our audit objectives.

Appendix B
Management Comments to the Draft Report

U.S. Department of Homeland Security
Washington, DC 20528

Homeland Security

July 18, 2014

MEMORANDUM FOR: The Honorable John Roth
Inspector General
Office of Inspector General

FROM: Jim H. Crumpacker, CIA, CFE
Director
Departmental GAO-OIG Liaison Office

SUBJECT: OIG Draft Report: "DHS Pandemic Preparedness"
(Project No. 13-155-AUD-DHS)

Thank you for the opportunity to review and comment on this draft report. The U.S. Department of Homeland Security (DHS) appreciates the Office of Inspector General's (OIG's) work in planning and conducting its review and issuing this report.

DHS agrees with the intent of all 11 recommendations outlined in the draft report. However, the Department is concerned that OIG has not appropriately characterized a number of issues discussed in the report, resulting in a misrepresentation of the information and evidence that DHS program officials and subject matter experts provided to the auditors during the audit, and of the DHS pandemic preparedness program in general. Specifically:

1. **The OIG seems to have overemphasized the final level of controls rather than viewing them in their role as last in a hierarchy of controls.** Personal protective equipment (PPE) and medical countermeasures (MCM) are the final levels of control available to the Department and are one part of a multi-level hierarchy. This hierarchy is a state-of-the-art occupational health principle, captured in American National Standards Institute (ANSI)/American Industrial Hygiene Association (AIHA) Z10-2012, "Occupational Safety and Health Management Systems," and summarized in Figure 1 below.[1] The concept is fundamental to Occupational Safety and Health Administration (OSHA) regulations and National Institute of Occupational Safety and Health training programs. This fundamental principle was utilized by the DHS Occupational Safety and Health Office and the DHS Office of Health Affairs (OHA) medical and occupational health professionals in developing pandemic response actions.

[1] MCM is equated to PPE in relative effectiveness and as a protective measure because it is administered AFTER a person actually is infected with a disease.

There are three applicable controls for the purpose of pandemic planning. These controls focus on limiting exposures first – by distancing personnel from sources of infection and using mechanical means such as barriers and ventilation to reduce potential contact with the infectious agent (known as engineering controls). The second level uses administrative controls including telework, shift rotation, vaccination programs, among other things, to reduce and provide a degree of protection to the population that may be exposed to infected co-workers or the public. The final level of controls, and least effective, from a business standpoint, as well as exposure reduction perspectives, includes PPE and MCM; sometimes these are all that can be reasonably provided for personnel that must perform higher-risk activities or who have become infected. There is not a single mention in the report of the two most important levels of controls and the effort the Department devoted to developing them, despite repeated discussions with OIG personnel in meetings and conversations. Exclusion of this principle overemphasizes the relative importance of the PPE and MCM controls.

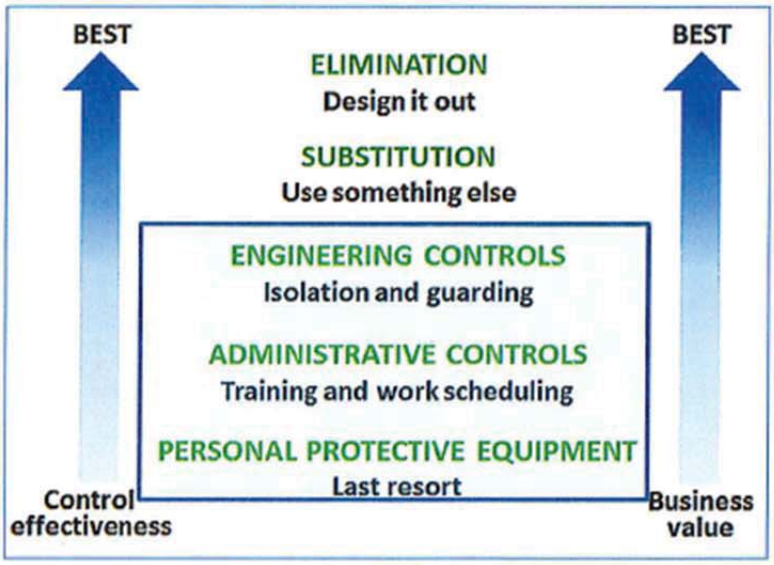

Figure 1: General Hierarchy of Controls, ANSI/AIHA Z10-2012, Occupational Safety and Health Management Systems. Controls applicable to pandemic planning are highlighted.

2. **OIG concluded that the Department has "no assurance it has sufficient personal protective equipment and antiviral medical countermeasures for a pandemic response" thus inhibiting DHS's ability to continue operations during a pandemic or ensure compliance with Department guidelines.** In fact, the Department is assured that it has sufficient PPE and antiviral MCMs. The OIG's conclusion seems to be reached by relying on the manufacturers' information rather than the judgment of published peer reviewed research, and DHS's highly experienced medical, safety, and health professionals with concurrence of subject matter experts from the U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC).

2

Both the PPE and MCM in the stockpiles audited have been tested and determined to be useable by DHS professional staff; this should not lead to the conclusion that there is no assurance that they are currently useable, and plans to replace these in upcoming years indicate the stocks are being managed, not allowed to become obsolete.

The PPE stockpile is very simple in nature: surgical-style nitrile gloves, surgical masks, and filtering facepiece disposable respirators. When these products were purchased, there were no established or published shelf life data, nor was shelf-life stated on the box or in the literature. When asked, the manufacturers stated that they tested them for five years, and as a result certified/guaranteed them for five years, but owners were told they could examine the products and determine if they were still useable based on visual inspection. The parts of these products that are most at risk are any flexible components; with exposure to heat, ultraviolet rays, and oxidation, the gloves, elastic headbands, and valves can become brittle or non-elastic. Filters and filter media are the most stable component of most filter facepiece respirators. Testing them is simply a matter of examining a random sample from stock in the same storage conditions and determining if they retain their flexibility.

The current PPE inventory is in useable condition at the time of this report, but with further aging it may not be useable in coming years. The manufacturers recently started placing firm 5-year expiration dates on respirator packaging; in the past users were told the respirators could be used after five years if they were inspected. Replacing the PPE by 2015 addresses concerns about it becoming unusable and also prevents regular trips to the warehouse to verify it is still intact. During a recent (spring 2014) inventory evaluation of the pandemic PPE stockpile, DHS offered this PPE to Components who use it regularly in daily operations, but little was requested; therefore most of these supplies must be placed in surplus when replaced. After this supply is replaced with new, there will be no inspection allowance and the PPE will have to be replaced after five years.

For MCM, the authority and expertise of the Food and Drug Administration (FDA) appears not to have been considered. The current stockpile of MCMs is part of an aggressive shelf-life extension program used by the FDA to analyze "outdated" MCMs and extend the original manufacturer's shelf life when they are shown to be still useable. This process conserves Departmental resources and establishes that the on-hand MCM are currently useable. Further, the Department provided DHS Components a copy of the most recent and relevant HHS guidance documenting that one or two courses of MCM were considered reasonable. Combined with coverage for the entire DHS workforce, critical contractors, and those in the Department's care and custody, it is unclear what the OIG considers sufficient.

Furthermore, the state of PPE and MCM supplies is not an appropriate indicator of pandemic readiness. As the last tools in a systematic hierarchy of controls, they are not the most efficient or effective means of maintaining workforce health. Despite this fact, PPE and MCM are commonly and erroneously viewed as the primary means of workforce protection, likely because they are more familiar to laypersons and they are more tangible and easily accounted for. The use of PPE also shifts much of the burden of

protection from the employer to the employee. Using PPE stock levels as an indicator of preparedness is based on a misconception that during a pandemic, the entire workforce should wear PPE, when in fact it will be determined by risk assessments and feasibility of other control methods.

OSHA requires agencies to perform pandemic risk analyses on their workforce and establish (due to work-related exposures) which risk level they fall under, ranging from low to very high. A risk analysis was completed by DHS during the H1N1 pandemic response and has recently been updated due to the new DHS plan. Based on risk assessments, DHS has only a limited number of personnel with risk assessments that recommend "mandatory PPE use" during a serious pandemic. Use is linked to specific activities that increase risk. The majority of these personnel already wear PPE regularly while performing their duties, so they are not expected to rely on pandemic stockpiles of PPE. The remaining employees, including almost all at the DHS Headquarters served by the PPE stockpile at the Federal Emergency Management Agency (FEMA) Cumberland warehouse, are termed by OSHA as "voluntary users," the lowest risk group. Employers are not required to provide any PPE to personnel in this low-risk group, and when they do, it is recognized in the standards that it is done both to help prevent a possible, but unlikely, exposure to the disease and to provide a degree of reassurance and comfort to the employee.

Similarly, the antiviral medications in the DHS stockpile are not vaccinations and do not prevent infection; they reduce the symptoms of an infected person and allow them to return to work earlier and provide an additional means of intervention when vaccines may not yet be developed or available in sufficient quantities. In cases where they are appropriate and effective for a given disease, they can provide a significant benefit when applied to a large workforce at times of high absenteeism and help ensure workforce coverage to continue mission essential functions. However, while employers were encouraged to stockpile antiviral MCM when used within the context of a broader occupational health strategy, there is no interagency mandate to provide antiviral MCM, but rather a determination of the Department leadership to enhance workforce availability and protection. Considering this, the on-hand goal of ensuring availability of MCM for all employees, contractors and those in the care and custody of DHS and the fact that the supplies available are currently useable do not support an implication of a readiness failure.

3. **The OIG incorrectly states that "about 81 percent of its [antiviral] stockpile will expire by the end of 2015 (shown in Table 1 of OIG's draft report)."** The Department provided OIG emails documenting that by July 1, 2013, the expiration dates of most of the current stockpile of antiviral MCM had already been extended according to criteria defined by the FDA, so that only 15 percent of DHS's antiviral stockpile is set to expire in 2015—an amount that DHS has budgeted to replace through purchase. An additional small percentage of antiviral stocks that have been returned from DHS Components following their deployment in response to the 2009 H1N1 Influenza pandemic may also be retired in 2015 because the small lot sizes do not meet the fiscal threshold for testing. The current stockpile of MCM is part of an aggressive shelf-life extension program

4

(SLEP) managed by OHA to analyze MCM and extend the original manufacturer's shelf life when they are determined to be still effective. Extending the shelf life of MCM is a responsible use of departmental resources providing significant cost deferrals and valuable time to smooth out replacement for the initial large MCM purchases made with one-time supplemental funding.

Additionally, many steps have been taken since the 2006 pandemic planning supplemental appropriation of $47 million to improve on the initial MCM planning. Specifically:

a. OHA has conducted five separate data calls from 2006 to 2013 to DHS Components to determine their specific MCM and PPE needs. DHS has used the results of these data calls to assess needs and make effective program management and purchasing decisions.
b. OHA developed methodologies for determining the MCM needs identified in the data calls, to include the amount of MCM needed to provide coverage, at the direction of the DHS Secretary's office, for the DHS workforce and all critical contractors and those in DHS care and custody.
c. OHA has conducted replenishment planning which has been captured in the budgeting process and other activities, such as pursuing shelf life extension opportunities.

DHS is more prepared than most federal agencies to provide MCM protection for its workforce. As the sole civilian Department with the only mature antiviral stockpile and dispensing program, DHS is working closely with CDC on the development of updated guidance for all federal departments and agencies.

4. **The report does not acknowledge the current state of affairs of DHS pandemic planning.** Beginning in March 2013, a working group consisting of DHS Headquarters and Operational Component representatives spent a significant amount of time and effort writing a Departmental Pandemic Workforce Protection Plan (PWPP). This PWPP, signed by the DHS Secretary in October 2013 – and subsequently provided to the audit team – outlines the total pandemic policy for DHS – from readiness measures including risk assessments and supply to actual response such as implementing the hierarchy of controls. This successful effort, along with the Component-specific plans and analyses it generated, should have been acknowledged in the audit report, as they were completed prior to the initiation of the audit, addressed many of the issues outlined in the report, and have a far greater effect on current DHS pandemic preparedness than irregularities in the stockpiles of PPE and MCM may have.

The draft report contained 11 recommendations with which the Department concurs. Specifically, OIG recommended:

Recommendation 1: That the Deputy Secretary identify and designate an office responsible for the management and accountability of pandemic PPE.

Response: Concur. The Office of the Under Secretary for Management designated the DHS Office of the Chief Readiness Support Officer as being responsible for the management and accountability of pandemic PPE effective January 2014. We request that OIG consider this recommendation resolved and closed.

Recommendation 2: That the Deputy Secretary develop a strategy for management, storage, and distribution of pandemic PPE.

Response: Concur. The DHS Chief Readiness Support Officer issued a Pandemic Logistics Support Plan Charter on May 30, 2014. This charter establishes the framework for the development of a Department pandemic logistics support plan for pandemic PPE. A Pandemic Logistics Integration Team (iTeam) has also been established with representation from DHS Components and pandemic PPE requirements have been drafted. Estimated Completion Date (ECD): September 30, 2014.

Recommendation 3: That the Deputy Secretary implement an inventory system for the current inventory and future inventories of pandemic PPE.

Response: Concur. Members of the Pandemic Logistics iTeam are reviewing the application of the Department's existing personal property inventory management systems for establishing management and inventory controls for pandemic PPE. The current pandemic PPE inventories are being distributed within DHS where operational requirements can be augmented; remaining items will be surplused in accordance with federal and Department requirements and standards. ECD: September 30, 2014.

Recommendation 4: That the Deputy Secretary work with components to establish a methodology for determining sufficient types and quantities of pandemic PPE to align with the department-wide pandemic plan.

Response: Concur. Work is underway. A workgroup has been established under the Pandemic Logistics iTeam to develop PPE requirements using an employee risk based approach supporting work place controls. ECD: September 30, 2014.

Recommendation 5: That the Deputy Secretary have components implement inventory control procedures for pre-positioned pandemic PPE to monitor stockpiles, track shipments, and ensure compliance with departmental guidance.

Response: Concur. This is in the planning stage. A policy and standards workgroup is being established under the Pandemic Logistics iTeam to establish PPE control procedures and standards. ECD: September 30, 2014.

Recommendation 6: That the DHS MCM Working Group and OHA determine requirements of antiviral MCM for the Department to maintain critical operations during a pandemic.

Response: Concur. OHA continues to solicit, receive, and address DHS component MCM needs and requirements as a standing agenda item during the monthly MCM Working Group

meeting, and as a key element of the MCM Quarterly Reports, OHA prepares and distributes as part of the MCM program. Additionally, DHS is working with CDC on an interagency process to define antiviral stockpiling needs on behalf of the entire federal government. We request that OIG consider this recommendation resolved and closed.

Recommendation 7: That OHA create an antiviral MCM Acquisition Management Plan to include:

a) A methodology for determining the ideal quantity of antiviral MCM OHA will stockpile and how frequently it will be reevaluated;
b) A replenishment plan; and
c) Inventory tracking, reporting, and reconciliation procedures for existing stockpile and new antiviral purchases.

Response: Concur. An MCM Integrated Logistics Support Program (ILSP) has been drafted and is currently in DHS clearance. Completion of the MCM ILSP will address all three elements of this recommendation. ECD: September 30, 2014.

Recommendation 8: That OHA revise procedures to ensure proper contract oversight by government employees for management of its MCM support service contracts and ensure the contracting officer's representatives follow procedures.

Response: Concur in principle. Existing procedures as described in the Homeland Security Acquisition Regulation, Homeland Security Acquisition Manual, the DHS Office of Procurement Operations Contracting Officer's Representative guidebook and component specific procedures addressing Contracting Officer Representative duties and responsibilities are adequate for ensuring proper contract oversight, but these procedures were not followed consistently in the administration of MCM support service contracts. Since OIG identified findings concerning inadequate oversight, OHA has taken steps to ensure that highly qualified contracting officer's representatives are assigned to all MCM support service contracts. These employees provide direct and comprehensive oversight of each aspect of the MCM project including detailed governance over all related contract support. We request that OIG consider this recommendation resolved and closed.

Recommendation 9: That OHA finalize and issue antiviral MCM guidance on the storage conditions, security, and distribution for antiviral MCM for all components.

Response: Concur. Storage and security guidance MCM standard operating procedures initially released in 2010 have been updated and expanded, and provided to Component MCM planners. They have also been posted to the DHS Connect Intranet MCM page. We request that OIG consider this recommendation resolved and closed.

Recommendation 10: That OHA finalize the antiviral MCM recall it has initiated on the CBP, ICE, FEMA, and USSS inventories.

Response: Concur. The recall is complete. OHA recently received a confirmation letter, dated July 7, 2014, from the HHS storage facility advising that all antiviral lots had been returned. We request that OIG consider this recommendation resolved and closed.

Recommendation 11: That OHA collaborate with CBP to determine the safety and effectiveness of the antibiotic MCM that have been stored alongside their antivirals.

Response: Concur. OHA continues to collaborate with all DHS Components to include U.S. Customs and Border Protection, through the MCM Working Group, to validate the safety and effectiveness of MCM. DHS employs the approved SLEP in close coordination with the FDA and the U.S. Department of Defense. To date, ten lots of antibiotic MCM have been submitted to SLEP for testing and of those for which testing has been completed all have been found to remain efficacious resulting in a cost avoidance of $5.1 million to the Department.

In addition to extending the shelf life, the SLEP testing verifies the safety/efficacy of MCM that may have been stored improperly (outside of the manufacturer's temperature range). In one instance, 5,450 bottles of antibiotics were exposed to a temperature spike over 100 degrees Fahrenheit for an unknown duration. The lot was submitted to SLEP in order to test for continued efficacy. It was found to be still safe and effective for use, and it was returned to the DHS stockpile.

Additionally, on July 7, 2014, OHA provided procedural guidance to DHS Components regarding MCM on measures to ensure the safety and effectiveness of medications – including antibiotics – in the MCM Program. We request that OIG consider this recommendation resolved and closed.

Again, thank you for the opportunity to review and provide comments on this draft report. Technical comments were previously provided under separate cover. Please feel free to contact me if you have any questions. We look forward to working with you in the future.

8

Appendix C
Major Contributors to This Report

Brooke Bebow, Director
Stephanie Christian, Audit Manager
Gary Crownover, Program Analyst
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Matthew Noll, Program Analyst
Mark A. Phillips, Auditor
Melissa Prunchak, Program Analyst
Kevin Dolloson, Communications Analyst
Priscilla Cast, Referencer

Appendix D
Report Distribution

Department of Homeland Security

Secretary
Deputy Secretary
Chief of Staff
Deputy Chief of Staff
General Counsel
Executive Secretary
Director, GAO/OIG Liaison Office
Assistant Secretary for Office of Policy
Assistant Secretary for Office of Public Affairs
Assistant Secretary for Office of Legislative Affairs
Chief Privacy Officer

Office of Management and Budget

Chief, Homeland Security Branch
DHS OIG Budget Examiner

Congress

Congressional Oversight and Appropriations Committees, as appropriate

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For further information or questions, please contact Office of Inspector General (OIG) Office of Public Affairs at: DHS-OIG.OfficePublicAffairs@oig.dhs.gov, or follow us on Twitter at: @dhsoig.

OIG HOTLINE

To expedite the reporting of alleged fraud, waste, abuse or mismanagement, or any other kinds of criminal or noncriminal misconduct relative to Department of Homeland Security (DHS) programs and operations, please visit our website at www.oig.dhs.gov and click on the red tab titled "Hotline" to report. You will be directed to complete and submit an automated DHS OIG Investigative Referral Submission Form. Submission through our website ensures that your complaint will be promptly received and reviewed by DHS OIG.

Should you be unable to access our website, you may submit your complaint in writing to:

Department of Homeland Security
Office of Inspector General, Mail Stop 0305
Attention: Office of Investigations Hotline
245 Murray Drive, SW
Washington, DC 20528-0305

You may also call 1(800) 323-8603 or fax the complaint directly to us at (202) 254-4297.

The OIG seeks to protect the identity of each writer and caller.

John Roth
Inspector General
Department of Homeland Security

The U.S. Senate on March 6, 2014 confirmed the nomination of John Roth to be Inspector General of the Department of Homeland Security (DHS).

Mr. Roth, who most recently served as Director of the Office of Criminal Investigations at the Food and Drug Administration (FDA), was nominated lead the DHS Office of Inspector General by President Barack Obama.

At the FDA, Mr. Roth led investigations of violations of the Food, Drug and Cosmetic Act and a crackdown on online pharmacies selling counterfeit and illicit drugs.

Prior to his move to the FDA in June 2012, Mr. Roth had a long and distinguished career with the Department of Justice (DOJ), beginning in 1987 as Assistant U.S. Attorney for the Eastern District of Michigan. From 1994 to 1999, he was Chief of the Narcotics Section at the U.S. Attorney's Office for the Southern District of Florida.

From 1999 to 2004, Mr. Roth served as Section Chief at DOJ's Criminal Division for the Narcotic and Dangerous Drugs Section and the Asset Forfeiture and Money Laundering Section. During that time, he served a detail as Senior Counsel and Team Leader for the congressionally chartered 9/11 Commission and helped to compile a monograph on terrorist financing for the Commission's final report.

In 2004, Mr. Roth became an Assistant U.S. Attorney for the District of Columbia, working on fraud and public corruption cases. In 2007, he served as Deputy Assistant Attorney General for the Criminal Division and became chief of staff to the Deputy Attorney General in 2008.

Mr. Roth culminated his DOJ career in Paris, France, as the department's lead representative on the Financial Action Task Force, an intergovernmental organization fighting against money laundering and terrorist financing.

Mr. Roth earned a B.A. and a law degree from Wayne State University in Detroit.

Testimony by Deborah Burger, RN
Co-President, National Nurses United
Committee on Oversight and Government Reform
U.S. House of Representatives
October 24, 2014

Thank you, Mr. Chairman and members of the Committee on Oversight and Government Reform. My name is Deborah Burger, I am co-President of the Nurses United and a registered nurse, representing 190,000 members in the largest organization of nurses in the United States.

Every RN who works in a hospital or healthcare facility could be Nina Pham or Amber Vinson, both of whom contracted Ebola while treating Thomas Eric Duncan at Texas Health Presbyterian Hospital in Dallas, Texas.

One patient diagnosed on U.S. soil, two infected nurses. So far.

In many ways, all nurses work at Texas Health Presbyterian. In a survey done by National Nurses United 85% of RNs say they have not been adequately trained and the level of preparedness for Ebola in our facilities is woefully insufficient. Specifically, the survey done by National Nurses United of over 3,000 nurses from over 1,000 hospitals in every U.S. state, the District of Columbia and the Virgin Islands reveals that:

- 68 percent still say their hospital has not communicated to them any policy regarding potential admission of patients infected by Ebola
- 84 percent say their hospital has not provided education on Ebola with the ability for the nurses to interact and ask questions
- 44 percent say their hospital has insufficient current supplies of eye protection (face shields or side shields with goggles) for daily use on their unit; 46 percent say there are insufficient supplies of fluid resistant/impermeable gowns in their hospital – significantly, these percentages have been rising
- 41 percent say their hospital does not have plans to equip isolation rooms with plastic covered mattresses and pillows and discard all linens after use;

only 8 percent said they were aware their hospital does have such a plan in place

A Texas Health Presbyterian Hospital nurse, Briana Aguirre, told NBC's "Today" show Thursday, October 16, 2014, that nurses did not have mandatory Ebola training, except for an optional seminar that didn't allow them any hands-on practice.

"We never talked about Ebola. We never had a discussion," Briana Aguirre said. Training for Texas Health Presbyterian's nursing staff amounted to "just information," she said. "We were never told what to look for." "All I know for sure is that he (Duncan) was put into an area where there are around seven other patients," she said.

"We took around three hours to make first contact with CDC to let them know what we had of our suspicion. There were no special precautions other than basic contact precautions. No special gear." She said the hospital did not know what to do with one of his lab specimens. A lab technician told Aguirre the specimen was "mishandled," she said. "It was a chaotic scene."

Ms. Aguirre said there was an effort to contact the hospital's infectious disease expert to determine the correct Ebola treatment protocol. Their answer was, 'We don't know. We will have to call you back,' " she said.

On CNN Ms. Aquire said, “And the most outrageous part about it is, is that every time I think about the facts that I'm saying right now, I just know that the nurses that have been infected . . . They were dealing with an Ebola positive patient with copious secretions of diarrhea, vomiting, continuous dialysis, you know, mechanical ventilation, all these dangerous, dangerous medical procedures and they put their life on the line and without the proper equipment. . . .

Anderson Cooper asked her:

“You believe Nurse Pham was wearing that kind of equipment when she was exposed?”

Ms. Aquire's powerful response was: I know she was because the equipment we needed was still on order."

These heroic nurses had to interact with Mr. Duncan with whatever minimal and woefully inadequate protective equipment was available, at a time when he was unfortunately most vulnerable with diarrhea and vomiting, and therefore most contagious.

Initially the nurses who interacted with Mr. Duncan wore a non-impermeable gown front and back, three pairs of gloves, with no taping around wrists, surgical masks, with the ***option*** of N-95s, and face shields. Some supervisors even told the nurses the N-95 masks were not necessary.

This is what happens when guidelines are insufficient and voluntary.

The porous gowns and eventual suits they were given also left their necks exposed, in other words, the part closest to their face and mouth.
The nurses had to innovate and use medical tape in a futile attempt to cover their dangerously exposed necks. The medical tape was not impermeable and has permeable seams, but the nurses had no other choice. And as if this weren't bad enough, in their effort to protect themselves, they also were forced to put the tape on and take it off, all on their own, which is counter-productive and increases the likelihood of spreading contaminants.

We note that the new CDC guideline that any protective equipment leave 'no skin exposed,' is a "direct testament to the courage of Briana Aguirre. Briana first spoke to National Nurses United with several others of her Texas Health Presbyterian colleagues whose joint statement we released publicly a day before Briana's appearance on NBC.

A hospital in the Bay Area last week provided nurses with a so-called "Ebola tool kit" that contained a gown similar to what was used at Texas Health Presbyterian, with no neck or full head covering. In southern California, a patient claiming Ebola infection presented at an ER where there had been no prior Ebola training and no appropriate Personal Protective Equipment. At a Florida hospital where the RNs had not been provided with any Ebola information or preparedness training, an understandably concerned nurse called the CDC. And how was her initiative and

concern for her patients met by the hospital at which she worked? Her hospital management suspended her without pay.

I offer these examples to illustrate the importance of the federal government mandating utilization of the highest, uniform optimal level of Personal Protective Equipment and the highest optimal uniform level of interactive hands on education and training for nurses and other caregivers.

We have called upon President Obama to invoke his executive authority, and have urged Congress legislatively to mandate uniform optimal national standards. That should include:

• Optimal personal protective equipment for Ebola that meets the highest standards used by the University of Nebraska Medical Center, including:

• Full-body hazmat suits that meet the American Society for Testing and Materials (ASTM) F1670 standard for blood penetration, the ASTM F1671 standard for viral penetration, and that leave no skin exposed or unprotected and National Institute for Occupational Safety and Health-approved powered air purifying respirators with an assigned protection factor of at least 50 — or a higher standard as appropriate.

• At least two direct care registered nurses dedicated to caring for each Ebola patient, with no additional patient care assignments. Additional RNs shall be assigned as needed based on the direct care RN's professional judgment.

• Continuous on-site interactive training with the RNs who are exposed to patients along with updates responsive to the changing nature of disease.

• If any Employer has a program with standards that exceed those used by the University of Nebraska Medical Center, the higher standard should be used. The "Precautionary Principle" must be utilized and adhered to when determining and developing public health policy designed to protect patients, the public, nurses and all healthcare workers who are directly interfacing with potential infectious patients.

Simply put – not one more nurse, not one more hospital worker, not one more patient should become infected with Ebola. Not one more community should

have fear of Ebola being spread in their neighborhoods. The only effective way to stop the spread of fear is to ensure full preparedness in every U.S. hospital.

And our long experience with U.S. hospitals is that they will not act on their own to secure the highest standards of protection without a specific directive from our federal authorities in the form of an Act of Congress or an executive order from the White House.

The response to Ebola from US hospitals and governmental agencies has so far been dangerously inconsistent and woefully inadequate. The lack of mandates in favor of shifting guidelines from multiple agencies, and reliance on voluntary compliance, has left nurses and other caregivers uncertain, severely unprepared and vulnerable to infection.

Regarding the new guidelines issued by the CDC, these represent progress particularly in the area of improved standards for training – as our members and organization have been demanding for two months.

But serious questions remain. Perhaps most important, the CDC guidelines remain unclear on the most effective protective equipment, and, significantly, have their own gaping hole in the option offered to hospitals to select which protective equipment to use "based on availability" and other factors.

The CDC identifies diarrhea, vomiting, and unexplained hemorrhage as signs and symptoms of Ebola.[1] Moreover, although the CDC refers in its guidance to the possibility of "an unexpected aerosol generating procedure" it does not acknowledge the very real possibility of unexpected diarrhea, vomiting and hemorrhage, as well as coughing or sneezing, that can generate aerosols which contain Ebola. So:

- Why do the updated guidelines issued this week by the CDC allow "fluid-resistant" gowns and aprons rather than specifying a full-body hazmat coverall impermeable to all body fluid, blood, and viral agents to ensure optimal protection of healthcare workers?
- Why didn't the CDC specify an assigned protection factor (APF) for respirators?

[1] http://www.cdc.gov/vhf/ebola/symptoms/index.html,

- Finally, given that the CDC leaves open the possibility that hospitals will not provide the same level of PPE to all nurses, when does the CDC recommend that healthcare workers immediately begin donning PPE when caring for patients identified as potentially exposed to Ebola? If not, at precisely what point does the CDC recommend the use of PPE for healthcare workers?

Granted, there is new information, and conditions can change. This is all the more reason however, to mandate measures based on the precautionary principle. Any lack of certainty does not justify inaction, but rather, points toward an approach that calls for taking the highest level of precautions.

The Ebola pandemic and the exposure of health care workers to the virus in Texas and the real threat that it could occur elsewhere in the US, represent a clear and present danger to public health.

We know that unless uniform optimal standards are universally required for all health care facilities, we are putting registered nurses, physicians and other healthcare workers at extreme and unnecessary risk.

And lest we forget, the risk of exposure to the population at large merely starts with frontline caregivers like registered nurses, physicians and other healthcare workers – it does not end there. As we've seen with school closures in Ohio, and quarantining of airline passengers, improper protection and inadequate protocols in hospitals can lead to public exposure outside of healthcare facilities.

Indeed, a critical lesson we should have learned from the horrifying Ebola outbreak in West Africa is what the World Health Organization has called an "unprecedented" infection rate of nurses, physicians and other frontline healthcare workers – and a record death rate for them. In Liberia, our sister union informed us this disease is not even called Ebola, it is called the "nurse killer disease."

If we cannot protect our nurses and other healthcare workers, we can not protect anyone.

We are your first line of defense. No leader would ever contemplate sending soldiers into the battlefield without armor and weapons. Why would we send

nurses into the battle with Ebola and other infectious diseases without the protection, training, and treatment protocols necessary to defeat this enemy?

You should not expect RNs to treat any highly infectious disease without optimal preparation and protection. Give us the tools, we will contain Ebola.

All we ask from President Obama and this Congress is: Not one more infected nurse.

Deborah Burger, RN

Member, Council of Presidents
California Nurses Association/
National Nurses Organizing Committee
National Nurses United

Deborah Burger is a registered nurse and member of the California Nurses Association/ National Nurses Organizing Committee's Council of Presidents. She is also Co-President of National Nurses United, the largest union and professional organization of registered nurses in United States history, with over 185,000 members nationwide.

Burger grew up in Sacramento, California, in a time when career options for young women were limited to teacher, secretary, or nurse. She chose nursing, and was soon a graduate of City College of San Francisco's ADN program. Since then, her career as an RN has spanned over forty years and covered such units and fields as Medical-Surgical, post-partum, labor, and delivery, neonatal intensive care, pediatric, otolaryngology head and neck surgery, and diabetes care management. Today she works in gastroenterology center at Kaiser Permanente Medical Group in Santa Rosa, California.

In 2001 she was elected as Chair of CNA/NNOC's Joint Area Bargaining Council, Kaiser Division.

Under her leadership the last round of negotiations with Kaiser Permanente led to the best wages, benefits, and working conditions for registered nurses in the entire United States.

Burger was crucial in pursuing the passage and implementation of California's Safe Staffing bill, which provided the country's first mandated RN-to-patient ratios. Her participation has aided CAN/NNOC's Government Relations program in successfully advocating for landmark nursing legislation, including whistle-blower protections, nurse title protection, and medical advice standards.

As President from 2003 to 2007, and a member of the Council of Presidents with three other outstanding nurse leaders since 2007, Burger has helped CNA usher in a new era of national nurse solidarity. She was instrumental in the creation of CNA's national organizing arm, the National Nurses Organizing Committee, and its fusion with the Massachusetts Nurses Association and United American Nurses to form National Nurses United in 2009 .

National Nurses United is the country's largest union and professional organization of registered nurses, with over 185,000 members nationwide.

National Nurses United

www.NationalNursesUnited.org

Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

Name: Deborah Burger

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2011. Include the source and amount of each grant or contract.

None

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

National Nurses United President

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2010, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

None

I certify that the above information is true and correct.

Signature: Deborah Burger

Date: 10/21/14

International Medical Corps

Statement of Mr. Rabih Torbay
Senior Vice President for International Operations
On Behalf of
International Medical Corps
Before the
House Committee on Oversight and Government Reform
The Ebola Crisis: Coordination of a Multi-Agency Response

October 24, 2014

Chairman Issa, Ranking Member Cummings, and distinguished members of the Committee. On behalf of International Medical Corps, one of only a small handful of international NGOs in the world to be treating Ebola patients, I would like to thank you for inviting me to testify today and for your leadership in convening this critically important hearing. We would also like to express our appreciation to the U.S. government for their pivotal action and generous support for the response.

International Medical Corps is a global, humanitarian, nonprofit organization dedicated to saving lives and relieving suffering through health care training and relief and development programs. Its mission is to improve the quality of life through health interventions and related activities that build local capacity in underserved communities worldwide. By offering training and health care to local populations and medical assistance to people at highest risk, and with the flexibility to respond rapidly to emergency situations, International Medical Corps rehabilitates devastated health care systems and helps bring them back to self-reliance.

My remarks today will largely be confined to our operations in Liberia and Sierra Leone—where the overwhelming majority of Ebola cases have been reported.

The Outbreak and Our Response

Our response to the Ebola outbreak has been robust. By the end of November, I anticipate we will have a total staff of about 800 in Liberia and Sierra Leone. Approximately 70 of these will be expatriates.

I would like to take you through the response of my organization to the Ebola outbreak. International Medical Corps has operated health care and humanitarian assistance programs in West Africa since 1999.

When the first Ebola cases were detected in the region in late 2013, we were operational in Sierra Leone, providing community level health care, mental health care, and support in the fight against malnutrition. Because of our longstanding work and familiarity with the West Africa region, we learned of the Ebola outbreak almost immediately, at the end of December 2013, and we continued to monitor the pace of the disease.

In March 2014, Liberia's Ministry of Health and Social Welfare provided details on suspected and confirmed cases of the Ebola Virus Disease (EVD) to the World Health Organization (WHO). Two months later (May 2014), the first case of Ebola was reported in the Kailahun District of Sierra Leone, about 270 miles east of the capital, Freetown.

Between mid-June and mid-July, the number of confirmed cases of Ebola in Sierra Leone spiked from fewer than 20 per week to more than 50. During the second half of July, the number of confirmed cases reported in Liberia also increased. After immediate discussions in the field and with partner agencies at headquarters to assess needs and gaps, we realized the epidemic had reached out of control levels.

By this time, we had already deployed teams to Sierra Leone to work with local NGOs as part of a community-level campaign to raise awareness about Ebola. On July 31st, Sierra Leone President Ernest Bai Koroma declared a state of emergency. The following day, we ordered a rapid assessment of the local conditions and triggered our highest category of emergency response. We also determined the more urgent task was treatment of those who had contracted the virus. Our Emergency Response Team arrived in Sierra Leone on August 9th. Since then, we have begun construction on—and will staff—a 50-bed Ebola Treatment Unit (ETU) in the town of Lunsar, a commercial hub with a population of more than 35,000, about 60 miles northeast of Freetown. The projected date of completion of this unit is November 7th and we anticipate receiving our first patient by November 15th. We plan to operate a transportation service for the ETU that will include minibuses, ambulances and hearses.

We also expect to manage a second 50-bed ETU in Makeni, a city of over 100,000 about 110 miles northeast of the capital. The locations of these two treatment units were chosen because they are in areas with the highest concentration of new cases in Sierra Leone in addition to the country's capital. Throughout this process, we have coordinated closely with the Sierra Leone Ministry of Health and Sanitation, with donors, including USAID, Britain's Department for International Development, the European Commission's Humanitarian Aid and Civil Protection department (ECHO), Irish Aid, WHO, the CDC and other International NGOs.

In Liberia, we trigged our highest category of emergency response and need for a rapid assessment of conditions on August 2, 2014. Five days later (on August 7th), Liberian President Ellen Johnson declared a

state of national emergency in the country. Our Emergency Response Team arrived in Monrovia 72 hours later to begin its assessment. What our team found on the ground in Liberia confirmed that urgent action was required. In a few short months, fallout from the Ebola outbreak had brought the country's already fragile health care system to the brink of collapse. Many were dying. Most were afraid. Previously busy hospitals and clinics were empty, with both staff and potential patients too frightened to go there for fear of being infected with the virus. Rather risk infection, mothers shunned life-saving vaccinations for their children, and if their child became ill—even seriously ill—all too many believed the safer option was to not seek treatment at all.

For us, coordination in emergency response is critical. In these critical circumstances, we reached out to key actors, such as WHO, the CDC and USAID even before the deployment of our team. We were also in regular communication with Médecins Sans Frontières (MSF) in Brussels. Once on the ground in Liberia, we immediately began coordinating our work with other groups involved in the response of the Ebola crisis, particularly Liberia's Ministry of Health and Social Welfare, as well as the representatives of USAID's Disaster Assistance Response Team (DART), WHO, the CDC and MSF. As part of an Incident Management System established to tackle the Ebola outbreak, International Medical Corps quickly agreed to manage and provide the necessary staff for an ETU being built by Save the Children in the Suakoko District of Bong County, about a four-hour drive north of the capital, Monrovia. MSF graciously offered training for our key staff who would be operating the ETU. The Ministry of Health provided us with a cadre of national health workers that would staff the ETU, and the management of Cuttington University provided us with their dormitories to house our staff, as well as other administrative buildings. We are thankful to all for their support.

We admitted our first patients to the Bong county ETU on September 15th. Currently, we have 53 beds occupied and staffed by a team of 17 expatriates and 161 Liberian nationals. We are gradually building up to 70 beds and a staff of around 230. I would like to take a moment to acknowledge the dedicated and courageous staff working in our treatment center. They have come from inside Liberia and outside – including physicians and nurses from many parts of the United States, Europe and Africa. Our staff is comprised of doctors, nurses, technicians, specialists in water, sanitation and hygiene, logisticians, mental health professionals, custodial workers, and members of burial teams.

To date, this ETU remains one of just two in Liberia operating outside of Monrovia. Our operations there involve isolating and treating patients, providing them with counseling, caring for the remains of those who succumb to the disease, operating ambulance service dedicated to transporting suspected Ebola patients to the ETU and returning those home who have either been cured or tested negatively for the virus, assisting in the reintegration of those returnees to communities that may be anxious about their return, and working with local NGOs on patient referrals.

After discussions with the Ministry of Health, WHO, the CDC, DART and the U.S. military, the U.S. Navy established a laboratory at Cuttington University, adjacent to our ETU. The presence of this laboratory and its ability to turn around the results of blood test for Ebola quickly has made a major difference to our work. It has also saved many lives by allowing those who test negative for the disease to leave the ETU far sooner than they did previously—from as long as five days to a matter of 5-7 hours. I want to take this opportunity to express my personal thanks to the U.S. military for establishing the laboratory in Bong.

In both Liberia and Sierra Leone, we are preparing to manage a second Ebola Treatment Unit—a 70-bed unit in Margibi County, Liberia and a 50-bed unit in Makeni, Sierra Leone. Approximately within the next three weeks, with funding from USAID, we expect to open a training center in Bong County to pass on the knowledge we have gained to members of other NGOs who want to join in the effort to stem the current outbreak. In this center, which will be on the grounds of Liberia's Cuttington University, adjacent to our ETU, we will offer a fast-paced 7-12 day training course for those arriving on the frontlines of the fight against this disease.

Physicians and nurses coming into direct contact with Ebola patients will receive up to 12 days training, while other essential skilled technical staff, such as logisticians and water and sanitation engineers, will receive 7-10 days. Among the individuals we plan to train are members of a U.S. Public Health Service team that will staff a 25-bed Ebola Treatment Unit in Monrovia dedicated to treating health workers who have been infected with the disease during the course of their work treating others. A similar training center will be established in Sierra Leone as well.

Such hands-on training is the key to protecting health workers who must operate in an environment where all know the Ebola virus is present. Strong guidelines and regulations are important, but they must be combined with hands-on training to be truly effective.

Procedures, Protocols and Practice

In its 30 years of providing humanitarian assistance to those in need, International Medical Corps has worked in more than 70 countries in some of the world's toughest, most dangerous environments, but had not previously encountered the Ebola virus or treated patients infected with it. However, our experience of working consistently in challenging, high-risk conditions taught us to move carefully, expect the unexpected and to err on the side of caution when weighing risk as we prepared to open our first treatment center. We consulted with staff from Médecins Sans Frontières to draw on the depth of their experience and the guidelines and protocols they had developed in treating Ebola patients during previous outbreaks in Africa. We also reviewed guidelines and protocols from the CDC and WHO.

We learned quickly that treating Ebola patients is a labor-intensive endeavor that demands very strong logistics to maintain the flow of large quantities of supplies, including personal protective equipment (PPE) for the staff, bedding and medications for patients, as well as disinfectant and water to keep the treatment

unit safe and clean. For example, most PPEs can be used only once, then are incinerated to prevent possible infection. We require approximately 840 PPEs per week to comply with the established guidelines to ensure the safety of our staff. We follow a ratio using 3 expatriate doctors per 50 patients, 8 expatriate nurses per 50 patients, 4 local physician assistants per 50 patients, 24 local nurses per 50 patients, and 2 consumable PPEs per patient.

To treat Ebola patients effectively, we require a staff of about 230 to operate a 70-bed treatment unit. This is a staff per patient ratio of over 3:1. At our Bong County, Liberia treatment unit, we currently have a staff of 178 serving 53 beds. Ebola treatment requires higher than normal staff levels to reduce the risk of mistakes that could potentially endanger both patients and staff. One common practice in our ETUs is for members of our teams to work in pairs—what we call a "buddy system." For example, two physicians or two nurses make every decision that in a regular setting would be made by one on their own. Each "buddy" is constantly checking the personal protective equipment of the other and that the delivery of care is running correctly. The "buddy system" is also used when removing a PPE, a procedure that can carry a high risk of infection if not done properly. To further diminish risk, we have also added one more Shift Supervisor, whose task is to make sure each "buddy team" is following the prescribed protocols and to monitor the overall movement of the team and the treatment it is delivering to our patients. Our staff follow very specific and meticulous, step-by-step donning and doffing protocols.

These protocols are demanding and arduous, requiring personal discipline, concentration and patience on the part of all involved to follow. They are needed because the danger to staff can be very high. We are painfully aware that as of middle of this month, more than 400 health workers had been infected with Ebola in the course of their work. In fact, Ebola has been nicknamed "the nurse killer" in Liberia.

I am pleased to report the strict guidelines and protocols we have implemented have been successful. We have been able to both protect and treat health workers at the Bong facility. Actually, one of the patients we admitted, treated and cured was a Liberian nurse infected while caring for Ebola patients at another facility.

Our protocols require that PPEs worn by our staff cover the entire body. No skin can show. We quickly learned that wearing a bulk, impermeable PPE with as many as three layers of protection in West Africa's high humidity with temperatures of 95 degrees means that staff can only work relatively short periods of time—usually between 1 and 2 hours maximum—inside the unit's restricted area before being rotated and replaced by another team.

In addition to the ETUs, a new approach is to be implemented in Liberia and Sierra Leone that is hoped to help contain the virus. Community Care Centers are to be established where suspected Ebola patients could be removed from their homes and relocated into a center in the community where they could be isolated and provided with palliative care. These would be centers with approximately 10 beds where patients could await testing. A patient testing positive for Ebola could be transferred to an ETU for treatment while those who test negative would be allowed to return home. An advantage of such centers

would be to protect families attempting to care for a loved one from being exposed to the virus. We would support this concept as long as the health workers serving in such centers receive both full training and are equipped with the same PPEs as those used in ETUs. The centers should also need to be linked to—and supported by—an ETU, acting as de facto satellites to that ETU.

Funding, Needs and Support

We are grateful for the timely and generous funding we have received from USAID's Office of Foreign Disaster Assistance, which has enabled us to open the ETU in Bong County and to prepare our staff training facility nearby. It has also funded the ETU nearing completion in Lunsar, Sierra Leone. Other government donors have also come forward to address the crisis, as have some private foundations and corporations. However, generating public donations, which are also necessary to support our efforts to fight Ebola, has been a challenge.

As we continue the scale-up in both Liberia and Sierra Leone for what we believe will be a prolonged fight to contain the Ebola virus in West Africa, the needs will grow accordingly. Put simply, we need three things: people, commodities, and money. We need to continue the recruitment and training of staff and to build a "human resource" pipeline. Conditions to facilitate this—which include travel to and from the affected countries, procedures and systems to protect and treat health workers—must be ensured and implemented as soon as possible.

By commodities, I mean everything from PPEs to disinfectant, to vehicles for transportation, mattresses and bed clothing. Many of these items can only be used once to contain the spread of the disease.

The fight to contain Ebola will be costly. Assuming there are 27 ETUs regionally, and 120 Community Care Centers, we anticipate it would require about $1.6 billion for the next 6 months to bring the disease under control. We will also need to consider the secondary impact of the outbreak—the added costs of food, security, and loss of economic activity are estimated at $500 million. Rebuilding the health care system and maintaining an adequate disease surveillance system could run an additional $600 million.

What Works

Mr. Chairman, I would now like to briefly share some of our lessons learned of what we know works. I believe this will help highlight several key areas of focus as we move forward.

First and foremost, we need to contain the disease. For that to happen, we have learned that several factors need to be in place. This includes having operational ETUs that are staffed by well-trained health professionals.

Community Care Centers, if well-staffed and equipped, could help limit the transmission. A robust referral system between the care centers and ETUs, as well as between ETUs to take advantage of available bed capacity in certain areas to alleviate pressure of overloaded ETUs can help reduce the wait, time, transmission rate and mortality rates. Furthermore, a smart and efficient coordination mechanism at the national level is critical for effectiveness of the response. Limiting the spread of the virus in the community is essential to the containment plan. Therefore, a focus on community sensitization, including education, awareness and outreach to build a trusting environment are of utmost important.

Second, building local capacity by carrying out training and supervision of personnel provides countries with the needed tools and mechanisms to be prepared to respond during outbreaks.

And third, we must focus on strengthening coordination of efforts. To turn the tide of this epidemic, we need to work together and use the strengths of all stakeholders involved. For instance, data analysis and sharing information about what is currently happening and where the gaps are is critical.

What is Needed Going Forward

As we have stated above when describing our response, the most critical challenge is the scarcity of health workers to treat patients and staff the treatment centers that are currently in operation and those being built and planned.

We are facing a severe shortage of adequately trained health professionals, both national and international. The difficult work environment, the personal risk, the need for 21 day self-isolation in some circumstances, all make it difficult for us to recruit volunteers. Health care workers also want to be assured that there are clear plans and procedures in place for possible evacuation and treatment should they fall ill. This has been slow in coming. The growing restrictions on travel to and from West Africa will only isolate the affected countries further, compromise the supply chain and inhibit efforts to recruit qualified staff. These factors will further enable the severe outbreak to continue.

Training of health workers and first responders continue to be a major need. This includes training of staff working in a treatment units, at community care centers, burial teams, ambulance attendants, community workers and educators. The training being conducted by the CDC, the training to be conducted by the U.S. military, training being led by other NGOs, as well as International Medical Corps needs to be supported. We, at International Medical Corps, are willing to train ETU staff, both in Sierra Leone and Liberia, to help contain the virus.

I would also like to underscore how vital has been and continues to be the availability of and proper usage of PPEs during the Ebola response. To this end, it is important to note that acquiring appropriate protective equipment has represented another challenge given the numbers required to effectively implement

treatment centers and protect workers, as well as the limited number of available qualified suppliers. The current demand far exceeds the supply. There are currently two main manufacturers for our "acceptable" coveralls (a key component of the PPE), and they are producing at full capacity. We estimate that, at the current stage, they will meet around 35 percent of the demand. Those manufacturers need to be supported and encouraged to increase their production capabilities to meet the demand.

I would like to conclude by offering some recommendations to the Committee for consideration.

First, one of the most critical lessons learned from this response has been the importance of having the human resources ready and prepared to address an outbreak of infectious disease. Cadres of health workers need to be well-trained (and supported) to staff the ETUs and care centers in the affected countries, as well as to prepare other countries in the region for any potential future outbreaks. This epidemic has very visibly demonstrated that it is communities, civil society - including NGOs - and government health workers at the local level who carry out the majority of the response related to treatment, patient care and case management, and community outreach. To be truly effective, it is important that training and supervision of personnel be led by entities with hands-on experience in treatment and management to undertake this task, which should involve actual practical training and not be limited to didactic methods. A comprehensive approach to the training that includes all aspects of addressing the outbreak should include case management and treatment, contact tracing, dead body management, as well as psychosocial support, community outreach and awareness, and social mobilization.

Second, we need to accelerate the construction and staffing of ETUs and community care centers to break the chain of transmission. We must also improve coordination among the centers so that beds are available to patients who need them. Today, some ETUs have many empty beds while others are at full capacity, forcing staff to turn suspected Ebola patients away.

Third, we must improve surveillance and referral systems that will help individuals access treatment quickly and strengthen the link between community-based and referral-systems.

Fourth, we need to establish clear and understandable linkages among various coordination structures that are now in place such as the UN Mission for Ebola Emergency Response and country coordination bodies. Such clarity is especially critical for NGOs who are closest to the ground and doing service delivery, as well as national governments and their agencies. Efficient coordination would also aid in supply chain and logistics issues.

Fifth, while we welcome the advances that have been made over the past few weeks in establishing procedures to evacuate and treat health workers who might contract Ebola, we recommend that the systems

being put in place now be institutionalized and made part of the global preparedness planning in the event of future epidemics.

Sixth, we need to maintain an open airspace to and from the Ebola-affected countries. This is critical for the humanitarian response, to get staff and supplies in and out of the region. It is critical for our recruitment and for the well-being of our staff. We need to contain this virus at the source and we cannot do this without the ability to get much-needed staff and supplies to and from the affected countries. As InterAction, a coalition of over 190 member organizations stated in their recent letter to Congress: "Without the NGO community and its supported health workers on the ground treating patients in West Africa, it will be very difficult to end this crisis."

Seventh, we need to accelerate and support the production of vaccines. The human and economic consequences of this outbreak are disastrous and an investment in vaccines would help mitigate future outbreaks.

Eighth, we need to invest in preparedness in the region at large to ensure these countries have the needed resources, proper training and systems in place to respond to possible future outbreaks. Also, as we have learned over the past few months, the virus does not recognize international borders and could affect other West African Countries with devastating effects.

Finally, in developing and implementing recovery efforts and a long-term strategy, we must focus on building stronger health care systems in the region. Some of the most serious side effects stemming from the Ebola outbreak have occurred within the countries' health care systems. Health centers have closed, emergency and maternity wards are not functioning, hospital staff have stopped coming to work, all of which has had a severe impact on the already dire circumstances facing these countries. As a consequence of the current situation, Sierra Leone and Liberia, which already experienced some of the highest burden of maternal and child deaths, are now facing conditions where there are no available places for women to have C-sections, for children to be immunized, trauma centers to go to after car and other accidents, as well as continue to manage the ongoing severe health problems affecting the countries such as high rates of malaria, pneumonia, and a wide range of chronic conditions. As a result, the mortality rate is expected to increase to higher levels.

Addressing these challenges will require increased financial investments and the engagement of other countries and various stakeholders working in tandem. At the same time, we need to consider the secondary and tertiary impacts of this outbreak such as its impact on economic conditions, livelihoods, food security, and vaccination coverage.

There is no doubt that we will stop this outbreak, end the deaths, and - if done correctly - build the tools to prevent another outbreak of such proportions. We look forward to working with you to make this possible.

Once again, thank you, Mr. Chairman and Ranking Member Cummings for allowing me to present this testimony before your very distinguished committee and for holding this timely hearing. I would be glad to answer any questions the Committee may have.

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International Medical Corps

Delivering emergency relief. Empowering long-term recovery through training.

Rabih Torbay is **Senior Vice President for International Operations** and oversees International Medical Corps' global programs in 31 countries on 4 continents and its staff and volunteers numbering over 8,000. Torbay has personally supervised the expansion of International Medical Corps' humanitarian and development programs into some of the world's toughest working environments, including Sierra Leone, Iraq, Darfur, Liberia, Lebanon, Pakistan, Afghanistan, Haiti, Libya and, most recently, Syria.

As the organization's senior representative in Washington DC., he serves as International Medical Corps' liaison with the U.S. government, including USAID, the Department of State, the Department of Defense, and the Department of Health and Human Services.

Raised in Lebanon, Torbay is a civil engineer who worked in that field until early 1999, when he joined International Medical Corps' humanitarian efforts in Sierra Leone. Following the September 11 terrorist attacks, Torbay first went to Pakistan, and then Afghanistan, to lead International Medical Corps' emergency regional response team. He remained in Afghanistan for 8 months establishing programs throughout the country.

In October 2002, Torbay moved to International Medical Corps' headquarters in Los Angeles where he became Vice President of International Operations. In 2003, he led International Medical Corps into Iraq as the first non-governmental organization (NGO) to enter the country, and later one of the first NGOs to enter Baghdad after the war. He remained in Iraq for seven months, setting up a comprehensive relief and development initiative.

Torbay led International Medical Corps' rapid response team in 2004 into the Darfur region of Sudan, where its programs currently address the needs of more than 230,000 displaced persons in some of Darfur's most desolated areas. In July, 2006, after war broke out in Lebanon, Torbay organized International Medical Corps' emergency relief efforts to residents of the southern part of the country, who had been trapped in the fighting there.

After the devastating January 12, 2010 Haiti earthquake, Torbay organized and deployed International Medical Corps' Emergency Response Team that was on the ground in Port-au-Prince providing services in 22 hours. Similarly, Torbay managed and closely supervised International Medical Corps' Emergency Response in Japan after the 2011 earthquake and tsunami, India after the 2013 cyclone and most recently in the Philippines after Typhoon Haiyan. Since 2011, Torbay has been overseeing the crisis in Syria and managing International Medical Corps' relief services for Syrian refugees, Earlier this year he supervised the organization's emergency response in Central African Republic and South Sudan after outbreaks of conflict in both countries. Torbay oversees International Medical Corps' Ebola response in Sierra Leone and Liberia, where International Medical Corps is providing treatment to EVD patients through Ebola Treatment Units. Torbay currently lives in Maryland with his family.

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Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

Name: RABIH TORBAY

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2011. Include the source and amount of each grant or contract.

None

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

I am testifying on behalf on International Medical Corps. I am the Senior Vice President of International Operations at International Medical Corps. International Medical Corps is a global, humanitarian, nonprofit organization dedicated to saving lives and relieving suffering through health care training and relief and development programs.

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2010, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

Please see attached list.

I certify that the above information is true and correct.

Signature: [signature]

Date: 10/22/2014

International Medical Corps
Federal Awards Received
Note: Agreement sign date was used as the criteria for FY classification

FY 2011

DONOR	Number of Grants	Total
CDC	2	2,839,161
DHHS	1	2,469,955
DOS	1	970,950
OFDA	9	28,887,580
PRM	17	25,164,148
USAID	3	31,583,249
USIP	1	5,535
Grand Total	34	91,920,578

FY 2012

DONOR	Number of Grants	Total
CDC	3	4,723,095
DHHS	1	214,683
DOS	1	50,000
DRL	1	2,399,955
OFDA	18	65,453,563
PRM	11	17,546,558
USAID	3	3,774,587
Grand Total	38	94,162,441

FY 2013

DONOR	Number of Grants	Total
CDC	4	6,709,708
OFDA	14	145,216,020
PRM	19	28,373,723
USAID	6	12,948,451
Grand Total	40	193,247,902

FY 2014

DONOR	Number of Grants	Total
CDC	4	1,784,690
DOS	1	1,979,919
DRL	1	1,499,508
OFDA	8	15,375,359
PRM	17	29,716,441
USAID	6	1,792,825
Grand Total	37	52,148,742

FY 2015

DONOR	Number of Grants	Total
OFDA	6	15,429,703
PRM	10	17,012,144
Grand Total	16	32,441,847