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 OVERSIGHT AND INVESTIGATIONS

HOUSE ENERGY AND COMMERCE COMMITTEE

U.S. HOUSE OF REPRESENTATIVES

"EXAMINING THE U.S. PUBLIC HEALTH RESPONSE TO THE EBOLA OUTBREAK"

October 16, 2014

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good afternoon Chairman Murphy, Ranking Member DeGette, 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's response to the Ebola epidemic in West Africa.

The Ebola epidemic in West Africa is the worst in recorded history. As of October 12, 2014, there have been 8,997 reported cases, including 4,493 documented deaths, according to the World Health Organization (WHO). And as you know, a single case had been detected in the United States in an individual who was infected in Liberia and subsequently traveled to the United States and died. A nurse treating this patient has now tested positive for Ebola.

The toll of this epidemic, with so many lives lost and so many others fighting for their lives, is heartbreaking and tragic. While it appears, so far, that the outbreaks in Senegal and Nigeria have been rapidly contained by the application of standard public health techniques, widespread and intense disease transmission continues in Guinea, Liberia, and Sierra Leone. It is still the case—as Dr. Thomas Frieden, Director of the Centers for Disease Control and Prevention (CDC), has noted—that the epidemic is larger than reported and the situation is going to get worse before it gets better.

The primary approach to containing the epidemic remains standard public health measures, such as identifying and isolating infected individuals, caring for patients who are ill, ensuring that

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, applying these public health measures on a large scale presents complex challenges because of the strains on health care and public health infrastructure within affected countries and the very limited capacity to provide medical 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

This Ebola outbreak is an extraordinary global event, and FDA is taking extraordinary steps to be proactive and flexible in our response. We have a critical role in helping to facilitate the development, manufacturing, and availability of investigational products for use against Ebola virus disease. In response to this urgent situation, FDA is actively working with Federal colleagues, industry, and international organizations to facilitate development, including evaluating the safety and efficacy, of treatments and vaccines with the potential to help mitigate this epidemic.

Each Federal partner has a vital part to play in the global race to find the therapeutic solutions to this deadly puzzle. FDA participates in a cross-cutting Federal workgroup that meets regularly to provide ongoing interactions between the different Federal participants. FDA provides 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) in the Office of the Assistant Secretary for Preparedness and Response (ASPR), and the U.S. Department of Defense (DoD), to help speed their development programs. We are also coordinating our activities with CDC.

In addition, we are reaching out proactively to multiple medical product developers to clarify regulatory requirements, provide input on pre-clinical and clinical trial designs (including for clinical trials that use a common protocol to test several products at once and that can be conducted in affected countries and in the United States), and expedite review of data as they are received from product developers. These efforts should help advance the development of investigational products as quickly as possible. As part of the overall response, FDA is expediting the review of Investigational New Drug (IND) applications, which are required by law for FDA-regulated clinical trials of drugs and vaccines to proceed. For example, FDA reviewed IND applications for two investigational Ebola vaccines in less than one week and, after such review, allowed them to proceed. Consequently, NIAID, which is co-developing an Ebola vaccine with GlaxoSmithKline (GSK), announced that it began Phase I clinical testing in early September of this year, and NewLink Genetics will soon proceed with Phase I clinical trials of its Ebola vaccine candidate. We also continue to work closely with therapeutic product developers to speed development of these products. To augment diagnostic capacity, we have contacted several commercial developers—entities we know are capable of rapidly developing these types of diagnostic tests—and have encouraged them to work with us to quickly develop and make available such tests. Several entities have expressed interest and have initiated discussions with FDA.

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, have the potential to contribute to 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. We believe this will facilitate international collaboration to respond to the current Ebola crisis, as well as more broadly to prepare for or respond to any future events.

I have had the opportunity to participate in WHO-sponsored consultations 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 most recent consultation—which was attended by 70 experts from around the world, including experts from affected and neighboring countries in West Africa—focused on Ebola vaccine development. Attendees agreed that the ultimate goal is to have a fully tested and licensed vaccine that can be scaled up for use in mass vaccination campaigns as quickly as possible. Moving forward, FDA will continue working with our international colleagues to foster development of and access to investigational products in affected countries.

While FDA is making every effort to encourage development, speed review, and use flexible approaches to authorize potential medical products to address Ebola, we cannot lose sight of the scientific fact that investigational vaccines and treatments for Ebola are in the earliest stages of development. Data on safety or effectiveness in humans are limited or lacking, and accurate assessment (especially of effectiveness) may be impossible if adequately designed clinical trials are not performed. Currently, there are only small amounts of some experimental products that

have been manufactured for testing. This supply issue constrains the options for properly assessing the safety and efficacy of these investigational products in clinical trials to respond to the epidemic, and also limits the possibilities for making products available for therapeutic use outside of a clinical trial (also known as expanded access). Nonetheless, while investigational products are being developed, with the ultimate goal of product approval and manufacturing for wide-scale use, FDA is doing all it can to facilitate access to these products when access has been granted by the sponsor and the clinical 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 appropriate, after the risks and benefits to the patient have been weighed.

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, when, among other reasons, based on scientific evidence available, 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. We were able to issue this EUA, in part, because of new authorities gained under the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, or PAHPRA, which provide greater flexibility in the issuance of EUAs. DoD's diagnostic 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 14 laboratories within the United States. These laboratories are located in states that serve as major "ports-of-entry," such

[1] Under the FD&C Act, as amended by the Project BioShield Act of 2004 [PL 108-276] and PAHPRA [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].

as Texas, known to have travelers from West Africa working in the energy business. In fact, this test was used to detect Ebola in the patient from Liberia. We are encouraging other diagnostic product developers to pursue 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. For example, we recently issued Warning Letters to three firms marketing products that claim to prevent, treat, or cure infection by the Ebola virus.

CONCLUSION

FDA is using its authorities to the fullest extent possible to continue its mission to protect and promote the public health, both domestically and abroad. This epidemic has placed incredible demands on FDA, but our staff is fully committed to responding in the most proactive, thoughtful, and flexible manner. We have explored multiple ways to be highly responsive and adaptive to the complex range of issues that this constantly changing 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, with our international partners, and with product developers

is essential to the global response to this epidemic. FDA looks forward to playing its part as events unfold.

I would also stress that improving the medical and public health infrastructure in the affected countries is critical, not just to improve ongoing response activities, but also to enable advancing product development. In the absence of improved medical and public health infrastructure, our ability to facilitate appropriate further testing and use of these products will be extremely limited.

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. We fully appreciate the gravity of the situation at hand and are exercising maximum flexibility in our activities. We are singularly focused on facilitating and expediting the development of medical products to diagnose, prevent, and treat Ebola virus disease. It is our sincere hope that the global community can have access to safe and effective products for Ebola in the most expedited manner.

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