

# THE COMMITTEE ON ENERGY AND COMMERCE

## **MEMORANDUM**

October 14, 2014

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing on "Examining the U.S. Public Health Response to the Ebola Outbreak"

The Subcommittee on Oversight and Investigations will hold a hearing on Thursday, October 16, 2014, at 12:00 p.m. in 2123 Rayburn House Office Building, entitled "Examining the U.S. Public Health Response to the Ebola Outbreak." This hearing will focus on the role of U.S. public health agencies and their efforts to prevent the spread of Ebola within the U.S. The preparedness of United States ports, points of entry, healthcare facilities and other institutions to identify, diagnose, isolate, and treat Ebola patients in a safe and appropriate manner also will be evaluated.

#### I. WITNESSES

- Dr. Thomas R. Frieden, Director, Centers for Disease Control and Prevention;
- Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health;
- Dr. Luciana Borio, Assistant Commissioner, Counterterrorism Policy, U.S. Food and Drug Administration;
- Dr. Robin Robinson, Director, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services;
- Mr. John P. Wagner, Acting Assistant Commissioner, Office of Field Operations, U.S. Customs and Border Protection, U.S. Department of Homeland Security; and
- Dr. Daniel Varga, Chief Clinical Officer and Senior Vice President, Texas Health Resources.

#### II. BACKGROUND

#### A. About Ebola Virus Disease

Ebola is a deadly disease caused by infection with an Ebola virus strain.<sup>1</sup> According to the Centers for Disease Control and Prevention (CDC), Ebola is not airborne and asymptomatic individuals are not contagious.<sup>2</sup> Ebola was first discovered in 1976,<sup>3</sup> and there have been sporadic Ebola outbreaks in several African countries<sup>4</sup>

The average incubation period for Ebola is eight to ten days, but symptoms may appear anywhere from two to twenty-one days post-exposure. The nonspecific nature of Ebola symptoms makes diagnosing Ebola difficult, particularly when a person has been infected for just a few days. Ebola symptoms include fever, headache, muscle pain, weakness, diarrhea, vomiting, abdominal pain, and unexplained hemorrhaging. Ebola is spread through direct contact with blood or bodily fluids of an infected person, infected animals, and objects contaminated with the virus. Healthcare providers, family, and friends in close contact with Ebola patients are at the highest risk for infection, as they are most likely to come in contact with a patient's infected blood or bodily fluids.

## B. The 2014 Ebola Epidemic

The World Health Organization (WHO) announced on March 23, 2014, that forty-one people had contracted Ebola in Guinea — the apparent starting point of West Africa's first Ebola outbreak — and twenty-nine had died from the virus. WHO estimated that the outbreak likely began in December 2013; the organization posited that detection was delayed due to poor disease surveillance and detection capacity. By mid-August, Ebola had spread to Sierra Leone, Liberia, and Nigeria, infecting more than 2,000 people and killing more than half, according to reports.

<sup>&</sup>lt;sup>1</sup> CDC, Ebola (Ebola Virus Disease), About Ebola Hemorrhagic Fever, <a href="http://www.cdc.gov/vhf/ebola/about.html">http://www.cdc.gov/vhf/ebola/about.html</a>.

<sup>&</sup>lt;sup>3</sup> CDC, Ebola (Ebola Virus Disease), About Ebola Hemorrhagic Fever, http://www.cdc.gov/vhf/ebola/about.html.

<sup>&</sup>lt;sup>4</sup> CDC, Ebola Hemorrhagic Fever, Risk of Exposure, <u>www.cdc.gov/vhf/ebola/exposure/index.html</u>.

<sup>&</sup>lt;sup>5</sup> CDC, Ebola Hemorrhagic Fever, Transmission, <a href="www.cdc.gov/vhf/ebola/transmission/index.html">www.cdc.gov/vhf/ebola/transmission/index.html</a>.

<sup>&</sup>lt;sup>6</sup> Id.

<sup>&</sup>lt;sup>7</sup> Id.

<sup>&</sup>lt;sup>8</sup> CDC, Ebola Hemorrhagic Fever: Transmission, <u>www.cdc.gov/vhf/ebola/transmission/index.html</u>.

<sup>&</sup>lt;sup>10</sup> WHO, Global Alert and Response, Ebola virus disease in Guinea, <a href="http://www.afro.who.int/en/clusters-a-programmes/dpc/epidemic-a-pandemic-alert-and-response/outbreak-news/4063-ebola-hemorrhagic-fever-inguinea.html">http://www.afro.who.int/en/clusters-a-programmes/dpc/epidemic-a-pandemic-alert-and-response/outbreak-news/4063-ebola-hemorrhagic-fever-inguinea.html</a>; CRS, The 2014 Ebola Outbreak: International and U.S. Responses (R43697). Current case counts are available at: <a href="http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html">http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html</a>.

<sup>&</sup>lt;sup>11</sup> WHO, Global Alert and Response, Ground aero in Guinea: the outbreak smolders – undetected – for more than 3 months, <a href="http://who.int/csr/disease/ebola/ebola-6-months/guinea/en/">http://who.int/csr/disease/ebola/ebola-6-months/guinea/en/</a>.

<sup>&</sup>lt;sup>12</sup> CDC, Ebola (Ebola Virus Disease), 2014 Ebola Outbreak in West Africa - Case Counts, <a href="http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html">http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html</a>.

<sup>13</sup> Id.

The 2014 Ebola epidemic in West Africa is now the largest in recorded history. According to CDC, three countries in West Africa —Guinea, Liberia, and Sierra Leone — are experiencing widespread transmission. As of October 8, 2014, there were 8,011 total cases and 3,857 known deaths in these countries alone. The outbreak has not been contained and transmission rates are high in Guinea, Sierra Leone, and Liberia.

## 1. United States Importation

On September 30, 2014, the CDC confirmed the first travel associated case of Ebola to be diagnosed in the United States.<sup>17</sup> On October 12, 2014, the CDC announced that a healthcare worker who had been providing care for the first U.S. case also had tested positive for Ebola.<sup>18</sup> Additionally, several individuals who contracted the disease in Africa have been transported into the United States and Europe for treatment.<sup>19</sup>

## 2. Treatment Options

There is no FDA-approved vaccine or therapy available for Ebola, but numerous experimental products have been and are under development. ZMapp, for instance, is an experimental treatment being developed for use in Ebola-infected individuals. At least two American missionaries who contracted the disease while working in Liberia were given ZMapp and have since recovered. Other experimental products, such as TKM-Ebola and Brincidofovir, have also been used to treat Ebola patients in the United States.

Urgently needed, but not-yet approved drugs can be made available to the public in some circumstances. For instance, the FDA can authorize access to potentially promising products through various mechanisms such as an Emergency Investigational New Drug (EIND) application.<sup>23</sup> Practical limitations, such as drug availability and manufacturing capacity, may limit access to experimental treatments.<sup>24</sup>

<sup>&</sup>lt;sup>14</sup> CDC, Ebola (Ebola Virus Disease), First Imported Case of Ebola Diagnosed in the United States: <a href="http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html">http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html</a>.

<sup>&</sup>lt;sup>15</sup> CDC, Ebola (Ebola Virus Disease), 2014 Ebola Outbreak in West Africa - Case Counts, <a href="http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html">http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html</a>.

<sup>&</sup>lt;sup>17</sup> CDC, Ebola (Ebola Virus Disease), Cases of Ebola Diagnosed in the United States, http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html.

<sup>18</sup> CDC, Media Statement, Texas Reports Positive Test for Ebola in Health Care Worker, October, 12, 2014, http://www.cdc.gov/media/releases/2014/s1012-texas-health-care-worker.html.

<sup>&</sup>lt;sup>20</sup> CDC, Ebola Hemorrhagic Fever, Questions and Answers on Experimental Treatments and Vaccines for Ebola, <a href="http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/qa-experimental-treatments.html">http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/qa-experimental-treatments.html</a>.

<sup>21</sup> Id.

<sup>&</sup>lt;sup>22</sup> See Patterson Clark, Experimental Drugs Used to Treat Ebola, The Washington Post, October 7, 2014, <a href="http://apps.washingtonpost.com/g/page/national/experimental-drugs-used-to-treat-ebola/1361/">http://apps.washingtonpost.com/g/page/national/experimental-drugs-used-to-treat-ebola/1361/</a>.

<sup>&</sup>lt;sup>23</sup> Public Health Emergency, Ebola Experimental Treatments & Vaccines, http://www.phe.gov/Preparedness/mcm/Pages/ebola-factsheet.aspx.

Publically and in private meetings with Committee staff, FDA has referenced these and other practical limitations to explain limited access to various Ebola drugs. See, e.g., FDA, Emergency Preparedness and Response, 2014 Outbreak in West Africa,

CDC emphasizes that supportive therapy (which includes balancing fluids and electrolytes, maintaining oxygen status and blood pressure, and treating for any complicating infections) remains the standard treatment for Ebola.<sup>25</sup> If utilized early, these basic interventions can significantly improve chances of survival.<sup>26</sup>

#### C. U.S. Response to the Ebola Epidemic

In August 2014, (U.S. Agency for International Development (USAID) activated a Disaster Assistance Response Team (DART) to assess and identify priority needs and coordinate key areas of the U.S. response to the West Africa Ebola outbreak, including planning, operations, and logistics.<sup>27</sup> Under the DART structure, the U.S. Department of State is leading diplomatic engagements; USAID is coordinating U.S. responses, as well as providing financial and material support; CDC is leading public health and medical response activities; and the U.S. Department of Defense (DOD) is providing logistical and operational support. <sup>28</sup> The U.S. Public Health Service (PHS) will staff a DOD-built hospital for health workers, which is currently under construction.

As of October 6, 2014, the U.S. government had committed over \$350 million towards efforts to combat the outbreak in West Africa, more than \$111 million of which took the form of humanitarian aid.<sup>29</sup>

The sections below provide further detail about the involvement and relevant authorities of key agencies involved in the public health response to Ebola. The following information was relayed to Committee staff during an extensive series of briefings and is now largely reflected in public information disseminated by CDC and other Federal agencies involved in response efforts.<sup>30</sup>

#### 1. U.S. Centers for Disease Control and Prevention

In March 2014, CDC teams traveled to West Africa to help the Health Ministries of Guinea and Liberia characterize and control the outbreak by collecting case reports, interviewing

http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/ucm410308.htm; also see Medscape, FDA Expert Interview, Responding to the Ebola Outbreak: The View from FDA, August 20, 2014, http://www.medscape.com/viewarticle/830142.

25 CDC officials have made this point repeatedly in meetings with Committee staff, congressional teleconferences

and public statements. See, e.g., CDC, Ebola Hemorrhagic Fever, Questions and Answers on Experimental Treatments and Vaccines for Ebola, http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/ga-experimental- $\frac{treatments.html}{^{26}}.$ 

<sup>&</sup>lt;sup>27</sup> USAID, Ebola, http://www.usaid.gov/ebola.

<sup>&</sup>lt;sup>29</sup> The White House, Office of the Press Secretary, FACT SHEET: The U.S. Response to the Ebola Epidemic in West Africa, http://www.whitehouse.gov/the-press-office/2014/10/06/fact-sheet-us-response-ebola-epidemic-westafrica.

<sup>&</sup>lt;sup>30</sup> Committee staff has been carefully monitoring the Ebola outbreak since July 2014. Staff has been in frequent contact with various groups and agencies involved in the response in order to understand issues related to international and domestic preparedness and response.

patients and family members, coordinating contact tracing, and consolidating data into centralized databases.<sup>31</sup> Initial efforts in the region seemed to slow the outbreak for a time, but new cases arose.<sup>32</sup> CDC has since deployed several teams to West Africa to help coordinate the response at the national level, assist with database management, and deliver health education.<sup>33</sup>

Although CDC is not providing direct care to Ebola patients, the agency has approximately 150 personnel on the ground in West Africa and hundreds of personnel are providing around-the-clock logistics, staffing, communication, analytics, management, and other support functions from the CDC Emergency Operations Center in Atlanta.<sup>34</sup> CDC is assisting with exit screenings and communication efforts in West Africa to prevent sick travelers from boarding planes, and has issued guidance for airline flight crews, cleaning personnel, cargo personnel, colleges, universities, and students regarding travel to the region.<sup>35</sup> CDC also developed recommendations for humanitarian aid workers traveling Guinea, Liberia, Sierra Leone, and Nigeria, including steps to take before departure, during travel, and upon return to the U.S.<sup>36</sup>

CDC has been working with U.S. Customs and Border Protection (CBP) and other partners at U.S. ports of entry to use routine processes to identify travelers with signs of infectious disease.<sup>37</sup> CDC is beginning to implement a new layer of entry screenings this week at five U.S. airports, which receive approximately 94% of travelers from Guinea, Liberia, and Sierra Leone.<sup>38</sup> As part of this new process, CDC will be responsible for training CBP officers, conducting enhanced passenger screenings, investigating any exposed travelers, notifying appropriate public health officials and working with airlines, Federal partners, and State, and local health departments to take appropriate public health action.<sup>39</sup> Related CDC authorities — such as a public health "Do Not Board" list, foreign airport screening authority (to identify travelers with communicable disease and alert local authorities), and the authority to impose isolation and quarantine measures — may help to prevent the spread of infectious diseases.<sup>40</sup>

CDC is also responsible for preparing both U.S. healthcare facilities and emergency medical service systems to safely manage patients with suspected Ebola.<sup>41</sup> CDC is in charge of enhancing domestic surveillance and laboratory testing capacity, and developing guidance and

<sup>&</sup>lt;sup>31</sup> CRS, The 2014 Ebola Outbreak: International and U.S. Responses (R43697).

<sup>&</sup>lt;sup>32</sup> Id.

<sup>&</sup>lt;sup>33</sup> Id.

<sup>&</sup>lt;sup>34</sup> CDC Director Tom Frieden, Press Briefing, Update on Dallas Ebola Response, October 13, 2014 (12:00 PM EST); The White House, FACT SHEET: US Response to the Ebola Epidemic in West Africa, September 16, 2014, <a href="http://www.whitehouse.gov/the-press-office/2014/09/16/fact-sheet-us-response-ebola-epidemic-west-africa">http://www.whitehouse.gov/the-press-office/2014/09/16/fact-sheet-us-response-ebola-epidemic-west-africa</a>.

<sup>35</sup> Id

<sup>36</sup> T.d

<sup>&</sup>lt;sup>37</sup> CDC, Press Release, Enhanced Ebola Screening to Start at Five U.S. Airports and New Tracking Program for all People Entering U.S. from Ebola-affected Countries (October, 8, 2014).

<sup>&</sup>lt;sup>38</sup> CDC, Ebola Hemorrhagic Fever, Outbreaks, <a href="http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/index.html">http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/index.html</a>.

<sup>&</sup>lt;sup>39</sup> Id.

<sup>&</sup>lt;sup>40</sup> CRS, Legal Sidebar, The Ebola Outbreak: Select Legal Issues (posted October 6, 2014, 3:33 p.m. by Jared P. Cole).

<sup>&</sup>lt;sup>41</sup> Id. CDC guidance and recommendations for U.S. healthcare workers and settings is available at: <a href="http://www.cdc.gov/vhf/ebola/hcp/index.html">http://www.cdc.gov/vhf/ebola/hcp/index.html</a>.

tools for health departments to conduct public health investigations and improve communications and recommendations for healthcare infection control.<sup>42</sup> The agency has developed guidance to provide public health authorities and other local, State, and Federal partners with a framework for evaluating exposure levels and initiating appropriate public health actions, based on exposure level and clinical assessment.<sup>43</sup>

# 2. U.S. National Institutes of Health (& Biomedical Advanced Research and Development Authority

The National Institutes of Health (NIH) is developing an investigational Ebola vaccine and supporting efforts to develop additional Ebola antivirals and therapeutics candidates. Among other things, NIH is working to evaluate the safety and efficacy in healthy adults of an experimental vaccine, which it co-developed with GlaxcoSmithKline, through trials at the NIH Clinical Center in Bethesda, Maryland. 45

Although the Defense Threat Reduction Agency (DTRA) within DOD and the National Institute of Allergy and Infectious Diseases (NIAID) within NIH supported initial work on Zmapp, HHS announced on September 2, 2014, that Biomedical Advanced Research and Development Authority (BARDA) will provide funding, subject matter expertise, and technical support for manufacturing, regulatory, and nonclinical activities. The 18-month, \$24.9 million contract with Mapp Biopharmaceutical Inc. aims to accelerate the development of Zmapp. BARDA plans to work closely with those agencies and the company to optimize and accelerate the manufacturing for trials. The Assistant Secretary for Preparedness and Response (ASPR) may extend the contract up to \$42.3 million.

### 3. U.S. Food and Drug Administration

There are no approved drugs on the market to treat or prevent Ebola, and many of the investigational drugs that might be used are in short supply.<sup>50</sup> This dynamic makes FDA's

<sup>&</sup>lt;sup>42</sup> CRS, Legal Sidebar, The Ebola Outbreak: Select Legal Issues (posted October 6, 2014, 3:33 p.m. by Jared P. Cole).

<sup>&</sup>lt;sup>43</sup> Id.; see CDC, Ebola (Ebola Virus Disease), Information for Healthcare Workers and Settings, <a href="http://www.cdc.gov/vhf/ebola/hcp/index.html">http://www.cdc.gov/vhf/ebola/hcp/index.html</a> (including guidance, recommendations, checklists and other information). For additional information about what CDC is doing, see: <a href="http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/what-cdc-is-doing.html">http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/what-cdc-is-doing.html</a>.

<sup>&</sup>lt;sup>44</sup> See NIH, News & Events, NIH to Launch Human Safety Study of Ebola Vaccine Candidate, August 28, 2014, <a href="http://www.nih.gov/news/health/aug2014/niaid-28.htm">http://www.nih.gov/news/health/aug2014/niaid-28.htm</a>.

<sup>&</sup>lt;sup>45</sup> HHS, Public Health Emergency, Medical Countermeasures: Ebola Experimental Treatments and Vaccines, September 3, 2014, <a href="http://www.phe.gov/Preparedness/mcm/Pages/ebola-factsheet.aspx">http://www.phe.gov/Preparedness/mcm/Pages/ebola-factsheet.aspx</a>.

<sup>&</sup>lt;sup>46</sup> Id.; CDC, Ebola Hemorrhagic Fever, Treatment, <a href="http://www.cdc.gov/vhf/ebola/treatment/index.html">http://www.cdc.gov/vhf/ebola/treatment/index.html</a>.

<sup>&</sup>lt;sup>47</sup> Id.; HHS, News, HHS Contracts with Mapp Biopharmaceutical to Develop Ebola Drug, September 2, 2014, <a href="http://www.hhs.gov/news/press/2014pres/09/20140902b.html">http://www.hhs.gov/news/press/2014pres/09/20140902b.html</a>.

<sup>&</sup>lt;sup>48</sup> Luciana Borio, FDA Works to Mitigate West Africa Ebola Outbreak, FDA Voice, August 22, 2014, <a href="http://blogs.fda.gov/fdavoice/index.php/2014/08/fda-works-to-mitigate-the-west-africa-ebola-outbreak/">http://blogs.fda.gov/fdavoice/index.php/2014/08/fda-works-to-mitigate-the-west-africa-ebola-outbreak/</a>.

<sup>49</sup> Id

<sup>&</sup>lt;sup>50</sup> Id.

authorities and flexible regulatory framework – which include mechanisms to allow access to available investigational products when appropriate – extremely important.<sup>51</sup>

Under certain circumstances, clinicians may request the use of EIND application<sup>52</sup> to help their patient access investigational products outside of clinical trials.<sup>53</sup> Per FDA's Emergency Use Authorization (EUA) authority,<sup>54</sup> when there are no adequate, approved, and available alternative, the agency can allow use of an unapproved medical products (or unapproved use of an approved product) for a larger population during emergencies.<sup>55</sup> In fact, FDA authorized use of a DOD-developed Ebola diagnostic test under an EUA to facilitate Ebola virus detection in DOD-designated laboratories.<sup>56</sup>

FDA has reported to Committee staff that it is working closely with other U.S. government agencies that support medical product development, medical product sponsors, WHO, and international regulatory counterparts to speed product development and facilitate investigational product access where appropriate.<sup>57</sup>

#### 4. U.S. Customs and Border Protection

Recently, it was announced that the CDC and U.S. Customs and Border Protection (CBP) will add new layers of entry screening at five U.S. airports that receive approximately 94% of travelers from Guinea, Liberia, and Sierra Leone. The new measures begin with CBP officers reviewing travelers' passports. After passport review, travelers from Guinea, Liberia, and

<sup>52</sup> 21 CFR 56.102(d). The emergency use provision in 21 CFR 56.104(c) (FDA regulations) is an exemption from prior review and approval by the Institutional Review Boards. FDA, Guidance, Emergency Use of an Investigational Drug or Biologic – Information Sheet, <a href="http://www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm">http://www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm</a>. <sup>53</sup> Id; also see, FDA, Emergency Investigational New Drug (EIND) Applications for Antiviral Products,

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm090039.htm.

<sup>&</sup>lt;sup>51</sup> Id.

<sup>&</sup>lt;sup>54</sup> 21 U.S.C. § 360bbb-3, available at: <a href="http://www.gpo.gov/fdsys/granule/USCODE-2010-title21/USCODE-2010-title21-chap9-subchapV-partE-sec360bbb-3/content-detail.html">http://www.gpo.gov/fdsys/granule/USCODE-2010-title21/USCODE-2010-title21-chap9-subchapV-partE-sec360bbb-3/content-detail.html</a>.

<sup>&</sup>lt;sup>55</sup> See FDA, Emergency Preparedness and Response, Emergency Use Authorization, <a href="http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryand">http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryand</a> PolicyFramework/ucm182568.htm.

<sup>&</sup>lt;sup>56</sup> HHS, Notice, Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus, 79 FR 47141, August 12, 2014, available at: <a href="http://www.gpo.gov/fdsys/pkg/FR-2014-08-12/pdf/2014-19026.pdf">http://www.gpo.gov/fdsys/pkg/FR-2014-08-12/pdf/2014-19026.pdf</a>; also see DOD, News, DOD Medical Countermeasures Find Use in Ebola Outbreak, October 8, 2014, <a href="http://www.defense.gov/news/newsarticle.aspx?id=123371">http://www.defense.gov/news/newsarticle.aspx?id=123371</a>.

<sup>&</sup>lt;sup>57</sup> Committee Staff Briefing by FDA and NIH on Ebola-Related Issues, Ford House Office Building, October 2, 2014. Also see Luciana Borio, FDA Works to Mitigate West Africa Ebola Outbreak, FDA Voice, August 22, 2014, <a href="http://blogs.fda.gov/fdavoice/index.php/2014/08/fda-works-to-mitigate-the-west-africa-ebola-outbreak/">http://blogs.fda.gov/fdavoice/index.php/2014/08/fda-works-to-mitigate-the-west-africa-ebola-outbreak/</a>.

<sup>&</sup>lt;sup>58</sup> CDC, Enhanced Ebola Screenings to Start at Five U.S. Airports and New Tracking Program for all People Entering U.S. from Ebola-affected Countries, October 8, 2014, http://www.cdc.gov/media/releases/2014/p1008 ebola screenings.html.

<sup>&</sup>lt;sup>59</sup> See DHS, News, Fact Sheet: Screening of Travelers at Airports, October 8, 2014, <a href="http://www.dhs.gov/news/2014/10/08/fact-sheet-screening-travelers-airports">http://www.dhs.gov/news/2014/10/08/fact-sheet-screening-travelers-airports</a>; also see, CDC, Press Release, Enhanced Ebola Screening to Start at Five U.S. Airports and New Tracking Program for All People Entering U.S. from Ebola-affected Countries, October 8, 2014, <a href="http://www.cdc.gov/media/releases/2014/p1008-ebola-screening.html">http://www.cdc.gov/media/releases/2014/p1008-ebola-screening.html</a>.

Sierra Leone will be escorted by CBP to an area of the airport that is set aside for screening. <sup>60</sup> Trained CBP staff will observe them for signs of illness, ask a series of health and exposure questions and provide health information and reminders to self-monitor for Ebola symptoms. <sup>61</sup> Medical staff trained by the U.S. Coast Guard will then take travelers' temperature with a non-contact thermometer. If the travelers have fever or other symptoms, or the health questionnaire reveals possible Ebola exposure, they will be evaluated by a CDC quarantine station public health officer. <sup>62</sup> The public health officer will again take a temperature reading and make a public health assessment. <sup>63</sup>

Ill travelers may be transferred to a health care facility for further evaluation, examination, testing, and treatment.<sup>64</sup> Travelers without symptoms but with a possible Ebola exposure will be linked with a health department for active monitoring for 21 days.<sup>65</sup> Regardless of symptoms or exposure, all travelers from Guinea, Sierra Leone, and Liberia will be required to complete a daily temperature log.<sup>66</sup>

#### D. Dallas Ebola Cases

Our investigation of the facts surrounding of the first two Ebola diagnoses in the U.S.—both of which involve patients at Texas Health Presbyterian Hospital of Dallas (Texas Presbyterian) located in Texas—is ongoing. Set forth below is a summary of the facts and circumstances of the Texas Ebola cases.

#### 1. Index Patient<sup>67</sup>

On September 30, 2014, CDC confirmed that a person, later identified as Thomas Eric Duncan, departed from Liberia on September 19, 2014, on an indirect flight to Dallas, Texas, via Brussels and Dulles. Duncan arrived in the United States on September 20, 2014.

Duncan sought treatment at Texas Presbyterian on the evening of September 25, 2014. According to the hospital, he was sent home in the early morning on September 26, 2014, with antibiotics after "a four-hour evaluation and numerous tests." According to medical records, Duncan had a fever of 103°F and complained of abdominal pain, dizziness, headache, and decreased urination. 69

<sup>60</sup> Id. 61 Id. 62 Id. 63 Id. 64 Id. 65 Id. 66 Id.

<sup>&</sup>lt;sup>67</sup> Unless otherwise noted, information in this section is from CDC or the Texas Department of State Health Services.

<sup>&</sup>lt;sup>68</sup> Texas Health Resources, Ebola Update, Oct 9, 3:01 CDT, Statement Regarding Mr. Thomas Eric Duncan, <a href="http://www.texashealth.org/blank.cfm?print=yes&action=detail&id=1629&ref=1879">http://www.texashealth.org/blank.cfm?print=yes&action=detail&id=1629&ref=1879</a>.

<sup>&</sup>lt;sup>69</sup> Emily Schmall et al., Ebola Patient's temperature spiked to 103 degrees, AP, October 10, 2014, http://hosted2.ap.org/APDEFAULT/3d281c11a96b4ad082fe88aa0db04305/Article 2014-10-10-US-Ebola-Medical-

Duncan returned to Texas Presbyterian via ambulance on September 28, 2014.<sup>70</sup> He was extremely ill at the time of transport to the hospital, with symptoms now including severe vomiting and diarrhea. Hospital officials testified that he was kept in the emergency department until a contact and droplet isolation area was established in the intensive care unit, at which time he was admitted to the hospital and put into isolation.<sup>71</sup>

The hospital notified Dallas County Health and Human Services (DCHHS) on Monday, September 29, 2014, whose personnel arrived on site shortly thereafter.<sup>72</sup> CDC officials were notified later on September 29, but did not arrive at the hospital campus until October 1, 2014.<sup>73</sup> CDC and Texas Department of State Health Services (DSHS) laboratory testing confirmed the diagnosis of Ebola on Tuesday, September 30, 2014.<sup>74</sup>

DCHHS states it is the lead agency charged with the ongoing contact investigation to determine who may have been exposed to Duncan while he was contagious.<sup>75</sup> The investigation has, thus far, identified forty-eight individuals out of a broader group with risk of exposure. Ten individuals are considered to be at high risk. These forty-eight contacts are being monitored for twenty-one days from their time of exposure.

Four close family members of the patient, believed to be amongst the "high risk" contacts, were asked to stay home at least until October 19, when the 21-day incubation period for the virus would have lapsed. After failing to comply with this request, they were formally ordered to remain confined to their apartment. The family was forced to remain in the apartment for days, despite the fact that it was contaminated with Duncan's waste product and bodily fluids. The family has since been moved to an undisclosed location.

Duncan received an experimental drug during the course of his treatment. He was also intubated and on dialysis for an unknown period of time.

#### 2. Infected Healthcare Worker<sup>76</sup>

On October 11, a healthcare worker who cared for Duncan at Texas Presbyterian Hospital reported having a low grade fever overnight and referred for testing.<sup>77</sup> The Texas Department of

<u>Records/id-e6b6ef8e892548298ea4ecba7c493f85</u>; also see Amy Ellis Nutt, *In Dallas, a focus on how hospital treated victim,* The Washington Post, A4, October 11, 2014.

<sup>&</sup>lt;sup>70</sup> Testimony of Dr. Gary Weinstein, Chief of Pulmonology and Critical Care Medicine for Texas Health Presbyterian Hospital Dallas, Senate Health and Human Services Committee (October 7, 2014).

<sup>&</sup>lt;sup>71</sup> Id.

<sup>&</sup>lt;sup>72</sup> Id.

<sup>&</sup>lt;sup>73</sup> Id.

<sup>&</sup>lt;sup>74</sup> Id

<sup>&</sup>lt;sup>75</sup> Texas Department of State Health Services, Ebola Case in Texas: Overview, October 5, 2014.

<sup>&</sup>lt;sup>76</sup> Unless otherwise noted, information in this section is from CDC or Texas Department of State Health Services. See generally, CDC, Ebola (Ebola Hemorrhagic Fever), Cases of Ebola Diagnosed in the United States, <a href="http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html">http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html</a>.

<sup>&</sup>lt;sup>77</sup> CDC, Media Statement, Texas Reports Positive Test for Ebola in a Health Care Worker, October 12, 2014, http://www.cdc.gov/media/releases/2014/s1012-texas-health-care-worker.html.

State Health Services' laboratory returned a preliminary test that was positive for Ebola at approximately 9:30 p.m. on October 11. CDC testing performed on October 12 confirmed this result. This patient was isolated and interviewed by CDC to identify any contacts or potential community exposures. To date, CDC officials have identified one close contact, who is being monitored for fever and other symptoms.

CDC Director Tom Frieden has attributed the healthcare worker's infection to a "breach in protocol," but says officials do not know yet what protocol was breached. A CDC investigation is ongoing.

#### III. ISSUES

The following issues will be examined at the hearing:

- What have we learned from the two Ebola cases in Dallas, and how can we use this information to improve protocols, training, guidance, hospital preparedness, patient care, and safety going forward, both in the U.S. and in West Africa?
- The global health community has not been able to control the ongoing Ebola outbreak. Why has this outbreak been so difficult to control, and is the current containment strategy appropriate?
- Is the United States adequately prepared to help contain the outbreak in West Africa, and what impact will these efforts have on American health systems?
- Screening procedures did not prevent an individual infected with Ebola from entering the United States on September 20, 2014. What were these procedures, and why did they fail to identify Mr. Duncan? Are the additional screening procedures announced this month adequate to prevent another importation?
- Are America's hospitals and health care workers adequately prepared for Ebola patients? What adjustments can be made to protocols, training, and guidance to enhance preparedness and safety now and in the future?
- What treatment options and diagnostics are available for Ebola, and what can be done to speed their development?
- What resources will the CDC and other impacted government agencies require when current funding expires?

<sup>&</sup>lt;sup>78</sup> Marshall Cohen, Face in the News: CDC under fire as Ebola spreads, CBS News, October 13, 2014, <a href="http://www.cbsnews.com/news/face-in-the-news-cdc-under-fire-as-ebola-spreads/">http://www.cbsnews.com/news/face-in-the-news-cdc-under-fire-as-ebola-spreads/</a>; also see Lisa Maria and Terry Wade, U.S. needs to rethink Ebola infection controls CDC chief says, Reuters, October 13, 2014, <a href="http://uk.reuters.com/article/2014/10/13/us-health-ebola-idUKKCN0I21M020141013">http://uk.reuters.com/article/2014/10/13/us-health-ebola-idUKKCN0I21M020141013</a>.

# IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Emily Newman, Alan Slobodin, Sean Hayes, or Karen Christian at (202) 225-2927.