

October 20, 2017

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “Examining HHS’s Public Health Preparedness for and Response to the 2017 Hurricane Season”

The Subcommittee on Oversight and Investigations will hold a hearing on Tuesday, October 24, 2017, at 10:00 a.m. in 2123 Rayburn House Office Building. The hearing is entitled “Examining HHS’s Public Health Preparedness for and Response to the 2017 Hurricane Season.”

I. WITNESSES

- Robert P. Kadlec, M.D., Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services;
- Scott Gottlieb, M.D., Commissioner, U.S. Food and Drug Administration;
- Kimberly Brandt, Principal Deputy Administrator for Operations, Centers for Medicare and Medicaid Services; and
- Stephen C. Redd, M.D., RADM, Director of the Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention.

II. BACKGROUND

a. Overview of the 2017 Hurricane Season

The 2017 hurricane season is an ongoing event occurring from June 1, 2017 to November 30, 2017.¹ Meteorologists classify hurricanes by using the Saffir-Simpson Hurricane Wind Scale, which assigns a one to five rating to a hurricane depending on the hurricane’s sustained wind speed. Hurricanes reaching category three and higher are considered major hurricanes due to their potential for significant loss of life and damage.²

¹ U.S. Dep’t of Commerce, National Oceanic and Atmospheric Administration, *Early-season storms one indicator of active Atlantic hurricane season ahead* (Aug. 9, 2017), available at <http://www.noaa.gov/media-release/early-season-storms-one-indicator-of-active-atlantic-hurricane-season-ahead>.

² National Oceanic and Atmospheric Administration, National Hurricane Center, *Saffir-Simpson Hurricane Wind Scale* (last visited Oct. 16, 2017), available at <http://www.nhc.noaa.gov/aboutsshws.php>.

As predicted by the National Oceanic and Atmospheric Administration, 2017 has been an active hurricane season.³ Recent major hurricanes include:

- **Hurricane Harvey:** Hurricane Harvey made landfall in Texas on August 25, 2017, as a category four hurricane, delivering a significant amount of rainfall to south and southeast Texas. Hurricane Harvey slowly moved east into the Gulf of Mexico and then made final landfall in Louisiana on August 30, 2017.⁴
- **Hurricane Irma:** Hurricane Irma made landfall in the U.S. Virgin Islands on September 6, 2017, as a category five hurricane and then brushed the northern coast of Puerto Rico, causing widespread power outages. Hurricane Irma made landfall in the Florida Keys on September 10, 2017, as a category four hurricane. Irma then hit mainland Florida as a category three hurricane later that day. On September 11, 2017, the hurricane was downgraded to a tropical storm, but rain and storm conditions continued to Georgia and other states on the southern east coast.⁵
- **Hurricane Maria:** Hurricane Maria made landfall as a category four hurricane in the U.S. Virgin Islands in the early hours of September 20, 2017, and moved on to Puerto Rico later that day, causing severe damage to both territories.⁶ The same day, the hurricane moved away from Puerto Rico, but torrential rain and storm conditions continued.⁷ Throughout the next week, Hurricane Maria moved up through the Caribbean and then parallel to the coast of the United States, causing swells along much of the east coast and storm surge flooding in North Carolina.⁸ On September 28, 2017, Hurricane Maria weakened to a tropical storm and moved out to sea.⁹

If the resources required to respond to a natural disaster or incident are beyond the capabilities of the state or territory and the affected local government, the governor may request federal assistance, including assistance under the Robert T. Stafford Disaster Relief and

³ Doyle Rice, *Not your imagination: This hurricane season has been much worse than usual*, USA TODAY (Oct. 5, 2017), available at <https://www.usatoday.com/story/weather/2017/10/05/not-your-imagination-hurricane-season-has-been-much-worse-than-usual/736649001/>.

⁴ National Oceanic and Atmospheric Administration, National Weather Service, Corpus Christi, Texas Weather Forecast Office, *Major Hurricane Harvey – August 25-29* (last visited Oct. 18, 2017), available at http://www.weather.gov/crp/hurricane_harvey.

⁵ Reuben Fischer-Baum, John Muyskens, Darla Cameron, *What Irma Left Behind*, WASH. POST (last updated Sept. 12, 2017), available at https://www.washingtonpost.com/graphics/2017/national/what-irma-looked-like/?utm_term=.21c8a75d39b0.

⁶ U.S. Dep't of Homeland Security, Federal Emergency Management Agency (FEMA), *Hurricane Maria* (last updated Oct. 17, 2017), available at <https://www.fema.gov/hurricane-maria>; See also Kevin Loria, *Hurricane Maria is thrashing the Caribbean*, BUSINESS INSIDER (Sept. 22, 2017).

⁷ National Oceanic and Atmospheric Administration, National Hurricane Center, *Hurricane Maria Advisory Number 20* (Sept. 20, 2017), available at <http://www.nhc.noaa.gov/archive/2017/al15/al152017.public.020.shtml?>

⁸ National Oceanic and Atmospheric Administration, National Hurricane Center, *Hurricane Maria Advisory Number 46* (Sept. 27, 2017), available at <http://www.nhc.noaa.gov/archive/2017/al15/al152017.public.046.shtml?>

⁹ National Oceanic and Atmospheric Administration, National Hurricane Center, *Hurricane Maria Advisory Number 49* (Sept. 28, 2017), available at <http://www.nhc.noaa.gov/archive/2017/al15/al152017.public.049.shtml?>

Emergency Assistance Act (Stafford Act).¹⁰ Under the Stafford Act, if a governor requests federal assistance and it is clear that the event exceeds the abilities of the state or territory and the affected local governments, the President may make an emergency or major disaster declaration.¹¹ Following the Presidential declaration, the Stafford Act allows the President to provide financial and other assistance to the state or territory and the affected local governments, certain non-profit organizations, and individuals to support response and recovery efforts. President Trump issued disaster or emergency declarations for Texas and Louisiana in response to Hurricane Harvey, for Florida, Georgia, South Carolina, Puerto Rico, and the U.S. Virgin Islands in response to Hurricane Irma, and for Puerto Rico and the U.S. Virgin Islands in response to Hurricane Maria.¹²

Pursuant to section 319 of the Public Health Service Act, the Secretary of the Department of Health and Human Services (HHS) may declare that a Public Health Emergency (PHE) exists in the affected state if he or she determines, after consulting with such public health officials as necessary, that a disease or disorder presents a PHE, or that a PHE, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. The Secretary of HHS made PHE declarations for Texas and Louisiana following Hurricane Harvey, for Florida, Georgia, South Carolina, Puerto Rico, and the U.S. Virgin Islands following Hurricane Irma, and for Puerto Rico and the U.S. Virgin Islands following Hurricane Maria.¹³

b. Office of the Assistant Secretary for Preparedness and Response (ASPR)

The Office of the Assistant Secretary for Preparedness and Response (ASPR) at HHS was established in the wake of Hurricane Katrina to improve coordination and direction across HHS preparedness and emergency response activities.¹⁴ Under the Public Health Service Act, as amended by the Pandemic and All Hazards Preparedness Act of 2006 and the Pandemic and All-Hazards Reauthorization Act of 2013, ASPR was created to lead the federal government's efforts in preventing, preparing for, and responding to adverse health effects of public health emergencies and disasters.¹⁵ To achieve this goal, the office works with all HHS operating and staff divisions to ensure preparedness is integrated into HHS' programs and to ensure that these services are used effectively during a natural disaster or public health emergency.¹⁶ In

¹⁰ U.S. Dep't of Health and Human Services, *Public health and Medical Services Support* (Dec. 20, 2016), available at <https://www.phe.gov/Preparedness/support/medicalresponse/Pages/default.aspx>.

¹¹ U.S. Dep't of Homeland Security, Federal Emergency Management Agency (FEMA), *The Disaster Declaration Process* (last updated Apr. 6, 2017), available at <https://www.fema.gov/disaster-declaration-process>

¹² U.S. Dep't of Health and Human Services, *Centers for Medicare and Medicaid Services, Hurricanes* (last updated Oct. 16, 2017), available at <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Hurricanes.html>.

¹³ *Id.*

¹⁴ U.S. Dep't of Health and Human Services, ASPR, *Organizational Overview* (last updated Apr. 27, 2017), available at <https://www.phe.gov/about/aspr/pages/default.aspx>.

¹⁵ U.S. Dep't of Health and Human Services, ASPR, *Mission, Vision, Values* (last updated Feb. 18, 2014), available at <https://www.phe.gov/about/aspr/strategic-plan2014/Pages/mission.aspx>.

¹⁶ U.S. Dep't of Health and Human Services, ASPR, *Introduction* (last updated Dec. 7, 2015), available at <https://www.phe.gov/about/aspr/strategic-plan2014/Pages/introduction.aspx>.

accordance with Emergency Support Function (ESF) #8 of the National Response Framework (NRF), ASPR also coordinates inter-agency public health and medical response efforts.¹⁷

The office supports many different HHS public health emergency services, including providing federal medical support to states, tribes, territories, and localities through a variety of public health and medical assets.¹⁸ ASPR's National Disaster Medical System (NDMS) is one of HHS' primary medical assets. NDMS teams include, but are not limited to: (1) Disaster Medical Assistance Teams (DMAT) that provide primary and acute care, triage of mass casualties, and other medical services; (2) Disaster Mortuary Operational Response Teams (DMORT) that provide technical assistance and personnel to recover, identify, and process deceased victims; (3) National Veterinary Response Teams (NVRT) that provide assistance in identifying the need for veterinary services following major disasters or emergencies; and (4) National Medical Response Teams (NMRT) that provide medical care following a nuclear, biological and/or chemical incident.¹⁹ Additional federal public health and medical assets include the U.S. Public Health Service (USPHS) Commissioned Corps, the Strategic National Stockpile (SNS), Federal Medical Stations (FMS), and the Medical Reserve Corps.²⁰

In response to Hurricanes Harvey, Irma, and Maria, ASPR has been actively engaged in response efforts and, at the request of the affected regions, has deployed a significant amount of HHS personnel and assets. At a staff briefing on October 18, 2017, with the Energy and Commerce Committee, ASPR noted that, in collaboration with a broad array of partners, the agency has deployed over 2,500 individuals in response to Hurricanes Irma and Maria, and over 1,000 individuals in response to Hurricane Harvey to provide emergency medical care and support.²¹ These professionals have provided care to more than 8,000 patients in Puerto Rico, more than 5,000 individuals in Texas, and to thousands of individuals in Florida as well.²² Moreover, the agency has transported more than 1,000 tons of supplies to Puerto Rico alone.²³

In addition to providing care to individuals in the affected regions, federal teams have worked with states, tribes, territories, and localities to provide a variety of other services and support functions at the request of state or territory officials. For example, on October 2, 2017, the Assistant Secretary for Preparedness and Response, Dr. Kadlec, met with Puerto Rico's

¹⁷ U.S. Dep't of Homeland Security, FEMA, *Emergency Support Functions* (last visited Oct. 17, 2018), available at <https://emilms.fema.gov/IS230c/FEM0104160text.htm>; U.S. Dep't of Health and Human Services, ASPR, *HHS Concept of Operations for ESF #8* (last updated Feb. 14, 2012), available at <http://www.phe.gov/preparedness/planning/mscc/handbook/chapter7/pages/hhsconcept.aspx>.

¹⁸ See U.S. Dep't of Health and Human Services, ASPR, *HHS Response and Recovery Resources Compendium* (last updated Jul. 15, 2015), available at <https://www.phe.gov/emergency/hhscapabilities/Pages/default.aspx>; See also U.S. Dep't of Health and Human Services, *HHS, FEMA, DOD and VA continue to provide sustained and critical medical care support for Puerto Rico as part of Trump Administration response to Hurricane Maria* (Oct. 12, 2017), available at <https://www.hhs.gov/about/news/2017/10/12/hhs-fema-dod-and-va-continue-provide-sustained-and-critical-medical-care.html>.

¹⁹ U.S. Dep't of Health and Human Services, ASPR, *Medical Assistance* (last updated Sept. 9, 2017), available at <https://www.phe.gov/preparedness/support/medicalassistance/pages/default.aspx>.

²⁰ *Id.*

²¹ Briefing by Chris Meekins, HHS, Ass't Sec. ASPR, to H. Comm. On Energy & Commerce Staff (Oct. 18, 2017).

²² *Id.*

²³ *Id.*

Health Secretary and the Commonwealth's Secretary of Housing to discuss current and long-term health concerns following Hurricane Maria.²⁴ To monitor Puerto Rico's health care infrastructure, HHS has implemented a three tier strategy that includes deploying medical teams with their own equipment and medical supplies to assist in providing care at Centro Medico, dispatching medical teams and setting up temporary medical sites to augment five regional hospitals, and placing a liaison at all other open hospitals to closely monitor supply and fuel needs.²⁵ Similarly, prior to Hurricane Irma, HHS prepositioned medical support and personnel near potentially impacted areas and alerted additional medical and public health teams to be ready to deploy into the affected areas.²⁶

ASPR also coordinates with other stakeholders for patient evacuation during and prior to an event if necessary. For example, after Hurricane Irma hit Puerto Rico and before Hurricane Maria hit the Commonwealth, HHS and other federal partners worked to transport residents with chronic medical conditions to more secure locations on the United States' mainland.²⁷ Moreover, HHS personnel remained in Puerto Rico as Hurricane Maria made landfall to ensure they were there immediately following the storm to provide assistance.²⁸

These examples of HHS' hurricane response efforts are not exhaustive, but are provided to demonstrate some of the inter-agency and intra-agency work that ASPR is overseeing in response to Hurricanes Harvey, Irma, and Maria. HHS divisions responding to the hurricanes include, but are not limited to, the Administration for Children and Families (ACF), the Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), the National Institutes of Health (NIH), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Food and Drug Administration (FDA). All of HHS' press releases detailing the agency's hurricane response efforts are available on HHS' website at HHS.gov.²⁹

c. Centers for Medicare and Medicaid Services

The Centers for Medicare and Medicaid Services is responsible for strengthening and

²⁴ U.S. Dep't of Health and Human Services, *HHS broadens support to shore up health care facilities impacted by Hurricane Maria in Puerto Rico* (Oct. 2, 2017), available at <https://www.hhs.gov/about/news/2017/10/02/hhs-broadens-support-shore-health-care-facilities-impacted-hurricane-maria-puerto-rico.html>.

²⁵ *Id.*

²⁶ U.S. Dep't of Health and Human Services, *HHS mobilizes medical staff and supplies to support response to Hurricane Irma* (Sept. 6, 2017), available at <https://www.hhs.gov/about/news/2017/09/06/hhs-mobilizes-medical-staff-and-supplies-support-response-hurricane-irma.html>; See also U.S. Dep't of Health and Human Services, *HHS continues buildup of medical support in Florida in preparation for Hurricane Irma landfall* (last visited Sept. 9, 2017), available at <https://www.hhs.gov/about/news/2017/09/09/hhs-continues-buildup-medical-support-florida-preparation-hurricane-irma-landfall.html>.

²⁷ U.S. Dep't of Health and Human Services, *HHS brings medical and public health relief to US territories recovering from Hurricanes Maria, Irma* (Sept. 26, 2017), <https://www.hhs.gov/about/news/2017/09/26/hhs-brings-medical-and-public-health-relief-us-territories-recovering-hurricanes-maria-irma.html>.

²⁸ *Id.*

²⁹ U.S. Dep't of Health and Human Services, *HHS Hurricane Response Updates* (last visited Oct. 18, 2017), available at <https://www.hhs.gov/about/news/hurricane-response/index.html>.

modernizing the United States' health care system while providing quality care at lower costs to CMS beneficiaries.³⁰ The agency therefore serves an essential role during the response to natural disasters to help ensure Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries have access to life-saving care and providers are reimbursed for their services. Furthermore, HHS helps oversee efforts to ensure that beneficiaries on dialysis or dependent on other medical equipment receive the appropriate services and assistance prior to, during, and after natural disasters and public health emergencies.³¹

Under section 1135 of the Social Security Act, once the Secretary of HHS declares that a Public Health Emergency exists in an affected state or territory, CMS has the authority to temporarily modify or waive certain Medicare, Medicaid, CHIP, and Health Insurance Portability and Accountability Act (HIPAA) requirements.³² CMS can issue these as blanket waivers, or if no blanket waivers are issued, providers can request an individual section 1135 waiver.³³ Pursuant to this authority, the agency has issued a significant number of blanket waivers to provide flexibility and accommodate the needs of those individuals impacted by the hurricanes.³⁴ For example, Florida alone received fourteen different waivers in response to Hurricane Irma.³⁵ The waivers for providers in Florida included, but were not limited to, waiving the requirement that Critical Access Hospitals limit the number of beds to 25 and that the length of stay be limited to 96 hours, waiving certain Medicare conditions of participation and certification requirements for health care providers, and requiring that Medicare Advantage Organizations in affected areas waive prior authorization and gatekeeper requirements.³⁶ CMS has comprehensive information about all of the waivers issued in response to Hurricanes Harvey, Irma, and Maria on the agency's website.³⁷

Additionally, dialysis patients are among the most vulnerable after a natural disaster.³⁸ HHS therefore has prioritized trying to ensure dialysis patients receive the requisite life-saving care and that dialysis facilities are closely monitored to ensure they have the supplies they need

³⁰ See U.S. Dep't of Health and Human Services, *About CMS* (last visited Oct. 18, 2017), available at <https://www.cms.gov/About-CMS/About-CMS.html>.

³¹ See, e.g., U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services, *CMS Continues to Efforts to help with Hurricane Irma Emergency Response* (Sept. 9, 2017), available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-09-09.html>.

³² U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services, *Hurricanes* (last updated Oct. 16, 2017), available at <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Hurricanes.html>.

³³ *Id.*

³⁴ *Id.*

³⁵ U.S. Dep't of Health and Human Services, *CMS Announced Ongoing Efforts to Support Florida with Hurricane Irma Emergency Response* (Sept. 11, 2017), available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-09-11-2.html>.

³⁶ *Id.*

³⁷ See, U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services, *Emergency Response and Recovery* (last updated Oct. 17, 2017), available at <https://www.cms.gov/About-CMS/Agency-Information/Emergency/index.html>.

³⁸ See, U.S. Dep't of Health and Human Services, *HHS, DoD rescue dialysis patients from U.S. Virgin Islands after Hurricane Irma* (Sept. 10, 2017), available at <https://www.hhs.gov/about/news/2017/09/10/hhs-dod-rescue-dialysis-patients-us-virgin-islands-after-hurricane-irma.html>.

to remain operational.³⁹ Prior to and following the storms, HHS has used a variety of different mechanisms to identify dialysis patients for assistance and evacuation.⁴⁰ One of the essential tools available to CMS and state and territory officials in preparing for potential health impacts is the emPOWER database. Launched in 2015, the emPOWER database provides authorities with the total number of Medicare beneficiaries in a zip code who rely on fourteen types of life-maintaining and assistive equipment, including, but not limited to, oxygen concentrators, electric wheel chairs, and dialysis services.⁴¹ HHS worked with state, territory, and local partners to use the emPOWER data to conduct lifesaving outreach to individuals in the affected regions. For example, after Hurricane Irma made landfall in the U.S. Virgin Islands, HHS and the Department of Defense (DoD) used data from the emPOWER database and other CMS systems to evacuate dialysis patients from St. Thomas to San Juan, Puerto Rico.⁴² Similarly, before Hurricane Maria hit the islands, HHS and federal partners transferred more than 350 dialysis and critical care patients to more secure locations in San Juan and the mainland.⁴³

d. Food and Drug Administration

The U.S. Food and Drug Administration is the federal agency that is principally charged with protecting the public health by ensuring the nation's drug supply and medical products are safe and effective, among other responsibilities such as performing oversight of the U.S. blood supply. In this capacity, FDA plays a critical role in responding to, mitigating, and recovering from the effects of natural disasters that pose a risk to the public health, such as hurricanes. FDA's Office of Emergency Management (OEM) generally spearheads the agency's response, which involves the entirety of its organizational divisions.

In accordance with the National Disaster Response Framework, the FDA also routinely engages in inter-agency coordination, including coordinating with state, local, tribal, and territorial governments, to identify and address any potential drug and supply shortages that may arise on account of a natural disaster. The FDA maintains an active long-term presence in areas that have been affected by natural disasters by performing damage assessments, increased monitoring of FDA-regulated industries, and availing state, local, tribal, and territorial governments of the FDA's subject matter expertise.

³⁹ See, e.g., Dep't of Health and Human Services, *Care for Dialysis patients a key focus of Hurricane Maria response efforts in Puerto Rico* (Oct. 17, 2017), available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-17.html>.

⁴⁰ *Id.*

⁴¹ U.S. Dep't of Health and Human Services, *HHS emPOWER Map 2.0* (last updated Dec. 30, 2016), available at <https://empowermap.hhs.gov/>; U.S. Dep't of Health and Human Services, *HHS, DoD rescue dialysis patients from U.S. Virgin Islands after Hurricane Irma* (Sept. 10, 2017), <https://www.hhs.gov/about/news/2017/09/10/hhs-dod-rescue-dialysis-patients-us-virgin-islands-after-hurricane-irma.html>.

⁴² U.S. Dep't of Health and Human Services, *HHS, DoD rescue dialysis patients from U.S. Virgin Islands after Hurricane Irma* (Sept. 10, 2017), <https://www.hhs.gov/about/news/2017/09/10/hhs-dod-rescue-dialysis-patients-us-virgin-islands-after-hurricane-irma.html>.

⁴³ U.S. Dep't of Health and Human Services, *HHS boosts post-Hurricane Maria medical surge into U.S. territories* (Sept. 28, 2017), available at <https://www.hhs.gov/about/news/2017/09/28/hhs-boosts-post-hurricane-maria-medical-surge-us-territories.html>.

The FDA has played an especially important role in the response to Hurricane Maria given damage that has been done to Puerto Rico's public health infrastructure and the prominence of the Commonwealth's pharmaceutical and medical device manufacturing industries. According to the Bureau of Labor and Statistics, pharmaceutical and medical device manufacturing accounted for 72 percent of Puerto Rico's exports in 2016, and were valued at \$14.5 billion.⁴⁴ It is estimated that Puerto Rico is responsible for the manufacture of 10 percent of all medications consumed in the United States annually.⁴⁵

The devastation wrought by Hurricane Maria carries the potential to disrupt the manufacture of pharmaceuticals and medical devices that are critical to the Puerto Rican economy and the entire U.S. public health system. In cases where the FDA has identified the potential for a shortage of an FDA-approved medical product, the agency has the authority under the Federal Food, Drug, and Cosmetic Act to authorize the use of unapproved medical products or may alternatively permit non-authorized uses of medical products during declared emergencies.⁴⁶ For example, in response to a potential shortage of a type of sodium chloride injection bags, which are produced in Puerto Rico and widely used in the administration of intravenous treatments, the FDA provided one of the product's principal manufacturers with a waiver that allowed for the importation of the products from Australia and Ireland.⁴⁷ In total, FDA is continuing to monitor the supply chain for more than 40 high-priority medications that have been deemed essential by the agency and are produced in Puerto Rico.⁴⁸

e. Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention is the principal federal agency responsible for monitoring and responding to infectious disease and environmental threats that imperil public health in the United States, among other responsibilities. The agency plays a critical role during the response to natural disasters that give rise to heightened environmental health risks such as those typically seen with hurricanes. The CDC is also responsible for maintaining the Strategic National Stockpile, which is the federal government's network of pharmaceuticals and medical supplies that are reserved for cases of public health emergencies.

Environmental hazards that are typically associated with hurricanes such as exposure to contaminated floodwaters, lack of access to potable water, and eventual mold formation all carry heightened risks for the contraction of infectious diseases. This is particularly so for vulnerable populations such as the elderly or immunosuppressed. In the aftermath of Hurricane Katrina, the

⁴⁴ U.S. Bureau of Labor Statistics, *Puerto Rico: Price Movements of Top Exports and Other Highlights* (July 2017) available at <https://www.bls.gov/mxp/puertorico.pdf>.

⁴⁵ Press Release, U.S. Food and Drug Admin., *Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA's continued assistance following the natural disaster in Puerto Rico* (Oct. 6, 2017), available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm579493.htm>.

⁴⁶ Federal Food, Drug, and Cosmetic Act §§561,564, 21 U.S.C. § 360bbb (2016).

⁴⁷ Laurie McGinley, *Hospitals scramble to avert saline shortage in wake of Puerto Rico disaster*, WASH. POST (Oct. 11, 2017), https://www.washingtonpost.com/news/to-your-health/wp/2017/10/09/hospitals-scramble-to-avert-saline-shortage-in-wake-of-puerto-rico-disaster/?utm_term=.d79ca34cecf7&wpisrc=nl_health202&wpmm=1.

⁴⁸ Press Release, U.S. Food and Drug Admin., *FDA Fast Facts: FDA's Support of the Hurricane Relief Effort* (Sept. 28, 2017), available at <https://www.fda.gov/NewsEvents/Newsroom/ucm578139.htm>.

CDC identified multiple instances of infections attributable to Methicillin-resistant *Staphylococcus aureus* (MRSA) and vibriosis, the latter of which has resulted in multiple deaths.⁴⁹ Additionally, the CDC also identified several individuals who had upper respiratory infections and pneumonias that were attributable to the environmental conditions that existed following Hurricane Katrina.⁵⁰

Following Hurricane Harvey, a 77-year-old woman died from necrotizing fasciitis, a bacterial skin infection, after an open wound came into contact with unsanitary floodwater.⁵¹ In Puerto Rico, there have also been reports of deaths that may be attributable to leptospirosis, which is a bacterial infection that is spread primarily by animals and can be transmitted to humans through contact with water, soil, or food.⁵² The CDC tracks such events in order to identify specific public health threats and to maximize the ability of both governmental and non-governmental entities to respond effectively.

Standing water from heavy rainfall and flooding also presents an environmental health hazard by serving as a breeding ground for mosquitos that have the potential to carry viruses such as Zika, dengue, chikungunya, and West Nile. According to the CDC, virus-spreading mosquitoes usually manifest two weeks to two months after a hurricane.⁵³ To guard against these potential serious public health threats, the CDC coordinates with federal, state, territorial, and local government entities to engage in vector control efforts.

III. ISSUES

The following issues may be examined at the hearing:

- What steps could HHS take to expedite the waiver process for hospitals after a public health emergency is declared?
- What are the most concerning long-term public health risks facing areas impacted by hurricanes?
- Have dialysis patients received adequate treatment during the hurricanes and in the aftermaths?

⁴⁹ Centers for Disease Control and Prevention, *Infectious Disease and Dermatologic Conditions in Evacuees and Rescue Workers After Hurricane Katrina --- Multiple States, August--September 2005* (Sept. 30, 2005), available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5438a6.htm>.

⁵⁰ *Id.*

⁵¹ Lindsey Bever, *A woman survived a fall into Hurricane Harvey's floodwaters – only to die of a flesh-eating infection*, WASH. POST (Sept. 27, 2017), https://www.washingtonpost.com/news/to-your-health/wp/2017/09/27/a-woman-survived-a-fall-into-hurricane-harveys-floodwaters-only-to-die-of-a-flesh-eating-infection/?utm_term=.a9f295b97e42.

⁵² France Robles, *Puerto Rico's Health Care Is in Dire Condition, Three Weeks After Maria*, N.Y. TIMES (Oct. 10, 2017), <https://www.nytimes.com/2017/10/10/us/puerto-rico-power-hospitals.html>.

⁵³ Centers for Disease Control and Prevention, *2017 Hurricane Key Messages* (Oct. 14, 2017), available at https://www.cdc.gov/disasters/2017_hurricane_keymessages/docs/CDC-Hurricane-Key-Messages-10-14-17.pdf.

- How long are hospitals in Puerto Rico expected to operate on generators and what operational limitations does that present?
- How did HHS coordinate its hurricane responses with other federal agencies and state governments?
- Do Puerto Ricans have access to a sufficient number of health care facilities, pharmaceuticals, and medical products?

IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Natalie Turner, Christopher Santini, or Lamar Echols at (202) 225-2927.