

QUESTIONS FOR THE RECORD OF THE HONORABLE MARK MEADOWS

**SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND
INTERNATIONAL ORGANIZATIONS,
COMMITTEE ON FOREIGN AFFAIRS, U.S. HOUSE OF REPRESENTATIVES**

“Global Efforts to Fight Ebola”
September 17, 2014

NOTE: CONTENT ACCURATE AS OF OCTOBER 23, 2014.

- 1. Provided success of clinical trials, is there a plan to accelerate the regulatory approval of therapies and vaccines that are currently in development to treat Ebola, and if so, what has been the extent of interactions between regulators and sponsors?**

Answer: This issue is largely outside of CDC's purview, as CDC is not involved in the development and approval of therapies. We do note that the U.S. Food and Drug Administration (FDA) has various programs that are intended to facilitate and expedite development and review of new medical products to address unmet medical needs for serious or life-threatening conditions, including, as appropriate, the development of medical products for Ebola.

We also note that the Department of Health and Human Services (HHS) Biomedical Advanced Research and Development Authority (BARDA) supports the preparation and submission of regulatory documents and filings by sponsors to FDA. We defer to FDA and BARDA for the specifics of their programs.

- 2. If treatment(s) for Ebola is/are approved, can you detail the extent of planning that has taken place thus far to ensure that treatment(s) are able to be paid for and distributed in an effective manner?**

Answer: Under the leadership of HHS, the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is the coordinating body for the Federal Agencies in charge of protecting the civilian population from potential adverse health impacts through the use of medical countermeasures (MCM), which are medicines, devices, or other medical interventions that can lessen the harmful effects of these threats. The PHEMCE coordinates Federal efforts to enhance preparedness against chemical, biological, radiological and nuclear threats (CBRN) and emerging infectious diseases from an MCM perspective. The PHEMCE is led by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes three primary HHS internal agency partners: the Centers for Disease Control and Prevention (CDC), FDA, and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs, the Department of Homeland Security and the U.S. Department of Agriculture. BARDA has used Project BioShield funds to support the development of an Ebola vaccine and therapeutic candidates that meet product specific requirements established by the PHEMCE.

The United States Government is currently supporting the development of several vaccine candidates in various stages of development.

CDC is prepared to deploy the critical medical countermeasures currently stockpiled in the Strategic National Stockpile (SNS) and has demonstrated capabilities to distribute small quantities of rare MCMs for treatment of isolated cases of anthrax or vaccinia infection, as may be the model for potential additional Ebola cases occurring in the United States.

3. What is the Administration doing to educate Americans about how to protect themselves when traveling?

Answer: CDC educates Americans on ways to protect themselves when traveling in numerous ways, such as:

- Issuing travel health notices advising U.S. citizens to avoid nonessential travel and to take enhanced precautions if they are visiting the affected West African nations.¹ The recommendation to avoid nonessential travel is intended to help control the outbreak and prevent continued spread by:
 - Protecting U.S. residents who may be planning travel to the affected areas, and
 - Enabling the government of the affected countries to respond most effectively to contain this outbreak.
- Working closely with Customs and Border Protection (CBP) in the Department of Homeland Security (DHS) and other partners to enhance practices at U.S. ports of entry to use routine procedures to identify travelers who show signs of infectious disease. In response to the outbreak, these procedures have been enhanced through guidance and training. CDC's quarantine station staff respond as needed, for example by evaluating ill travelers identified by CBP officers.
- Providing comprehensive information to travelers at U.S. ports of entry through airport messaging to outbound and inbound travelers, CDC website, and social media. Ebola-specific travel messages have been developed for electronic monitors and posted to reach travelers from West Africa, and posters have been displayed in Transportation Security Administration (TSA) screening areas of airports to reach outbound travelers. Furthermore, CDC maintains detailed and updated actions for travelers to take before international travel on the CDC website, including Ebola-related recommendations.
- Developing interim guidance to provide public health authorities and other partners with a framework for evaluating people's level of exposure to Ebola and initiating appropriate public health actions on the basis of exposure level and clinical assessment. Specifically, CDC developed "*Interim Guidance about Ebola Virus Infection for Airline Flight Crews, Cleaning Personnel, and Cargo Personnel,*" As well as "*Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure.*"
- Issuing advice for colleges, universities, and students about study abroad, foreign exchange, and other education-related travel, as well as advice for students who have recently traveled from a country in which an Ebola outbreak is occurring.
- Developing guidance for humanitarian aid organizations whose employees or volunteers are working in countries where an Ebola outbreak is occurring. Humanitarian aid workers play a

¹ For more information about travel notices to the West Africa region and other countries, please visit CDC's Travelers' Health website.

vital role in the Ebola outbreak response, and CDC encourages them to continue the important work being done to stop the disease's spread at its source.

CDC will continue to update its communication products and webpages with new information on the Ebola outbreak for the general public and specific audiences to share credible, factual information and to dispel misconceptions about Ebola.

4. Does the Administration have a plan in place, if the virus spreads beyond its current locations? Have these plans been clearly communicated to state, local and tribal governments?

Answer: *International*

The United States is leading the global effort to curb this epidemic at its source and prevent its further spread. The United States is dedicated to achieving zero cases in the affected countries and is simultaneously working to build Ebola preparedness capacity in the surrounding vulnerable nations. The approach emphasizes cross-border surveillance, communication, and cooperation to rapidly detect and respond to potential EVD transmission before it escalates into an outbreak.

The U.S. Agency for International Development (USAID) continues to lead the United States' overseas response to the Ebola outbreak, while DoD, CDC, the Department of State, and other Federal Departments and Agencies are supporting the whole-of-government approach to this national security priority. USAID has deployed a Disaster Assistance Response Team (DART) to coordinate planning, operations, logistics and other components of the interagency effort. CDC staff is working with Ministries of Health to improve surveillance, contact tracing, laboratory capacity, emergency operations planning and other critical capabilities.

To expand on the current response, the United States plans to leverage the unique capabilities of the U.S. military and broader uniformed services to help bring the epidemic under control. These efforts will entail command and control, logistics expertise, training, and engineering support, including:

- A Joint Force Command set up by the U.S. Africa Command and headquartered in Monrovia, Liberia, to provide regional command and control support to U.S. military activities and facilitate coordination with U.S. Government and international relief efforts. This effort will involve an estimated 3,000 U.S. forces.
- Additional Ebola Treatment Units that will be built in affected areas by Command engineers, and the U.S. Government will help recruit and organize medical personnel to staff them.
- A Command-established site to train up to 500 health care providers per week, enabling healthcare workers to safely provide direct medical care to patients.
- Deployment of up to 65 United States Public Health Service Commissioned Corps officers to Liberia to manage and staff a hospital to care for healthcare workers who become ill, to include administrators, clinicians, and support staff.

HHS, and in particular CDC, is working closely with the World Health Organization (WHO), the United Nations, the Ministries of Health in affected countries, and other international partners to respond to the current Ebola outbreak in West Africa. The Ebola epidemic reminds us that our Global efforts to build the capacity to prevent, detect, and rapidly respond to infectious-disease threats like Ebola have never been more vital. In February 2014, CDC came together with nations around the world to launch the GHSA as a five-year effort to accelerate action. On September 26, 2014, President Obama met with leaders of 40 nations as well as top Administration officials to advance progress in the GHSA.

- CDC is contributing to the GHSA by partnering with nations to help them establish measurable global health security capacity. This includes core CDC partnership programs like the Global Disease Detection Centers and Field Epidemiology Training Program, which enable the laboratory systems, disease surveillance workforce, emergency operations center capacity, and biosafety and biosecurity best practices required to counter Ebola and other biological threats.
- Over the next five years the United States has committed to working with at least 30 partner countries to invest in model systems to advance the GHSA. CDC and DoD will work with other U.S. agencies and partner countries to establish emergency operations centers, build information systems, and strengthen laboratory security to mitigate biological threats and build partner capacity.

Domestic

To ensure the United States is prepared to respond to an Ebola epidemic, the CDC has detailed response plans in place for once an Ebola case is confirmed to respond to Ebola cases in the United States. The plans includes: instructions to rapidly disseminate information about the Ebola case(s) to key public health, health care system, and emergency management partner organizations; providing current information to state, local, and territorial public health departments; and coordinating critical issues management regarding state and local needs for the CDC EOC incident manager and other response task force teams. CDC has also developed a web-based document, for use in state and local planning that identifies rapidly emerging CDC guidelines for public health preparedness national standards regarding Ebola.

Additional CDC efforts include:

- Preparing providers, hospitals, state and local health departments and others involved in public health preparedness and response for the possibility of an Ebola case in the United States, including guidance documents on the identification and treatment of an Ebola patient, infection control guidelines, laboratory testing and other recommendations necessary to protect U.S. health care workers and the general public. Over the coming days and weeks, CDC will be working with other Federal, state, and local governments and private organizations to strengthen U.S. readiness for detecting and preventing additional cases of Ebola in this country. These efforts include the entry screening at U.S. ports of entry and enhanced outreach to healthcare workers and hospitals to improve their infection control practices and policies.
- Providing funding and assistance to state and local health departments for all-hazards preparedness, including an infectious disease outbreak. This funding and assistance helps public health departments develop capabilities that are applicable to responding to many public health threats.

- Developing guidance for laboratory technicians and other health care personnel who collect or handle specimens in the United States.
 - Working closely with DHS's CBP and other partners at U.S. ports of entry to conduct enhanced entry screening to identify travelers who show signs of infectious disease. CBP is conducting entry screening at five U.S. airports (New York-JFK, Washington-Dulles, Newark, Chicago-O'Hare, and Atlanta), that receive 94 percent of travelers from the Ebola-affected nations of Guinea, Liberia, and Sierra Leone, as of October 11, 2014. If a potentially sick traveler is identified during or after a flight, the traveler will be immediately isolated, and CDC will conduct an investigation and work with the airline, Federal partners, and state and local health departments to notify them and take any necessary public health action. Entry screening is part of a layered process that includes exit screening and standard public health practices, such as patient isolation and contact tracing in countries with Ebola outbreaks. Successful containment of the recent Ebola outbreaks in Nigeria and the Democratic Republic of Congo demonstrate the effectiveness of this approach.
 - Assisting with exit screening and communication efforts in West Africa to prevent sick travelers from boarding commercial planes, buses, trains, or ships. CDC also has issued interim guidance about Ebola virus infection for airline flight crews, cleaning personnel, and cargo personnel.
- 5. The African nations are trying to fight & contain the Ebola outbreak, as well as keep their fragile economies on track. With the potential slowing of the economies of these countries, what kind of economic challenges are, or could, these countries encounter due to this outbreak? What can US companies with a presence in the region do to mitigate these risks? Particularly those outside of the healthcare industry?**

Answer: This issue is outside CDC's purview; we defer to USAID and other appropriate offices on matters pertaining to international economies.