DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT

OF

LUCIANA BORIO, M.D.

ASSISTANT COMMISSIONER FOR COUNTERTERRORISM POLICY

DIRECTOR, OFFICE OF COUNTERTERRORISM AND EMERGING THREATS

DEPUTY CHIEF SCIENTIST (ACTING)

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

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

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good afternoon Chairman Smith, Ranking Member Bass, and members of the Subcommittee. I am Dr. Luciana Borio, Assistant Commissioner for Counterterrorism Policy, Director of the Office of Counterterrorism and Emerging Threats, and Acting Deputy Chief Scientist at the Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to appear today to discuss FDA actions in response to the need for interventions against the Ebola epidemic in West Africa.

As you know, the Ebola epidemic in West Africa is the worst in recorded history. As of September 8, 2014, there are 4,293 confirmed or suspected cases in Guinea, Liberia, Nigeria, and Sierra Leone, and 2,296 deaths. A single imported case has been documented from Guinea to neighboring Senegal. In addition, Ebola infections have re-emerged in Central Africa in the Democratic Republic of the Congo, and appear to be unrelated to the epidemic in West Africa, with 62 suspected cases and 35 deaths.

The toll of this epidemic, with so many lives lost and so many others fighting for their lives, is heartbreaking and tragic. As Dr. Thomas Frieden, Director of the Centers for Disease Control and Prevention (CDC), who advised this Committee a few weeks ago and has since visited the countries affected in West Africa, has noted, the epidemic is larger than reported and the situation is going to get worse before it gets better. The World Health Organization (WHO) recently assessed that the actual number of cases may be two to four times higher than reported and the number of infections could exceed 20,000 over the course of the epidemic.

The primary approach to containing the current epidemic remains standard public health measures, such as identifying, isolating, and caring for patients who are ill, making sure health care workers have access to personal protective equipment and are properly trained in infection control measures, and tracing patients' contacts to detect any secondary infections as soon as possible. However, this epidemic presents complex challenges because of the minimal health care and public health infrastructure available within affected countries and very limited capacity to provide supportive care in-country. This tragic situation is further complicated because there are no treatments or vaccines shown to be safe or effective for the Ebola virus, and products currently under development are in the very early stages of investigation. FDA is dedicated to do all that we can to respond effectively and rapidly to this epidemic.

FDA's Response to the Ebola Epidemic

FDA has a critical role in helping to facilitate the development, manufacturing, and availability of investigational products for use against Ebola virus disease. FDA is actively working to facilitate development of treatments and vaccines with the potential to help mitigate this epidemic. We are providing scientific and regulatory advice to U.S. government agencies that support medical product development, including the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the U.S. Department of Defense (DoD), to help speed development and production programs. We also are working interactively with medical product sponsors to clarify regulatory requirements and expedite regulatory review of data, and thereby help advance the development of investigational products as quickly as possible. This includes expediting the review of Investigational New Drug (IND) applications, which are required for FDA-regulated clinical trials of drugs and vaccines to proceed. For example, FDA

reviewed IND applications for two investigational Ebola vaccines and, after such review, allowed them to proceed. NIAID, which is co-developing an Ebola vaccine with GlaxoSmithKline (GSK), publicly announced that it began Phase I clinical testing in early September of this year. Additionally, NewLink Genetics stated publicly that it will proceed with Phase I clinical trials of its Ebola vaccine candidate. We continue to work closely with therapeutic product developers to speed development of these products as quickly as possible.

FDA also is collaborating with WHO and working with several of our international regulatory counterparts, including the European Medicines Agency, Health Canada, and others, to exchange information about investigational products for Ebola. These efforts support regulatory collaboration to harmonize and accelerate development and, we hope, will result in approval of medical products in the United States and in other nations. With this important goal in mind, FDA recently entered into a confidentiality commitment with WHO to allow the exchange of non-public information concerning medical products that address issues relevant to response to the current Ebola crisis, as well as more broadly to prepare for or respond to any future events.

Last week, I had the opportunity to participate in a WHO-sponsored consultation with my Federal colleagues, as well as representatives of the international public health community and medical product sponsors, to discuss leading investigational treatments and vaccines for Ebola and key considerations for deployment in West Africa. The complex issues discussed included clinical testing (e.g., study designs and location of studies), availability and evidence supporting the use of novel therapeutic drugs, ethical considerations such as inclusion of patients in experimental protocols, and data collection. Moving forward, FDA is participating in a regulatory working group of international health regulators that includes members of the affected

countries in West Africa. We are looking forward to working with our international colleagues to foster development of and access to investigational products in affected countries.

The investigational vaccines and treatments for Ebola are in the earliest stages of development and have not been tested for safety or effectiveness in humans. Currently, there are only small amounts of some experimental products that have been manufactured for testing. This constrains our options for both properly assessing safety and efficacy of these investigational products in, and making material available for therapeutic use outside of, a clinical trial (also known as expanded access) to respond to the epidemic. Nonetheless, while investigational products are being developed, with the goal of product approval and manufacturing for wide-scale use, FDA is doing all it can to enable access to these products when requested and the circumstances warrant. FDA has one of the most flexible regulatory frameworks in the world, which includes mechanisms to enable access to investigational medical products when, based on criteria that, among other considerations, balance expected risk and benefit to the patient, it would be appropriate to use such products. It also means that FDA's regulatory decisions are based on the best available science and the best interest of public health.

Under certain circumstances, clinicians may submit an emergency IND (eIND) application to FDA under the FDA's Expanded Access provisions to make available investigational products for individual patients outside of clinical trials. FDA has enabled access to Ebola products under an eIND in response to this epidemic. In addition, under the FDA's Emergency Use Authorization (EUA)[1] authority, we can allow the use of an unapproved medical product—or an unapproved use of an approved medical product—for a larger population during emergencies,

[1] Under the Federal Food, Drug, and Cosmetic Act, amended by the Project BioShield Act of 2004 [PL 108-276] and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 [PL 113-5], the Secretary of HHS has the authority to authorize the "emergency use" of medical countermeasures in certain situations [21 USC § 360bbb-3].

when, among other reasons, there is no adequate, approved, and available alternative. FDA authorized the use of an Ebola diagnostic test, developed by DoD, under an EUA to detect the Ebola virus in laboratories designated by DoD. This test can help facilitate an effective response to the ongoing epidemic in West Africa by rapidly identifying patients infected with Ebola virus and facilitating appropriate containment measures and clinical care. The authorized test also has been made available to 12 laboratories within the United States. These laboratories are located close to "ports-of-entry," such as those in Texas known to have travelers from West Africa working in the energy business. The tests also are being used to rule out Ebola in individuals with signs and symptoms similar to Ebola infection, such as those with malaria infection. We are continuing to work with other diagnostic product developers who are interested in pursuing an EUA, or other appropriate mechanisms, for their investigational diagnostics to test for Ebola.

Unfortunately, during epidemics such as this, fraudulent products that claim to prevent, treat, or cure a disease rapidly appear on the market. FDA has learned of several fraudulent products that claim to prevent or treat Ebola virus infection. In response, we issued a statement, warning consumers about fraudulent Ebola treatment products, and we are taking actions against fraudulent claims to protect public health.

CONCLUSION

This epidemic has posed incredible demands on FDA, and, I could not be more proud of the dedication and leadership the Agency has shown in responding to this epidemic. We have explored multiple ways to be highly responsive and adaptive to the complex range of issues this epidemic has presented and will continue to present.

Developing the medical products to help bring this Ebola epidemic under control is highly complex and will, unfortunately, take time. The close cooperation and collaboration within FDA, within the U.S. government, and with our international partners, is essential. These efforts will help facilitate the development and availability of medical products to respond to Ebola.

FDA is fully committed to sustaining our deep engagement and aggressive response activities. We will continue to work closely with our U.S. government and international partners and with product developers to speed the development and availability of promising medical products that offer the potential to end this epidemic as quickly as possible. Finally, we are committed to sustaining these efforts to help prevent such epidemics in the future.

Thank you, and I am happy to answer your questions.